

**SD Board of Pharmacy Meeting Minutes**  
**Friday, December 9, 2016; 8:00 a.m. CST**  
**Pharmacy Specialty and Clinic Conference Room**  
**Yankton Trail Medical Building**  
**2333 W. 57<sup>th</sup> Street, Sioux Falls, South Dakota 57108**

**Board Members Present:** President Diane Dady, Lisa Rave, Lenny Petrik, and Dan Somsen

**Board Staff Present:** Executive Director Kari Shanard-Koenders; PDMP Director Melissa DeNoon, Inspectors Gary Karel and Paula Stotz; and Senior Secretary Beth Windschitl

**Attendees Present:** Justin Manning, Sue Schaefer, Cheri Kraemer, Jane Mort, Bill Ladwig, Melissa Goff, Julia Becker, Marc Thorstenson, David Bain, Scott Peterson, and Mike Meekins

**A. Call to Order and Introductions**

The meeting was called to order by President Diane Dady at 8:01 AM CST and attendees welcomed. New Board member Dan Somsen introduced himself and shared that he is in his 22<sup>nd</sup> year with Yankton Rexall and is currently a pharmacist/co-owner. Dan also served as the Pharmacy Director at Avera St Luke's in Aberdeen for ten years. Attendee introductions were completed.

**B. Approval of Board Minutes**

President Dady asked for a motion to approve the September 15, 2016 Board of Pharmacy meeting minutes as written. Motion was made and seconded by Board member Petrik; motion carried.

**C. Financial Report**

Financial Reports (Remaining Authority by Object/Sub-object and Revenue Report by Month) were reviewed. Executive Director Shanard-Koenders indicated fiscal year 2017 remaining funds are at 57% noting there are many budget areas where 50 to 100% of funds are available. Employee salaries appear to be a little high at this interval. Technician and Wholesale licensing fees were responsible for the majority of October and November revenue.

**D. Staff Reports**

**1. Employee Update**

Senior Secretary Jessica Neal returned to work from maternity leave; the Board is again fully staffed. Executive Director Shanard-Koenders congratulated inspector Paula Stotz on being in the first class of inspectors to participate in the FDA sponsored Critical Point Training in Sterile Compounding Certification class. Paula completed several modules prior to attending training and participated in many hands-on activities during training and tested for Certification in Sterile Compounding for Inspectors (CISCI). Paula holds a certification in CISCI for three years.

**2. Inspector Reports**

**a. Paula Stotz**

Paula had the opportunity to participate in a DEA inspection along with her other inspections and noted the following items:

- DEA inquired about whether or not background checks are being completed to uncover felonious activity by individuals prior to hire. This is required by the DEA for persons who will be allowed to work in an area where access to controlled substances exists.
- DEA noted that biennial inventories must be taken on any date which is within two years of previous biennial inventory date; not over several days. The inventory may be taken either at the opening of business or at the close of business on the inventory date and shall be documented on the inventory; it cannot be intermittently conducted through the day.
- DEA 222 forms must be filed chronologically per the DEA
- Faxes for CII prescriptions from long-term care facilities or hospice need to be marked “LTC” or “Terminally Ill” or it is a violation of DEA rule
- Observation - retail pharmacies are understaffed; pharmacists not allowed meal breaks; morale is low at this time of year; and retailers are focused on immunization numbers. Often the pharmacist, when one pharmacist is on duty at a time, will leave the pharmacy to administer an immunization and the pharmacy is left unsupervised for several minutes. (The pharmacist should spend several minutes with a patient when providing immunizations). Is there something that the Board can do?

Discussion ensued and Bill Ladwig (Lewis Drug) stated he is not sure the Board has the authority to address missed lunches as it is difficult to mandate a business model. In such circumstances, pharmacists need to voice their concern(s) to management. PDMP Director Melissa DeNoon said the profession is evolving, more tasks are being added to the pharmacist’s plate, immunization numbers have increased, and reimbursements have not. Pharmacists want to ensure patient focus and safety but society as a whole is impatient and does not want to wait. A lengthy discussion regarding DIR fees and their impact on retail and independent pharmacies followed.

**b. Carol Smith** – Unable to attend

**c. Gary Karel**

Gary noted the following items and/or occurrences in various pharmacies:

- Punch lock on pharmacy door and nursing staff could enter any time because they all knew the access code (no controls)
- Chemo room was dirty and had not been clean in a longtime; staff took immediate action, cleaned room prior to preparing chemo drugs
- A wholesale distributor had no lock on the back door and water leaking into the room where cleaning takes place. Concern for mold.
- Multiple facilities getting compliant with USP 800
- Brookings Hospital opens in February 2017
- Milbank Hospital opens in December 2016

### **3. Statistical Reports for September, 2016 – November, 2016**

Shanard-Koenders briefly reviewed both the Activity Report and the License Summary Report noting the following for the given timeframe:

Pharmacist: 2,028 current licenses (12 new licensees),  
 Pharmacy Interns: 324 current registrations (84 new registrations)  
 Full-Time Pharmacy permits: 267 current (3 new permits)  
 Part-Time Pharmacy permits: 55 current (3 new permits)  
 Technician Registrations: 1406 current (108 new registrations) (406 renewals expired 2016)  
 Wholesale permits: 1,247 current (51 new permits)  
 Non-Resident pharmacy permits: 743 current (22 new permits)

The Executive Director emphasized that 406 technician permits were not renewed this cycle. This gave rise to discussions about how to increase numbers, create a career path, attract quality individuals, certification requirements, education costs, and compensation.

#### 4. PDMP

Prescription Drug Monitoring Program Director Melissa DeNoon reported the following PDMP updates:

- In October, SD PDMP had record numbers of online queries performed by pharmacists (5286) and prescribers (3985)
- PDMP data integrity and quality is solely dependent upon all stakeholders consistently providing current, accurate, and complete prescription information
- Due to Sanford and Regional Health's promotion of the SD PDMP to their practitioners, account registrations have averaged 10-15 per day in the last month
- SD PDMP Advisory Council meeting was held October 28; topics discussed included mandating registration and/or use, inappropriate access, data submission requirements, and two proposed statute changes, SDCL 34-20E-2 and SDCL 34-20E-3
- SD PDMP presentations in fourth quarter of 2016 included the SDPhA Annual Meeting, SD Legislative Summer Study Substance Abuse Prevention Committee, and Prescription Opioid Abuse Advisory Committee
- SD PDMP was awarded a \$400,000 Harold Rogers PDMP Enhancement Grant. Grant funds are allocated for two projects: the Sanford Health System EHR/SD PDMP integration and a pilot drug take-back program in select SD retail pharmacies

Board members asked Melissa if she is seeing any changes in prescriber habits or prescription numbers. Not at this time; however, new SD Medical Board administrative rules as well as the DEA's decrease in the manufacturing amount of opioid controlled substances in 2017 may have an impact.

**E. Approvals/Information** – The following was reported by Shanard-Koenders and were approved by Board members previously via email.

1. Avera St. Mary's Campus Pharmacy (CHOW) #100-2044 - Pierre
2. Rapid City Rehab AMDD #200-1705 – Rapid City
3. SD Human Services Center State Penitentiary AMDD # 100-2045 – Sioux Falls,
4. Rambo LTC Inc., dba Brothers Pharmacy LTC # 100-2046 - Brookings
5. Regional Health Home Plus Hospice CHOW #100-1923 – Rapid City
6. Regional Health Home Plus Home Infusion CHOW # 100-2019 – Rapid City
7. Regional Health Home Plus Pharmacy CHOW #100-1986 – Rapid City
8. Regional Health Home Plus Long Term Care Pharmacy CHOW #100-1987 – Rapid City
9. Regional Health Home Plus Specialty Pharmacy CHOW #100-1988 – Rapid City
10. Regional Health Home Plus Pharmacy CHOW #100-1970 – Spearfish
11. Regional Health Home Plus Long Term Care Pharmacy Penn Co Jail CHOW #200-1696 – Rapid City
12. Regional Health Home Plus Long Term Care Pharmacy – Sturgis Regional Senior Care CHOW #200-1695 – Sturgis
13. Regional Health Home Plus Long Term Care Pharmacy – Custer Regional Senior Care CHOW #200-1693 – Custer
14. Sioux Falls Specialty Hospital Pharmacy LLP(2) – #200-1707 – Sioux Falls
15. McFleeg Inc. #600-2695 – Watertown
16. Buffalo Ranch Supply LLC #600-2684 – Buffalo
17. JR Distributing #600-2702 – Lake Norden

**F. Variances** – The following was reported by Shanard-Koenders and were approved by Board members previously via email.

1. PharMerica Renewal of E-kit Variance
2. Aristada in Minnehaha County Jail – Board via email

**G. Complaints, Investigations, Disciplinary Actions, Loss/Theft Report**

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

1. Walgreens (41<sup>st</sup>/Louise) Sioux Falls: DEA 106
2. Dakota Dunes: Propofol
3. Flandreau Santee Sioux Tribal Clinic Pharmacy: DEA 106 x 2
4. Lewis Family Drug #73 in Chamberlain: DEA 106
5. Walgreens #09512 on LaCrosse in Rapid City: Complaint

#### **H. SD Pharmacists Association Update – Sue Schaefer, Executive Director**

SDPhA Executive Director Sue Schaefer instructed attendees to review Association handouts at their leisure as the Association's financial reports were unremarkable. Due to the passage of Initiated Measure 22, the Association has decided to cancel Legislative Days and flu shots in 2017.

#### **I. Other Reports**

##### **1. SDSU College of Pharmacy – Dr. Jane Mort, Acting Dean and Professor, Pharm D**

The following were reported by Dr. Mort. Discussion followed.

- Seventy-six SDSU students took the NAPLEX; 75 passed. The pass rate average nationally is 87.8%
- In January/February, NABP makes available the complete list of scores for all parties who sat the exam
- Changes to NAPLEX standards, the number of exam questions and time allotted for exam completion may impact future pass rates
- First time MPJE pass rates were as follows: in-state 100%, out-of-state 95%, and nationally 84%
- Nationally applications for entrance in pharmacy programs are down; the SDSU pharmacy program mirrors this trend both of which peaked in 2010
- The number of applications institutions receive are about half of what they were in the past as the number of Colleges of Pharmacy have increased from 78 to 136 giving student more options
- Twenty-one companies participated in Pharmacy Days on the SDSU campus and 113 P4 interviews were conducted. Would like to get P2 and P3 students involved as well

##### **2. SD Society of Health System Pharmacists – Rhonda Hammerquist, PharmD**

Not in attendance; no materials

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

Not in attendance; no materials

##### **4. HPAP Update – Maria Piacentino, MA, LPC-MH, GMHP, LAC**

Not in attendance; no materials

#### **J. Old Business**

##### **1. USP <797> proposed revisions – Update – Gary**

- Compounding Expert Committee continues to work on reviewing public comments and revising the chapter. It may be likely that the chapter will be re-published for another round of public comments. An estimated publication timeline has not been provided.

##### **2. USP <800> - NIOSH 2016 – Gary**

- When building new facilities Gary suggested working USP <800> language in to contracts

##### **3. Hy-Vee Tech Check Tech Pilot Project Update – Justin Manning**

The following were reported by Justin Manning.

- Two technicians are currently performing in Tech Check Tech role; pharmacist is actively working on enrolling one pharmacy student in the role

- In a the validation period, technician #1 has processed 217 of 300 scripts and identified two intentional error and four unintentional errors; technician #2 identified one intentional error and two unintentional errors
- At this point in the pilot, there is not enough data to present; by the next meeting three technicians will be in the Tech Check Tech roll and two of those will have completed validation phase
- There have been no changes on the clinical services side yet

#### **4. Report from Avera Outpatient Pharmacy starter pack – Melissa Goff, Pharm D, MBA**

As reported by Melissa Goff, the pilot just started last week so there is not much to report. The start was delayed due to staffing issues.

#### **5. Report from Alchermes/ Aristada – David Bain**

The SD Board of Pharmacy approved a waiver to allow the use of Aristada, a long-acting anti-psychotic injectable medication for schizophrenia clients held in the Minnehaha County Jail (see section F. Variances/Waivers, number 2). David Bain, a representative from Alchermes the manufacturer who will provide the medication for use in the jail, came before the Board to discuss the program. The SD Board of Pharmacy has no regulating authority over South Dakota jails. Jails currently contract with outside vendors for their medication needs. Per Mr. Bain, the program is being implemented at the request of Warden Gromer and is an attempt to maintain medication adherence among this group of individuals and to keep them out of jail longer. The long-acting injectable addresses the gap in medication compliance that can occur after an individual is released and before out-patient social services kick-in. All doses of Aristada will be provided to Minnehaha County Jail at no charge. Company has little to gain as since the approval of Aristada, 8 of 10 doses have been provided to institutions free of charge. Ultimately, the medication cost will fall to the taxpayer or patient. Patient consent can be either a requirement of release or a clinician/inmate agreement.

### **K. New Business**

#### **1. Remote Pick Up Sites Policy Statement Revision – Paula/Kari**

Recently the SD BOP learned the Des Moines DEA considers automated dispensing devices, such as Asteres ScriptCenter, cannot dispense controlled substances under existing DEA regulations. In addition, the SD BOP has a policy statement on Remote “pick-up” sites which is utilized by several pharmacies. Prescriptions, including controlled substances, are delivered to grocery stores, convenience stores, etc. This would not be allowed either. Based on this determination, the SD BOP must change its existing policy statement guidelines. Lisa Rave made a motion to amend the SD BOP policy statement to exclude the dispensing of controlled substances via remote pick-up sites. Lenny Petrik seconded the motion. Motion passed 4 – 0. The Board will communicate the policy change to the pharmacy community as well as provide instructions and implementation timeline. Attendees expressed a desire to have a DEA representative attend the next Board meeting to answer questions as it appears DEA regions maybe interpreting and applying the regulation inconsistently from Region to Region.

#### **2. Regional Home Plus Asteres Scriptcenter Request – Scott Peterson, Pharm D**

Scott Peterson, Director of Pharmacy at Regional Health Home Plus, came before the Board today to ask for approval to place Asteres ScriptCenter kiosks in two new locations: 1) inside Hill City Regional Medical Clinic and 2) inside Regional Medical Clinic-Aspen Center in Rapid City. The primary goal of the dispensing kiosks is to expand pharmacy access to Regional Health patients in coordination with other healthcare services. In September, 2015, the Board approved a similar request for the use of a ScriptCenter kiosk inside Rapid City Regional Hospital and placed just outside the pharmacy. The kiosk allows employees increased access to new and refill medications and has improved compliance adherence.

At proposed locations, kiosks will dispense new prescriptions and renewal meds; no refrigerated items or controlled substances. Patients will have access to kiosks during clinic hours only (8-5, Monday through Friday). Proposed kiosk fill schedules are (2-5 x /week - Hill City, completed by a technician) and (2-3 x/week – Aspen, completed by a pharmacist). Pharmacist counseling via video or phone will occur before new medication will be released to patient.

Attendees asked whether Regional Health Home Plus considered telepharmacy as an option, and if the kiosks are equipped with auxiliary power source. Mr. Peterson indicated the telepharmacy idea was not considered and kiosks have a supplemental power source. With no additional questions, Lisa Rave made a motion to approve the request the use of two ScriptCenter kiosks in the new locations. New Board member Dan Somsen seconded the motion. Motion passed 3-0; Petrik recused himself from discussion and voting.

### **3. Avera McKennan Tech check Tech proposal – Mike Meekins, Pharm D**

Mike Meekins came before the Board to request a variance to SDCL 36-11-11, ARSD 20:59:21:20 (Delegation and supervision of technical functions) for the Avera McKennan Hospital and University Health Center Pharmacy. The request is to use technicians, serving in an advanced role, to verify automated dispensing cabinet (ADC) and central distribution replenishments without final verification by a pharmacist by implementing a Tech-Check-Tech (TCT) program at Avera McKennan. Rapid City Regional Health currently has a similar TCT program. Avera currently has two technicians in the advanced role (one year of service with Avera and PTCB certified) and one technician coordinator. In the initial validation phase, technicians are expected to perform at 99.8% accuracy level. Avera Central Fill currently distributes medications to over 200 different locations. Avera's Central Fill Pharmacy utilizes barcode technology for all medication distribution activities and final verification. Perpetual inventory management allows for the ability to perform routine quality assurance around dispensing activities as well as functional reporting at any point. If at any point in the medication distribution process, two bar codes do not match up, the transaction cannot continue and is rejected. The intent of the program is to promote the advancement of pharmacy technician staff and increase operation efficiencies and clinical pharmacist encounters.

Somsen made a motion to approve the Tech-Check-Tech Program Variance requested by Avera McKennan with appropriate follow-up and reporting to the Board in six months. Petrik seconded the motion. Motion passed 3 – 0, Lisa Rave recused herself from discussion and voting.

## **L. Other Business**

### **1. NABP Interactive Member Forum – Re-Cap Diane Dady, RPh**

- President Dady attended the National NABP Interactive Member Forum held for Boards of Pharmacy members. The mission of the National Boards of Pharmacy is to support State Boards. The average BOP has eight members (six pharmacists, two lay persons) who serve for a term of four to five years.
- Concerns across the nation included an increase in tech-check-tech programs and the use of auto-dispensing machines in public places (not in clinics or hospitals)
- Topics discussed included medication errors with e-prescribing, medical marijuana, PDMP funding sources, and the technician shortages

### **2. Future Board Meeting Dates**

- i. March 3, 2017
- ii. June 9, 2017
- iii. September 21, 2017 in conjunction with SDPHA – Lodge at Deadwood
- iv. December 8, 2017

### **3. Other Meetings**

- i. SDSHP Annual Meeting, April 7-8, 2017
- ii. NABP 113th Annual Meeting, May 20-23, 2017, Hyatt Regency Orlando

## **M. Executive Session – Discussion of Law Review**

Lisa Rave moved that the Board proceed into Executive Session for the purpose of law review. Motion seconded by Petrik. Motion passed 4-0. Motion to move out of Executive Session by Rave, second Petrik. Motion passed 4-0

**N. Adjourn – Motion by Rave, second Petrik. Meeting adjourned. Motion passed 4-0**