

SD Board of Pharmacy Meeting Minutes
April 7, 2022, 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 and via Zoom conference.

Board Members Present: President Dan Somsen, Tom Nelson, Ashley Hansen, Cheri Kraemer, and Curt Rising (zoom).

Board Staff Present: Executive Director Kari Shanard-Koenders; PDMP Director Melissa DeNoon, Inspectors Tyler Laetsch, Carol Smith, and Lee Cordell; and Secretary Rhea Kontos.

Attendees (in-person and via Zoom): Jessica Strobel, Jeremy Daniel, Emily Van Klompenburg, Amanda Bacon, Bill Ladwig, Chelsea Conway, Amanda McKnelley, David McVey, Michelle Aytay, Megan Borchert, Shanna O'Connor, Maimana Bruce Uzzell, Lori Ollerich, Jim Mennen, Gail Elliott, Andy Tonnesen, Lersula Chizhik, Ariel Clark, Alyssa Larson, Dan Hansen, Brett Stark, Lisa Greene, Amelia Koster, Sean Grosklags, and Hailey Kloiber.

A. Call to Order, Mission, Roll Call, and Introductions –President Dan Somsen

At 1:00 pm, the meeting was called to order by President Somsen. Board mission statement was read, roll taken, introductions completed, and it was determined that a quorum was present.

B. Public Comment

The floor was opened for comment. President Somsen added that comments are allowed during the entire meeting if appropriate. Hearing no comments, President Somsen moved to the Consent Agenda.

C. Consent Agenda

The consent agenda was ratified by voice vote (Kraemer/Hansen/unanimous).

D. Contested Case Hearings - Megan Borchert, JD, Assistant AG, David McVey, JD, Assistant AG

1. In The Matter of The Disciplinary Proceedings of Pharmacist Scott Mouw – completion of Probation

- Scott Mouw has completed his probation and is requesting a stipulation where he requests his pharmacist license be active without restrictions. He has completed his probation and stipulations therein. Ms. Borchert explained the process, documents served, and signed document by Mr. Mouw. Mr. McVey explained that if the board desires, the board motion should be to approve the AMENDED STIPULATION FOR ENTRY OF CONSENT ORDER as written. A motion to accept the AMENDED STIPULATION FOR ENTRY OF CONSENT ORDER was ratified by voice vote (Kraemer/Nelson/unanimous).

2. In The Matter of The Disciplinary Proceedings of Pharmacist Brett Stark – requested reduction of Probation

- Mr. Stark was present and not represented by council. Ms. Borchert stated that Mr. Stark was placed on probation on 9/20/2018 and is requesting to end his probation 4 months early. She explained the legal process. His motivation according to Amanda McKnelley, Midwest Health & HPAP is to return to work but stay in the HPAP program, until completion. The board is asked to approve the AMENDED STIPULATION FOR ENTRY OF CONSENT ORDER as written. A motion to approve the AMENDED STIPULATION FOR ENTRY OF CONSENT ORDER as written was ratified by voice vote (Kraemer/Hansen/unanimous). David McVey requested that Megan Borchert send the board all documents for President Somsen signature today.

E. Staff Reports

1. Operations Reports – Kari Shanard-Koenders, R.Ph., M.S.J., Executive Director
 - Regarding Board attorneys, the Department of Health (DOH) has hired Jennifer DeHueck to replace Justin Williams and they are searching for a replacement for Megan Borchert. We are working with AAG David McVey in the interim and are very happy with him.
 - Kari attended the Opioid Regulatory Collaborative Summit with American Association of Dental Boards (AADB), the Federation of State Medical Boards (FSMB), the National Association of Boards of Pharmacy (NABP) and the National Council of State Boards of Nursing (NCSBN). The opioid epidemic nationwide may have been backburnered by COVID but is now worse than ever. CDC reports 100,000 opioid overdoses in the last year. This collaboration allowed us to discuss all aspects for all represented providers. Student Education, Continuing Education, curriculum, standards of practice and much more were discussed. A huge concern noted by Addiction Medicine physicians is that pharmacies are not stocking buprenorphine, so it is not readily available when a patient has a prescription. Further, there still is a stigma to its use throughout the country. Statistics provided that upwards of 80% of Opioid Use Disorder (OUD) patients will recidivate without Medication Assisted Treatment (MAT) and most will die without it. HPAP does not allow Rx used to get back to work. Pharmacies used to be the gatekeeper for opioid prescriptions, but now may need to allow patients who have legitimate prescriptions to obtain them, but also assist those who want to quit using them.
 - Pharmacists refusing to fill prescriptions is something that we are receiving complaints on. Some are for reasons that a pharmacist seems to be projecting their personal biases onto the prescription. A CII Rx is on the same paper as an antibiotic post-surgery is one reason given. Pharmacist told patient it was illegal to fill. Others where the pharmacist is flat out telling the physician that they are not prescribing appropriately in their specialty is also concerning. Calling patients and upsetting them because of a bias. These things need to end. Pharmacists are super intelligent clinically, but don't always have the best common-sense skills.
2. Inspector Reports
 - a. Carol Smith, Inspector reported the following observations/occurrences:
 - Biennial Inventory reports continue to be an issue. Some pharmacies are not counting all controlled substances on the same day; counting C-II controlled substances one day and counting the C-III-V another day. Forgetting to count the outdated controlled substances, the controlled substance prescriptions that are filled but not yet picked up by patients (in the will call bin) and controlled substances in the AMDD's (pyxis and Omnicell). Everything must be counted on the same day at the same time BOB or EOB.
 - Improper documentation of partial filling of C-II prescriptions. The quantity dispensed must be written on the face of the prescription or in the electronic record of the prescription. Documenting, in only the perpetual inventory in not acceptable.

Collector receptacle was noted that was not secured to the floor and improper documentation was noted when the liner was sent in. The liner and seal number were not recorded.

C-II prescriptions were filled using nicknames and not the legal name from the insurance card. Ex Jim instead of James and Pat instead of Jean. This affects PDMP documentation. A person looking for James prescriptions will not find those with Jim on the name.
 - b. Lee Cordell, Inspector reported the following observations/occurrences:
 - It is difficult to do an audit on CIII-CIV medications if pharmacies are only doing an estimate per the DEA guidelines on Biennial inventory. If the audits are off by large margins, we are requesting they do exact counts or have accountability for the unaccounted-for controlled substances.
 - Some pharmacies are not removing patient specific information from bottles when they are reversed and placed back on the shelf.

- Main facility ordering controlled substances for off-site facilities and not executing DEA 222 form properly or sending them with the product.
 - Pharmacies not knowing they need to submit a request for the 4:1 variance of technicians to pharmacists.
 - Hazardous medications in robots.
 - “White Bagging” among mail order pharmacists for vaccinations and other injectables.
 - A hot topic amongst pharmacies is that of testosterone RX filling for gender reassignment in a minor. This potentially has implications and pharmacists need further education. Others added that parental consent is required at the point of gender reassignment, prior to any prescriptions being written. Board members and attendees discussed the variables and sought to find the aid of an expert in the field of gender reassignment to help educate the board and pharmacists. David McVey said he would contact one of the state’s experts in the field to ask for their input. Dan Somsen suggested to table the topic, no action is required.
 - More discussion was had regarding PBM practices and how they affect pharmacy. SB163 would have been a helpful tool, unfortunately it did not pass. Transparency is needed in PBM practices. Cheri Kraemer suggested pharmacists maintain a list of overcharges. Dan Somsen said there has been a history of Medicare Part B overcharges since 2005 when PDM’s made it to their advantage. Generic and brand effective rate plays into the billing which makes it more difficult.
- c. Tyler Laetsch, Inspector reported the following observations/occurrences:
- In the next school year, the Board (Tyler) will precept 6 interns.
 - The new NABP test questions have been written.
 - Listened to the ACPE Webinar from CE Impact. Many classes offered, including a PIC Boot Camp and a pharmacist refresher course, which may be valuable with disciplined individuals and reinstatements. Ashley Hansen interjected that she uses CE impact for the IA pharmacist licensure program.
 - Unit dosing in baggies is not appropriate. Signatures are required on CS inventory. There must be a Logbook for all parts of take back sites and it needs to be completed.
 - The Board has had more questions about central fill from chains. Hy-Vee is the only one in the state at present.
 - We get many Telemedicine questions. Often confusion between telemedicine and telepharmacy.
 - PDMP audits are being performed as a pilot.
 - In the case of the Vanderbilt nurse, where the patient died due to a medication error, there now is fear of retribution amongst the health care field and will there be less error reporting because of that fear? Kari Shanard-Koenders interjected that some boards are considering law/rules for a medical error and the pharmacy board may need to consider this as well to have some liability protections.
 - Compounding FDA approved commercially available products can lead to potential errors. Some compounding is not covered by third parties. Dan asked how many recalls are known on commercially available products.
3. PDMP Director Melissa DeNoon reported the following program updates:
- PDMP Updates
 - BJA FY 21 Harold Rogers PDMP Grant – funding draw down still pending final budget clearance; project period start date was October 1, 2021
 - PMP InterConnect data sharing set up with FL – currently share with 39 other PDMPs
 - Current staff focus on data integrity including data submission compliance and error correction
 - Presentations Given/Events Attended
 - Opioid Abuse Advisory Committee – PDMP update
 - SD Legislature’s Senate and House Health and Human Services Committees – Annual PDMP Opioid Report
 - NASCSA Executive Committee Midyear Meeting – Savannah, GA
 - New SD DOH Opioid Program Director – PDMP 101 presentation

- Upcoming Events
 - SDSU College of Pharmacy P2 Class PDMP presentation – April 19, 2022
 - APhA Institute on Substance Use Disorders June 1-5, 2022 – Salt Lake City, UT
- PDMP Statistics
 - SD Legislature’s Annual Report 3-year (2019/2020/2021) trending statistics shared: 1) Opioid prescription metrics to SD patients – rx count, rx total quantity dispensed, and rx total days of supply, 2) Top SD patient counties by opioid rx count, and 3) PharmaDrop Drug Take-Back Program receptacle count and total pounds returned from 2017 through 2021
 - PDMP utilization by SD prescribers and pharmacists from January 2018 through December 2021

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

Reported by Tyler Laetsch, Lee Cordell, and Carol Smith.

1. DEA Form 106- HyVee Vermillion
2. Complaint #2022-0001 Technician diversion
3. Complaint #2022-0002 Pharmacist refusal to fill
4. Complaint #2022-0003 Dispensing error
5. Complaint #2022-0004 Compounding error
6. DEA Form 106—HyVee Minnesota Ave.
7. DEA Form 106—Safeway Mt. Rushmore Rd
8. DEA Form 106—Walgreen’s Yankton
9. DEA Form 106—Scotland Pharmacy
10. DEA Form 106—Brandon Pharmacy
11. DEA Form 106—CVS Louise Ave.

G. SD Pharmacists Association – Amanda Bacon, SDPHA Executive Director; Kristin Carter, Pharm D., SDPHA President

1. Activity Report
 - The 97th Legislative Session has drawn to a close with many interesting features such as covid-19 considerations. 20% of legislator turnover proved to be a challenging session to achieve the gains we’d hoped for.
 - The SB 163 cleared the Senate Committee, but it was an uphill battle from there with PBM and Insurance lobby in full force. SD 163 failed on a 17-17 vote. The sponsor gave intent to reconsider, but that reconsideration failed. IA ran a similar bill last year but Wellmark’s lobby killed it. The NCPA was helpful in the endeavor.
 - Other Key bills: HB 1086- passed, HB 1267 - failed, & HB 1242 – passed.
 - Continue to need funding to aid in the lobbying efforts.
 - Legislative Days was Jan 25-6. Lindsey Riter-Rapp and Amanda Bacon discussed various bills with attendees, including excellent student participation. Considering moving the Legislative Days to February in 2023 to capture more students.
 - Amanda joined Dr. Erin Miller’s classroom virtually on February 24th to provide the students with a walk thru on how the legislative process works.
 - Please attend the Spring District Meeting(s) which be held April 10 – April 28, 2022.
 - The 136th Annual meeting is to be held Sept 9-10 in Brookings SD. Early bird registration to open soon.
 - SDPHA has submitted comments to the FTC, the Centers for Medicare and CMS regarding detrimental PBM practices regarding DIR feeds and their 2023 proposal.
 - Pharmacy Technician University (PTU) has now enrolled 123 students since SDPHA started working with them.
 - Continue to work closely with SDSU pharmacy students and they worked extremely hard assisting with the 2021 virtual meeting.

- Kari Shanard-Koenders interjected that donating to the C & L fund is critical. Amanda thanked Kari for the plug and that for instance, 9 lobbyist represented Insurance and PDM's and with the 2 lobbyists the SDPHA places on the Senate floor this uneven representation is challenging.
 - Kari Shanard-Koenders shared that Lisa Rave is running for Senate in District 25.
2. Financial Report – provided not reviewed

H. Other Reports

1. SDSU College of Pharmacy – Dan Hansen, PharmD, Dean and Professor reported that ACPE approved the accreditation of the CE program through January 31, 2028. The peer review process will take place in a few weeks and the on-site evaluation is scheduled for October 18-20, 2022.
 - Faculty & Staff Updates:
 - Stacie Lansink, MLS program director, was recognized in the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) Annual Report for her service as on-site evaluator for MLS programs.
 - Dr. Brittney Meyer, IPE coordinator and associate professor, received the University's Excellence in Outreach Award.
 - Dr. Om Perumal, associate dean for research and professor, received the Global Achievement Award in International Affairs from the Office of International Affairs.
 - Two new people joined the College. Jacob Ford started on January 10th as the scientific writer for the Community Practice and Innovation Center (CPIC). Dr. Tareq Al-Maqtari joined the College of Pharmacy & Allied Health Professions on January 24th as a visiting scholar and to help teach pharmacology.
 - Dr. Brad Laible, a professor of pharmacy practice and a member of the College of Pharmacy and Allied Health Professions since 2004, was named the college's interim associate dean for academic programs. He began his duties Jan. 10, when Teresa Seefeldt transitioned into the vice-provost for undergraduate education for SDSU. Dan Hansen recognized and thanked Teresa for her years of service to the College.
 - Searches are underway for the following positions: associate dean for academic programs, department head of pharmaceutical sciences, post-doctoral fellowship in population health, recruitment and outreach coordinator, and a program assistant in the Department of Allied and Population Health.
 - Kari Shanard-Koenders shared that the school is aiding in helping with the district 5 meeting.
2. SD Society of Health System Pharmacists – Jeremy Daniel, Pharm.D., SDSHP President
 - Three Virtual Resident CE Presentations were successfully h in February with solid attendance each day and great feedback from attendees. SDSHP is very grateful to Scout Forbes-Hurd from SDSU for taking care of all the ACPE items on the back end, especially with complicated and last-minute changes.
 - Resident Conference – planning is underway for the 2022 Resident Conference hosted by SDSHP each summer. They are in very early stages of planning but looking at June/July for dates. Current resident liaison Kathryn Brummels from Monument Health oversees organizing the activity. Planning on an in-person event at Arrowwood Cedar Shore Resort in Oacoma.
 - The GVR Golf Classic planning for the 20th annual GVR open has begun. Look for more details coming soon. Planned for July 2022
 - DEI Statement – SDSHP has drafted a Diversity, Equity, and Inclusion statement and will debut this for the membership at the Annual Meeting. This will also be shared with the BOP during this meeting.
 - SDSHP Annual Conference will April 8-9th. Looking forward to our second (and hopefully last) virtual meeting. The 2023 SDSHP Annual Meeting will be held in Sioux Falls on March 31-April 1.
 - Board Changes – Haylee Allen cycling off as current Past President, Jeremy Daniel moving to Past President, Alyssa Larson moving to President. Khia Walser (Warzecha) moving from Treasurer to President Elect and being replaced by Hannah Reedstrom from Avera. Stephanie Iverson cycling off at Board Member at Large, replaced by Billy Anderson from Avera. Jenna Lund remains secretary and Leah Garland remains Board Member at Large.
3. SD Association of Pharmacy Technicians – John Thorns, CPhT (Not in Attendance).

- No report submitted but Jeremy Daniel said that the pharmacy technicians are working with them to assist with upcoming CE.

I. Old Business

1. Board Policy Statement Number 22-01-02, which allows pharmacies to request a 4:1 technician ratio variance in special circumstances was discussed. This was a December Board Meeting request for staff to write since pharmacies are overwhelmed with immunizations. Since then, Walmart was approved at the December meeting, Walgreens and Safeway have requested this variance and been approved.
 - A motion to approve Policy Statement 22-01-02 as proposed was ratified by voice vote (Nelson/Kraemer/unanimous.)
2. Hy-Vee – Report on Technician Immunization Pilot Project – Jim Mennen, BPharm, MS, MBA, Asst. VP Pharmacy Compliance, Hy-Vee
 - Originally approved in October 2021. Hy-Vee seeking a year extension. Dan Somsen inquired if there is a trainer on site and what happens if adverse event. Board members asked who gives the immunization counseling before the vaccine is given. Other board members had questions and a pause on topic was given so the original variance could be sourced and reviewed.
 - During the pause, Dan Hansen, shared the SDSU College of Pharmacy report which is above in “Other Reports”.
 - With the variance located it was determined that the pharmacist does provide the counseling not the technician. Ashley Hansen commented that they need to be sure that the pharmacist is involved in the vaccination counseling. Dan Somsen stated that vaccinations are a good time for pharmacists to educate the client on vaccine benefits and that it is not the responsibility of the technician.
 - Board members raised questions regarding what will occur once the PREP Act ends. Kari stated that the policy statement provides that it will expire if the PREP Act expires, or the Board rescinds the policy statement. Technicians would then go back to doing only those jobs authorized by rules or, we make change in the rules to allow this going forward.
 - A motion to accept the variance renewal for one year (including reporting to the Board) as proposed with an addition that the pharmacist is doing the education was ratified by voice vote (Hansen/Kraemer/unanimous).
3. FDA MOU with States on Compounding
 - Cheri Kramer reported that when she was in DC last November, she learned that the MOU was tabled because not all procedures we followed so at this point it will need to be redrawn. Approximately 7 -9 pharmacies made a case that it was unlawful, and the judge approved. Kari Shanard-Koenders commented that rules need to be created first. Cheri Kramer said that it did not address percentages and it will come back. Dan Somsen asked when it will come back. Kraemer said 2023 and what can be done to prepare. Most pharmacies who ship compounded products across state lines are aware.
4. Update on USP <795>, <797>, <800>, <825> - Tyler Laetsch
 - Tyler said that a public comment period end was March 31st. Proposed changes made are not much different than that of 2019.
 - 797 is cleaner since it removed categories
 - Cheri Kraemer added that IA adopted 800.

J. New Business

1. HB 1086--provide for the redistribution of donated prescription drugs and medical supplies. The bill has passed and signed into law by Governor Noem
 - Kari Shanard-Koenders shared that Avera had requested a pilot project to do this with reusable sealed packaging. If reviewed by pharmacist, it can be re-dispensed.

- Board needs to write the rules yet and create a database and forms for patient.
 - Possibility of adding a fee for dispensing/shipping.
 - IA has similar program but geared to prison population. \$800,000 budget funded by legislature.
 - SD program will start with expensive prescription medications, only non-Controlled Substances, no liquids, or refrigerated medications.
 - SD program is unfunded, and need to search best and least expensive data base
2. Canadian medications were discussed as Board Office is fielding many questions regarding this.
- More and more people are asking if they can use medications from Canada.
 - Monument Health Specialty Pharmacy shared with us a concern regarding a message they received when trying to fill a patient's prescription. The PBM/Insurance company referred the Rx to SHARx who finds the best price for the prescription and told them that the patient needs to have it filled in Canada at Mark's Marine Pharmacy. Upon review, this pharmacy is on the NABP "not recommended" list. Not only that, but it is illegal to ship into our state for a South Dakota resident without a license. We have no Canadian pharmacies licensed.
 - Apparently, if a US Rx is sent to a Canadian pharmacy, a Canadian Dr who is affiliated with the pharmacy can cosign an Rx if physician completes paperwork on the patient.
 - ND has passed a law allowing their patients to obtain medications from Canada, but SD has not.

K. Other Business

1. Recent Meeting News
- a. 2022 ASHP Virtual Meeting of Health System Pharmacists on State Boards of Pharmacy – Ashley Hansen, Pharm D
- Off-label COVID-19 Therapies. Seemed to be about state legislatures and legality of prescribing ivermectin for COVID. Discussed it was essentially a non-issue to allow off-label prescribing of an FDA approved medication
 - White Bagging was another topic. The group discussed what State Boards of Pharmacy are doing about this issue. Only a handful of states discussed making a policy around this issue. At current state, it is left up to the individual hospitals/facilities on if the practice is allowed. Discussed the risks of allowing this practice (lack of track/trace info, patient delay in treatment due to delay with shipping pharmacy, shipping integrity) vs. risks of not allowing (patient's navigating how to get treatment from a participating location, resources at facilities to assist patients, travel of patient to find therapy).
 - Hospital Compounding section of meeting discussed new USP chapters and enforcement.
 - Pharmacy Workforce issues were also brought forth with Interstate Pharmacy Practice and Pharmacy Licensure Compact status mentioned.
 - Board Oversight of "Hospital at Home" program also was discussed around how BOPs are going to inspect these and/or offer regulations for this model.
 - Controlled Substances and Marijuana were discussed from both a patient own meds in hospital setting and recreational policy perspectives.
 - Kari Shanard-Koenders added that NABP has a 'Verify' program which for \$50 a year and if in good standing a license will be issued based on 1st license. The state needs to adopt it prior to us recognizing it.
- b. Opioid Regulatory Collaborative Summit, March 7-8, 2022, National Academies of Medicine, Washington DC already discussed.
2. Future Board Meeting Dates – all held in Sioux Falls Board Room unless otherwise noted
- a. June 24, 2022, 8am – 12 pm CDT

- b. September 8, 2022, in conjunction with SDPhA 136th Annual Convention, Brookings, location TBD
- c. December 9, 2022, 9am – 1pm CST
- d. March 30, 2023, Sioux Falls, SD 1pm – 5pm CDT in conjunction with SDSPH Annual Meeting, Sioux Falls

3. Upcoming Meetings

- a. SDSHP 46th Annual Conference, April 8-9, 2022, Virtual
- b. 118th NAPB Annual Meeting – May 19-21, 2022, Sheraton Wild Horse Pass, Phoenix
- c. NABP/AACP 85th Annual District V Meeting, August 3-5, 2022, Custer State Park, working with the College of Pharmacy and Allied Health Professions to prepare
- d. 136th SDPHA Annual Meeting September 9-10, 2022, Brookings

4. Tom Nelson suggested board staff investigate what would be needed to create an emeritus status for retired pharmacists. NE and MN have emeritus status and he gets many questions on this topic.

L. Adjourn

President Somsen again opened the floor for public comment. Hearing none, Hansen made motion to adjourn. Meeting adjourned at 4:30 pm.

Dan Somsen, President

Date

Kari Shanard-Koenders, Ex. Director

Date