

SD Board of Pharmacy Meeting Minutes
Friday, March 3, 2017; 8:00 a.m. CST
Avera ePharmacy, eCARE Board Room
4510 N. Lewis Avenue, Sioux Falls, South Dakota 57104

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

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

Attendees Present: Justin Manning, Chad Sherard, Sue Schaefer, Cheri Kraemer, Andrea Darr, Brenda Jensen, Joe Bergsmith, and Melissa Goff.

A. Call to Order and Introductions

The meeting was called to order by President Diane Dady at 8:02 AM CST and attendees welcomed. Attendee introductions were completed. Appreciation was expressed to Avera ePharmacy and Andrea Darr for hosting the meeting.

B. Approval of Board Minutes

President Dady asked for a motion to approve the December 8, 2016 Board of Pharmacy meeting minutes as written. Motion was made by Board Member Rave and seconded by Board Member Somsen; motion carried.

President Dady asked for a motion to approve the January 4, 2017 Board of Pharmacy meeting minutes as written. Motion was made by Board Member Rave and seconded by Board Member Nelson; motion carried.

Executive Director Shanard-Koenders will be changing approval of board minutes, financial report, approvals, and variances/waivers to a consent calendar format in the future.

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 shown on the report with percentage remaining reflected. Benefits along with rent are higher. Rent being higher due to the office moving.

D. Staff Reports

1. Inspector Reports

a. Paula Stotz

Paula noted the following items:

- Noted facility that has isolator not using sterile gloves over the isolator gloves, not using sterile alcohol. A new pair of sterile gloves need to be donned between compounding products and when returning to the isolator.
- After December board meeting, FDA differentiated, through guidance, 503a compounding from an outsourcing facility; 503b. Also eliminated compounding for office use without a patient specific prescription. A pharmacist may compound a drug product before receipt of a prescription in anticipation of receiving a patient specific prescription. The compounded prescription may be provided to the patient or a prescriber upon receipt of a patient specific prescription. Looking for clarification from FDA regarding interfamily compounding and if covered anticipatory compounding. Still waiting for documents to come out as part of the Compounding Quality Act.

Discussion from Cheri Kramer regarding 503b continued. Cheri said regarding 503b facilities, that only compounding could be done within a list and must report to FDA. Cheri is going to DC in March and will be asking for more information. Now compounding is done patient specific for physicians' offices with list of names being provided by physicians prior to compounding. The patient names are on compound and patient specific. They are generally nonsterile and topical anesthetics.

b. Carol Smith –

Carol noted that she completed a new facility inspection at Bien Pharmacy and Milbank Area Hospital. Appreciation expressed to Gary and Paula for their assistance while she is still learning.

c. Gary Karel

Gary noted the following items in various pharmacies:

- Immunization certificates for pharmacists were outdated in two different locations.
- Take medication back from patients and delivery to Sioux Falls Police station.
- Ceiling tiles not caulked/sealed in two pharmacies.
- Found multiple outdates in compounding section in one retail pharmacy.
- Power of Attorney form not revoked for PIC that had left.
- New pharmacy with new IV room had windows in both buffer rooms with blinds.
- Chicago Tribune article, 'Pharmacies Miss Half of Dangerous Drug Combination'. Article revealed pharmacists are not counseling patients regarding various drug interactions. Inspectors will be asking PICs about their operation and how they counsel patients on drug interactions.

2. Statistical Reports for December 1, 2016 – February 28, 2017

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

Pharmacist: 1,961 current licenses (6 new licensees),
Pharmacy Interns: 333 current registrations (6 new registrations)
Full-Time Pharmacy permits: 265 current (No new permits)
Part-Time Pharmacy permits: 55 current (No new permits)
Technician Registrations: 1,461 current (41 new registrations)
Wholesale permits: 1,195 current (37 new permits)
Non-Resident pharmacy permits: 756 current (39 new permits)

3. PDMP

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

- Online profile queries by prescribers outpaced pharmacists for the first time in December 2016 and January 2017. In December 2016, prescribers had 6,076 queries while pharmacists had 5,756. In January 2017, prescribers had 6,320 queries while pharmacists had 5,862. Increase of prescriber inquiries are due to the medical board ruling for treating noncancer pain patients, prescribers seeing the PDMP as a valuable tool, and the increased media coverage regarding the opioid epidemic.
- Healthcare systems are encouraging registration of prescribers and delegates including Sanford, Regional, IHS, and the VA.
- Avera Health System's integration of Meditech and the SD PDMP has increased our prescriber users substantially. 92% of pharmacists are signed up along with 64% of prescribers which is up from 60% in December.
- Regional Health has contacted the board to integrate with the PDMP. A Harold Rogers grant will be written to assist with costs.
- Most prescribed drug changes from 2015 to 2016 include an increase of 28.9% in prescriptions and a 63.9% increase of quantity for Dextroamphetamine Sulf-Saccharate/Amphetamine Sulf-Aspartate. Prescriptions increased by 18.9% with quantities increasing by 41.4% for Methylphenidate.
- Unsolicited reports are going out. There were 4 patients that met the threshold for December 2016 resulting in 25 prescriber letters and 15 pharmacy letters. In January 2017, 9 patients met the threshold resulting in 42 prescriber letters and 32 pharmacy letters.

- Since the last board meeting, PDMP Director Melissa DeNoon gave presentations on the SD PDMP to Great Plains Quality Innovation Network's Medication Safety Webinar (1/24/17) presenting on PDMP integrations with health systems' electronic health records; and to Sanford Clinical Supervisor Meeting (2/23/17) presenting on delegate accounts.
- A stakeholder conference call was held for the drug take-back grant project was held on February 28, 2017. Discussion followed.

Board member Somsen remarked that PDMP is changing prescriber practices as a prescription was received in his pharmacy that noted the PDMP was checked prior to prescribing.

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

1. JR Distributing, Lake Norden, #600-2702
2. Jensen Livestock, Huron, #600-2714
3. CHS/Northern Plains, Isabel, #600-2719
4. CHS dba Northern Plains, Dupree, #600-2720
5. Agri-Tech, Watertown, #600-2727

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

1. Walgreens #12906 AMDD Yuyama, Spearfish
2. Walgreens #10656 AMDD Yuyama, Rapid City
3. Regional Home + LTC Pennington County Jail waiver renewal
4. MedVantx Pharmacy Services Off Site Storage approval renewal

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

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

1. Dan's Pharmacy, Sioux Falls: Break In
2. Sanford Chamberlain Medical Center: DEA 106
3. Lewis Family Drug (Wessington Springs): Break In
4. Medaus Pharmacy, Birmingham Alabama: Complaint
5. SF Prison Jameson Annex: DEA 106
6. Lewis Family Drug #70 (Flandreau): DEA 106
7. Counseling Complaint
8. Food Complaint

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

SDPhA Executive Director Sue Schaefer reviewed the following from the written report in the packet:

- Legislative session bills.
- Legislative days were cancelled due to Initiated Measure 22.
- Six of nine Spring districts meetings have been scheduled.
- Efforts of the Diabetes Toolkit.
- South Dakota Immunization Registry availability to pharmacists.
- South Dakota Pharmacist Association annual Meeting will be September 22-23 at the Lodge in Deadwood.
- Schaefer will be attending RxIMPACT March 14-16, 2017 in Washington, DC. Schaefer and Board President Trisha Hadrick will attend the APhA Annual meeting March 23-27, 2017 in San Francisco.
- National bills were reviewed.
- Support of the HPAP program.
- C&L Fund importance emphasized.

- Executive Director Sue Schaefer will be stepping down as of July 1, 2017. Shanard-Koenders recognized Sue's assistance with the board bills. President Dady extended appreciation to Sue for the excellent job she has done.

I. Other Reports

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

The following were reported in a written report from Dr. Mort:

- 2016 Pharm D graduates had a pass rate for the NAPLEX of 98.7% which was the second highest in the country.
- Strategic Planning for 2017 is in process.
- Ambulatory Care Positions in the VA System in Sioux Falls and Fort Meade are being recruited for.
- Dr. Dave Helgeland and Dr. Deb Farver are retiring at the end of this academic year.
- Two endowed positions are being recruited for. One for the William R. Hoch Family Endowed Professorship in Community Pharmacy practice and for the Kevin and Lorie Haarberg Endowed Chair in Oncology Research.
- Congratulations to Dr. Dean Hedge as being named Provost at South Dakota State University.

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

A written report was submitted with the following information:

- Listing of presentations made and to be made along with outreach from June 1, 2016 through May 1, 2017.
- HPAP Support Group availability
- Program Development surveys for current and past participants are being collected with data to review soon.
- Utilization of HPAP by the SD Board of Pharmacy includes two voluntary participants and two board mandated participants.

Executive director Shanard-Koenders noted that there is a transition with HPAP as HPAP may be asking the Board of Pharmacy for more funding.

J. Old Business

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

- January 27, 2017 – United States Pharmacopeial Convention. The United States Pharmacopeial Convention (USP) announced that its Compounding Expert committee is evaluating more than 8,000 public comments to inform future revisions of General Chapter <797> Pharmaceutical compounding – Sterile Preparations. A second revision will be published in the *Pharmaceutical Forum* for another round of public comment, but there is no anticipated date for republication at this time. The published version of the chapter, which became official on June 1, 2008, is currently the official standard.

2. USP <800> - NIOSH 2016 – Gary

- There is minimal change. Some PICs have not read the information. Most are taking some kind of action. Hazardous drug labels are being used—some are updating their software system while some are making cautionary lists. Inspectors encourage the review of this document.
- Board President Dady commented appreciation for document being sent out.
- Cheri Kramer advised that her office is offering hazardous training in August and could be offered to others at a cost. Also noted was the USP has added more to FAQs.

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

The following were reported by Justin Manning as part of the quarterly update.

- Currently two techs are fully trained on the program with a third in the process of completing their initial validation.
- Scripts verified by TCT: last 3 months (Dec, Jan, Feb) – 793 scripts.
- Quality verifications have gone well, no errors found and the errors introduced have been identified.
- MTM, immunization, and labor statistics were provided.

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

The following was reported by Melissa Goff:

- Pilot ran from November 28, 2016 through February 17, 2017 at the Avera Medical Group McGreevy 69th and Western location.
- Two family practice providers participated with the top 50 e-prescribed medications offered as a take home starter pack option to every patient who newly started on medication. Only offered Monday-Friday during clinic hours. If a pharmacy technician was not present, then service was not offered.
- Statistics on results of program were provided.
- There were no reported med errors.
- A patient survey was taken with results provided. Results were positive.
- Future of program is now going to a business plan with discussions following. Part of this initiative is to reduce readmission and recurrence, advance technician roles to be more a part of patient care. Full evaluation is forth coming with next steps to be advised.

5. Report from Alchermes/ Aristada – David Bain

Executive Director Shanard-Koenders received an email from David Bain. This medication is used for inmates who have schizophrenia. Once a person enters jail, the person no longer has their own benefits. Due to this, the jail does not have funds to purchase these medications. As of this meeting, no product has been shipped to the jail yet.

6. Remote Pick Up Sites

Executive Director Shanard-Koenders provided overview. Justin Manning and Bill Ladwig PDM limited mailing on prescriptions. Dana Darger has no controlled substances in their Asteres center. According to the DEA, controlled substances are not allowed in a remote pick up site or device unless it is between DEA registrants. Shanard-Koenders expressed this is a rural health issue with the need for access in remote places.

7. Legislative Update – Pharmacy Practice Act, Wholesale Distributor Act

Executive Director Shanard-Koenders reported the following:

- House Bill 1043, a cleanup revision of our practice act, SDCL 36-11, was challenged by the Medical Association and we asked to have it tabled. Dana Darger is organizing a group to change the practice act. A copy of 36-11-19-1 was provided. Discussion followed.
- House Bill 1044 had many last minute changes. 3PLs will be exempted from being licensed. There are 93 3PLs currently licensed. This bill passed and becomes effective July 1, 2017.
- Senate Bill 1 has passed and waiting for governor's signature. This bill changes the version of ASAP, changes data submission to every 24 hours, changes credentialing for integrations, and adds mandated prescriber registration with the PDMP with a prescriber holding a DEA number.

K. New Business

1. Hy-Vee Protocol

Justin Manning provided a copy of the Hy-Vee Protocol. Review of document and discussion was held. Dr. Burchett is signer. He is a Board Certified Family Medicine practitioner. Board members had no concerns with protocol as presented.

2. Hughes County Jail Request

A letter was presented from Jackie Lowitz of the Hughes County Jail requesting approval to store and utilize an injectable long-acting antipsychotic medical in the medical storage room. Executive Director Shanard-Koenders commented that this is the same program as for the Minnehaha County Jail. There would be no charge for the product to the facility and there would be a follow-up after care program. Diamond supplies the product to the jail. Storage is appropriate.

Board member Rave motioned for approval of the variance for the Hughes County Jail. Board member Somsen seconded. Motion carried.

3. Hooding Ceremony Request

Executive Director Shanard-Koenders will administer the oath if no other board member is available.

4. District Five Request

A request from the Iowa Board of Pharmacy was made asking if one or more representatives from the South Dakota Board of Pharmacy would participate in the upcoming NABP/AACP District Five Meeting scheduled August 3-5, 2017 in West Des Moines, IA. Seven member panels are being put together to cover various topics with a representative from each state/province being requested to be on each panel.

Executive Director Shanard-Koenders asked for one voting member to represent South Dakota at the NABP Annual Meeting. Also requested are the names who will be attending by the end of the month.

L. Other Business

1. Future Board Meeting Dates

- i. June 9, 2017 – Sioux Falls, Location TBD
- ii. September 21, 2017 in conjunction with SDPHA – Lodge at Deadwood
- iii. December 8, 2017 – Sioux Falls, Location TBD
- iv. March 9, 2018 -- Sioux Falls, Location TBD

3. Other Meetings

- i. SDSHP Annual Meeting, April 7-8, 2017, Sioux Falls, Holiday Inn City Centre
- ii. NABP 113th Annual Meeting, May 20-23, 2017, Hyatt Regency Orlando
- iii. District Five annual Meeting, August 3-5, 2017, West Des Moines, IA
- iv. SDPHA September 22-23, 2017, The Lodge at Deadwood

M. Adjourn at 12:04 PM – Motion by Board Member Rave, second by Board Member Somsen. Motion passed 4-0. Meeting adjourned.