

# SD Board of Pharmacy Meeting Minutes

Thursday, September 15, 2016; 1:00 p.m. CST

Hampton Inn Board Room

3017 Lefevre Drive, Brookings, South Dakota 57006

**Board Members Present:** President Diane Dady, Lisa Rave, Lenny Petrik, and Tom Nelson

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

**Attendees Present:** Justin Manning, Amy Huntimer, Jodi Heins, Mark Dady, Troy Redler, Sara Redler, Eric Grocott, Rob Loe, Trisha Hadrick, Julia Becker, Jane Mort, Darrel Mutchler, Melissa Goff, Brian Lounsbery

## A. Call to Order

The meeting was called to order by President Diane Dady at 1:05 PM CST, attendees welcomed, and round table introductions completed.

## B. Approval of Board Minutes

President Dady asked for a motion to approve the June 10, 2016 and July 13, 2016 Board of Pharmacy meeting minutes as written. Motion was made and seconded by Board member Nelson; motion carried.

## C. Financial Report

The Board Financial Report was reviewed. Executive Director Shanard-Koenders noted higher than normal employee travel expenses and substantial fund expenditures for contractual services, computer purchases for new inspector and PDMP program as well as office rent.

## D. Staff Reports

### 1. Employee Update

Carol Smith, from Groton, South Dakota, filled the 0.25 FTE inspector position vacated by Bill Vander Aarde. Carol began work the end of July. She is married and has six children.

### 2. Inspector Reports

#### a. Paula Stotz

During inspections continues to see expired Combat Meth certificates and experience pharmacist resistance to conduct monthly random controlled substance audits. Paula emphasized the importance of making information in the final NIOSH document, available to retail pharmacies once published; expected in 2016.

#### b. Carol Smith

Carol is shadowing Inspector Gary Karel and enjoying seeing the different types of operations.

#### c. Gary Karel

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

- Magnehelic gauge not installed to measure pressure differentials between clean room and anteroom
- Narcotic counts for biennial inventory not completed in entire facility x 3 locations
- A methadone prescription was filled for narcotic dependence
- Failed viable count in buffer room
- Selling controlled substances (CII's) to ambulance without DEA 222 forms
- Media Fill Testing not completed in 2 locations
- Found multiple outdated syringes made by Pharmedium in CRNA medication cart. Also some opened multiple dose vials that were not dated.

Gary stated he learned more about conditions of participation: Pharmaceutical Services by CMS. There is a different set of rules for Acute Care (Appendix A) than Critical Access Hospitals (Appendix W) as it pertains to the first dose of medication which must be reviewed by a pharmacist before it is given. This applies to inpatients and out-patients but excludes Emergency Department patients.

### **3. Statistical Reports for June, 2016 – August, 2016**

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

Pharmacist: 2,014 active licenses (57 new licensees),  
 Pharmacy Interns: 253 currently registered (5 new registrations)  
 Full-Time Pharmacy permits: 265 (0 new permits)  
 Part-Time Pharmacy permits: 52 (2 new permits)  
 Technician Registrations: 1691 current (54 new registrations)  
 Wholesale permits: 1,202 (44 new)  
 Non-Resident pharmacy permits: 790 current (35 new permits)

The Executive Director added that wholesale license applications continue to increase due to feed & seed entities and veterinarian operation submissions. Inspector Stotz inquired if these types of facilities were performing compounding services. Shanard-Koenders affirmed the Board receives application with both wholesaler designations (503A and 503B).

### **4. PDMP**

Per Melissa DeNoon, the Prescription Drug Monitoring Program continues to increase the number of approved users and enrolling new delegates daily. Total number of approved users as of July 31, 2016 is 2,860 an increase of 154 from April, 2016. PDMP Directors are not just pharmacists. Program Directors span a variety of professional arenas including public safety, law enforcement, and the Dept. of Health.

Melissa attended the NABP PMP Interconnect Steering Committee Meeting in Chicago, IL July 19-21; The NASCSA Model PMP Act Drafting Group Meeting July 21-22, and the Harold Rogers PDMP National Meeting in Washington, DC in August where she presented "Project Update: Comparing South Dakota Prescription Drug Monitoring Program Law Enforcement Profile Requests to Criminal History Data". The conferences provided great networking and learning opportunities. Melissa is in the beginning stage of planning her first Advisory Council Meeting to be held in October of 2016.

Melissa reported a comparison of PDMP drug profiles and law enforcement data showed arrests have decreased. The change could be due to many influences including increases in number of deceased individuals and the program's deterrent effect. She plans to partner with law enforcement to grow a relationship.

President Dady inquired how other states fund their PDMP programs. Per Ms. DeNoon, Indiana's program is fully funded from DEA license fees. Lisa Rave asked if funds might be available through revenue stream sharing with Interconnect.

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

1. Wyodak Pharmacies, dba Vilas Pharmacy, License #100-2042 - Lead
2. Shopko Pharmacy, #2596, License #100-2043 – Dell Rapids
3. Dakota Plains Surgical Center (CHOW to Avera), License #200-1703 – Aberdeen
4. Avera Medical Group Family Health Center Emergency Department, License # 200-1704 -Sioux Falls
5. Paul's Feed and Seed, LLC, License #600-2628 – Faith
6. Eagle Butte Co-Op Feed & Ranch Store, License #600-2618 – Eagle Butte
7. Nehl Feed, License #600-2592 – Watauga

A brief discussion regarding distance requirements between telepharmacies occurred. It was also noted that a telepharmacy cannot be open if its central/oversight location is closed.

**F. Variances** – No new variances proposed

A follow up to topic raised at last meeting regarding the Board's authority to consider and grant variances: AG Doug Barnett in an unwritten opinion stated, "the Board has all the power in 36:11 to grant a variance."

The Department of Health will be changing the rules in 44:58:07:09 to delete subpart (5) in a upcoming Rules hearing. This is because they determined that we may no longer be able to provide variances to their Rule regarding controlled substances in E-Kits.

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

The following were reported by Gary Karel. Discussion followed.

1. Lewis Drug-Brookings: DEA 106
  - a. Missing 70 tablets of controlled substance
2. Sturgis Regional Senior Care: DEA 106
  - a. Employee stole oxy and hydrocodone over more than a year's time
3. Salem Community Drug: Break In DEA 106; Per PIC Eric Grocott
  - a. 12,000 tablets stolen / 59 different drugs/strengths
  - b. Store cameras worked well and helped identify individual who was not from the area
  - c. Thanks to perpetual inventory practice, PIC knew exactly what was taken/missing
4. Lewis Family Drug-DeSmet: DEA 106
5. Walgreens (41<sup>st</sup>/Louise)-Sioux Falls: Armed Robbery DEA 106
6. Lewis Drug Southgate-Sioux Falls: DEA 106
  - a. Was the result of over filling script; too many pills in a bottle
7. Mylan-Greensboro, NC: DEA 106
  - a. Transport vehicle broken into; Mylan is the only deliverer that sends DEA notices to Board of Pharmacy
8. Avera McKennan Hospital: DEA 106
  - a. Employee diverting; employer increased scrutiny methods taking a team investigating approach for reporting
9. MedVantx-Complaint
  - a. Investigation into shipping Symbicort inhalers without climate controls; patient contacted FDA claiming product did not work as a result of shipping/storage temperatures; Gary requested the patient mail product to SD Board of Pharmacy and we would ship it to Astra Zeneca quality department.

## **H. SD Pharmacists Association Update – Rob Loe, SDPhA President**

SDPhA President Rob Loe highlighted the following items from the SDPhA Annual Report and Revenue Budget handouts provided to attendees:

- Attendance for SDPhA annual meeting looks good
- TAR fees
- Association will again sponsor flu shots for SD legislative members
- SDPhA fiscal year ended June 30, 2016; due to location change and rent decrease FY 2017 started with a surplus of \$50.00.

## **I. Other Reports**

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

- April 1, 2016, the College provided an interim report to the Accreditation Council for Pharmacy Education (ACPE) and received a very positive evaluation with no further reports needed. Reporting is complete till 2022-2023.
- Continuing Education Program received a full accreditation cycle approval for the next 6 years
- The Masters in Public Health degree program, offered in conjunction with USD has grown to 63 students enrolled
- PharmD Curriculum review/revision and evaluation design continues. In the coming year the College will create a complete curriculum including selecting curricular structure, content/skill to achieve, credit hour allocation and optimal pedagogy.

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

Not in attendance; No materials provided.

### **3. SD Association of Pharmacy Technicians – Sue DeJong not in attendance**

Per Kari Shanard-Koenders, PTCB is having a summit meeting to determine if their goal of requiring all technicians to attend a full, formal technician training program is still on track. A meeting attendee asked whether there was any discussion in South Dakota regarding changes to pay/wages due to formal training requirement. This remains a valid concern. A discussion centered on the problems of finding and retaining certified technicians ensued. Some of the challenges voiced were individuals not entering the arena, size of the state, rural vs. urban settings, prohibitive cost of education, and wages.

### **4. HPAP Update – Maria Eining**

Not in attendance; No materials provided.

## **J. Old Business**

### **1. Past Variances to E-Kit Rules – Repeal of 44:58:07:09 Emergency Supply of CS in LTC**

- Per Executive Director, CII Pain medications filling change with Feds based upon the Comprehensive Addiction and Recovery Act – more to come from DEA, but will be able to partial fill within 30 days if patient wants a smaller quantity than written quantity.
- Department of Health revising all assisted living rules and will also revise this rule as well

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

- Brenda Jensen currently serves on the USP Board. The Board is reviewing nearly 9000 responses submitted in response to the first draft of proposed revisions.

### **3. USP <800> - Update – Gary**

- Officially released February, 2016
- Effective July, 2018
- 2016 NIOSH document not yet available

#### 4. Hy-Vee New Business Model Tech Check Tech Variance Request – Justin Manning

Justin Manning presented an overview of the Tech Check Tech Program Hy-Vee wants to implement at its Marion Road & 26 Street Pharmacy. The variance would allow a technician to complete the final verification (check) in the prescription fulfillment process instead of the pharmacist (as required by SD law). A handout explaining the policy, procedures and practice model and discussing eligibility, training, workflow, safeguards and recordkeeping was provided. Hy-Vee added two additional components to their variance proposal as requested by the SD Board during their June 10, 2016 meeting. The additions were 1) Quality Assurance Evaluation of Technicians/Interns at initial validation and continued validation audits, and 2) inclusion of the statement “the program must not be used as a mechanism to reduce pharmacist staff”.

The SD Pharmacist Association developed a survey regarding the proposed Tech Check Tech program and mailed it to 1,500 SDPhA members. A total of 245 pharmacists completed the survey. Association President, Rob Loe read the survey responses aloud to attendees and highlighted some of the survey results including,

- Members are in opposition to variance
- 36% of pharmacists feared job loss and lack of pharmacist oversight
- 73.7% of pharmacists are not in favor of program
- Expressed safety assurance issues

Lisa Rave expressed concern that the survey, as constructed, was somewhat misleading and did not provide any context. Perhaps the survey should have included more information regarding the components of Tech Check Tech program – training, workflow, safeguards, quality assurances, etc. Without this information, a survey completer may not have an understanding of the program.

Justin informed attendees that it will take approximately 3 months to train a technician and implement the Tech Check Tech role. Additionally, he explained that Hy-Vee current pharmacy practice is that all scripts, except immediate needs, go to Central Fill and have a one day turn around. Immediate needs prescriptions, which is a smaller percentage of scripts, would utilize the Tech Check Tech process if applicable.

President Dady stated, as a pharmacist, it would be difficult for me to not do a final check. It is the pharmacist’s liability and license at stake. She stated hospitals have a lot more verifications in place in the process and indicated pharmacists in the state may not understand Hy-Vee’s process.

Use of the Tech Check Tech practice may be setting precedent and it is better suited to more automated environments, not rural. Hy-Vee plans on using 2 technicians and 2 interns for the Tech Check Tech process.

Board member Nelson made a motion to grant a temporary variance to Hy-Vee on Marion Road & 26<sup>th</sup> Street in Sioux Falls to expire on October 1, 2017 with quarterly reports to the Board. Board to determine information Hy-Vee will be required to report such as number of people in program, turnover, error rates, information pertinent to process, increases/decreases in counseling hours, etc. Board may request changes in reporting during the variance period. Lisa Rave seconded the motion. President Dady expressed her reservations stating this may not be the best practice for pharmacy. Inspector Carol Smith expressed concern regarding the need to post signage in the pharmacy to tell consumer their prescription is being filled using the Tech Check Tech process.

Nelson amended his motion to include the additional requirement that signs be posted in the pharmacy stating the Tech Check Tech process is being used to fill prescriptions at this pharmacy location.

Motion passed 3-1; yay (Nelson, Petrik, Rave), nay (Dady).

## K. New Business

1. NAPLEX Changes - Kari Shanard-Koenders highlighted changes
  - Increase in number of test items from 185 to 250
  - Increase in testing time to six hours
  - Increase in registration fee from \$505 to \$ 575
  - New NAPLEX will launch on November 1, 2016
2. CARA - Comprehensive Addiction and Recovery Act of 2016 – Kari
  - Changes regarding filling of CII – partial filling allowed within 30 day window
  - Controlled Substances Act was amended, Federal Regulation to allow immediate implementation due to opioid problems
  - Give the smallest quantity to get opioids off the street/keep out of circulation
3. Avera Clinic Starter Pack Technician Variance Request – Melissa Goff, Pharmacist

Appearance before the Board to request a variance to SDCL 36-11-2 (22) and ARSD 20:51:29:20. Pilot program focuses on transition of care and is being implemented in an attempt to improve medication compliance. Avera has not set forth any outcome expectations to be proved. Their goal is to collect and analyze data to see if dispensing model is a viable method to increase medication adherence.

Per Ms. Goff, 30-50% of medications never make it into patient's hands. Model options to increase medication adherence could include placing pharmacies in medical clinics (cost prohibitive), kiosks in medical clinics (outsourcing), and pharmacist direct patient access. To close the gap, Avera's pilot program proposes two models for consideration for implementation in two clinic locations.

First dispensing model uses a Starter Pak (5-day partial fill) that is pre-defined, labelled, filled by technician, verified by pharmacist then sent to clinic for dispensing by pharmacy technician in clinic location after physician provider sign offs on partial fill of prescription. An e-prescription for the remaining 25 days of prescription would be sent to Avera pharmacy then mailed to patient. Child resistant packing will be used, and patient would know costs at the point of adjudication.

Second dispensing model allows dispensing of full courses of medication to patient by provider upon leaving clinic office

Inspector Karel voiced concern that the six week variance being requested may not be an adequate amount of time for the Pilot program. Board member Petrik made a motion to grant a variance to ARSD as proposed but with a timeframe of 90-days to report at the next Board Meeting. Motion second by Nelson. Motion passed (Nelson, Dady, Petrik). Board member Lisa Rave recused herself from voting.

4. Redler's LTC Pharmacy AMDD Statsafe Medication Management - Troy Redler, Sara Redler

Troy and Sara Redler came before the Board as required by ARSD 20:51:17:01.01 to request approval to utilize Statsafe, an automated mechanical distribution device (AMDD) in their skilled nursing facilities. The system would house E-Kits only. System security measures include staff login with pin and computer picture taken at login as well as dual control. System restock requires two individuals. The pharmacy can access system to verify usage and access to the system. Pharmacist would conduct inventory monthly to verify expiration dates and check accuracy.

Board member Lisa Rave made a motion to approve variance to ARSD 20:51:15:15.01 to allow increased numbers of legend drugs available in the StatSafe. Motion was seconded by Petrik and passed unanimously.

5. Changing quantities – request to address in rules – Gary

Gary Karel reviewed the guidelines of policy statement for pharmacist changing quantity dispensed with attendees. A pharmacist is allowed to exercise professional judgment to dispense a greater or lesser quantity than indicated on a prescription when it serves the best interest of the patient. Request that policy statement be considered for inclusion in future administrative rules.

6. Biosimilars – request to address in law/rule – Lenny Petrik

Biosimilars are a type of biological product that is licensed (approved) by FDA because they are highly similar to an already FDA-approved product biologic (known as a reference product) and have no clinically meaningful difference from the reference product. Per Lenny Petrik, biosimilar products are “big things” in specialty pharmacies. Twenty-two states have already adopted legislation regarding medication substitutions using biosimilars and interchangeable products. This emerging prescribing option will need to be addressed in law and rule in the future.

**L. Other Business**

1. December 2, 2016, Sioux Falls, Location TBA (**Meeting Date Changed** after meeting to December 9, 2016 8:00 – 1:00 CST)
2. March 3, 2017
3. June 9, 2017
4. September 14, 2017 in conjunction with SDPHA
5. December 8, 2017

**M. Other Meetings**

1. NABP/AACP District V Meeting, Lincoln NE, August 4-6, 2016 - update
2. SDPHA Annual Meeting, Brookings, September 16-17, 2016
3. NABP Interactive Member Forum, November 30 - December 1, 2016
4. SDSHP Annual Meeting, April 7-8, 2017
5. NABP 113th Annual Meeting, May 20-23, 2017, Hyatt Regency Orlando

**N. Executive Session**

Nelson moved that the Board move into executive session for the purpose of law review. Motion second by Petrik. Board moved out of executive session.

**O. Petrik moved Board adjourn. Seconded by Rave. Meeting adjourned at 5:45pm**