

SD Board of Pharmacy Meeting Minutes
Friday, December 7, 2018; 8:00 a.m. CST
South Dakota Board of Pharmacy Conference Room
4001 W. Valhalla Blvd Suite 202, Sioux Falls, SD 57106

Board Members Present: Acting Chair – Lenny Petrik, Diane Dady (by phone), Tom Nelson, Lisa Rave, and Dan Somsen

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

Attendees Present: Amanda Bacon (SDPhA), Justin Manning Hy-Vee (by phone), Jessica Harris (SDSHP), Chad Sherard (Cigna), Cheri Kraemer (Pharmacy Specialties & Clinic), Melissa Goff (Avera McKennan), Maria Piacentino (HPAP), Amanda McKnelly (HPAP), Dean Jane Mort (SDSU), Bill Ladwig (Lewis Drug), Kaylee Amundsen (Lewis Drug), Joe Bergsmith (Walmart)

A. Call to Order and Introductions

At 8:02 a.m. the meeting was called to order by Acting Chair, board member Lenny Petrik. The Board of Pharmacy mission statement was read followed by introductions of Board Members, Board Staff and meeting attendees. Roll call was taken and a quorum present.

B. Consent Agenda

The Acting Chair reviewed the consent agenda noting any items could be removed for discussion. Dan Somsen made a motion approve the consent agenda; motioned seconded by Lisa Rave. Voice roll call taken; motion passed (5-0).

C. Staff Reports

1. Operations Report – Kari Shanard-Koenders, R.Ph., Executive Director

- a. The Executive Director recognized and congratulated Cheri Kraemer the recipient of the (PCCA International Compounding Award). In its thirty first year, Cheri is the second female PCCA award recipient. The award ceremony took place in Houston, Texas and Cheri's family members were in attendance.
- b. The Executive Director officially recognized and congratulated Dr. Jane Mort on her appointment to Dean of the College of Pharmacy and Allied Health Professions.
- c. In October, Inspector Tyler Laetsch attended Critical Point Compounding Boot Camp in New Jersey. The one-week sterile compounding training consisting of modules and hand-on components and yielded 58 continuing education credits. Tyler achieved certification/accreditation for sterile compounding for inspectors. All three of our inspectors are now certified inspectors.
- d. On November 1st, the Board rolled-out its new online licensing platform (I-GOV) for wholesale renewal processing.

2. Inspector Reports

- a. Tyler Laetsch, Inspector
Reported the following items/observations/occurrences:

- Pharmacies waste med procedures, there is no single way to accomplish the disposal; pharmacies are encouraged to do what works best for their situation/circumstance.
- Pharmacist signing daily as per DEA requirement
- CAH's looking into sterile compounding needs; immediate use vs. emergent (outpatients), need for hood/SCA
- Starter packs are completed/produced in many ways
- Controlled substance counting (mostly 3-5) needs to improve; several sites to not complete a perpetual inventory
- Pharmacy area security measures vary greatly from facility to facility - from no cameras to very high tech and everything in between
- Preparing for USP 800 and NIOSH – New: CDC plans to push back the 2018 list till June 2019
- In the News: a nonresident pharmacy in Oklahoma was fined over \$10,000 and placed on two years of probation for two occurrences where there was no pharmacist in the pharmacy/on site.
- Remember to post a sign (no pharmacist on duty no medications can be dispensed 20:51:06:10
- In the News: the pharmacy director at Children's Hospital in Omaha has allegedly diverted \$4.4 M through invoicing.

b. Paula Stotz, Inspector

Reported the following items/observations/occurrences:

- Several PDMP reversal issues; working with pharmacies to get corrected
- Used the new med gas form at several locations
- New blister pack systems, expiration date not being marked on items
- Continue discussing USP 800 with pharmacist/pharmacies
- Had two pharmacies that moved locations but did not inform the DEA

c. Carol Smith, Inspector

Reported the following items/observations/occurrences:

- Discovered a pharmacy using prescription dispensing as their invoicing method to other clinics – this led to discussion about this process
- Started using the new med gas form

3. PDMP Report

PDMP Director Melissa DeNoon reported the following updates:

- a. Appriss, the PDMP platform vendor, improved reporting capabilities this year and SD BOP can now isolate SD patient data specifics.
- b. PDMP utilization, measured by the number of queries performed by SD users, continues to increase as is shown by an almost eightfold increase from January 2016 to October 2018.
- c. Total number of PMP AWARxE approved users as of the end of October 2018 is 6,552 which is double the number of users from the end of 2016; compliance with SD's mandated prescriber registration is at 95%.
- d. The number of PDMP integrations continues to grow. To date, Avera Health System, Walmart/Sam's Club Pharmacies, Yankton Medical Clinic, and Regional Health System have integrated having in-workflow, one-click access to PDMP information. The integration with Sanford Health System is in progress and is projected to be live in January 2019.
- e. PMP AWARxE Enhancements: 1) Clinical Alerts – the number of alerts is trending downward for 2018 and the number of prescribers receiving alerts remains consistent (1,000 – 1,200/month), and 2) Prescriber Reports – 4th round of reports was delivered on November 21, 2018 for Q2 and Q3 2018.

- f. 2016 MedDrop Drug Take-Back Grant Project - To date, ten receptacles are operational in South Dakota community pharmacies and have returned a total of 1,362 lbs. for destruction, two receptacles are on order, and the last three sites are in progress. The Department of Social Services has also made additional funds available for MedDrop receptacles in the future. Melissa is working with the Department of Health (DOH) and 211 Helpline Center to establish a SD master site list which is accessible at www.avoidopioidsd.com.
- g. Federal HR 6 – Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (referred to as SUPPORT for Patients and Communities Act). Act covers a broad range of areas related to the opioid epidemic and contains provisions that will or may affect state boards of pharmacy, pharmacies and pharmacists. Several provisions relate to prescription drug monitoring programs and require the federal government to annually support states for the purpose of improving efficiency and use of PDMPs.
- h. SD Board of Pharmacy competed for and was awarded a 2018 COAP Grant in the amount of \$749,972. Awardees later learned of 51 additional special conditions not previously disclosed which awardees must comply with and complete prior to release of funds. The additional grant conditions are currently under review.

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 - Hy-Vee Pharmacy #6, Sioux Falls / 3-4 C2 bottles missing
- 2. DEA Form 106 – Rogers Pharmacy, Yankton / 2 open bottles of outdated C3-5 cannot locate

E. SD Pharmacists Association – Amanda Bacon, SDPhA

- 1. Activity Report – the following items were highlighted by Ms. Bacon
 - a. Briefly reviewed the list of newly-elected SDPhA officers, 2018 Convention Award winners, and acknowledged Ron Huether, the Fifty Years in Pharmacy recipient
 - b. Fall District meetings were held in Aberdeen, Huron, and Sioux Falls; Spring District meetings will be held in February
 - c. SDPhA board members and staff attended the Rules Hearing held October 23rd in Sioux Falls. The Association submitted written questions/comments asking for clarification regarding the handling of complaints and PDMP delegate rules.
 - d. October SDPhA American Pharmacists Month activities focused on developing resources for use year-round, while the American Pharmacists Association (APhA) launched a campaign designed to help patients understand their pharmacist’s role as a part of their health care team. Pharmacists also participated in special health screening events, offered med check-ups, over-the-counter tours, and brown bag events for geriatrics during the month.
 - e. On December 4, SDPhA hosted a Welcome Reception for new 2019 legislators. The event provided an opportunity for members and legislators to get to know one another as well as introduce them to the SDPhA agency
 - f. SDPhA will again this year host Legislative Days in Pierre and coordinate with the LRC to sponsor the flu shot clinic at the Capitol
 - g. Pharmacy Technician University (PTU) enrollment continues to grow. Currently the SDPhA has 40 technicians enrolled in the program and will be placing a resource hub for PTU information on the SDPhA website. For more information regarding PTU technician certification opportunities, contact the Association.
 - h. The Iowa Regional Pharmacy Expo, February 8-10, will be held at a new location – the Hilton Des Moines Downtown in Des Moines, IA. Watch the website, more details to come.

2. Financial Report – (not reviewed)

F. Other Reports

1. SDSU College of Pharmacy – Jane Mort, Pharm D., Dean and Professor, College of Pharmacy and Allied Health Professions Department

- Reported a NAPLEX pass rate of 100% for the 2018 graduating class. Since 1998, 1266 individuals have taken the NAPLEX with only eight individuals requiring a second testing.
- Dr. Pinto obtained a multimillion dollar contract from the State for research focusing on diabetes, stroke and cardiovascular disease
- Dr. Rayna, a pharmaceutical science researcher with a cancer focus has filled the open Harbor Chair position.
- Searches continue for the following open faculty positions – Associate Dean of Academics, Assistant to the Dean, and Pharmacology (an added position)
- Preceptor education was held in SDSU new Pharmacy lab in September; the College continues to evaluate ways to support preceptors
- The SDSU ASP Chapter was awarded the Operation Health Award for their heart and blood screening efforts throughout the year
- The Foundation is embarking on a new capital campaign
- The College expects 76 PharmD students to graduate in May

2. SD Society of Health System Pharmacists – Jessica Harris, Pharm D., BCPS

- 158 people attended the SDHP mid-year annual meeting
- Tom Johnson was nominated for SDHP President
- Technician and Pharmacist of the Year nominations are due by January 2019
- Continuing education events are planned for January 26th and February 2nd
- Dates being considered for a West River event are February 16th or 28th

3. SD Association of Pharmacy Technicians – Jerrie Vedvei, CPhT (no report)

4. SD Health Professionals Assistance Program (SD HPAP) – Amanda McKnelly, MS, LAC; Maria Piacentino, MA, LPC-MH, QMHP, LAC

- HPAP utilization by the SD Board of Pharmacy has increased; the number of voluntary and Board mandated referrals are both up
- In 2016 and 2017 HPAP served 4 Board participants; in 2018 that figure doubled
- Participants are no longer presenting with a single issue; treatment has become increasingly complex due to multiple diagnosis as well as a general lack of civility
- For the last five years (through 2019), the Board has paid \$10,000 a year for HPAP services.
- In 2020, HPAP is asking for a fee increase due to increasing number of program participants. HPAP would optimally like to receive \$20,000 but would accept \$15,000 annually for services delivered as HPAP is a great resource for the Board. Program participants pay all costs associated with screening/drug testing; all remaining costs are covered by the annual fee paid by the Board.
- To access HPAP services, an individual must be licensed; HPAP services are not available to technicians.

Dan Somsen made a motion to increase the fee paid to HPAP for support services to \$15,000 annually; Lisa Rave seconded the motion, a voice roll call taken, and motion passed (5-0).

G. Old Business

2. Rules – In the Interim rules review committee, the following rules were approved as amended by our hearing on October 23, 2018
 - a. ARSD 20:51:32 Prescription Drug Monitoring Program
 - b. ARSD 20:67 Wholesale Drug Distributors revisions
 - c. ARSD 20:51:33 Complaint Procedures
 - d. ARSD 20:51:34 Contested Case Hearing Procedures

Per Kari Shanard-Koenders, rules have gone through the LRC Interim Committee, were passed and will go into effect December 20, 2018. The Board has more work ahead as Tyler Laetsch is continues to work on Administrative rules.

2. Documentation of Discipline on Website – Motion

- New Board website offerings:
 - Online primary verification for individuals (pharmacists / technicians) and businesses (pharmacies / wholesale)
 - Discipline tab – other Boards upload stipulation to their website for public view

Board member Dan Somsen made a motion to upload discipline/stipulation documents to the South Dakota Board of Pharmacy's website. Lisa Rave seconded, a voice roll call was taken, and motion passed 5-0. The issuance of a stipulation is the final step in the process and is issued only after all due process procedures/measures have been completed. Stipulation documents are currently public records that are available for viewing. Posting documentation to the Board's website allows for easier access to the information.

H. New Business

1. Hy-Vee Brookings TPV Request – Justin Manning (by phone)

- The Board has previously approved TPV variance requests for three Sioux Falls Hy-Vee Pharmacy location. The proposed Hy-Vee Brookings variance is identical to the Sioux Falls program; it is simply a change of location.
- Currently Hy-Vee reports to the Board annually regarding the variances. There have been no incidents or errors to date. Pharmacist is completing the first check verification on everything. TPV is not used for controlled substances, compounding, or injectables.
- Technician turnover remains a challenge to growing the program.
- The two Brookings technicians each have 15 + years of pharmacy experience and want to advance their careers.
- Dan Somsen asked if Hy-Vee plans to expand the use of its TPV model. Mr. Manning indicated you need high volume and enough staff for the model to work; it is not appropriate in some markets.

Board Member Lisa Rave made a motion to approve the Hy-Vee Brookings TPV variance with quarterly reporting to the Board for the first year. Tom Nelson seconded the motion; voice roll call was taken, and motion passed (5-0).

2. Avera Long Term Care Variance for all E-Kits – Mark Gerdes, Avera McKennan Information provided by Melissa Goff, Avera McKennan

- Variance requesting expanded inventory for all E-kits

- Expanded inventory E-kits are necessary due to geographical limitations, Part B formulary variability, and meeting the pain management needs of hospice patients
 - E-kit access protocols are in place; however, they do not offer the enhanced security a Pyxis or Omnicell
 - Expanded E—kits would be used in 72 facilities. Some of those facilities will get automated dispensing in the future; some facilities will not. Those numbers are not currently available.
 - The Board tabled the variance request, asked for information regarding the policies and procedures around E-kits and how they are managed. When received, the Board will distribute the information, discuss, and take action.
3. Licensure bill for spouses of military members – waiver of fees
- Military spouses are in a location for 3-4 years. Currently, there are no testing sites in Rapid City which thus requires applicants to incur additional travel expenses to test.
 - A new 2019 bill requires military applicants to comply with all licensing requirements and will waive fees (\$35 initial certification fee and \$150 reciprocity fee).
 - Would the Board support the bill? It would have minimal financial impact as Board would expected 1-2 applicants a year in this category.

I. Other Business

1. Recent Meeting News – Kari Shanard-Koenders, R.Ph., Executive Director
- a. SDPHA 2018 Annual Meeting September 21-22, 2018
 - b. FDA Intergovernmental Meeting on Compounding and MOU, September 24-27, 2018
 - If the State of South Dakota does not sign the MOU, South Dakota sterile compounding pharmacies can ship only 5% across state lines and are not exempt from CGMP requirements
 - Many meeting attendees expressed concern stating they have no authority to sign for their State
 - Additionally, SD BOP has no means to determine how many physicians in the State are compounding, has no authority over physicians, and therefore cannot monitor physician compounding.
 - Redlined version from NABP is more in line with what SD can support
 - c. NABP Executive Officer Interactive Forum October 2-3, 2018
 - The Executive Director encouraged Board Members to consider attending an NABP meeting; it is an informative experience
 - NABP encourages greater use of their services by Board. This year, NABP will complete the annual pharmacist continuing education audit. In previous years, the task was accomplished by Board staff.
 - Discussed future upgrades to NABP’s CE system and the possibility of uploading non-ACPE CE
2. Future Board Meeting Dates
- a. April 11, 2019, 1 pm – 5 pm MST Location TBD – in conjunction with SDSHP, The Lodge at Deadwood
 - Changed date from March 8, 2019 to April 11, 2019 to coordinate with SDSHP meeting
 - b. June 7, 2019, 8 am – 12 pm, CDT
 - c. September 12, 2019, Deadwood in conjunction with SDPHA, 1 pm – 5 pm MDT
 - d. December 6, 2019, 8 am – 12 pm CST
3. Future Meetings
- a. SDSHP 2018 Annual Meeting, April 12-13, 2019, The Lodge at Deadwood
 - b. NABP 115th Annual Meeting, May 16-18, 2019, Minneapolis, MN

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 Tom Nelson motioned to adjourn, Lisa Rave seconded the motion. Meeting adjourned at 11:20 am CST