

SOUTH DAKOTA BOARD OF PHARMACY

April 4, 2025

Unapproved Draft Minutes

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, Beth Windschitl, and Dani Melton

Other parties in attendance

Meeting called to order at 9:07 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.

Request to modify consent agenda, none. Motion to approve consent agenda as written (Rising/Clarambeau/unanimous). Kraemer indicated budget discussions would occur during the New Business section of meeting.

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

REPORTS

Operations

Tyler Laetsch

- Preparing FY 26 contracts for DOH approval. Contracts are for the Prescription Drug Monitoring Platform (PDMP) and licensing platform and cover 6/1/25 to 5/31/26.
- Licensing platform initial RFP contract spans 5-10 years. Vendor is phasing out platform in year eight. A request for proposal (RFP) has been initiated.
- Dani Melton joined the board staff in March replacing Melissa Wipf who resigned in November 2024.
- Board pays over \$20,000 in Merchant credit card charges each year to offer online licensing to applicants. Board is investigating options to reduce costs including passing credit card fee to licensee.
- Full-time, part-time, and nonresident license renewal begins 5/1/25. Current licenses expire 6/30/25.
- Executive Order 2023-07 established the Drug Shortage Workgroup. Workgroup meets quarterly with DOH and includes the board ED.
- Attended Opioid Abuse Advisory Committee meeting. Members meet semi-annually and discuss stigmatizing language.
- SDSU student Aaron Mulvihill completed a five-week P4 rotation with the board. Inspector Jenna Heyen will assume the responsibility of student preceptor.
- GLP-1s, Semaglutide and Terzepitide have been removed from the FDA shortage list. All pharmacies and outsourcing facilities must cease sales of compounded medications as of 4/22/25.
- Department of Corrections is no longer using a Talyst machine to dispense and label inmate medications for administration at four locations. The four pharmacies licenses held by DOC were surrendered. Medication fulfillment is completed at a central location in Yankton.
- Renee Stellagher replaced David McVey as board's Assistant AG representative.
- House Bill (HB) 1016 in Review
 - In 36-11 for pharmacists/pharmacies, changed terms (permit/registration/certificates) to license
 - Changed quorum requirement from two to three members
 - Established a \$50 renewal application late fee for pharmacists, pharmacies, and wholesale
 - Changed wholesale annual application fee to \$500
 - Established a \$50 fee for pharmacist-in-charge transfers

Inspector Highlights

Carol Smith

- Completed 15 retail, 7 hospital, 5 AMDDs and 2 medical gas inspections in Q1. Good weather allowed for more travel.
- Key Findings:
 - Multiple pharmacies with medications and vaccines stored in refrigerator door
 - New "controlled substance ID verification" sign not posted at most retail pharmacies
 - Med gas quarantine area not marked appropriately, and junk stored in the area
 - Asking and verifying pharmacists are finalizing CSOS order; discovered one who is not finalizing theirs
 - Expired posted med gas registration and expired posted FDA documents
 - Pharmacist verification logs not signed by all pharmacists who filled controlled substances on a given day
 - Pharmacist-in-charge admitting a technician-in-training gave immunizations

Lee Cordell

- Completed 6 wholesale and/or med gas, and 16 pharmacy inspections in Q1
- Key Finding:
 - Unable to access the assessment of risk during certain inspections. At several sites, no one but PIC was aware of where to locate these.
 - NIOSH list not available on site. A grace period was provided for the new updates.
 - License Verification - Actual physical licenses not available for inspection; verified licenses by other means
 - At inspection, identified DEA license expiring day of inspection. Prompt renewal avoided issues.
 - Temperature monitors not in rooms housing AMDDs. Follow-up inspection scheduled for 5/1/25 for MH Ortho and Specialty areas, Lynns Dakota Mart RC
 - Observed dirty dishes stored on same shelves with medication - sanitation and safety issue
 - Observed technician-in-training performing immunizations highlighting a need for proper certification and supervision
 - Noted a required controlled substance identification sign was not posted; patient identification not being checked
 - Expired Combat Methamphetamine certificate found; must be renewed if selling pseudoephedrine

Jenna Heyen

- Completed 45 inspections in Q1 - 29 retail, 7 hospital, remaining were wholesale and medical gas
- Key Findings:
 - Occurrences of technicians performing functions outside their scope (.ie. Counseling)
 - Outdates in shelf inventory
 - Educating on non-sterile compounding various issues including equipment, cleaning, training, BUD being applied
 - Issues with repackaging and incomplete labeling
 - Issues with controlled substance management and information retrieval
 - Discovered several entities that did not report DEA 106s to the board
 - NIOSH 2024 list discussions
 - Pharmacy required signage/postings - ensure all public facing postings are not expired
 - Environmental humidity question – immediate use compounding performed but was adjacent to equipment that requires a higher humidity level. Pharmacy inquired if a humidifier could be used in the space. Humidifier could not be used per Board given USP 797 regulations.
 - Ensure protect from light items are adequately covered during storage.
 - Reminders: A change of pharmacist-in-charge (PIC) must be reported to board within ten days and controlled substance inventory needs to be completed with every PIC change
 - A Knox box is a box affixed to the outside of a building that holds a key to allow fire fighters emergency access to the pharmacy. Per law and rule, no one can have access to the pharmacy other than pharmacist so Knox box cannot give access.
 - The Legacy Foundation (aka Owen's Outfitters) is a nonprofit organization that accepts donations of medical devices and supplies for distribution for free or a small fee. Board discovered entity also has prescription medications on its inventory list. Educated the foundation about the Drug Depository program (DDP) and connected them with Lewis Drug a DDP participant who will partner with them to optimize supplies, devices and medications.
 - Discussed ongoing inventory control issues and available action options; at what point does the DEA need to be contacted

Prescription Drug Monitoring Program – Melissa DeNoon

- Set-up interstate data sharing with the state of New York; SD currently shares data with 41 states
- Wrote a PDMP article on data integrity/data accuracy for the April NABP newsletter
- Most common data integrity errors – errors in the data base and errors that are preventing the record from getting into the database.
- Most frequent error - Prescription was submitted under an incorrect DEA number; best practice is to educate technicians to use the DEA number on the prescription to select the correct provider. At final verification, pharmacist verifies provider DEA number on the screen corresponds to the provider DEA number on the prescription.
- Presented to the SDSU P2 class in February
- 2024 program statistics
 - Opioids fill three positions on the top ten list, including the top spot
 - Stimulant use is trending up nationally; three on the top ten list
- Drug Take-Back Program concerns – receptacle boxes are full (not being emptied) or are locked (not accessible for use)
 - PIC is responsible for their store's receptacle – problem is task gets handed off to another team member to complete
 - Some locations have a high volume of people dropping off which requires more frequent emptying of box and more box liners
 - Vendor has been slow to issue destruction certificates to pharmacies (waiting four to six months)
 - Direct all PDMP questions to Melissa DeNoon; participating pharmacies should not contact vendor

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

Refer to audio record for compliant specific information.

- Complaint 2025-0001, Pharmacy
- Complaint 2025-0002, Pharmacy

- Complaint 2025-0003, Pharmacy
- DEA Form 106, Lewis Brandon
- DEA Form 106, Vilas- Eagle Butte
- DEA Form 106, Lewis – Mitchell
- DEA Form 106, Lewis Brandon
- DEA Form 106, Hy-Vee – Sioux Falls

OTHER REPORTS

SD Pharmacists Association – Amanda Bacon

Refer to handout and recording for details.

Highlights:

- Review of HB 1016 and repeal of SDPhA from statute
- SB 154 Contracts between 340B entities and pharmacies
- Other key bills of interest – HB 1223, HB 1152, and HB 1141
- Legislative Days held February 13-14, 2025. Mark your calendar for next year's event February 10-11, 2026
- Coming changes - SDPhA will look different in the future with a mix of different memberships – associate memberships, corporate sponsors, pharmacist memberships and possibly technician memberships

SD Society of Health System Pharmacists – Jenna Lund; handout read by Tyler Laetsch

- Annual SDHSP conference was held April 11-12 in Deadwood. Attendance was good
- SDHSP board held its meeting after the conference and elected Alyssa Howard as their new President
- SDHSP is actively working to provide more CE opportunities for technicians.

SDSU College of Pharmacy - Dan Hansen, Dean

- Board of Regents / College working on FY 2026 budgets.
- Tuition and fees have been flat for the last five years but will increase 2.8% in 2026.
- SDSU is still the most affordable pharmacy school in the nation.
- Calendar Items – Miller Lecture, Public Health Week, Dean's Advisory Counsel
- Admissions – last weekend conducted 50 student interviews for the Early Assurance Program
- Student numbers are looking positive in all programs and freshman students
- Every program in Pharmacy and Allied Health is going through accreditation
- Incoming P1 class should number more than 50 students

SD Association of Pharmacy Technicians (none)

OLD BUSINESS

Wellbeing First Champion Challenge, application updates – Jenna/Tyler/Jeremy Daniel

- Discussed license application questions/terminology to identify and address potential stigmatizing language
- Reviewed proposed modified text options (red/current text, colored/proposed options)
- Final text version to be a melding of the purple and dark blue text options presented
- To date, three Boards of Pharmacy have received Wellbeing Champion Label

Hy-Vee Distribution Center Variance One Year Update – Judy Zachariasen, PharmD.

- Board required annual variance report / start of variance year two
- Provided handout outlining Hy-Vee Pharmacy Fulfillment Center's 2024-2025 Yearly Error Report (11-month review).
- Total scripts filled per quarter; provided detailed categorized breakdown of near misses.
- Common errors – either sent to a wrong store, refrigerated item put into a non-refrigerated tote.
- Nothing has changed since original variance that was approved for three years.
- 50% of the prescriptions up to 90% are bypassed.
- All technician hand-counted prescriptions are checked by a pharmacist for final verification
- Take two pictures of every prescription regardless of which fulfillment method used (bypass or tech count)
- Fulfilled about 12,000 more prescriptions this year than last year.

Lewis LTC Tech-Check-Tech Update – Jessica Strobl, PharmD

- Variance report – technicians validating the work of other technicians independent of pharmacist review for Lewis LTC
- Program has not been rolled out to date due to personnel turnover and the extensive training required
- Requested extension of granted variance

Motion was made to extend the Tech Check Tech variance for a period of one year from the date of program establishment with a one-year reporting requirement. (Kraemer/Rising/unanimous). Lewis to notify the board of Tech Check Tech program start date.

NEW BUSINESS

Legislative Update -Tyler Laetsch

HB 1016

- Changes take effect 7/1/2026
- Bill cleaned up law language and terms (permit, license, registration)
- LCR recommended quorum requirement change from two to three individuals
- Established a \$50.00 late fee for all pharmacist, pharmacies (full-time, part-time, nonresident), and wholesale for licenses renewed after expiration date
- Established a \$50.00 fee charge for pharmacist-in-charge transfers
- Wholesale application fee (initial and renewal) increased from \$250 to \$500
- 503B outsourcing facilities application fee (initial and renewal) increased from \$200 to \$500
- Discussed bill's progress through legislature (2:10:00 in recording)

Rules Update Planning and Discussion

Potential rule change topics identified by board ED Laetsch and inspector Heyen.

Rules must be modified by September. A public hearing will be held prior. Perhaps in conjunction with the July board meeting.

- Interns and intern hours – currently need 2,000 hours (1740 IPPE and APPE) and (260 external experience work hours). Provided a comparison of hours completion for other states. South Dakota is one of three states that require 2,000 hours. More common requirement 1,500 to 1740 hours. Issue is that SD licensure requires 260 external experience hours for licensure. Licensure requirement (260 hours) is waived for student from out-of-state pharmacy program that do not track intern hours. Unequal to hold SDSU graduates to a higher standard than out-of-state graduates. Question - should requirement be adjusted to what the college requires (1740) at graduation; keep as is; or require out-of-state students to submit external experience hours to the board for tracking? SDSU Dean Hansen provided history of requirement. His recommendation is to go to what ACPE requires and the curriculum which is 1,600 hours total (1440 APPEs and 160 IPPEs) because that will be true for every college regardless of where they graduate assuming they are accredited. If student graduated from a program, they met the hours standard. If new hours standard is 1600 it does not make sense for South Dakota to require 1740. Board determined it will follow the college's hours standard of 1600. Motion not required.
- 20:51:06:10 "sufficient" security measures – address vague language; should, at the least, minimum security standards requirement be defined/established (a camera to detect motion and an alarm); investigate what other states require.
- 20:51:15:11 "sufficient" numbers/services - address vague language; topics discussed - defining the actual number of hours pharmacist must be on site, concerns for patient safety, type of services that require a pharmacist be on site, the abundance of automated dispensing services being used and need for pharmacist on site, is the profession devalued when a pharmacist on site.
- 20:51:15:01 & 20:51:17:03 – AMDD licensing and inspection requirements. Currently, an AMDD requires a pharmacy license; a tacklebox/expanded E-kit requires a variance. Should licenses be required for AMDDs in the future? Should AMDDs and tackle/expanded E-kits have the same requirements and level of scrutiny? DEA has a guidance document on the topic and does not require they obtain a DEA certificate. Law states licensed AMDDs must be inspected monthly. Discussion of controlled substance regulation. Machines are being filled by non-pharmacist personnel. Focus should be on "drug storage". The pharmacy that provides the medication for the AMDD / tackle box is the responsible party; however expanded E-kits contain more controlled substances and medications than allowed by the Department of Health. Clarity is needed and requirements applied consistently across all parties. Perhaps DOH should not have the authority to set medication qualities.
- 20:51:29 established technician continuing education requirements. Board surveyed technician CE requirements in other state (ranges vary from none to up to 30 credits). Certified technicians are required to complete 20 hours of CE every two years to maintain certification. We recommend six hours of continuing education annually for technicians. Technicians who immunize must be certified. Every three years, immunizing technicians are required to complete a refresher course. Certified technicians could track their CE using the NABP CPE monitor. Non-certified technicians do not have access to CPE monitor.
- 20:51:22 Support Personnel – currently there is no registration for pharmacy support personnel (i.e. cashier). Iowa registers all support personnel. Implementing a new registration would require a law change. Support staff have the highest turn over rate. Clear delineation of staff role is necessary. Pharmacist is responsible for the activities of all staff including support staff. No change pursued at this time. Discussed methods one might use to track support personnel that were disciplined / sacked.
- 20:51:19:03 Pharmacist CE – ACPE or board sponsored. Current law can be interpreted two different ways: (1) all pharmacist CE credits must be ACPE accredited or (2) allows for CE credits to be either ACPE or non-ACPE accredited (board sponsored). Go forward, ACPE and board sponsored CE.

- Quality Improvement - Current SD law/rule does not address quality improvement. Is there an interest in addressing topic? NABP has a samples model rules act we can look at as well as complete a survey of other states position can be investigated.

SDPhA invoice – Tyler Laetsch (Recording at 3:19:00)

- Recap - \$200,000 amendment to HB 1016, payment to be made from state general fund resulting from a meeting between the governor's office and the association. Initially, board was told payment amount was \$100,000. Invoice received was for \$110,000, \$10,000 more than what was conveyed. Payment was a one-time only final payment to the association for services rendered. Board was not a party to the discussions.

Motion was made to approve payment of the SDPhA invoice for \$110,000. (Clarambeau/Rising/pass 4 to 1) (Nelson against)

OTHER BUSINESS

Recent Meeting News

Future Board Meetings – all held in Sioux Falls Board Room unless otherwise noted.

- July 18, 2025, 9:00 am
- October 10, 2025, 9:00 am
- January 16, 2026, 9:00 am
- April 10, 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
- SDSHP 50th Annual Conference, Sioux Falls, SD April 17-18, 2026

Motion to adjourn (Kraemer/Nelson/unanimous). Meeting adjourned at 12:56 pm (CDT).