

SD Board of Pharmacy Meeting Minutes
Friday, June 7, 2019; 8:00 a.m. CDT
South Dakota Board of Pharmacy Conference Room
4001 W. Valhalla Blvd, Suite 202, Sioux Falls, SD 57106

Board Members Present: President Diane Dady; Members Lenny Petrik, Tom Nelson, and Lisa Rave

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

Attendees Present: Amanda Bacon (SDPhA), Justin Manning (Hy-Vee), Rose Fitzgerald (SDSHP), Lucas Kraemer and Kiera Kraemer (Pharmacy Specialties & Clinic); Melissa Goff, Rachel Elsey, Robin Lockhorst, and Matt Toennies (Avera); Joe Bergsmith (Walmart), Jon Beeler (Avera LTC Pharmacy), Dennis McAllister (Express Scripts), Bill Van Camp, Elizabeth Stoll and Vince Hanks (Baxter Healthcare); by phone Mark Gerdes (Avera LTC), Becca Mellum and Kerri Ashby (Regional LTC).

A. Call to Order and Introductions

At 8:00 a.m. the meeting was called to order by President Dady who read the Board of Pharmacy mission statement. Board Members, Board Staff and meeting attendee introductions followed. Voice roll call was taken and a quorum was present.

B. Consent Agenda

The President reviewed the consent agenda noting any items could be removed for discussion. Lisa Rave made a motion approve the consent agenda; motion was seconded by Tom Nelson. Voice roll call was taken; motion passed (4-0).

C. Staff Reports

1. Operations Report – Kari Shanard-Koenders, R.Ph., Executive Director
 - a. The Executive Director indicated all Board efforts are currently focused on PDMP enhancements and funding, new graduate processing/licensing, as well as full-time, part-time and nonresident license renewals.
 - b. This is the first-time new graduate licensing, full-time, part-time and nonresident license renewals are utilizing the new online licensing platform. This year, new licensing requirements were added for in-state pharmacies (i.e. business description, a listing of other states pharmacy is licensed in) to align in-state and nonresident pharmacy licensing requirements.
 - c. Feedback has been positive for the most part as licensees appreciate having 24/7 access to complete the licensing process, are now able to print their updated license from the platform and understand technology glitches are being addressed and worked through. Vendor response time has been excellent.

2. Inspector Reports

a. Tyler Laetsch, Inspector

Reported the following items/observations/occurrences:

- Staffing of small hospitals being done by retail pharmacist coming in 2-3 hours a day to stock/fill and does not have access to online platform to order meds.
- Small entities including OR and post-surgical do not have good methods of documenting/recording med wasting.
- Many pharmacies are not signing log book or print out.
- Fielding many questions regarding sterile compounding, hazardous drugs, hospital telepharmacy and staffing in small hospitals
- Inspectors started using new I-Gov inspection platform in January and it is working well
- Board received over two dozen calls regarding fake scripts hitting the eastern side of the state. Scripts are believed to come from Iowa and Chicago, IL, the callers are using legitimate doctors with valid DEA numbers. South Dakota pharmacists have been calling the prescribing doctor(s) to verify. No arrests have been made, that we are aware of.
- Most retail chain pharmacies are establishing Narcan protocols.
- Report of nursing home RN taking patient medications; incident does not qualify for 106 report because diversion is patient specific and not a pharmacy diversion

b. Paula Stotz, Inspector

Reported the following items/observations/occurrences:

- Helped the Pharmacists-in-Charge (PIC) close Shopko pharmacies in the western part of the state. The Board website (<https://doh.sd.gov/boards/pharmacy/pharmacies.aspx>) offers helpful information on the subject. PICs received minimal directives from headquarters and were under a short timeline to accomplish pharmacy closures
- Questions regarding filled prescriptions on hold continue. Some chain pharmacies do not allow the transferring of prescriptions on hold. The Board's Policy Statement regarding prescription holds is posted on its website.
- After an employee granted POA authority leaves employment, entities are forgetting to revoke the former employee's Power of Attorney and establish a new POA. If corporate personnel order CII's,
- A current POA needs to be on file at the registered pharmacy location
- Biennial inventory is to be conducted on one day and completed the same day at opening or closing, in printed or written form, and signed and dated by persons conducting the inventory. It should not be carried out over multiple days.
- CSOS is not finalized on the wholesaler website.
- When changing package size be accurate and use the correct NDC numbers; it may be the same drug, but different package size can impact audit and may be potential insurance fraud.
- Pharmacy findings:
 - Pharmacy thought they could sell Narcan without a prescription after seeing a news report that Narcan was available over-the-counter. Currently in SD, Narcan can be obtained by a prescription order, or at a pharmacy that has a Protocol with a SD Prescriber.
 - Pharmacy not reporting immunizations to the Registry per protocol; they reported the immunization to the primary care provider only and assumed the provider would report the immunization to the registry.

c. Carol Smith, Inspector

Reported the following items/observations/occurrences:

- Pharmacies not working toward implementing USP 800 and NIOSH
- Two unregistered technicians in one pharmacy, who had been employed almost 3 months
- Found unrevoked POAs
- Two pharmacies with no log book to sign for controlled substances that were dispensed
- Pharmacy who has not conducted a biennial inventory for two years
- Pharmacy staff, no one wearing name tag
- Pharmacists leaving the pharmacy without the “Pharmacy Services Closed” sign
- Pharmacists not including all controlled substances in biennial inventory
- DEA number missing from the transaction invoice when controlled substance was sold

3. PDMP Report

PDMP Director Melissa DeNoon reported the following updates:

a. Statistics

- SD patients’ opioid prescriptions for 2016/2017/2018 are trending as follows: prescription count is down 19.3%, prescription total quantity is down 26.4%, and prescription total days of supply is down 21.5%
- PDMP utilization increased four-fold for prescribers and five-fold for pharmacists
- Top ten controlled substances year over year in three measured parameters show a continued opioid decrease but a rise in stimulants
- New report, opioid prescription count by SD counties by patient zip code. Expected to yield some interesting information regarding activity by county populations

b. Presentations Given

- SD Senate and House Health & Human Services Committees Annual PDMP Opioid Report
- SDSU College of Pharmacy P2 law class
- SD Association for Healthcare Quality Spring Conference
- USD Sanford School of Medicine first year medical students
- SDSMA Ad Hoc Committee on Pain Management and RX Drug Abuse
- Webinars
 - SDAHO Project “Opioids: Change the Script”
 - Great Plains Rural Communities Opioid Response Program

c. Project Updates

- 2016 Harold Rogers PDMP Grant Funds
 - Sanford Health Integration Project – go-live January 8, 2019
 - Additional proposed projects with remaining funds - six months of NarxCare and a license integration project with SD’s professional licensing boards
- 2018 COAP Grant Funds
 - Grant projects – enhancement of PMP AWAxE with NarxCare and statewide Gateway integration; must first fulfill grant special condition of connection with the RxCheck hub to receive this federal funding
 - SD BOP currently participates in PMP InterConnect through NABP which was developed by Appriss Health, our PDMP platform vendor; a majority of states participate in PMP InterConnect.

- The SD PDMP's connection to the RxCheck hub will allow states who submit a query to SD through RxCheck to get data returned through RxCheck; the SD PDMP will continue current use of PMP InterConnect.
 - 2019 CDC OD2A Grant - the SD DOH applied for this grant which also requires connection to the RxCheck hub; the SD BOP's proposed grant projects are continued funding of Clinical Alerts and Prescriber Reports and the addition of the Advanced PMP Analytics tool.
- d. Due to additional funding through the SD DSS, the MedDrop Program has expanded to include hospitals, added more locations, and is one step closer to achieving the Board's goal of having one MedDrop receptacle in each county. Trilogy MedWaste currently provides a report of the number of pounds incinerated each month. The SD BOP's program is for pharmacies; however, many SD law enforcement agencies also have permanent receptacles and those that don't will store returned medications on site until they can be given to the DEA during the two take-back days they sponsor each year.

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

The following were reported by Tyler Laetsch, Paula Stotz, and Carol and discussed.

1. DEA Form 106 - CVS #16018 Sioux Falls
2. Complaint—Labeling of medications
3. Complaint—IV Medication for oral use
4. DEA Form 106—Lewis Family Drug #72 Mitchell
5. DEA Form 106—Avera Sacred Heart Hospital
6. DEA Form 106—Sioux Falls Specialty Hospital
7. DEA Form 106—Lewis Drug Brandon
8. Complaint—Controlled substance refilling without authorization
9. DEA Form 106--Avera Queen of Peace Hospital
10. Complaint—Shipping into state without proper license
11. Complaint—Selling trademark medication without authorization
12. Complaint— Dispensing Error
13. Complaint—Changing quantities on prescriptions
14. DEA Form 106—Rapid City Regional Hospital
15. DEA Form 106—Avera St. Luke's Hospital
16. Complaint—Dispensing medications too soon for possible addicted family member
17. Complaint—Refusing to fill a prescription by provider as out of providers scope of practice

E. SD Pharmacists Association – Amanda Bacon, SDPhA

1. Activity Report – the following items from the March and May Updates were highlighted by Ms. Bacon
 - a. The SDPhA Board completed its annual retreat on May 31st. Topics discussed included budgets, PDMP, how to engage new pharmacists and pharmacy students, what do members want from the Association (to provide/focus on). Issues/suggested session topics included work life balance, human resources, and how to run a pharmacy. The number one reason why individuals age 40 and under do not attend SDPhA meetings is childcare.
 - b. 2019 Legislative Session – The Association spent most of its energy on HB 1137 which unanimously passed through both chambers and was signed into law. The bill's three major components are preventing Pharmacy Benefit Managers (PBM) clawbacks, preventing retroactive DIR fees, and establishing 340b program protections. The law goes into effect July 1, 2019. For a brief review of industry national bills see handout.

- c. Former SDPhA president Eric Grocott, along with SD pharmacists Shane Clarambeau and Curt and Shirley Rising attended the NCPA Congressional Pharmacy Summit held in Washington, DC April 10-11, 2019.
- d. Pharmacy Technician University (PTU) - SDPhA continues to offer low-cost access to this online training module. Currently 49 individuals are enrolled in the one-year program at a cost of \$325.00 with a \$25 administration fee for total fee of \$350. Enrollees have one year from the date of enrollment to complete the program and test. New requirements, from PTCB, are coming in 2020.
- e. In the coming year, SDPhA plans to focus on Commercial and Legislative fundraising efforts.
- f. The SDPhA annual convention will be held September 13-14, 2019 at the Deadwood Lodge. Angela Kennecke will be the keynote speaker. Register online at www.sdpha.org.

2. Financial Reports were not reviewed

3. SDPhA Annual Funding Discussion (SDCL 36-11-6)

Board member Tom Nelson inquired whether there were any discussions regarding changes to SDPhA funding. Currently, 80 percent of all funds generated from pharmacist license renewals processed by the Board of Pharmacy is given to SDPhA each year. There was no further discussion on the topic.

Tom Nelson made a motion to approve SDPhA funding of 80% per SDCL 36-11-6 for the 2020 fiscal year. Motion was seconded by Lenny Petrik and unanimously approved (4-0). Motion carried.

F. Other Reports

1. SDSU College of Pharmacy – Jane Mort, Pharm D., Dean and Professor, College of Pharmacy and Allied Health Professions Department (report highlights read by Lenny Petrik)

College's activities since 12/8/19 SD Board of Pharmacy meeting

- P4 students on track to graduate spring of 2019 (77) compared to earlier classes - 2018 (77), 2017 (76), and 2016 (73)
- SDSU Pharm.D. students had the highest first-time pass rate in the nation on the NAPLEX for 2016-18 graduates with a pass rate of 99.1% compared to a national average of 87.8%.
- In 2018, 100% of College of Pharmacy graduates at SDSU passed the NAPLEX exam on the first attempt.
- The College has an overall PGY1 Residency match percent of 82.2% versus 64% nationally.
- Applicant numbers are down; admitted students for fall 2019 are academically strong (GPA 3.73, ACT 27.3)

Faculty Updates

- MLS Instructor – Ms. Kassi Erickson
- Assistant to the Dean – Ms. Kristy Ullom
- Associate Dean for Academic Programs – Dr. Teresa Seefeldt
- Searches are underway for Assistant Professor/Coordinator MPH and Pharmacy Administration Faculty positions

Please refer to the SDSU College of Pharmacy handout for a listing of funding and grant successes as well as faculty and staff award and recognition recipients.

2. SD Society of Health System Pharmacists (SDSHP) – Board Member Rose Fitzgerald, Pharm D.

- Despite adverse weather conditions, the April 2019 annual meeting in Deadwood went well with in-person and digital hybrid delivery of CE. SDSHP Board transitions also occurred, and Gary Van Riper officially stepped down.
- SDSHP is offering a new \$500 grant for a residency project in the state that aligns with SDSHP's strategic plan. Applications will be sent to new residency class.
- Congratulations to Tadd Hellwig who was named as ASHP Fellow
- Congratulations to Tom Johnson who is slated for an ASHP national position as a candidate for president. A full listing of candidates can be viewed on the ASHP website.

3. SD Association of Pharmacy Technicians – Jerrie Vedvei, CPhT (not in attendance, no report)

G. Old Business

1. Avera Long Term Care E-Kit Variance for all LTC E-Kits - Mark Gerdes, R.Ph.; Melissa Goff, Pharm. D.

As stated in handouts dated 11/1/18 and 03/29/19, Mark Gerdes, Avera Long-Term Care Pharmacy, comes before the Board requesting a three-year variance to the number/quantities of medications available in emergency kits (E-Kits) as set forth in (20:51:15:15) and (44:58:07:09). Avera LTC currently has an E-Kit variance that was granted for the purpose of transitioning to AMDD utilization.

Avera LTC is requesting a variance to allow for 60 oral medications, 40 injectable medications and 6 controlled substance medications in each facility's E-Kit. Long term care systems are experiencing significant changes including increased utilization of IV medications, massive growth in hospice care, increased scope of care with eCare collaborations, geographic limitations, and an increase in hospital discharges of higher acuity patients. The variance would also give medical directors at facilities the flexibility to determine what should be in medical kits.

President Dady noted law and rule in this area is antiquated and needs revision. Executive Director Shanard-Koenders concurred and shared that changes are underway. Board member Petrik made a motion to allow Avera LTC facilities a one-year variance allowing all E-Kits a supply of up to 60 oral medications, 40 injectable medications and 6 controlled substance medications whether or not a facility has an AMDD with no reporting requirements. Tom Nelson seconded the motion. Voice roll call was taken; motion passed (3-0). Board member Rave abstained.

2. Pharmacy Technician Scope in Neighboring States - Tyler Laetsch on Behalf of Kenton Welbig P4 intern

The main objective of P4 intern Kenton Welbig's research was to delineate the differences in tasks/requirements South Dakota pharmacy technicians versus technicians in surrounding states (MN, IA, NE, WY, and ND) may perform. Key data points of comparison also included licensing, certification, CE requirements, settings-pharmacy, hospital/institutional, community, as well as tasks technicians may and may not perform. Data was obtained from the National Boards of Pharmacy (NABP) website.

3. Talyst (Swisslog) Edgewood Assisted Living Facility (ALC) update - Becca Mellum, CPhT, Kerri Ashby, R.Ph.

Becca Mellum and Kerri Ashby came before the Board to provide an annual update, a requirement of their current variance. A summary review of objectives, improvements, staffing, services, dispensing mechanisms and post implementation was provided for both entities that use the Talyst/Swisslog system (Regional LTC Pharmacy and Edgewood Assisted Living). Feedback from families and residence has been positive overall. Initially there was some hesitancy switching from a pharmacy to in-house dispensing.

Paying for only what is dispensed, instead of a 30-day supply of a medication, is a cost savings that families appreciate.

4. USP <795> & USP <797>

- USP 795 and USP 797 published June 1, 2019 for go live date of December 1, 2019
- South Dakota has rules for previous USP 797 only; a rewrite will need to be done
- Implementing yearly testing in compounding competency
- UPS 795 changes to note – BUD dates, environment, no carpet, clean daily, temperature taken daily
- USP 800 / NIOSH go live December 1, 2019
- Still getting conflicting information regarding who USP 800 applies to (all facilities or only compounding facilities)

H. New Business

1. Baxter Healthcare, Dialysate – Bill Van Camp, Elizabeth Stoll, Vince Hanks

Per Elizabeth Stoll, Baxter Healthcare delivers peritoneal dialysis solutions and device products to the homes of patients undergoing end-stage renal disease (ESRD) therapy and transplants. Delivery of products occurs from a closed-door distribution center/warehouse located in one of 39 locations. Baxter offers an alternative to in-hospital treatment by shipping solutions and tubing directly to the home allowing patient to stay at home for up to three months. Prior to beginning services, patients train on-site with a registered nurse. Product is FDA approved and labelled for specific patient, based on a prescription. Baxter holds both a South Dakota wholesale license and a non-resident pharmacy license in Minneapolis. Baxter has asked the Board for an exception to the requirement of having a full pharmacy license for its distribution centers/warehouses as a different model is needed for the dialysate product and specific patient group. Currently 27 states operate under a variation of this model.

Board member Rave made a motion allowing Baxter Healthcare (a manufacturer) to ship dialysate directly to patients in South Dakota from its out-of-state distribution center/warehouse for a term of one year (exempting the distribution center/warehouse from pharmacy licensure). Motion was seconded by Lenny Petrik; voice roll call was taken, and motion passed (4-0).

The Board is currently in the process of drafting administrative rule revisions (20:51:05:23) addressing the distribution of dialysate from sites other than the manufacturer.

2. Professional Judgement Regulations - Dennis McAllister, R.Ph., FASHP, Express Scripts

In a letter, Dennis McAllister asked the Board to consider proposing legislation or rule regarding the ability of pharmacists to use their professional judgment to adapt non-controlled prescriptions while still meeting the intent of the prescriber without additional contact. Letters were sent to individuals in all 50 states.

As delineated in the rule language in the Washington draft (Prescription Drug Orders: Adaptation), a pharmacist using their professional judgment may:

- Make changes to quantity, dosage, dosage form or direction of medication dispensing
- Complete missing information on prescription
- Extend a maintenance drug's quantity to coordinate patient refills med synchronization program

Comments/Concerns:

- Pharmacist could make an unwanted adjustment
- When making minor changes, is the doctor still notified
- Is PBM push back a possibility as minor changes may deviate from PBM contracts/Provider manuals
- With electronic prescribing, there would be a mismatch at time of audit (doctor to pharmacy refill)

The Board will further consider the information provided by Mr. McAllister when making rule changes.

3. Avera Drug Repository Pilot – Robin Lockhorst, Pharm. D; Rachael Elsey, Pharm.D.; Melissa Goff

Pharmacists Robin Lockhorst and Rachael Elsey presented a proposal for the implementation of a Drug Repository Pilot Program at Avera Specialty Pharmacy to redistribute oncology related drugs which are high cost medications. Patient needs, and the financial burden of medications may cause individuals to pursue alternate medication solutions – black market purchases, social media medication sharing, patient med swapping putting patients at risk. Currently, four of our surrounding states have medicine donation reuse programs. A Drug Repository Program would result in improved medication access, improved time to medication for high cost drugs requiring approvals / co-pay assistance, and cost savings. For these reasons, the Avera team members are requesting a variance to ARSD 20:51:12:02 *Return of unused drug* prohibiting pharmacists and pharmacies from accepting unused medications from patients.

Implementation, patient donation, pharmacy storage, record retention and product dispensing were addressed followed by discussion. Drug inventories (donated vs. pharmacy) would be separated and the last two digits of a donated drug's NDC number changed to 99 for no cost billing. Medications could only be dropped off at the Avera Specialty Pharmacy.

Tom Nelson made a motion to grant Avera Specialty Pharmacy a variance to ARSD 20:51:13:02 for a term of one year with a rollout date of July 1, 2019 for the Drug Repository Pilot program and a reporting requirement to come before the Board in six months with project updates. Lenny Petrik seconded the motion; voice roll call was completed. Motion passed (3-0); Board member Rave abstained.

4. Policy Statement Revision on Repackaging Patient's Own Medications – Tyler Laetsch

Tyler Laetsch briefly reviewed the expanded policy statement allowing retail pharmacies to repackage a patient's own medications. Lisa Rave made a motion to approve the expanded policy statement; motion was seconded by Tom Nelson. Voice roll call was taken; motion unanimously passed.

I. Other Business

1. Recent Meeting News
 - a. SDSHP April 12-13, 2019
 - b. NABP 115th Annual Meeting, May 16-18, 2019
2. Future Board Meeting Dates – All meetings held in Board Conference Room unless otherwise noted
 - a. September 12, 2019, 1 pm – 5 pm MDT, Deadwood in conjunction with SDPHA
 - b. December 6, 2019, 8 am – 12 pm CST
 - c. April 2, 2020, 8 am – 12 pm CDT, in conjunction with the SDSHP 44th Annual Conference, Sioux Falls
 - d. June 5, 2020, 8 am – 12 pm, CDT

3. Future Meetings

- a. SDPHA, September 13-14, 2019, The Lodge at Deadwood
- b. 2019 District V NABP/AACP Meeting, August 7-9, 2019
The Inn on Lake Superior, 350 Canal Park Drive, Duluth, Minnesota 55802
Phone: 218-726-1111 or 888-668-4352, Website: <https://theinnonlakesuperior.com/>
Room reservations must be made by Monday, July 8, 2019.
Group Room Rate: \$189.99 plus 13.875% tax (Standard Poolside Room)
Group Name: NABP/AACP District Five Meeting

J. Public Comment (no public comments heard)

K. Executive Session: per SDCL 1-25-2; Legal Issues (no Executive Session held)

L. Adjourn

Board member Lisa Rave made a motion to adjourn, Lenny Petrik seconded the motion, and the meeting adjourned at 12:03 pm CDT