SOUTH DAKOTA BOARD OF PHARMACY

January 17, 2025

<u>Unapproved Draft Minutes</u>
9:00 am CST
Public Board Meeting

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

Other parties in attendance

President Kraemer called the meeting to order at 9:00 am CST. Voice roll call was 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 (Clarambeau / Hansen).

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

REPORTS

Operations

Tyler Laetsch

- Wholesale license renewal period ended 12/31/24. Current licensing platform will be replaced in 2025. Details to follow. Parties (licensing vendor and board) have not had a signed contract for two years.
- Staffing Melissa Wipf left the board November 2024. Interviews for position are under way. Employee reviews are completed.
- Inspector Heyen reviewed and revised all approvals and policy statements.
- Laetsch, Cordell, and Heyen attended the State Surveyor Seminar.
- BJA grant payments are current. Grant runs through 9/2025. Continue to search for new PDMP funding sources.
- Eight in-state pharmacy licensures surrendered/closed in 2024.

Inspector Highlights

Carol Smith

- Completed 14 inspections in Q4: nine retail, two medical gas/ wholesale and three hospital. Completed one NABP 795 inspection.
- Reviewed and updated retail and hospital inspection questions.
- Reviewed policy statements and rules; updated pharmacy signage to align
- Will conduct five unannounced, random inspections in 2025
- Pharmacy I inspected was visited by the DEA last spring. Pharmacy still waiting for DEA's written report. They have not received notice of any issues or infractions.
- Identified several non-sterile compounding pharmacies that are not completing all UPS 795 requirements (i.e. SOP documentation, record keeping, and training).

Lee Cordell

- Completed 12 inspections in Q4
- Issue found faxed in prescription/no wet signature, USP 800, one chain where script was valid for two years instead of one
 year. WY, IN, IA allow two years.
- Follow up complaint food stored in refrigerator for medication, no temperature monitoring
- Medical gas facility with no security, no cameras, no tracking in and out; was in the facility for ten minutes before anyone noticed.

Jenna Heyen

- Last quarter completed 58 inspections across a variety of types
- Biggest issue staff lacking training in 795, 797, and 800
- Issues with labeling of product/medications stored in the pharmacy (stock bottles, no NDC, ripped label, no expiration date ...).
- Found outdates at several locations
- All retail pharmacy inspections have a controlled substance audits completed; audits revealed issues/discrepancies with DEA numbers.
- Safety concern with generic Lyrica all strengths being the same color; sizing only differed on the higher strengths. Found wrong med in wrong bottle and have reported the issue to Med Watch as it is a patient safety issue.
- In January, board was notified of three fake oxycodone paper, printed scripts with signatures. Overall for this situation 12 different pharmacies had received fake scripts, and the scripts continued to change. Four scripts were filled. Law enforcement and the DEA are involved.

Prescription Drug Monitoring Program - Melissa DeNoon

- Reviewed information in PowerPoint deck
- The third PDMP delegate reverification project will launch 1/21/25 2/14/25. Going forward verfiication will be completed each year. Notices were sent to PDMP users. Providers were tasked with updating their delegate list (re-approving or deleting delegates as needed). Verification process was explained.
- Three new roles were added to the PDMP.
- Maintaining user integrity is a major part of managing the PDMP validating users, credentialling providers, and ensuring the correct individuals have access.
- Opioid website was rebranded from "Avoid Opioids" to "Let's Be Clear"

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

Refer to audio record for compliant specific information.

- Complaint 2024-0008, Nonresident Pharmacy
- Complaint 2024-0009, Pharmacy
- Complaint 2024-0010, Pharmacy
- Complaint 2024-0011, Pharmacy
- Complaint 2024-0012, Pharmacy
- Complaint 2024-0013. Pharmacy
- DEA Form 106, Lewis Aberdeen
- DEA Form 106, Lewis Southgate, Sioux Falls
- DEA Form 106, Dosch Pharmacy, Eureka
- DEA Form 106, CVS, Rapid City
- DEA Form 106, Hy-Vee, Yankton
- DEA Form 106, Medvantx, Sioux Falls
- DEA Form 106, Medvantx, Sioux Falls
- DEA Form 106, Shane's Pharmacy, Pierre
- DEA Form 106, Walgreens, Yankton

OTHER REPORTS

SD Pharmacists Association – Amanda Bacon

For detailed information refer to handout. Highlights included:

- New SDPhA officers, 2024 award winners, and new members of the 50 Years in Pharmacy club.
- Current bills of interest (HB1016) and clarification of existing bills (HB 1135).
- Drug Takeback Event reminder; spring date to be determined
- Access to HPAP services continues thanks to board funds, totaling \$30,000, provided to the association
- SDPhA continues to support technicians by offering access to online training modules
- Connect with the association via their website, the action center, social media and email blasts.

SD Society of Health System Pharmacists - Jenna McGeehon

- Updates: annual meeting in April in Deadwood; great topics planned, working on keynote speaker
- Legislative session give an overview of the legislative process
- SDSHP has two legislative liaisons that have committed for a period of two years.
- Starting a committee to work with technicians and provide some CE opportunities
- Will continue holding After 5 Events. Each event focuses on a specific topic of interest. Past events leadership after 5 event, new practitioner after 5 event.
- Resident CE virtual events coming up: three different day and in east and west river; dates TBD

SDSU College of Pharmacy - Dan Hansen

- Classes in session Monday, January 13, 2024
- College has a busy semester program admission process review, high school junior recruiting events, accreditation and reaccreditation for all programs.
- Renovation have begun on the Sioux Falls Metro Center located at 33rd and Minnesota.
- 2025 Hooding ceremony is May 9th and Commencement ceremony is May 10th

SD Association of Pharmacy Technicians (none)

SD Health Professionals Assistance Program

- Review of 2024 Annual HPAP report presented by board ED Tyler Laetsch
- Total number of current participants (4) voluntary, (0) mandatory
- New admissions in 2024 (1) voluntary
- 5024 discharged (3); 2025 expect discharges (2)
- Total number of pharmacists enrolled in HPAP as of 12/31/24 (4 active participants)
- Request HPAP funding level remains the same as 2024 (\$10,000)

OLD BUSINESS

Technician Policy Statement & Starter Pack Statement Review/Approval – Tyler Laetsch

Discussed proposed additions to Starter Packs statement #08-12-12. Action taken to clean up policy (address log issues and
off-site storage).

Motion was made to approve changes as stated in revised Starter Pack policy statement handout (Hansen / Rising / unanimous).

• Discussed proposed revision to Technician policy statement #24-08-12.

Motion was made to approve revised Technician policy statement (Rising / Hansen / unanimous).

Board Reappointments - Tyler Laetsch

- Curt Rising, 2nd term appointment
- Tom Nelson, 3rd term appointment
- Ashley Hansen, 2nd term appointment

NEW BUSINESS

Legislative Update -Tyler Laetsch

The following legislative items were put forth for consideration

- Modifications to the Department of Health medical marijuana card identifiers. DOH placed item on hold as they explore other
 options.
- Moving administration of the controlled substance registration (CSR) from the Department of Health to the Board of Pharmacy. Due to the state's financial budget this was not supported at this time.
- Board of Pharmacy licensure fees increase bill discussed changes outlined in HB 1016 and language clean up in section. Bill
 assigned to the House Health and Human Services committee for review on 1/21/25. Board staff Laetsch, DeNoon, and
 Heyen will attend and field questions.

Election of Officers (President and Vice President)

Motion was made to approve Ashley Hansen as President and Curt Rising as Vice President (Clarambeau / Nelson / unanimous)

Wellbeing First Champion Challenge - Tyler Laetsch/Jenna Heyen

- Provided informational PowerPoint deck regarding the Dr. Lorna Breen Foundation and Wellbeing First Champion and discussed its initial presentation at NABP meetings over the past few years.
- Explained the origins of the Wellbeing First Champion Challenge. The Dr. Lorna Breen Family Foundation is asking all board to remove stigmatizing questions/language from all licensing applications.
- This is the first time the pharmacy board has been asked to review its license application language.
- The board would like to move forward on this topic and contact other state boards to learn what they have done with the possibility of adopting common licensure application language across all boards.

Avera Tech-Check-Tech Variance Request - Autumn Klaudt, Pharm.D., Jeff Derouchey, Pharm.D.

- Avera representatives came before the board to request the renewal of current variance with revisions.
- Slide deck reviewed. Document not in meeting handouts.
- Current variance allows technicians to perform activities outside their scope (repackaging, destination fills, sterile batching, breaking down larger bags to smaller bags [another form of repackaging not compounding]).
- Variance allows off-loading of low-risk activities to technician instead of being done by pharmacist.
- Pharmacist completes pre-verification; technician completes post package inspection/verification.
- Pharmacist audits 5% technician post-verification

Motion was made to approve the extension of the current Tech Check Tech Program for two years (to 1st Qtr 2027 board meeting) with the proposed modifications and no reporting requirements (Clarambeau / Nelson / unanimous).

OTHER BUSINESS

Recent Meeting News

- 138th SDPHA Annual Convention, September 13-14, 2024, Brookings, SD.
- NABP Executive Officer Forum, September 25-26, 2024, Mount Prospect, IL
- NABP Member Forum, December 4-5, 2024, Mount Prospect, IL

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

- April 4, 2025, 9:00 am
- July 18, 2025, 9:00 am
- October 10, 2025, 9:00 am
- January 16, 2026, 9:00 am

Upcoming Meetings

- SDSHP 49th Annual Conference, Deadwood, SD April 11-12, 2025.
- NABP 121st Annual Meeting, Fort Lauderdale, FL May 13-16, 2025.
- District V NAPB/AACP 2025 Meeting: Coralville, IA August 6-8, 2025
- 139th SDPhA Annual Convention, September 19-20, 2025, Deadwood, SD

Motion to adjourn (Hansen / Clarambeau / unanimous). Meeting adjourned at 11:52 am (CDT).