SD Board of Pharmacy Meeting Minutes
Thursday, September 21, 2017; 1:00 p.m. MST
The Lodge at Deadwood, Roosevelt Room
100 Pine Crest Lane, Deadwood, South Dakota 57732

Board Members Present: President Diane Dady, Tom Nelson, and Dan Somsen

Board Staff Present: Executive Director Kari Shanard-Koenders; PDMP Director Melissa DeNoon, Inspectors Gary Karel, Paula Stotz, and Carol Smith.

Attendees Present: Justin Manning, Trisha Hadrick, Erica Bukovich, Jane Mort, Aaron Larson, Sue DeJong, Carrie Gerdmann, Jennifer Wagner, Zachary Mullin, Julia Becker, and Dave Hilbrands

A. Call to Order and Introductions

The meeting was called to order by President Dady at 1:02 PM MST. Diane read the Board of Pharmacy mission statement, followed by introductions of Board Members, Board Staff and audience attendees. Roll call was taken; a quorum was present.

B. Consent Agenda

Executive Director Shanard-Koenders briefly reviewed the components of the consent agenda noting that any item could be removed from the consent agenda for discussion. Motion to approve consent agenda was made by Board Member Dan Somsen and seconded by Board Member Tom Nelson. Motion carried; Diane Dady–aye, Tom Nelson–aye, and Dan Somsen–aye.

C. Staff Reports

1. Secretary Jessica Neal has submitted her resignation, her last day is September 22, 2017, Interviews are scheduled for next week.

2. Inspector Reports
   a. Gary Karel

   Gary noted the following items in various pharmacies:

   - Single dose vials used as multiple dose vials in a Hospital pharmacy
   - Recommend posting the current Do Not Crush list of medications in the pharmacy
   - Pharmacy not using sterile 70% isopropyl alcohol in sterile compounding
   - Recommend pharmacies have more than 1 person as Power of Attorney – 3 sites with only 1 person as Power of Attorney.
   - A CRNA was found to have access to the hospital pharmacy – CRNAs should not have access to the pharmacy.
   - Found expired diphenhydramine carpuject in Immunization Emergency kit. Remind PICs to check the Immunization emergency kit prior to each immunizing season.
   - Found Hospital pharmacy compounding oxytocin bags stored on shelf in pharmacy with a BUD of 9 days. USP <797> guidelines Low Risk – 48 hours room temp or 14 days @ cold temp.
   - Retail pharmacy powder hood not certified in 6 months, pharmacy also needs to make changes to be in compliance with USP <800>
   - Multiple outdated meds in Hospital pharmacy, OR, Central storage and ED.
   - One pharmacy converted from biennial inventories to annual controlled substance inventories.
b. Carol Smith
Carol noted the following items during inspections:

- Poison Control phone number not posted in the pharmacy – dropped off Poison Center magnets
- Hood in a Hospital pharmacy was not certified in over 1 year, the hood surveyor will be called to certify the hood.
- Carol will be attending the Critical Point Sterile Compounding Boot Camp for State Inspectors in October. She has been busy completing the 33 Credit hours of the Critical Point Sterile Compound modules.

c. Paula Stotz
Paula noted the following items:

- One nursing home facility disposed medications in a Sharps container. Recommended that the PIC review proper ways to discard medications with the Director of Nursing.
- One Pharmacy had an expired Combat Meth certificate. Pharmacies that continue to sell pseudoephedrine products while their Combat Meth certificate is expired are in violation of the Combat Meth Act and can face fines, penalties, and loss of the privilege to sell pseudoephedrine products.
- Recent Controlled substance audits have been long and short, nothing significant.
- One pharmacy's biennial inventory was not completed with the 2 year date of the previous biennial inventory. Recommended a controlled substance inventory as soon as possible.

Executive Director Shanard-Koenders stated the inspector’s role is to keep pharmacies and pharmacists in compliance with Federal and State laws.

3. PDMP Report

The Executive Director Melissa DeNoon reported the following PDMP updates:

- Senate Bill 1 mandated that all prescribers with a South Dakota Controlled Substance Registration have a PMP Aware account by July 1, 2017. Board of pharmacy staff have been busy comparing the prescribers that currently have PDMP access with those remaining prescribers yet to sign up. Avera Prescribers may already have access to PDMP data without requiring an individual registration. A letter was sent in conjunction with Department of Health, to identify prescribers that had not enrolled by July 1, 2017.
- A second letter will be sent by the prescriber’s regulatory board in early October to prescribers that still have not registered for PDMP access.
- Goal is to reach 100% prescriber participation, talk of possibly coordinating PDMP registration with Controlled Substance license renewals. Out of the 4,476 prescribers in SD approximately 82% are currently enrolled for PDMP access.
- Pharmacies are required to submit controlled substance dispense data every 24 hours. Many pharmacies were already submitting controlled substance data daily.
- Hydrocodone and tramadol still the top two most prescribed controlled substances in South Dakota.
- Discussion of drafting a Bill to add the verbiage “drugs of concern” to be reported to the PDMP registry. Drugs of concern to be determined by Board and PDMP Advisory Council. Tom Nelson moved that the Pharmacy Board draw up legislation to add drugs of concern to PDMP reporting by pharmacies, 2nd by Dan Somsen. Motion carried; Diane Dady–aye, Tom Nelson–aye, Dan Somsen–aye.
- 2016 Harold Rogers grant to integrate PDMP data with the Sanford Health Medical record
- Still waiting to hear on the 2017 Harold Rogers grant – proposal to integrate with Regional Health
- CDC grant to help in the Opioid crisis – proposal was to provide MedDrop Take Back Containers to a limited number of pharmacies wanting to provide this service in their communities
- The DEA will be holding a Pharmacy Diversion Awareness Conference (PDAC) on Sunday, October 1, 2017. See DEA website for details and to sign up
D. Complaints, Investigations, Disciplinary Actions, Loss/Theft Report

The following were reported by Gary Karel, Carol Smith, and Paula Stotz. Discussion followed.

1. Shopko Pharmacy #2101 (Arrowhead Parkway) Sioux Falls: DEA 106
2. AlixaRx Covington Heights in Sioux Falls, Armour, Salem, Madison: DEA 106
3. Sanford Winner LTC: Diversion
4. Kelly's Retirement Home, Pierre: Diversion
5. Sanford Canton-Inwood Medical Center: DEA 106
6. Prairie Lakes Campus Pharmacy: Complaint
7. Medicine Shoppe, Rapid City: Complaint
8. Rapid City Regional Hospital: Diversion
9. Hy-Vee Pharmacy (S. Minnesota Ave) Sioux Falls: DEA 106
10. Safeway S. (Mt Rushmore Rd) Rapid City: Complaint
11. Shopko Pharmacy #2076 (41st Street) Sioux Falls: DEA 106
13. Tienda America Store, Sioux Falls: Complaint
14. Review of a January 2017 complaint regarding OptimRx mail order Numbers 1, 2, and 11, are under investigation

E. SD Pharmacists Association Update –

SDPhA President Trisha Hadrick and Erica Bukovich submitted the written report in the packet:
1. Activity Report
2. Financial Report

F. Other Reports

1. SDSU College of Pharmacy – Dr. Jane Mort, PharmD, Acting Dean

   College of Pharmacy and Allied Health Professions Department Interim Dean Dr. Jane Mort reviewed the following from a written report provided to attendees:
   - Eighty students were welcomed into the PharmD program; experienced a slight reduction in applicant numbers.
   - Sixteen months into curricular revision process; anticipate implementation fall of 2018; evaluating facility modifications to support new curriculum.
   - South Dakota State University will complete their strategic planning process this fall.
   - Search committee for the new Dean has been established.
   - Gary Karel has been awarded the SDSU 2017 Distinguished Pharmacy Alumni.

2. SD Society of Health System Pharmacists – Aaron Larson, PharmD,

   - GVR Golf Tournament raised $1,600 for SDSU Pharmacy Students, funds for scholarship and travel.
   - New website being developing and should go live approximately September 20, 2017.
   - Upcoming Statewide Pharmacotherapy Conference via phone or computer, 3 CE events, two in Sioux Falls and one in Rapid City.
   - Dakota Night Reception at the National ASHP Convention, Orlando, FL, December 4, 2017, 5:30-7:30PM

3. SD Association of Pharmacy Technicians – Sue DeJong, CPhT

   Report submitted,
   - Annual Fall Technician Conference, October 7, 2017, Avera, Sioux Falls, SD
   - SDAPT received a $1000 sponsorship for the Fall Technician Conference
• SDAPT offers one $150.00 scholarship to a pharmacy technician student that attends either SE Tech in Sioux Falls or Western Dakota Tech in Rapid City; scholarship winner to be announced at the Fall Technician Conference.

G. Old Business

1. **USP <797> proposed revisions – Update – Gary**
   - USP committee still reviewing comments; waiting for second draft of document.
   - Suggest building cleanroom to current regulations, no release date yet for updated USP <797>

2. **USP <800> and NIOSH 2016 - Paula**
   - USP <800> Official document on July 1, 2018; many pharmacies waiting for corporate to develop policies and procedures, pharmacies can begin by identifying Hazardous drugs handled by their pharmacy
   - Hazardous Drug Tip sheet will be available to help pharmacies make steps toward USP <800> compliance

3. **Office Software**
   - RFP responses have been received – review in process
   - The Board is implementing a paperless system to enable on-line licensure
   - Proposed start date Early Spring 2018

4. **Hy-Vee Tech Check Tech Pilot Project Update (Renamed Technician Product Verification (TPV)**
   The following was reported by Justin Manning as part of the quarterly update.
   - Staff trained: 1 Technician and 1 Pharmacy intern, 1 Technician left the company.
   - 16 Hy-Vee locations are participating in the TPV pilot program – 15 pharmacies in Iowa and 1 in South Dakota. No quality errors and planned errors are being successfully found by technicians.
   - TPV is for new and refill prescriptions
   - No real measured increases in MTM, or immunizations since the program has only been fully implemented for a few months, 1 trained TPV technician left the company, and influenza season is just beginning. It takes several months to train a new technician for the TPV program.
   - Freeing up time for Pharmacists to provide more patient/customer interaction, MTM services is the goal.

   Diane Dady moved to grant a continuing variance to renew the TPV program to Hy-Vee Pharmacy #4, Sioux Falls location for one year to include quarterly reports to the Board. 2nd –Tom Nelson. Motion carried; Diane Dady–aye, Tom Nelson–aye, Dan Somsen–aye.

5. **Report on Alchermes/Aristada Pilot Project Minnehaha County Jail - Dave Hilbrands**
   - Aristada is 1064 mg dose is the preferred dose, lasts two months, allows for greater control while discharged to transitional care.
   - Similar jail pilot programs are in all 50 states.
   - 17 Minnehaha County Jail Nurses are trained to start treatment, continuing training is needed, to work closely with discharge assessment team
   - Programs similar to the Minnehaha pilot have been established in Hughes County and Armour
   - The current variance expires November 1, 2017; a letter will need to be sent to the Board of Pharmacy requesting another year extension.

6. **PDMP Rules ARSD 20:51:32**
   - Changes during the last legislative session require changes to the PDMP Administrative rules
   - Controlled substance prescription dispense data will need to be dispensed every 24 hours or by midnight of the next business day after dispensing.
   - Other data elements will also be required, such as: dispenser name, dispenser phone number, payment type, prescriber last name, first name, and phone number.
• Credentialing of prescriber licenses will be done by the health system wishing to integrate with the PDMP program
• Requests for PDMP data must be submitted in writing or electronically
• Adding the definition parole to probation compliance

7. Drug Distributor Rules ARSD 20:67
• To further define wholesale licenses, suggest adding “or other” to the definition, and wholesale or other drug distributor applications will be electronically or in a form supplied by the Board
• Including third party logistic providers to list of drug distributors to be inspected.
• Additional information to be included on the wholesale or other drug distributor application
  ○ Convictions, suspension or revocations of said license in the last seven years
  ○ Type of distribution
  ○ Type of products distributed
  ○ Type of entity distributed to
• Repeal of ARSD 20:67:02:09 Temporary 90 day Wholesale License
• Repeal of Chapter ARSD 20:67:08 Wholesale Drug Advisory Committee

8. Red Tape Cleanup of SDCL 36-11
Board President Diane Dady reported the following regarding the Pharmacy Practice Act:

• The Practice Act committee members will work with the Board of Pharmacy and SD Pharmacists association to rework the Practice act.
• Some items must be done when this is put forth. We need to clarify 36-11-19.1(1). We should add Pharmacy Technician continuing education requirements as Board approves CE for technicians now that they must have it for national certification.
• A “clean up” of the practice act could be submitted to the 2018 session to remove old reference requirements, etc., however the Board discussed and feels that no clean up should be submitted this session and that it should all go at once with the full revisions in 2019.

9. Association Funding per SDCL 36-11-6
The AG opinion regarding the relationship between the South Dakota Board of Pharmacy and South Dakota Pharmacists Association has not been given. President Diane Dady read a portion of a letter sent to the SD Attorney General by Robert Riter, Attorney and Lobbyist for the SD Pharmacists Association. The letter explained that the Board and Pharmacists Association was one entity until it was split into two entities by the legislature in 2005. The legislation spelled out that up to 80% of the pharmacists licensure renewal fees may be distributed to the SDPhA annually. The Commercial and Legislative Branch of the Pharmacy Association is the lobbying branch of the association and is supported by voluntary contributions only. The Board of Pharmacy has, since she has been a member, never authorized the payments to the Association and these payments have been automatically dispersed. The monies the Association receives are to be used for continuing education, registration standards of the profession and payment to the Health Professional Assistance Program. Monies are to be used for pharmacy related issues. Disbursements usually occur in January of the following year. A lengthy discussion ended with a motion by Diane Dady to authorize 80% of this year’s pharmacist licensure fees to be dispersed to the SD Pharmacists Association in early January 2018, and each spring meeting the authorization will be reviewed. 2nd by Tom Nelson. Motion carried; Diane Dady–aye, Tom Nelson–aye, Dan Somsen–aye.

H. New Business
1. Docket Processes
• The Board of Pharmacy needs to have uniform processes and procedures in place to address disciplinary activity for its licensees and registrants. Currently processes for discipline are not solid.
• The Board of Pharmacy would like to model the disciplinary procedures which are in rule, after the Board of Medicine and Board of Nursing, to move forward on rules to address discipline.
• Use of an Administrative Law Judge in cases of an impaired person on the job. Referrals to the HPAP program. HPAP would determine when the person could practice with reasonable skill and safety.
• Clear procedures when law enforcement is involved in handling diversion.
• No discipline or probation of license, five year agreement of sobriety
• Define clear procedures for the complaint process
• Board voiced that this sounds like a good idea and rulemaking should proceed. Rules to be sent to the group.

I. Other Business

Future Board Meeting Dates

1. Future Board Meeting Dates
   i. December 8, 2017 – Sioux Falls, Location TBD
   ii. March 22, 2018 -- Sioux Falls, Location TBD – in conjunction with SDSHP??
   iii. June 8, 2018 – Sioux Falls, Location TBD
   iv. September 20, 2018 Sioux Falls Ramkota -in conjunction with SDPhA

2. Other Meetings
   i. District Five annual Meeting, August 3-5, 2017, West Des Moines, IA recapped by attendees
   ii. SDPHA September 22-23, 2017, The Lodge at Deadwood
   iii. 50 State Intergovernmental FDA meeting on Compounding, September 26-27, 2017, Silver Springs, MD
   iv. Pharmacy Diversion Awareness Conference (PDAC) October 1, 2017 –Sheraton, Sioux Falls and Convention Center
   v. NABP Executive Officer Interactive Forum, October 3-4, 2017, Chicago, IL
   vi. SDAPT, October 7, 2017, Avera Prairie Center, Sioux Falls,
   vii. National Association of State Controlled Substance Authorities (NASCSA) October 16-20, 2017 San Antonio, TX
   viii. Law Enforcement Coordinating Committee, November 7-8, 2017 Sioux Falls
   ix. SDSHP 2018 Annual Meeting March 23-24, 2018, Sioux Falls, Ramkota
   x. NABP Annual Meeting, May 5-7, 2018, Denver, CO Hyatt Regency

J. Adjourn at 4:42 PM MST – Motion by Board Member Tom Nelson, second by Board Member Dan Somsen. Motion passed; Diane Dady – aye, Tom Nelson – aye, Dan Somsen – aye. Meeting adjourned.

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Diane Dady, President                               Date

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Kari Shanard-Koenders, Ex. Director                Date