

Draft of SD Board of Pharmacy Meeting Minutes

Friday, June 9, 2017; 8:00 a.m. CST

Pharmacy Specialties and Clinic Conference Room

2333 W. 57th Street, Sioux Falls, South Dakota 57108

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

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

Attendees Present: Justin Manning, Bruce Jorgensen, Joe Bergsmith, Amanda Bacon, Sue Schaefer, David Bain, David Hilbrands, Jim Clem, and Jessica Harris

A. Call to Order and Introductions

The meeting was called to order by President Dady at 8:00 AM CST, attendee introductions made and roll call taken by recorder; all Board members were present.

B. Consent Agenda

Executive Director Shanard-Koenders briefly reviewed the components of the consent agenda noting that any item could be removed from the consent agenda for discussion. Motion to approve consent agenda was made by Board Member Tom Nelson and seconded by Board Member Dan Somsen; motion carried.

C. Staff Reports

1. Inspector Reports

a. Paula Stotz

Paula noted the following items:

- Board of Pharmacy inspectors completed 12 Consumer Product Safety Commission Safety Cap checks in pharmacies that serve high numbers of senior citizens. One pharmacy had one prescription without a safety cap. Discrepancy was identified and corrected prior to leaving the pharmacy.
- DEA Inspection/Visits
 - Checked controlled substances for correct documentation on invoices, proof of receipt, and finalization of CSOS orders on the wholesaler's CSOS site.
 - Patient address, provider address and DEA # are required on the face of all controlled substance prescriptions.
 - Drug collection boxes – Pharmacy must be registered as a Collector with the DEA; box liner must be correct size, labeled with a non-removable serial number and be self-sealing.
- Reviewed aspects of Wholesale Veterinary Feed Directive Inspections (VFD). Main VFD drug is Aureomycin (chlorotetracycline [CTC]) broad spectrum antibiotic to be mixed with feed. VFD (this may not be called a prescription) must be from a veterinarian in paper or electronic form; cannot be faxed or phoned in. If faxed, original written VFD must be provided to the supplier within five days and retained on file for two years.

b. Carol Smith

Carol noted the following items during inspections:

- Many pharmacists-in-charge (PIC) have taken no steps to implement/comply with NIOSH requirements; several PICs were not familiar with NIOSH.
- Found one POA that was not revoked.
- Found unlabeled capsules in a refrigerator (boric acid)
- Pharmacies in the Northeastern part of South Dakota are being audited by Humana. Auditor is a PAAS member, has been very helpful, and contacts physicians to clarify days supply.

c. Gary Karel

Gary noted the following items in various pharmacies:

- Retail pharmacy not reporting pseudoephedrine sales using NPLEX. Still using manual system.
- Found outdated product.
- Reverse distributor not registered in South Dakota.
- No cove molding in an IV room.
- Failed viable counts not followed up on and some not completed.
- First dose review not done by pharmacy. This is a requirement of conditions of participation for acute care hospital.
- Ceiling in buffer installed incorrectly in facility. It was not a washable ceiling.
- DEA license expired.
- Failed to count controlled substances outside pharmacy in a hospital.
- One pharmacist using another pharmacist password for PDMP.
- Couple pharmacies failed to conduct any audits since last inspection.

Executive Director Shanard-Koenders stated in South Dakota we feel that an inspector's role is to help keep pharmacies and pharmacists compliant and thus protect the health and safety of the residents of SD.

2. PDMP

The Executive Director reported the following PDMP updates:

- Senate Bill 1
 - Bill mandates all prescribers with a South Dakota Controlled Substance Registration (SD CSR) be registered with the program by July 1, 2017.
 - BOP is working in conjunction with Bob Coolidge, Department of Health, Division of Controlled Substances in Pierre to identify all parties needing to enroll.
 - Have received push back from some practices and small offices with few personnel have presented some unique challenges but overall going well.
 - Submissions will change to every 24 hours; which is not a great change as most pharmacies already submit data every 24 hours.
- Currently Appriss provides all reports for PDMP data; we are encouraged and continue to work with them to improve reporting options and data quality as the current reporting situation is not optimal.
- Next Advisory Council meeting will be held June 20, 2017.

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

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

1. Walgreen's #12906 Spearfish: DEA 106
2. Lead-Deadwood Regional Hospital: DEA 106
3. Hy-Vee Pharmacy #3 (Minnesota Ave) Sioux Falls: DEA 106
4. Mylan in Greensboro, NC: DEA 106
5. Parkston Drug: Complaint/Concern
6. Walmart Pharmacy, Stummer Rd, Rapid City: Complaint
7. Community Health Center of Black Hills Pharmacy, Rapid City: Complaint
8. Shopko Pharmacy, Dell Rapids: DEA 106
9. Shopko Pharmacy, Watertown: DEA 106

10. Walgreen's #05242 S Cliff in Sioux Falls: Complaint
11. Sanford Aberdeen Medical Center: DEA 106
12. Tea Storm Chasers: Complaint

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

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

- Executive Director Sue Schaefer introduced Amanda Bacon the new SDPhA Executive Director starting July 1, 2017. Amanda has a background/training in communications and broadcast journalist. Her professional experience includes work with Regional Health, Avera-St Mary's in Pierre, and the South Dakota Beef Council.
- In May, President elect Eric Grocott met with congressional delegates in Washington, DC to discuss direct and indirect remuneration (DIR) fee.
- The Association continues to prepare for the Annual SDPhA Meeting securing speakers, vendors, and sponsors. The Russell Room in the Deadwood Lodge has been reserved for the September BOP Board Meeting.
- The Association donated \$1,000 to the Annual Pharmacy Technician Meeting and is working with the Therapeutic Research Center (TRC) to secure online pharmacy technician training modules at a reasonable price.
- Financial report show significant funds rolling to new fiscal year; funds are for out-going Executive Director's payout.

F. Other Reports

1. SDSU College of Pharmacy – James Clem, Pharm D, Dpt. Head Pharmacy Practice

College of Pharmacy and Allied Health Professions Department Head Jim Clem reviewed the following from a written report, provided by Dr. Jane Mort, found in the Board Meeting packet:

- Seventy-three students graduated with their PharmD on May 6, 2017. Twenty-three graduates have taken residencies (31.5%). Of those students applying for residency, 76.7% were placed.
- The College is currently revising its curriculum; faculty will vote on changes in August. If approved, implementation will be fall, 2018.
- SDSU will complete Strategic Planning fall, 2017 then the College will begin its own strategic plan.
- Faculty Position Update- hired two new faculty in Ambulatory Care, are recruiting for the Hoch Family Endowed Professor in Community Pharmacy Practice position and are recruiting for a faculty member specializing in pharmacogenomics
- Search committee for the new Dean has been established and will be headed by Dr. Fahrenwald, Dean of the College of Nursing. Interviews will start this fall. Start date unknown.

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

- Golf Tournament is scheduled for June 28, 2017.
- Strategic Plan will be sent out when completed.

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

Not in attendance; no materials

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

Attending later, No report

G. Old Business

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

- Still reviewing comments; waiting for second draft of document.
- A Pew Trust article (May, 2017) lists U.S. illnesses and deaths associated with compounded or repackaged medications, 2001-2016. In summary, the report reflects 1197 reported cases and 99 reported deaths.
- South Dakota has 5-6 non-sterile compounding pharmacies and 1 sterile compounding pharmacy. Everything is patient specific.

2. USP <800> - NIOSH 2016 – Gary

- Implementation July 1, 2018; applies to all pharmacies compounding hazardous drugs.
- Outlines what to do, how to do it; pharmacies need to do a risk assessment associated with compounding hazardous drugs. This includes receiving, handling, storing, and dispensing of hazardous drugs.

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

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

- Staff from other Hy-Vee stores are rotating through location.
- Reported no quality errors and introduced planned errors are being successfully found by technicians.
- MTM, immunization, and labor statistics were consistent.
- Fifteen locations in Iowa are participating in a pilot program that pays pharmacists \$1.00 for patient care counseling. Pilot is through Wellmark and is looking at total cost of care per patient, recurrence, and freeing up time for patient/customer interaction-relationships. Pilot identifies high-, moderate- and low-risk levels; focuses on high/moderate group to counsel to better understand history and identify potential problems in the future.

4. Report on Alchermes/Aristada Pilot Project Minnehaha County Jail–David Bain, David Hildbrands

David Hildbrands the representative responsible for coordinating project parties in South Dakota reviewed the following from the written report in the packet:

- Aristada is now available in 1060 milligram dose. The two month dose interval allows for greater levels of control after discharge.
- Similar jail pilot programs are in all 50 states.
- As of March 8, 2017, all Minnehaha County Jail Medical staff have completed formal training.
- To date, three patients have been discharged from the jail on Aristada; two additional patients in facility have started Aristada.
- Programs similar to the Minnehaha pilot have been established in Hughes County and Armour

5. Remote Pick Up Sites

- Controlled Substances are still a question – DEA is looking into the matter
- Regional was told that controlled substances may be placed back into ScriptCenter but are awaiting official information from the DEA.

6. Legislative Update – PDMP Changes, Pharmacy Practice Act, Wholesale Distributor Act

Board President Diane Dady reported the following regarding the Pharmacy Practice Act: (House Bill 1043, a cleanup revision of our practice act, SDCL 36-11)

- The Practice Act Committee met once via phone. Committee conversation centered on one question, why examine the Practice Act?
- The Act spells out what pharmacists can and cannot do in their role. The Governor is encouraging all Boards to “clean up” their practice act in the coming year making adjustments where needed.
- Committee members want to ensure they communicate to South Dakota pharmacists all Practice Act discussion items, are methodical in their review and do not rush to make changes to the Act.

- Board Meeting attendees discussed how the relationship between the Board of Pharmacy and the South Dakota Pharmacist Association, as stated in the current Practice Act, might be viewed as a conflict of interest and not transparent.
- President Dady suggested the Board request an AG Opinion regarding the relationship between the Board of Pharmacy and Pharmacists Association. The AG opinion rendered in the 1980's, established the bifurcated relationship currently in place.
- The outcome and impact of an AG decision cannot be predicted. However, should it be determined the relationship must be severed, other revenue generating options for Association funding including the Board contracting with the Association for specific services/tasks and pharmacist paying annual Association dues needs to be investigated.
- A motion was made by Board Member Lisa Rave to seek an AG Opinion regarding the relationship between the South Dakota Board of Pharmacy and the South Dakota Pharmacists Association, the funding of the Association by the Board and to determine/assess whether a conflict of interest exists. Motion was seconded by Board Member Dan Somsen; motion passed unanimously (Dady, Nelson, Petrik, Rave, and Somsen).

Executive Director Kari Shanard-Koenders report the following Wholesale Distributor Act and PDMP updates:

- House Bill 1044 bill passed and becomes effective July 1, 2017. Rules have to be written.
- Senate Bill 1 passed; it mandates prescriber registration with the PDMP for any prescriber holding a SD Controlled Substance registration; data submission will occur every 24 hours.

H. New Business

1. Telepharmacy and Technician Certification Variance Request – Alyssa Howard PharmD, Community Memorial Hospital Avera / Redfield Community Memorial Hospital Avera

Meeting attendees received a copy of the variance applying to operate under Telepharmacy licensure with Avera St Luke's Hospital in Aberdeen as the Central Pharmacy. Alyssa is a "shared" pharmacist working three days a week at one location with one full-time pharmacy technician and two days per week at the Marshall County Healthcare Center in Britton with no pharmacy technician. She is the only pharmacist on-site at either location, and she completes order entries for both facilities. The Telepharmacy practice (cameras and phone) will be implemented in Redfield so grandfathered pharmacy technician will complete Pyxis fill, floor stock and unit dose verification during days when pharmacist is working at other location. Board Member Lisa Rave made a substitute motion 1) approve Telepharmacy in Redfield, 2) to approve an exception to the requirement that Telepharmacy technicians be certified and 3) added a requirement to the variance (grandfather technician must complete 20 hours of continuing education every other year as is required of certified pharmacy technicians). Motion was seconded by Board Member Dan Somsen; motion passed unanimously (Dady, Nelson, Petrik, Rave, and Somsen).

2. Bruce Jorgenson, PharmD, BCNP; Cardinal Health Nuclear Pharmacy Technician Certification Variance Request

Mr. Jorgenson comes before the Board to request a variance to South Dakota ARSD 20:51:29:06 which requires national certification of pharmacy technicians. Cardinal Health currently employs two pharmacy technicians-one certified, one studying for certification on-line through PTU. Cardinal Health requires pharmacy technicians complete vigorous training/coursework specific to nuclear medicine annually under the supervision of a Preceptor Pharmacist. A review of PTU's certified pharmacy technician training modules and found very little curriculum having to do with the practice of nuclear medicine. As such, national certification would not prepare one to be a nuclear pharmacy technician as thus should be exempt from the national certification requirement. Meeting attendees discussed the topic further. Board members asked Mr. Jorgenson to provide a history of what others states are requiring Cardinal Health nuclear pharmacy technicians to complete and tabled the variance request till the September or December Board meeting.

3. Policy Statement: Transfer of Unfilled Prescriptions, including CII-CIV Prescriptions Prior to First Fill)

Board provided clarity on this issue (ARSD 20:51:23:01). Since the prescription has never been filled, the purpose of the transfer would not be for “refills” but would be for an original fill; therefore, review of our rule may conclude that it should not be standard of practice. The DEA has been consulted and the practice is currently under review by DEA Headquarters for a potential CFR change. Per Sarah Boblenz, DEA, “if the state allows it, DEA accepts the practice as long as it follows 21CRF 1306.15, 1306.25 and 1306.27.”

The Board feels strongly that prohibiting a transfer of a prescription because they have not yet been filled is contrary to timely and proper patient care and could contribute to diversion. Until administrative rules can be changed, the Board clarifies that the practice of transfer of a prescription prior to fill is acceptable in South Dakota. The Board suggests a rule change, for the purpose of clarification, that “first fill” and “refill” mean the same under statute so transfer can occur within the state. Board members unanimously approved the policy statement (Dady, Nelson, Petrik, Rave, and Somsen).

4. Policy Statement: What Can Be Changed on a CII–CV Prescription

Policy statement handout was reviewed with attendees. Board Member Lisa Rave made a motion to approve policy statement as presented; motion was seconded by Board Member Dan Somsen. Motion carried, Board members unanimously approved the policy statement as presented (Dady, Nelson, Petrik, Rave, and Somsen).

I. Annual Election of Officers

1. A motion was made by Board Member Lisa Rave to re-elect President Diane Dady and Vice-President Lenny Petrik for a second term. Motion was seconded by Board Member Tom Nelson; motion carried unanimously (Dady, Nelson, Petrik, Rave, and Somsen).

J. Other Business Future Board Meeting Dates

1. Future Board Meeting Dates

- i. September 21, 2017 in conjunction with SDPHA – 1pm at the Lodge at Deadwood, Russell Room
- ii. December 8, 2017 – Sioux Falls, Location TBD
- iii. March 9, 2018 -- Sioux Falls, Location TBD
- iv. June 8, 2018 – Sioux Falls, Location TBD

2. Other Meetings

- i. District Five annual Meeting, August 3-5, 2017, West Des Moines, IA
- ii. SDPHA September 22-23, 2017, The Lodge at Deadwood

3. Meetings Recap – NABP 133rd Annual Meeting, Paula, Kari

K. Executive Session: per SDCL 1-25-2

Attendees Joining for Executive Session: Amanda McKnelly, Maria Piacentino, Kent Munger, Diana Munger

At 12:08 pm, Board member Tom Nelson made a motion to move to Executive Session to discuss licensure; motion seconded by Board Member Petrik, motion carried unanimously. Board came out of executive session.

- L. Adjourn at 1:05 PM – Motion by Board Member Somsen, second by Board Member Nelson. Motion passed 4-0. Meeting adjourned.**