

SD Board of Pharmacy Meeting Minutes

Friday, December 4, 2015 @ 8:30 AM

South Dakota Board of Medical and Osteopathic Examiners

101 N Main Ave, STE 215, Sioux Falls, SD 57104

Members Present: President Lisa Rave, Diane Dady and Jeff Nielsen

Staff Present: Executive Director Kari Shanard-Koenders; Inspectors Gary Karel, Paula Stotz, Bill Vander Aarde and Beth Windschitl, Senior Secretary

Others Present: Sue Schaefer (SD Pharmacists Association); Joe Bergsmith (Walmart); Dennis McAllister (Express Scripts); Chad Sherard (Cigna); Julie Becker (Western Dakota Tech); Brenda Jensen (Compounding Consultants); Cheri Kraemer (Pharmacy Specialty Clinic); and Bill Ladwig (Lewis Drug)

A. The meeting was called to order by President Lisa Rave at 8:30 AM CST

B. Approval of Board Minutes

Board member Nielsen moved to approve the September 17, 2015 meeting minutes. Motion was seconded by Board member Dady. Motion carried.

C. Financial Report

The Board Financial Report was reviewed and approved. Executive Director Shanard-Koenders provided an overview of the Revenue Report by Month highlighting the earnings generated per licensing category since the beginning of the fiscal year and reiterated that the 140,000 encumbrance is for Grant funds promised to Avera for development of the PMP Integration project.

D. Staff Reports

1. Employee Update

Beth Windschitl filled the open Senior Secretary position as of October 7, 2015. An offer was extended to a candidate to fill The PDMP Director position which remains opens. Interviews for the position have been completed and an employment offer extended on December 3, 2015.

2. Inspector Reports

a. Paula Stotz

Paula discussed some of the measures being taken by Jim Stevens, Vilas Pharmacy to meet standards/ensure safety and meet requirements of his several Remote Pick Up sites, including placing all patient information inside bags and using locked cabinets. Paula reported a rise in the number of questions and issues regarding E-signatures, electronic prescriptions and tamper proof paper. In one instance, a clinic stopped using tamper proof paper for controlled substance prescriptions as a cost saving measure. Gary Karel stated that this is a CMS requirement dating back to April 1, 2008. All written prescriptions for outpatient drugs prescribed to a Medicaid beneficiary must be on paper with at least one tamper-resistant feature.

b. Bill Vander Aarde

Bill reported on his continuing controlled substance audits and the violations found/observed during pharmacy visits including unlabeled, controlled substance freezer pops. Findings indicate CII's are generally consistent and on point. However, CIII-CIV audits vary greatly and are inconsistent (not required by law but very advantageous to the PIC).

c. Gary Karel

Gary reported the new Madison Hospital is open; the pharmacy is very nice and contains an IV room. A new hospital is being built in Milbank, South Dakota. The following items were as one-time occurrences in various pharmacies:

- Finger-tip testing not completed
- Ambulance service requesting purchase of morphine without a DEA 222 form
- Not using sterile 70% Isopropyl Alcohol
- Missing laminate on cover top, exposed particle board
- During biennial inventory, facility failed to include a count of controlled substances outside the pharmacy (AMDD machine on Nursing Unit)
- One location with two different DEA permits
- Found progesterone suppositories without a BUD on the container or BUD on the suppositories

E. Statistical Reports For September 1, 2015 to November 30, 2015

Shanard-Koenders stated that we are in the process of licensing Wholesalers and shared the licensing stats for the group:

Pharmacist: 1,993 active licenses (16 New licensees),
Pharmacy Interns: 322 currently registered
Full-Time Pharmacy permits: 273 (5 new permits)
Part-Time Pharmacy permits: 46 – (2 new permits)
Technician Registrations: 1,485 current (136 new registrations)
Wholesale permits: 1,169 (50 new)
Non-Resident pharmacy permits: 734 current (28 new permits)

Nielsen asked if the Board of Pharmacy tracks Wholesalers that do not renew their license and what happens when a Wholesaler continues to ship without a current license? Shanard-Koenders stated currently there is no established policy and procedures addressing these concerns. It is a challenge in all states. In states with fining authority, timely notification is vital for all licensees.

Per Shanard-Koenders, verification requests for pharmacies and pharmacists are up substantially. The new software system will allow individuals to complete an online verification independently as needed. Primary source verifications will continue to be completed by the BOP as the Executive Director's signature is required.

The Executive Director reviewed the SD Prescription Drug Monitoring Program statistics. At the end of November 84% of pharmacists, 25% of MD/DO's, 52% of PA's, 43% of NP's and 20% of dentists were approved for data access. Appriss (PDMP vendor) recently added two new capabilities-the reporting of morphine milligram equivalents and the ability to aggregate the number of Rxs, prescribers, pharmacies and private pay transactions. The top controlled substance in SD remains Hydrocodone combination products (HCP) despite moving them to CII status. A discussion of hydrocodone and oxycodone usage and prescribing followed. Dennis McAllister indicated physicians are conferring more with patients regarding medicine in an effort to reduce medication quantity.

Other updates provided by Shanard-Koenders included a brief review of findings from SDSU College of Pharmacy research project examining opioid prescribing patterns and the Avera Health Integration project.

F. Approvals – The following was reported by Shanard-Koenders and approved by Board members.

1. Luther Manor AMDD; Angela Bomgaars PIC
2. CSRx Inc., dba Rushmore Compounding Pharmacy; Curt Rising PIC
3. Closing of Getskow Pharmacy, Marion, SD and changing it to Remote Pick Up Site under Norm's Thrifty White; Norm Kaufman PIC
4. Heritage Pharmacy, Freeman SD Packaging unit dose medications and Credit/Reuse
5. Roger's Pharmacy, Yankton, SD change of ownership; Byron Olson PIC
6. Lewis Family Drug #37, Elk Point, change of ownership; Kevin Wurtz PIC

The following was reported by Shanard-Koenders.

1. Flandreau Santee Sioux Pharmacy Scriptpro - AMDD

G. Variances – The following variance was reported by Shanard-Koenders and approved by Board members.

1. E-kit Variance for Luther Manor AMDD

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

The following were reported by Gary Karel and Kari Shanard-Koenders. Discussion followed.

1. Omnicare Complaint
2. Lewis Family Drug-Dell Rapids; DEA 106
3. Lewis Drug Southwest-Sioux Falls; DEA 106
4. K-Mart-Huron; DEA 106
5. Lewis Drug-Huron; DEA 106
6. Martin Drug & Mercantile Complaint
7. Flandreau Santee Sioux Tribe Clinic Pharmacy; DEA 106 X 3

I. SD Pharmacists Association Update – Sue Schaefer

Association is behind on C & L collection. New development, Alex Middendorf is taking the point on a grant project for enhanced MTM service in South Dakota. A Providers' Status Committee is being assembled; the first meeting will be held in November, 2015. A pharmacist has been assigned to serve on the committee for the Governor's Work Group for expansion of Medicaid in South Dakota. Lastly, pharmacists will be administering flu vaccinations to SD Legislative members on the first day of the new session. It is an opportunity to contribute and showcase pharmacists. See handout provided for additional Association updates.

J. Other Reports

SDSU College of Pharmacy – Dean Dennis Hedge not in attendance

A written report from Dean Hedge was distributed to meeting attendees.

SD Society of Health System Pharmacists – No Report

SD Association of Pharmacy Technicians – No Report

HPAP – In the past, the SD Board of Pharmacy has provided \$10,000 in funding support to HPAP through SDPhA. By statute, SDPhA pays the fee annually to HPAP. The funding goes toward substance abuse and mental health services for individual pharmacists seeking assistance at little to no charge to them. The fee is \$10,000 for FY 2016. Maria Eining, from HPAP, would like the SD BOP to enter into a contract stating that we agree to provide financial support to HPAP similarly to the Board of Dentistry contract.

Action: Develop a state contract and distribute to SD BOP members via email for approval.

K. Old Business

1. FDA Draft MOU – 503A and 503B

Inspector VanderAarde attended the FDA Intergovernmental Working training meeting held in Washington DC on November 16-17, 2015. He reported that the FDA wants states to take over inspection responsibility and associated costs. The FDA's role will be to provide oversight only. No State endorsed the proposal and expressed concerns about the liability, cost, and benefit to each state. A discussion of compounding pharmacies, inspection practices, standards and criminal cases followed.

There was a presentation or update on 503A Memorandum of Understanding (MOU). It included statutory basis for MOU, MOU History, Provisions of Draft Standard MOU, over 3,000 comments, submitted on the draft MOU. There are various challenges such as the percentage of number of units compounded and non-compounded drug products distributed or dispensed both intrastate and interstate by a pharmacy during a calendar month. Also, there would be access issues, challenge of handling complaints and investigation of complaints.

L. New Business

1. CE – Clarification of Hours – Heck letter

The current BOP policy regarding immunization credits is that the two CE units can be applied toward meeting the annual 12 hour CE unit requirement for either the immunization certificate OR the pharmacist renewal but NOT both. This was not the understanding of many attendees and, after much discussion, it was determined that no state law or administrative rule addressing the issue exists. Attendees discussed rendering a decision on the issue and sending out a clarification notice to interested parties. Consensus occurred with Board members which noted that since there is nothing in law or rule stating that the items could not be used for both requirements, we would change our internal policy and allow immunization CE to also apply toward meeting the required 12 hours of continuing education credits until we can fix this with law or rule.

2. Immunization Clarification – Protocols

Current immunization protocols do not define what types of immunizations a pharmacist can or cannot provide and protocol language is very broad, vague and interpretive. Attendees expressed no concerns about pharmacist administering influenza vaccines. This option creates greater access to individuals and does not require them to schedule a doctor appointment or visit a clinic. There is no law or mandate pertaining to protocols, defining or restricting what is and is not allowable. It was suggested that the Board provide guidance and interpretation regarding protocols. Executive Director Shanard-Koenders stated the Board of Pharmacy encourages protocol reporting to be sent to the Board but it is not mandated. Do we allow a protocol to be used for all patients or select patients? What is the liability? The Board was encouraged to write a Q&A, recommendations or a policy until the law can be changed. Suggestions included creating a list the immunization that can be administered by the pharmacist, having protocols available for review at inspection time, checking the immunization registry prior to administering immunization as well as recording the immunization on the registry after.

Action:

- The Board of Pharmacy will write up guidelines; disseminate to Board members for review, then place on BOP website
- Place samples of available protocols and best practices on the BOP website
- Take no stance or other action at this time

3. DOH Rule Changes 44:73:08, 44:75:08, 44:75:14:11

Executive Director Shanard-Koenders reviewed the DOH Rule changes with attendees. The BOP plans to put a copy of the Law Book and new rules in a PDF format on the website.

4. CMS Revised State Operations Manual Appendix A

Inspector Karel discussed the importance of the information in the CMS Centers for Medicare & Medicaid Services report and provided three pages of the report to attendees. The subject involves revised hospital guidance for pharmaceutical services and expanded guidance related to compounding of medications. He highly recommended all PICs read the full revision of the document.

5. USP <797> proposed revisions – Inspectors Karel and Stotz

The USP is undergoing revisions. The chapter was just published in the Pharmacopeial Forum 41(6) November 2015. The public comment period ends on January 31, 2016. Proposed revisions include major changes in concept and terminology, contamination risk levels, master formulation records and compounding records. Please refer to handout in packet. Also, Paula Stotz attended a webinar by Critical Point which focused on “Top 10 Areas to Focus on During an Inspection”.

6. USP <800> update – Inspector Karel

The official UPS 800 document will be published in February, 2016 in the First supplement to USP 39-ND 34 with a delayed implementation and compliance date of June, 2018. The Board will need to communicate the rule and regulation change and provide education regarding the changes.

7. DLR Application Changes

The Department of Labor and Department of Health bill of last year has set forth a list of 29 data elements that must be collected and therefore will need to appear on all pharmacist and technician applications in the future. It was suggested that an application be populated with information from BOP current database and pharmacists and technicians can provide the remaining, outstanding information. The information is being collected to assist with access to primary care across South Dakota and will not be shared with other parties.

M. Other Business

1. Tentative Board Meeting Dates for 2015/2016

- a. April 1, 2016
- b. June 10, 2016
- c. September 15, 2016 In conjunction with SDPHA
- d. December 2, 2016

Board of Pharmacy is moving to a new location three buildings to the west of current location on the 49th Street. The lease for the current space expires March 31, 2015.

Shanard-Koenders asked Board members to identify several alternate dates for the April meeting and send feedback to her.

N. Other Meetings

1. NASCSA Annual Meeting October 2015 Recap

Inspector Stotz attended the NASCSA Annual Meeting in October and stated it was an excellent conference and attendees included DEA, FDA heads across the U.S. She also indicated there are many problems with information sharing between Federal agencies which hampers efficiency and effectiveness.

2. NABP Legal Forum Meeting December 2015 Recap

Bill Vander Aarde provided an update on a very interesting meeting on December 1-2, 2015 with several attorneys and inspectors for each state who discussed various aspects of their case findings for licensees. Every state indicated they continue to see medication diversion by technicians and other personnel.

3. SDSHP Annual Meeting, April 8-9, 2016 in Rapid City

4. NABP 112th Annual Meeting, May 14-17, 2016, San Diego, CA

There being no further business Lisa Rave made a motion which was seconded by Jeff Nielsen, to adjourn the meeting. The meeting adjourned at 12:05 p.m.