

SOUTH DAKOTA BOARD OF PHARMACY

December 8, 2023

Unapproved Draft Minutes

9:00 am CST

Public Board Meeting

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

Board staff present: Kari Shanard-Koenders, Melissa DeNoon, Tyler Laetsch, Lee Cordell, Carol Smith, and Rhea Kontos.

Other parties in attendance: Emily Van Klompenberg, Gail Elliott, Jessica Strobl, Chelsey Conway, Melissa Gorecki, Sara Watson, Lindsey Riter-Rapp, David McVey, Amanda Bacon, Stephanie Monteiro, Makenzie Huber, Scout Forbes-Hurd, Lorri Walmsley, Khia Walser, Brad Liable, Bill Ladwig, and Maria Piacentino.

President Nelson called the meeting to order at 9:00 am CST. Mission statement read, introductions completed, and a quorum confirmed. A call for public comment was made pursuant to SDCL 1-25-1 and there was no public comment.

Health Professionals Assistance Program, HPAP, Maria Piacentino was allowed to present due to time constraints: I.4. Summary within Other Reports below.

Consent agenda: Cheri Kraemer asked for today's agenda to be pulled from Consent Calendar. There was no opposition. A motion for approval of the remaining consent calendar was approved (Somsen/Kraemer/unanimous).

Amend current agenda to:

Item D, Executive Session change per SDCL 1-25-2 (4) to: SDCL 1-25-2 (3) (Hansen/Somsen/unanimous).

Add Governor's interpretation of fee increase and Association funding after Discipline Section (Somsen/Hansen/unanimous).

9:17 am Move to Executive session. (Hansen/Kraemer/unanimous)

10:07 am Reconvened (Hansen/Kraemer/unanimous)

Motion to accept the volunteer surrender of Gina Hanson's pharmacist license #5151 (Somsen/Kraemer/unanimous).

E.1 Government Interpretation of denial of license fee increase and repealing funds to SDPHA.

Motion made to rescind the June 2023 motion to provide 80% of 2023 pharmacist renewal funding from pharmacist license renewals to the SDPHA.

Discussion: Shanard-Koenders shared that the Board has worked closely with the association and has high regard for the work being done by SDPHA. It is a perfectly bad storm due to lack of funding, being told to spend down, and no fee increases in over 20 years for most license types. The Governor's Office will not allow the fee increase bill to go to legislative session. Our original bill has been revamped and sent to Governor's LTF to provide for no increases for individual licensees, increases going for businesses only. We are told as long as the association is still being funded by the board, there will be no fee increase bill. The board will have approximately \$21,000 left in the bank at the end of FY24. The board feels strongly that we need to draft a letter to the Governor for reconsideration of this fee increase bill. If the Governor's office submits a repeal bill for SDCL 36-11-6, and they are planning to, we will need to support the repeal because we are an executive branch agency. Member Kraemer said that the Association has done incredible work but that the board must be kept viable. Member Hansen repeated the importance of the board's mission. Member Rising said that this is an opportunity for the association to explore other avenues and the board needs to support the association in other ways. Currently, the bill would incrementally change the funding from 80% to 50% - FY24, 25% - FY25, and complete repeal FY26. Makenzie Huber inquired how the SDPHA became fiscally tied to the board. Kari gave a brief history. A repeal was tried in 2005 and failed. No other state boards are tied to their respective associations. Kari added that the boards need to see if the Governor will add the fee increases to the repeal bill planned. The repeal SDCL 36-11-6 will evolve over the next few months according to Chair Tom Nelson. Bill Ludwig is concerned about the timing because pharmacists are struggling as it is. SD pharmacists have undervalued the association. Other states have strong associations. Seems to be no, "safety net". Motion carried (Hansen/Rising/unanimous)

Letter to governor discussion:

Chair introduced that the board is asking for a meeting with the governor and staff to discuss other options to the license fee increase bill. Board members have seen the letter. Chair recommends signing the letter as we are asking for a meeting to discuss and provide alternatives with revisions to the proposed bill. Member Somsen understands where the problem lies but we cannot let the Association dissolve, so asking pharmacists to support the association the best way they can. Motion carried (Hansen/Kraemer/unanimous)

REPORTS

Operations

Kari Shanard-Koenders report:

Regarding the expired terms of board members, Kraemer, Somsen, and Hansen, the state has not yet filled the expired term positions. Cabinet Secretary Melissa Magstadt has resubmitted the proposed recommendations. Currently, the board has had an extra year with Somsen; Kraemer and Hansen are up for reappointment. The board is working with DOH for acquiring increased funds from the Opioid Settlement Fund. The Department of Health is not asking the legislature to repeal the Controlled Substance Registration this year. Regarding the administrative rules, we are rewriting § 20:51:28 to remove that pharmacists may order all ACIP vaccinations. SDCL

requires a meeting of a three Board Committee, Pharmacy, Nursing and Medicine to determine administration standards. Medicine and Nursing Board representatives state that they have no problem with pharmacists administering vaccines, but they say there is no authority in law for ordering them, even though § 20:51:28 was written so that pharmacists could order influenza. We shared the rules with the SD Medical Association and asked for their support for them, we had a meeting and they stated that they did not want pharmacists ordering and administering to children 6 years or younger. We agreed with the SDSMA to leave those vaccinations to the well-child visits, if they agreed to allow SDPHA to submit a bill to allow pharmacists to order vaccinations to those 7 years old and older. Their response was that they support pharmacists vaccinating; however, they believe pharmacists should administer only seasonal vaccines. SDPHA believes it is too late to get a bill into session since they will not agree with us.

Inspectors

Carol Smith - An NABP USP 795 non-sterile compounding inspection was performed. Received questions on the new compounding rules. Responded to pharmacies that did not have any policy and procedures on what to do if refrigerator temps are out of range. Pharmacies were not recording refrigerator temps as well as a pharmacy with a new freezer with medication where temps were not recorded. Discovered pharmacies that were not having all the pharmacists sign the log verifying the controlled substance prescriptions that had their initials on it. One PIC was signing his name for everyone every day. Another pharmacy was not counseling or offering to counsel new prescriptions that were mailouts or deliveries. Lastly, another pharmacy was discovered using the entire NIOSH list as their pharmacy's NIOSH list as it must be specific to your pharmacy.

Lee Cordell - Controlled substance invoices were found not to be signed or not signed properly with each line item. Lots of questions fielded about new USP 795/797/800. SOPs not finished for new guidelines in locations. Noticed a lot of take-back bins are locked every time a visit was made so continued investigation of this matter. Looking into some trace waste guidelines for USP 800. Waiting to get telephone number on label for a tele-pharmacy.

Tyler Laetsch –USP questions for both hospital (797) and retail (795) continue. Have found that some pharmacies have stopped doing simple compounding. NABP inspection forms are improving with all questions on the documents. Noting improvement of billing of controlled substances rather than selling to an entity. Met with the other inspectors recently and worked on the proposed bill for the changes to SDCL 34-20-B. Board member, Ashley Hansen requested that new 222 forms be available for pharmacies. Tyler shared that the forms are available online on the DEA website.

Prescription Drug Monitoring Program

PDMP Assistant, Melanie Houg, retired on September 22. Brandi Dux, her replacement, started on November 20 and has been a great addition. The PDMP has still not received funding from the BJA FY '21 Harold Rogers PDMP Grant; per a call yesterday with BJA, a scope change request and budget modification request will be submitted for consideration. The PDMP Director stated a sustainable funding source is still needed since federal grants are not guaranteed, which is evidenced by the situation with this 2021 grant. A PharmaDrop drug take-back program update was provided. Refer to handout for PDMP statistics shared. Board member, Dan Somsen, asked what the PDMP budget is; \$300K is the base program budget the board has been funding; other program enhancement costs are being funded by the DOH's CDC grant.

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

Other Reports

SD Pharmacists Association

Executive Director, Amanda Bacon, shared that the recent news of SDCL 36-11-6 significant changes are "hard and sad". Presentation of the report followed starting with a recap of the September annual convention in Deadwood. Newly elected President, Jessica Strobl, of Lewis Drug, joined the SD BOP board meeting. Many awards were given at annual convention with many pharmacists celebrating 50 years of service. Currently preparing for the 99th legislative session which starts on January 9 with SDPhA Legislative Days following on February 13-14, 2024, which is a pivotal time. Since HB 1135 has passed, SDPhA has been focusing on how it works in practical application for regulating PBM's. Amanda explained the funds received through SDCL 36-11-6 provide for the day-to-day operations to the association, continuing education, and the Health Professionals Assistance Program. The funds are not to be used for lobbying. The C&L Fund accomplishes the work of the C&L Branch. Please consider contributing to the C&L Fund. Senator John Thune has played an important role as a member of the Senate Finance Committee. Next week is another meeting regarding CMS provisions. Attended many recent national and state meetings the last few months with spring ones coming up. The PTU program continues to grow with an increase in the Oglala Lakota student body. Amanda stated that the pharmacy industry is at a pivotal point and the association is asking pharmacists to engage. Board member Rising asked Amanda where the Division of Insurance information can be found. Amanda replied that the web page provides a link and that she would be adding more information regarding the division within future emails. Jessica Strobl, shared that she is looking forward to working with BOP.

SDSU College of Pharmacy

Brad Liable, Associate Dean, shared the latest updated regarding the Pharmacy program. The university is awaiting the results of the aggregated NAPLEX exam scores which typically come in year end. The new location on 33rd & Minnesota Ave is being utilized and may be expanded as the Nursing program may also move to this location. Regarding follow up to concerns on class size: P1's are 38, P2's are 41, P3's are 56 & P4's are 59. Many other colleges have seen decreased student numbers in pharmacy programs; however nationally Pharmacist enrollment is up 5%. Currently, two staff positions are open at SDSU with one being that of Associate Dean for Research in which there are 4 applicants. The other position is Dr. Liable's former position, and it is now entitled "Clinical Research in Transitions of Care" which is a partnership between SDSU & Avera.

SD Society of Health-System Pharmacists, SDSHP

Dr. Khia Walsler, PharmD presented an update for SDHSP. There were 2 social events hosted in October to celebrate National Pharmacy Month. The next annual meeting will be held April 5-6, 2024, at the Holiday Inn Downtown in Sioux Falls. There was a board member who stepped down and was replaced by Dr. Courtney Rogen, PharmD. She will take over as secretary. This year's resident liaison is Dr. Alisha Halver, PharmD from the Sioux Falls VA Health Care System. The annual Dakota Night was held on December 4th at Hotel Lulu in Anaheim, CA during the ASHP Midyear conference. This year the SDSHP Board of Directors has developed a strategic plan item for SDSHP to be more involved in the legislative process and be involved in promoting the advocacy for health-system pharmacists. Khia stated if there is anything that SDSHP could assist with or partner on to contact her and they will determine if they can assist.

SD HPAP

Maria Piacentino presented a brief update and reminded attendees that the purpose of the SD HPAP is to provide resources for recovery. Currently, the program has 6 participants which is down from recent years. It is estimated that 1-3 will successfully complete the program and will be able to achieve employment in the pharmacy field. Considering the downward trend, the request for annual funding will be reduced from \$15,000 to \$10,000/year if all goes well. 2 pharmacists are on the evaluation committee and, the program sees benefit from the volunteers who serve on this committee.

SD Association of Pharmacy Technicians (no report)

OLD BUSINESS

Donated Prescription Drug and Medical Supply Redispensing Program

Tyler shared that the paperwork portion is complete and the program should be ready to go live in Jan/Feb 2024.

Move to Sioux Falls One-Stop

Kari reported that a revised One-Stop plan with smaller space was provided to her; however, that revision did not meet what BOP can afford. After this revision, a second letter has been sent to the State with the request to opt out.

Update on Rules Rewrite

Proposed rules rewrite of Article 20:51 was submitted to the Department of Health and so to date, the Governor's office has not approved their moving forward. We believe they will, but we are moving toward rule hearing in February and IRRC in late March or early April after 2024 Legislative Session is complete.

NEW BUSINESS

Election of Officers, President, Vice President

Board decided to wait until the next board meeting on April 4, 2024, to elect board members. Kari shared that it would be good if the new Board member had been appointed and the currently expired members were reappointed.

Zoom Meetings vs. Teams Meetings

Should the Board continue to provide Zoom access to everyone? This provides live stream capabilities, which is a requirement. Does Zoom provide too many options for hackers? Teams or Zoom could be by invite only. State is moving generally to Teams format. As a side note, the BON has moved to in-person only meetings.

OTHER BUSINESS

Recent Meeting News

137th SDPHA Annual Convention, September 15-16, 2023, Deadwood, SD was a great meeting. NABP Member Interactive Forum, November 28-30, 2023. Member Ashley Hansen shared her experiences. Mental health was a highlighted topic. Understaffing, ability to hire, exploring new technologies to aid in Rx fulfillment. Pop-up Hydration clinics was a topic of discussion and concern about oversight and integrity of product. Learned about new tool called "pulse" for inspectors and pharmacies to use for compliance with DSCSA, that is available for no cost on NABP.

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

- April 4, 2024, 1pm-5pm CDT
- June 21, 2024, 8am-12pm CDT
- September 12, 2024, 1-5pm CDT in Brookings location TBD
- December 6, 2024, 9am-1pm CST

Upcoming Meetings

- SDSHP 48th Annual Conference, April 5-6, 2024, Sioux Falls, SD
- NABP 120th Annual Meeting, May 15-17, 2024, Ft Worth, TX
- District V NABP/AACP 2024 Meeting: Omaha, NE July 31 - August 2, 2024
- 138th SDPHA Annual Convention, September 13-14, 2024, Brookings, SD

Motion to adjourn (Somsen/Rising). Meeting adjourned at 12:16 pm (CST).