

SOUTH DAKOTA BOARD OF PHARMACY

September 14, 2023

Unapproved Draft Minutes

1:00 pm MDT

Public Board Meeting

Board members present: Cheri Kraemer, Tom Nelson, Curt Rising, and Dan Somsen.

Board members excused: Ashley Hansen

Board staff present: Kari Shanard-Koenders, Melissa DeNoon, Tyler Laetsch, Lee Cordell, and Beth Windschitl.

Other parties in attendance: Emily Van Klompenberg, Judy Zachariasen, Joe Bergsmith, Gail Elliott, Nicholas Hodgen, Jessica, Strobl, Chelsey Conway, Melissa Gorecki, Ashley Hess, Hyunji Oh, Bob Mercer, Sara Watson, Miamuna Bruce Uzzel, Andy Tonneson, Kyle Heer, Jeff Barnabal, and Victoria Kroeger.

President Nelson called the meeting to order at 1:02 pm MDT. 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. A motion for approval of the consent agenda was ratified (Rising/Kraemer/unanimous).

REPORTS

Operations

The Governor's Office has not named a replacement for member Dan Somsen. License renewals for pharmacist and technicians continues. In FY '24, board will receive Opioid Settlement Fund dollars totaling \$186,000. The board is in concerning financial straits due to spend down directives, decrease in revenue, loss of grant, and commencement of payments to PDMP vendor Bamboo Health. As of 8/31/23, board available funds total \$396,595.

Proposed rule changes in ARSD Article 20:51 were submitted for consideration and distributed to pharmacists via Listserv for comments. Rules hearing is tentatively set for October 23, 2023. The Department of Health (DOH) tentatively approved proposed license fee increases in a bill to be submitted to the 2024 legislature. The Governor has been informed. DOH tentatively plans to repeal the current controlled substance registration. USP compounding changes go into effect 11/1/23 and were including in requested changes by reference while DSCSA implementation has been postponed one year.

Executive Director Kari Shanard-Koenders announced her tentative retirement in April 2024, and PDMP Program Assistant Melanie Houg's last day is September 22, 2023. A search for her replacement is underway.

Inspectors

Lee Cordell – Attended District Five meeting in Medora and had positive reviews of DEA presentation. Continue Critical Point training online with a completion date of September 2023. Completed multiple AMDD inspections and noted problems with staff using other team members login credentials and staff not properly trained how to use AMDD. Most questions from pharmacists are in reference to USP and DSCSA guidelines. Pharmacy staffing continues to be a concern. Identified a pharmacy closed outside of posted hours due to server shutdown. A reminder, the Board needs to be notified of any variation from normal business hours.

Tyler Laetsch – Inspection issues include expired pharmacy licenses and combat meth certificates. USP questions for both hospital (797) and retail (795) continue. A few entities have a glove box that is using the full beyond use date which will change with the new guidelines. Also fielding questions regarding RN compounding, IV Hydration clinics, technician immunization, DSCSA and off site medication storage. Some pharmacies were closed multiple days for unknown reasons. Closures outside of the posted hours should be limited to extreme emergencies and the board needs to be notified prior to the closures. Found during routine inspection medication storage outside the facility was reported to have occurred, this is not allowed without approval.

Prescription Drug Monitoring Program

Due to BJA's interpretation of our vendor relationship, SD PDMP has received no funding from the BJA FY '21 Harold Rogers PDMP Grant. Payments to vendor Bamboo Health have begun for the two BJA FY '21 grant projects that were continued from 10/1/21 through 1/31/23 in anticipation of receipt of funds. A new PDMP report (Error Report Notifications) was implemented 8/14/23. It identifies data errors (errors in individual prescriptions and errors in the database) and allows in-state pharmacy pharmacists-in-charge (PIC) to fix the error themselves in Rx Management without involving other parties. Prior to rollout, a PIC had to contact their platform vendor who then corrected the data error. Oftentimes a disconnect between PIC and vendor occurred and issues went unresolved. A significant decrease in the number of unresolved issues speaks to the success of the new report. PharmaDrop receptacles were placed in Plankinton and Watertown for a total of 93 receptacles statewide. Refer to handout for PDMP utilization statistics and patient opioid trends.

Inspector Laetsch reviewed the complaints (none), disciplinary actions (none), and loss/theft reports under investigation by the board.

SD Pharmacists Association

SDPhA President Gorecki addressed the board on behalf of Amanda Bacon. Last year the Association had a very busy year. This coming session, Association does not plan to bring any old bills forward during session. The Association will continue to be active monitoring other bills during session. Ms. Gorecki referenced the SDPhA handout and solicited questions. Legislative Days are February 13-14, 2024. Member Rising initiated a discussion regarding DIR fees beginning January 2024. Some wholesalers estimate 30% to 40% of pharmacies will go out of business in the first three months of next year. It is an advocacy issue for pharmacy. In a small state like South Dakota, it can become a public health issue if a patient cannot get their prescriptions because of the travel distance. Dissatisfaction with the profession is growing. The political part of pharmacy and the profession is becoming more prevalent.

SDSU College of Pharmacy (no report)

SD Society of Health System Pharmacists (no report)

SD Association of Pharmacy Technicians (no report)

OLD BUSINESS

Hy-Vee Error Report

Judy Zachariasen presented Hy-Vee Pharmacy Fulfillment Center's quarter two error report summary for 2023 covering April 1 to June 30, 2023. All prescriptions are dispensed through an ADDS and monitored for quality control errors. In Q2 a total of 136,069 scripts were filled and 26 logged errors all caught by the pharmacist during pre-verification and never reached the patient. Two errors did reach the patient. Both were incorrect quantities of insulin pens and the result of human error (handpicked by a technician and adjudicated by a pharmacist). All staff directly involved were counseled and retrained where necessary. Currently re-educating staff focusing on data integrity, putting more information into the system which will initially result in an increase in errors in Q3. Would like to consistently fill approximately 4,000 scripts per day. Activity level depends upon the help needed by the Des Moines Central Fill facility.

Donated Prescription Drug and Medical Supply Redispensing Program

The board is finalizing forms with project partner Optum Health which is providing the BIN and PCN numbers. A communication will be sent to all South Dakota pharmacies with directions and forms. Pharmacies enroll voluntarily to participate in the program by completing three steps. Step 1 complete and retain on site the Participating Pharmacy Notice of Intent to Participate form, Step 2 complete and retain on site the Donation Record form, and Step 3 complete the Dispensing / Recipient Record form. The program should be self-explanatory. Avera and Monument each have pilot programs. All information will be maintained on a single registry with Avera and Monument adding their information to the registry.

DOH and BOP Website

The Department of Health redesigned their website as well as the board's site. A brief review of the new website's navigation was shown. The Nursing and Medical boards opted to have their websites independently designed at their expense.

Move to Sioux Falls One-Stop

The board was approached by the Department of Health (DOH) to move to the Sioux Falls One Stop building that is scheduled to be built in east Sioux Falls in 2025. All Sioux Falls boards (pharmacy, nursing, and medical) have been asked to move to the new location. Currently, DOH is gathering information regarding each board's needs – i.e., furniture, office space, configuration, etc. The assessed cost for the board's space in the new facility is 270% more than the board's current rent and expenses. The executive director respectfully requested to opt out of moving to the new location given the board's current financial obligations, revenue decline and having to approach the legislature for additional funding just to survive and don't want to add to this just to move. Pharmacy board funding comes from licensing fees only. Non-licensing board entities which are moving to the Sioux Falls One Stop building have access to general fund monies to cover moving expenses/increased rent. Members were asked to vote on measure. A motion was made for the board not to participate in the Sioux Falls One Stop. (Kraemer/Rising/unanimous).

Rules Rewrite

Proposed rules rewrite of Article 20:51 was submitted to the Department of Health. The rules escalation process has changed since last year with additional levels of review added by BFM and Governor's office. Executive director provided a high-level overview of proposed rules. All proposed changes were provided. Member Kraemer referenced page 73, nonhuman compounding records and discussed data collection requirements (DOB, weight). Most revisions are clean-up, form and style, and pharmacist fee increase allowed by current statute. Any rules that are removed are immediately deleted from the MPJE. If proposed rule changes make it into the interim rules review final cycle, the hearing with IRRC will be held on November 7, 2023, and rules become effective late November or early December 2023. If we are not allowed to have rules in this cycle, they will go to spring IRRC cycle. A motion was made to move forward with the proposed rule change process (Kraemer/Rising/unanimous).

NEW BUSINESS

USP Updates Go into Effect 11/1/2023

The board presented a policy statement draft as an interim stop gap measure to address USP updates until such time as the rules are passed so that when they go into effect on 11/1/23, we can enforce them. A motion was made to approve policy statement #23-09-14 (Kraemer/Somsen/unanimous).

Clair French Request for Waiver

Waiver request from Canadian Pharmacist French was reviewed and NABP's foreign pharmacist licensure requirements (FPGEC) were discussed. Although some states have implemented an expedited licensing path for Canadian pharmacists, attendees expressed concerns including potential issues when deviating from NABP's established licensing requirements, the impact of granting exceptions to a specific group of individuals and inadvertently establishing a precedent. The board elected to take no action.

OTHER BUSINESS

Recent Meeting News

- NABP District 5 Annual Meeting, August 9 – 11, 2023, Medora, ND

Future Board Meetings – all held at the Board Conference Room unless otherwise noted

- December 8, 2023, 9am-1pm CST
- April 4, 2024, 1pm-5pm CDT
- June 21, 2024, 8am-12pm CDT
- September 12, 2024, 1-5pm CDT in Brookings location TBD

Upcoming Meetings

- 137th SDPHA Annual convention, September 15-16, 2023, Deadwood, SD
- SDSHP 48th Annual Conference, April 5-6, 2024, Sioux Falls, SD
- NABP 120th Annual Meeting, May 15-17, 2024, Ft Worth, TX

Motion to adjourn (Rising/Somsen). Meeting adjourned at 3:36 pm (MDT).