

**SD Board of Pharmacy Meeting Minutes**  
Friday, June 24, 2022, 8 am  
South Dakota Board of Pharmacy Conference Room  
4001 W. Valhalla Blvd Suite 202, Sioux Falls, SD 57106

Members of the Board in Attendance: President Dan Somsen, Ashley Hansen, Cheri Kraemer, Tom Nelson, and Curt Rising

Board Staff in Attendance: Executive Director Kari Shanard-Koenders; PDMP Director Melissa DeNoon, Inspectors Tyler Laetsch, Carol Smith, and Lee Cordell; and Secretary Beth Windschitl.

Others in Attendance: Joe Bergsmith (Walmart); Jessica Strobl (Lewis, SDPhA); Michelle Aytay (Walgreen); Eric Brandt (U of MN P4 student); Bill Ladwig (Lewis); Alyssa Larson (SDSHP); Maimuna Bruce Uzzell (Cardinal Health); Catherine Ronalder (Cardinal Health); Lori Ollerich (Pharmacy Specialties); Dan Hansen (SDSU); Jessica Adams (Cardinal Health); Michele Kooiman (Monument Health); Jace Muramoto (Continued Care LTC Pharmacy); Carli Krogman (SDSU P4 student); Amanda Bacon (SDPhA); Shannon Katz (SDSU P4 student); Justin Manning (Vivid Clear Rx); Rhea Kontos (Secretary);

A. Call to Order and Introductions

Dan Somsen called the meeting to order at 8:04 am, welcomed attendees, and read the mission statement. Member Somsen called the roll. A quorum was present. Attendee introductions completed.

B. Public Comment

Floor was opened for public comment; none received.

C. Consent Agenda

Consent agenda was presented. No items were removed. A motion was made to approve the consent agenda (Hansen/Kraemer/Pass.)

D. Staff Reports

1. Operations Report – Kari Shanard-Koenders

- a. Bob Coolidge, Licensure and Certification employee who managed the Controlled Substance Registrations (CSR) for the Department of Health (DOH), has retired. Over the years, the board has requested CSR to move to its purview. Monies generated from CSR fees are the logical choice to assist with funding the Prescription Drug Monitoring Program. Request determination falls to Joan Adam, DOH Cabinet Secretary.
- b. The FDA recently approved both Moderna and Pfizer COVID-19 vaccines for children 6 months – 3 years of age. Prior to the PREP ACT, board policy allowed vaccination by prescription or protocol. With the FDA change, board policy review is advised. Bill Ladwig stated pharmacists are looking to the board for guidance and direction due to liability and patient safety concerns. The Board decided to add this as an agenda item to New Business.

- c. The donated repository drug program becomes law on July 1, 2022, after passing in the 2022 legislature. A preliminary draft of program rules was sent to DOH. The board continues to work with providers to obtain drug lists for its database and talk with Medicaid regarding zero cost billing.
- d. Renewal application processing for full-time, part-time, and nonresident license holders ends June 30<sup>th</sup>.
- e. Research into an emeritus license option for pharmacists has not been completed.

## 2. Inspector Reports

Carol Smith reported she worked on an article for the July Board of Pharmacy quarterly newsletter, completed an NABP program review and training webinar, and continues to work on her sterile compounding recertification online. The most common inspection deficiency was biennial inventory documentation. Several pharmacies, in Carol's inspection area, are looking for part-time, full-time, and relief pharmacists.

Lee Cordell reported he begins initial sterile compounding training for inspectors in July through Critical Point. During inspections he identified pharmacies missing mandatory sign postings and observed a bottle containing a C2 drug purposefully left in an accessible area as a "decoy" for drug seeker access should a robbery situation arrive during an inspection. DEA policy requires C2 drugs be locked up. During a CVS inspection, inspector observed technicians bagging drugs without pharmacist final visualization. Pharmacist never sees what is in the bag, never sees the stock bottle / vial, method creates room for errors, allows for the addition of other items to bag, and exposes pharmacist to potential liability. Last year, the board granted CVS a workflow variance which requires further review and potential modification given inspector's recent findings.

Tyler Laetsch reported fielding questions regarding immunizing technicians and their role after the PREP ACT ends, a decrease in COVID testing, and noted the FDA approved additions to the commercially available product list. Under the 503A standard definition, a pharmacy cannot compound a product that is FDA approved and commercially available. A pharmacy must provide a specific reason why a patient cannot use a commercial version before compounding. The FDA does not consider cost a valid reason. Inspector also reported pharmacy service hour changes at select chain locations. Inconsistency in hours has caused confusion for patients who cannot get their meds or have them sent elsewhere. Consistent hours of operation across all chain locations helps patient care. Inspector continues his work on PDMP pharmacy audits to identify entities not reporting prescriptions correctly to PDMP, during the last quarter we have found three pharmacies not reporting schedule five prescriptions.

## 3. PDMP Report

Melissa DeNoon gave an update on continuing efforts to improve PDMP database quality and integrity. Two main areas of concern: prescriptions with missing information resulting in data not making it into the database and identifying inaccurate prescriptions in the database and correcting them. An audit of PDMP reporting to identify pharmacies not submitting C5 prescriptions and incorrect DEA numbers attached to dispensed drugs is underway. The BJA 2021 Grant funds which were awarded to the board in November have not been received. BJA's continual criteria and eligibility changes after the fact hampers recipients' efforts to maintain their PDMP programs and pay vendors. The need to identify an independent funding source for PDMP is urgent. Melissa gave a brief synopsis of the topics and learnings from attending the APhA Institute on Substance Use Disorder conference. See handout for a listing of presentations given, events attended, and upcoming events.

## E. Complaints, Investigations, Disciplinary Actions, Loss/Theft Reports Inspection Laetsch discussed

1. Complaint 2022-0005 Emergency script procedure for C2
2. Complaint 2022-0006 Vaccination of Minor

3. Complaint 2022-0007 HIPPA
4. Complaint 2022-0008 Medication fill error
5. Complaint 2022-0009 Diversion
6. DEA FORM 106 – Sanford Vermillion
7. DEA FORM 106 – Safeway Mt. Rushmore Rd.
8. DEA FORM 106 – Safeway Mt. Rushmore Rd. – Resolved
9. DEA FORM 106 – Landmann Jungman Memorial Hospital

F. SD Pharmacists Association – Amanda Bacon, Executive Director

1. Activity Report

Per Amanda Bacon, all SDPhA district meetings are completed. At the SDPhA board retreat June 3-4, 2022, discussions focused on strategic planning, legislative goals, CE, and agenda items for the annual meeting. The SDPhA annual meeting will be in person in Brookings, SD September 9-10, 2022, with a special reception planned for Thursday or Friday evening in conjunction with SDSU. Work on PBM state and national initiatives for 2023 have begun; to assist with these efforts, SDPhA has retained Craig Matson, Roger Tellinghuisen, Bob Riter, and Linsey Riter-Rapp. Amanda emphasized the increasing importance of C&L funds in the lobbying process, and a potential phone-a-thon campaign to raise additional C&L funds in the future. For additional information regarding SDPhA activities and initiatives refer to handout.

2. Financial Report – not discussed, see handout

3. Funding Discussion SDCL 36-11-6

A brief discussion of SDCL 36-11-6 occurred. To avoid the appearance of a conflict of interest, board members review SDPhA funding annually at the June board meeting and a vote is taken. A motion was made to approve funding SDPhA at 80% of the annual pharmacist license renewal fees received by the board (Kraemer/Rising/Pass.)

G. Other Reports

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

The Class of 2022 graduated 74 Pharm.D. students with 32 matched to PGY1 residency programs. SDSU's match rate remain strong at 71%. Working with the Board to plan the 85<sup>th</sup> Annual NABP/AACP District V meeting in Custer State Park with a good showing of faculty attending. The Pharm.D. accreditation on-site visit is scheduled for October 18<sup>th</sup> – 20<sup>th</sup>. The self-study document was approved at the May faculty meeting. New additions to staff and faculty include Brooke Merry, recruitment and outreach coordinator and Hiruni Amarasekara, project manager/population health instructor for the Community Practice Innovation Center in the Department of Allied and Population Health. Recent faculty, staff and student achievements/recognition include Dr. Brad Laible being named the college's associate dean for academic programs, Dr. Hemachand Tummala named department head of pharmaceutical sciences, and the selection of Bill Ladwig as the college's alumni of the year.

2. SD Society of Health System Pharmacists (SDSHP) – Alyssa Larson, Pharm.D., SDSHP President

SDSHP Meeting Updates - The annual meeting was held virtually on April 8<sup>th</sup>-9<sup>th</sup>, 2022. Next year's meeting is scheduled for March 31<sup>st</sup> through April 1<sup>st</sup> and in person. The strategic plan for 2022-23 was approved by SDSHP's Board of Directors in May. Upcoming events include the Annual Residency Conference July 11<sup>th</sup> at

Arrowwood Cedar Shore Resort in Oacoma, and the 20<sup>th</sup> Annual GVR Open Golf tournament July 22<sup>nd</sup> at Central Valley Golf course in Hartford.

3. SD Association of Pharmacy Technicians (SDAPT) – John Thorns, CPhT (not in attendance/no report)

H. A motion was made to go into executive session for the purpose of contract discussions (Kraemer/Hansen/Pass).

A motion was made to come out of executive session and resume the board meeting (Nelson/Hansen/Pass.)

I. Old Business

1. Legal Counsel

A motion was made to draft a letter to the Secretary of Health regarding future attorney representation for the Board of Pharmacy (Kraemer/Hansen/Pass.)

2. Drug Repository Rules 20:51:35

Shanard-Koenders asks the board for approval to move forward with the rules writing process for the drug repository. We are required by the legislature to complete the rules; a draft was sent to board members. There will be many revisions throughout the process. A motion was made to move forward with the drug repository rules development process as required by HB1086 (Nelson/Kraemer/Pass.)

J. New Business

1. Monument Health/Cardinal Central Fill – Michele Kooiman, Pharm.D., Monument Health, Jessica Adams, Pharm.D., Cardinal Health, Catherine Ronalder, Pharm. D., Cardinal Health

Michele Kooiman came before the board to request a waiver to rule 20:51:20:04 (use of common electronic database). The rule requires that a common database be utilized by two or more pharmacies license by the board to practice pharmacy and applies to central fill services. Monument Home + Pharmacy in Spearfish wishes to engage Sonexus Health, a pharmacy owned Cardinal Health in Texas, to provide central fill services which consist of primarily unit dose packaging. Offering a central fill option will enable Monument to expand service offerings to patients. Processing details, i.e., data entry, date review, and adjudication, are discussed in the handout. Because a commonly shared database between the parties does not exist, a waiver is required so Monument and Sonexus can utilize technology that permits the sharing of information needed to safely process, fill, and dispense prescriptions. Monument would like their waiver request to cover their location at 353 Fairmont Blvd. in Rapid City (SD license 100-1986). A motion was made to grant Monument Health a waiver to chapter 20:51:21:04 for a period of one year (Nelson/Hansen/Pass.)

2. Continued Care LTC (CC LTC) Pharmacy e-kit quantities variance request – Jace Muramoto, Pharm.D.

Jace Muramoto came before the board to request a waiver to rules 20:51:15:26 and 44:73:08:11 to better supply readily available medications to remote skilled nursing facility residents served by CC LTC. CC is a new long-term care pharmacy in South Dakota going live July 1, 2022. CC LTC uses the same Nexsys automated dispensing cabinets in facilities in five states. Both the pharmacy and the nursing home management can track and monitor any transactions in real time or pull reports after a transaction is completed. The

machine requires a unique credential login for each user and every transaction and is electronically time stamped to link to the user pulling the medication. Controlled substance medications are stored in individual cells and require dual control (two nurses to login to access medication). All medications supplied will have minimum and maximum stock on hand to ensure sufficient quantities to meet residents' needs. Machine medication audits occur monthly. Refer to handout for additional information. A motion was made to grant a one-year variance to rules 20:51:15:15 and 44:73:08:11 to allow CC LTC Pharmacy e-kits to contain 189 legend drugs and 25 controlled substances stocked in the Nexsys ADT machine per the quantities provided on the drug list (Nelson/Hansen/Pass.)

### 3. Vaccination Administration for Infants (Agenda Addition)

As discussed in the Operations Report, Shanard-Koenders suggested board issue a policy statement on this topic. President Somsen asked for how to address this. It was discussed that due to no liability in the PREP Act for administration to children under the age of three years, as well as the extra time and effort to administer vaccinations to infants, to limit pharmacist vaccine administration to children at least three years of age. This may impact patients who need a vaccine and either do not have or cannot afford to go a physician; however, there will be pediatric vaccine clinics offered at some hospitals. Discussion ensued if the PREP Act is amended to add infant vaccinations, do we stay with the age parameters of the policy statement? Technically, the policy statement may be rescinded at any Board Meeting. Should the situation arise, the board can issue a strong recommendation to limit pharmacist administered vaccination to individuals three years of age and older due to safety and comfort of pharmacists in administration to this age group.

A motion was made for the board to draft a policy statement on pediatric immunizations to align with the PREP Act, patient safety, and pharmacist comfort with immunizing infants to state that pharmacists should not immunize individuals younger than three years of age (Hansen/Kraemer/Pass.)

## K. Other Business

### 1. Recent Meeting News

- a. SDSHP 46<sup>th</sup> Annual Conference, April 8-9, 2022, virtual
- b. 118<sup>th</sup> NAPB Annual Meeting - May 19-21, 2022, Sheraton Wild Horse Pass, Phoenix

Member Hansen spoke on the Annual Meeting. She attended along with Member Kraemer, Inspector Laetsch, and ED Shanard-Koenders. Presentations included the state of the wellbeing of pharmacists/technician in the workplace with boards of pharmacies soliciting wellness information from pharmacists/technician via surveys. Should the board develop a survey tool to gather wellness information pertinent to South Dakota pharmacists/technicians? Member Hansen also shared that there are currently 13 technicians servicing on boards of pharmacy in 12 states. To promote technicians within the profession, Member Hansen encouraged the board to consider appointing a pharmacy technician to the board as technicians are a part of the team, are governed by Board laws and rules, and deserve to have a voice at the table. It would require a statute change and opening the Practice Act but could be done in the 2023 Legislative session. Board staff will work with DOH to determine feasibility.

Member Kraemer also attended and spoke to the fact that several boards are increasing their level of investigation into pharmacy errors. South Dakota does not require error reporting. Error reporting should not be punitive but should be constructive and a learning tool with root cause analysis. Access to error data from chains is barred due to Patient Safety Organization affiliations and a claim that they are proprietary. Additional hurdles to reporting errors includes a lack of standardization. Every pharmacy defines errors differently and there are no common definitions of errors that all use, so there are many variables to track them.

2. Future Board Meeting Dates – all held in Sioux Falls Board Room unless otherwise noted
  - a. September 8, 2022, 1pm – 5pm CDT in coordination with SDPHA 136<sup>th</sup> Annual Convention in Brookings (location TBD)
  - b. December 9, 2022, 9am – 1pm CST
  - d. March 30, 2023, Sioux Falls, 1pm – 5pm CDT in conjunction with SDSHP Annual Meeting, Sioux Falls
  - e. June 23, 2023, Sioux Falls, 8am – 12pm CDT
  
3. Upcoming Meetings
  - a. NABP/AACP 85<sup>th</sup> Annual District V Meeting, August 3-5, 2022, Custer State Park
  - b. 136<sup>th</sup> SDPHA Annual Meeting September 9-10, 2022, Brookings
  - c. SDSHP 47<sup>th</sup> Annual Conference, March 31 – April 1, 2023, Sioux Falls

L. Adjourn

A motion was made to adjourn (Hansen/Kraemer/Pass.) Meeting adjourned at 12:13 pm CST

Dan Somsen, President	Date
Kari Shanard-Koenders, Ex. Director	Date