

SD Board of Pharmacy Meeting Minutes
September 16, 2021 1:00 p.m. CDT
South Dakota Board of Pharmacy Conference Room
4001 W. Valhalla Blvd Suite 202, Sioux Falls, SD 57106

The board meeting was held in-person on site and via Zoom conference.

Board Members Present: President Tom Nelson, Ashley Hansen, Cheri Kraemer, Lenny Petrik, and Dan Somsen.

Board Staff Present: Executive Director Kari Shanard-Koenders; PDMP Director Melissa DeNoon, Inspectors Tyler Laetsch, Paula Stotz, and Carol Smith; and Secretary Beth Windschitl.

Attendees (in-person and via Zoom):

Jessica Strobel, Dana Darger, Dan Hansen, Lori Ollerich, Jim Mennen, Chuck Hudek, Wade Hanson, Ursula Chizhik, Gail Elliott, Kari Gerdeman, Mark Gerdes, Jeremy Daniel, Dustin Williams, Bernie Hendricks, Megan Borchert, Victoria Peta, and Ali Schaeftbauer.

A. Call to Order, Mission, Roll Call, and Introductions –President Tom Nelson

At 1:01 pm, meeting was called to order by President Nelson. Board mission statement was read, introductions completed, roll taken, and a quorum present.

B. Public Comment

The floor was opened for comment. Hearing no comments, President Nelson moved to the Consent Agenda.

C. Consent Agenda

The consent agenda was reviewed. Floor was opened for discussion. Hearing no comments, a motion to approve consent agenda was made by Cheri Kraemer and seconded by Lenny Petrik. A vote was taken, and motion passed.

D. Staff Reports

1. Operations Reports – Kari Shanard-Koenders, R.Ph., M.S.J., Executive Director

- Board member Petrik's third term ends 10/1/21 or once a replacement is named. Executive Director Shanard-Koenders thanked him for nine years of service and his contributions while serving.
- President Nelson's second term also ends. He agreed to serve for another term should the governor reappoint him.
- Staff member Stotz retires December 2021. Her half-time position will be filled by staff member Smith. Four individuals have applied for the quarter time position vacated by Smith and two will be interviewed.
- Be aware of a new scam being perpetrated in South Dakota. An individual claiming to be from the SD Board of Pharmacy is contacting pharmacies and requesting information. A similar scam occurred in IA.
- The board continues to work with NABP and I-Gov Solutions on a project that allows data sharing between the two platforms.
- An 8th amendment to the PREP Act added seasonal influenza to the list of COVID countermeasures. A 9th amendment, declared by HHS, states COVID therapeutics, monoclonal antibodies may now be ordered by pharmacists and administered by pharmacists, interns, or technicians under certain circumstances.

- Walgreens has relinquished their variance allowing technicians to administer all vaccines. They found it difficult to complete the required adverse event reporting as the Patient Safety Organization considers all adverse events confidential.
- The board and DOH intend to pursue increases in license fees as a sustainable funding source for PDMP. To date, PDMP has depended on federal grant funds. The current grant runs out September 30, 2021. Wholesale distributors will see the largest increase and a late fee would be added to in-state and non-resident pharmacies and wholesalers.
- Talks are ongoing regarding increasing fees for controlled substance registration and having a portion of fee go to the board
- The board continues to research drug repository program for this legislative session. The South Dakota program would be modeled after the repository program in the state of Georgia. Sanford Health and Monument are looking at pilot programs also.

2. Inspector Reports

a. Paula Stotz, Inspector

Reported the following observations/occurrences:

- A pharmacy, that had a break-in 16 months ago, still has a piece of plywood covering the window that was broken during the event.
- A pharmacy's computer system allowed refill of a CII beyond 72 hours. Pharmacist thought CARA Act (effective 7/22/16, refilling a CII for up to 30-days) was allowed in SD. This is only allowed where the State also allows it which is not the case in SD.
- Pharmacies incorrectly posting copies of *license/registration verifications* as pharmacist's license or technician's registration.
- Two pharmacies did not include the filled controlled substances in the Will Call area in the biennial inventory.
- One pharmacy finalized the CSOS orders on wholesaler website several days after the day of receipt.
- Two pharmacies unclear if the CSOS orders are being finalized by corporate officers.
- One Med Drop box with none of the initial, required DEA paperwork/log.
- One pharmacy with outdated controlled substances (CS) in an open box.
- One pharmacy transferring CS inventory between stores and not including purchaser/seller address with required DEA information.
- Four pharmacies not aware if they are receiving 3T information with each prescription drug purchase or how to locate
- Two pharmacies with no Temporary Pharmacist absence sign
- One pharmacy no site visit log for the remote pick-up locations
- Comment – overall pharmacies providing prescriptions and immunizations during the pandemic are feeling overwhelmed and stretched very thin. Limited pharmacist overlap, technician availability, and inability to hire quality technicians add to the situation.

b. Carol Smith, Inspector

Reported the following observations/occurrences:

- Pharmacists experiencing low morale due to technician shortage, long hours, no overlap, low reimbursement fees, decreasing salaries, stress resulting from too many tasks - script filling, counsel, answer questions...
- Fielded questions regarding mandated COVID vaccinations and promethazine/codeine fraudulent prescriptions

- Completed one new pharmacy construction consultations and inspected two medical gas facilities, four hospitals, eight retail (including two AMDDs)
- Four pharmacies no Assessment of Risk done for NIOSH products in pharmacy.
- Four pharmacies no biennial inventory for controlled substance prescriptions that were filled but not picked-up by patient.
- Two pharmacies who did not keep proper refrigerator temperature logs, are not using any type of oxidizing agent to deactivate/decontaminate the NIOSH counting trays, remote drop sites not approved by the Board of Pharmacy
- Repackaging medications with manufacturer's expiration date longer than a year from package date
- Biennial inventory not done within two years
- Biennial inventory did not include outdates
- C-II invoices were not filed separately
- Outdated medication in inventory
- Sterile compounding buffer room did not have humidity or temperature gauges
- Documentation of buffer room cleaning not completed
- C-II prescription with wrong doctor
- Expired Combat Meth Certificate
- DSCSA 3T procedures were not done when selling to outside entities
- Reviewed MPJE questions

c. Tyler Laetsch, Inspector

Reported the following observations/occurrences:

- Biennial inventories missing requirements
- Out dates
- Compounding records
- Controlled substance signature log or print out
- Hospital pharmacy entry to pharmacy policy and procedures questions
- Expired licenses posted
- Fielded calls about hydroxychloroquine, Ivermectin - use, can it be filled, seeing a lot of prescriptions from out-of-state tele-medicine providers
- Multiple fake prescriptions received via phone, written, escript, and faxes
- Brother's Pharmacy had second attempted robbery that was unsuccessful

3. PDMP Report

Director Melissa DeNoon reported the following program updates:

PDMP

- Statewide Gateway Integration Project – RedSail Technologies QS/1 pharmacy software now able to integrate via the Gateway due to format change from XML to HTML.
- SUPPORT Act - BOP/PDMP is collaborating with SD Medicaid on the Act's required PDMP query of C-II beginning 10/1/21
- Appriss Health has changed its name to Bamboo Health.

MedDrop Program Update

- In May 2021, the Davis Pharmacy in Vermillion became the newest entity to be added to the list of SD retail pharmacies and hospitals participating in the MedDrop program for a total of 90 sites serviced by the BOP's program.
- Total pounds returned for destruction since program inception have nearly reached 19,000 lbs.

Presentations Given/Events Attended

- SD Opioid Abuse Advisory Committee – PDMP Update
- KS BOP/CDC OD2A Peer to Peer Learning Collaborate – Member of Data Dissemination Panel
- SD Academy of Physician Assistants 2021 Summer/Fall CME Conference – PDMP Presentation

Upcoming Events

- SDPhA 135th Annual Convention – September 2021 – BOP/PDMP Presentation
- NABP PMP InterConnect Steering Committee Meeting - October 2021, Chicago, IL
- NASCSA Annual Conference – October 2021, San Antonio, TX
- Waiting to hear the outcome of pending grant funding for PDMP; decision expected September 30th but may not be awarded until year end.

Meeting diverted to agenda item H2 due to presenter time constraints.

E. Contested Case Hearings – Megan Borchert and Justin Williams, Department of Health and Board Counsel

1. In the Matter of the Disciplinary Proceedings of Jacquelyn Porter, Technician- a motion to approve the voluntary surrender of her pharmacist technician registration was ratified by voice vote (Kraemer/Somsen/unanimous).
2. In the Matter of the Pharmacist License of Christopher Sonnenschein- a motion to approve the voluntary surrender of his pharmacy license was ratified by voice vote (Kraemer/Petrik/unanimous).

F. Complaints, Investigations, Disciplinary Actions, Loss/Theft Reports

Reported by Tyler Laetsch, Paula Stotz, and Carol Smith.

1. DEA Form 106—Omnicare Sioux Falls
2. Complaint #2021-0004
3. DEA Form 106—Seven Sisters Center
4. Complaint #2021-0005
5. Complaint #2021-0006
6. Complaint #2021-0007
7. DEA Form 106- Sanford Health Network, Chamberlain

G. SD Pharmacists Association – Dana Darger, R.Ph., SDPhA President; Jessica Strobel, Pharm. D, SDPhA Treasurer

1. Activity Report

SDPhA Treasurer Jessica Strobel highlighted the following items from the Activity Report handout.

- The Association encourages everyone to join the SDPhA Facebook Group page and watch for pandemic and vaccine-related information posting on the website which also houses a COVID-19 Resources page.
- Advocacy efforts are focused on maintaining the flexibilities extended to pharmacists by the federal government including emergency provider status, immunizations, testing, payment, compounding, and funding.
- SDPhA national efforts include COVID-19 related bills, DIR fee relief, PBM reform, pricing transparency and improvements to Medicare. For a complete list of the federal bills being followed refer to SDPhA's Online Bill Tracker.
- The South Dakota Attorney General has signed on to the amicus brief from the National Association of Attorneys General for the Rutledge v. PCMA case. SDPhA also signed on as Amicus Curiae in PCMA v. Wehbi 8th Cir.

- SDPhA and other stakeholders are working to establish a path forward to address PDM reform in the 2022 legislative session.
- Due to the pandemic, this year's legislative flu shot clinic was conducted by the Department of Health instead of SDPhA.
- Spring District meetings and the SDPhA Board retreat were held via Zoom due to COVID-19

2. Financial Report – provided not reviewed

H. Other Reports

1. SDSU College of Pharmacy – Dean Dan Hansen, Pharm.D.

The following College of Pharmacy and Allied Health Professions updates were shared:

- On campus classes resumed August 23, 2021 with program enrollment numbers as follow - 66 P1 students, 12 Master of Public Health students, 22 on-campus Medical Lab Science students, 10 2nd year A.S. Respiratory Care students, 15 Medical Lab Science Upward Mobility students, 6 Accelerated Medical Lab students, and 4 Phlebotomy Certificate students.
- The A.S. Respiratory Care program received 100% board pass rate in 2021
- The College has created a true Office of Experiential Education lead by Director/Residency Program Director Jodi Heins. Scout Forbes-Hurd serves as the experimental education and continuing education/health systems coordinator.
- In FY 21, the College secured over \$2.7 million in grants a 69% increase from FY20.
- In 2022, the College was awarded a HRSA grant for the Rural Communities Opioid Response Program-Psychostimulant Support project.

Faculty and Staff Updates

- Dr. Om Perumal – Associate Dean for Research
- Dr. Hemachand Tummala – Interim Dept. Head for Pharmaceutical Sciences
- Dr. Tanvir Khaliq – Asst. Professor in Pharmaceutical Science (Med Chem)
- Dr. Emily Van Klompenburg – Ambulatory Care at Avera Clinic (Brookings)
- Michelle Day – Program Asst. 1, Office of Experimental Education

Faculty Searches

- Dept. Head for Pharmacy Practice
- Post Doc
- Population Health faculty position
- Director of Clinical Education in Respiratory Care
- Internal Medicine faculty position

2. SD Society of Health System Pharmacists – Jeremy Daniel, Pharm.D., SDSHP President

- GVR Open Golf Classic was held on July 23rd; attendance numbers were similar to last year.
- ASHP Midyear will be a virtual format secondary to continued pandemic; plans for a Dakota Night (ND & SD) continue
- Check out SDSHP Facebook for a series of posted on professional development
- In the upcoming months, will be exploring Diversity, Equity, and Inclusion (DEI) statement and CE; currently do not have a statement
- Making plans to host an in-person social event for Pharmacy Month in October
- In the early stages of working on updates to website and developing new logo

- Working with SDSU regarding CE platform and hosting resident CE in winter

3. SD Association of Pharmacy Technicians – John Thorns, CPhT (Not in Attendance)

Shanard-Koenders reminded attendees the SDAPT’s annual continuing education seminar would be held virtually on Saturday, October 2, 2021.

I. Old Business

1. FDA MOU with States on Compounding – Shanard-Koenders

The signing deadline for the FDA MOU has been delayed another year. The board continues to wait for a decision, from counsel in Pierre, regarding whether the board has the authority to sign the MOU.

2. Eighth and Ninth Amendment to the PREP Act - Policy Statement Amendment – Shanard-Koenders

The proposed policy statement revisions delineated in green ink were reviewed. Providing amended information was necessary so individuals may continue to perform actions under the PREP Act. The 8th Amendment added seasonal influenza vaccine to the COVID-19 countermeasures and allows technicians to administer influenza vaccines (new authority). The 9th Amendment added COVID-19 therapeutics to COVID-19 countermeasures which may be ordered by a pharmacist and administered by a pharmacist, intern, or technician with proper training (new authority). The original board policy statement (20-12-11) was approved November 2020. A motion to approve revised Board Policy Statement Number 11-12-11 was ratified by voice vote (Somsen/Kraemer/unanimous).

3. Hy-Vee Technician Immunization Pilot Report to Board - Jim Mennen, BPharm, MS, MBA

Jim Mennen came before the board to meet reporting requirement as part of Hy-Vee’s Technician Immunization Pilot Program variance. For the reporting period May 2021 through August 2021, eleven Hy-Vee pharmacy locations provided a total of 17,141 vaccinations with two adverse events noted. Of the total vaccinations provided, 4,980 were administered by technicians with one patient refusal of vaccination by technician noted. Jim asked the board to continue the granted variance for an additional six months. A motion to extend the Hy-Vee Technician Immunization Pilot Program variance for an additional period of six months with the same reporting requirements was ratified by voice vote (Somsen/Hansen/unanimous).

4. Avera Long Term Care – Variance Continuation of Expanded EKit – Mark Gerdes, RPh

Mark Gerdes came before the board to request a continuance of Avera LTC’s expanded EKit (tacklebox) variance that addresses the number of medications that can be contained in an emergency kit within a nursing home and to change the variance term from one to three years. A motion to provide a continuance of Avera LTC’s expanded EKit (tacklebox) variance to three years or until law/rule changes are put into place was ratified by voice vote (Kraemer/Somsen/unanimous).

J. New Business

1. Avera Long Term Care – Variance Request for Expanded EKit Quantities Utilizing AMDD – Mark Gerdes, RPh

Mark Gerdes also came before the board on behalf of Avera Long Term Care seeking a variance, for a period of three years, to the quantity restrictions on medications in Nexsys System AMDD devices in nursing homes with

the goal being improved time to delivery and potential prevention of hospital readmissions. Current, Avera has licensed AMDD devices in four locations. Each Nexsys System holds up to 300 medications. The Board ratified a motion to approve Avera's variance request for AMDD medication quantities for three years (Somsen/Hansen/unanimous).

2. Updated USP 795 & 797 open for public comment thru January 31, 2022 – Tyler Laetsch, Pharm.D., Inspector
 - September 1, 2021 USP compounding general chapter new revisions available; comment period open until January 31, 2022.
 - USP Compounding Expert Committee is hosting four open forum sessions. Anyone can attend; session information can be found on the USP website.
 - Annual competencies for all individuals doing nonsterile compounding and at least every 6 months for those performing sterile compounding
 - Required, monthly viable air testing is an area of big concern

K. Other Business

1. Recent Meeting News
 - a. NABP/AACP 84th Annual District V Meeting, August 6, 2021 Virtual Meeting
2. Future Board Meeting Dates – all held in Sioux Falls Board Room unless otherwise noted
 - a. December 10, 2021, 9am – 1pm CST
 - b. April 7, 2022, 1pm – 5pm MDT at The Lodge at Deadwood in coordination with SDSHP 46th Annual Conf
 - c. June 24, 2022, 8am – 12 pm
 - d. September 8, 2022 in conjunction with SDPhA 136th Annual Convention, Brookings
3. Upcoming Meetings
 - a. 135th SDPhA Annual Meeting, September 17-18, 2021, Virtual
 - b. NABP Interactive Executive Officer Forum, September 28-29, 2021
 - c. NABP Interactive Compliance Officer and Legal Counsel Forum, November 30 – December 1, 2021
 - d. SDSHP 46th Annual Conference, April 8-9, 2022, Deadwood
 - e. 118th NAPB Annual Meeting – May 19-21, 2022, Sheraton Wild Horse Pass, Phoenix
 - f. NABP/AACP 85th Annual District V Meeting, August 3-5, 2022, Custer State Park

L. Adjourn

President Nelson again opened the floor for public comment. Hearing none, the Board approved a motion to adjourn (Petrik/Kraemer/unanimous). Meeting adjourned at 3:04 pm.