

SD Board of Pharmacy Meeting Minutes

Friday, April 1, 2016 at 8:30 AM

South Dakota Board of Pharmacy Office

4001 W. Valhalla Blvd, Sioux Falls, SD 57106

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

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

Attendees Present: Sue Schaefer (SD Pharmacists Association); Chad Sherard (Cigna); Brenda Jensen (Compounding Consultants); Cheri Kraemer (Pharmacy Specialty Clinic); Bill Ladwig (Lewis Drug); Justin Manning (Hy-Vee); Amanda McKnelly (SD HPAP); and Maria Eining (SD HPAP)

A. Call to Order

The meeting was called to order by President Lisa Rave at 8:30 AM CST, attendees welcomed, and introductions completed.

B. Approval of Board Minutes

President Rave asked for a motion to approve the December 4, 2015 meeting minutes as written. Motion was made by Board member Nielsen and seconded by Board member Petrik, motion carried.

Agenda Order Adjusted

I. Other Reports

4. HPAP Update – Maria Eining

Maria Eining explained HPAP's vision, how it functions, the relationships, and asked for input regarding how HPAP could assist the Board in accessing and utilizing their services. Currently, one pharmacist is actively using the program, and one pharmacist was discharged from the program for non-compliance. Board member Dady asked for clarification regarding HPAP's definition of non-compliance. Per Ms. Eining, the definition differs from participant to participant as each program is individualized. Participation in HPAP is voluntary. If a participant is non-compliant, by statute HPAP is obligated to discharge the individual from the program and report to the Board. HPAP has no leverage but asks participants to step out of work site practice. This discussion gave rise to the question, how does the Board deal with participants who are non-compliant? The Board is considering developing a policy and protocols to address standards for discipline including HPAP referrals. Per Amanda McKnelly, the Board could elect to establish a relationship with HPAP similar to the SD Board of Dentistry's contract with HPAP. (The Board would decide whether to include technicians in HPAP participation.)

Maria Eining stated that according to national statistics we can assume two percent of South Dakota licensed pharmacists, who are working are clinically impaired (suffer from an illness or addiction) and should be participating in an HPAP program. Current HPAP utilization is less than one percent. Are we failing to identify pharmacists who have an illness and are in need of assistance? Suggestions to make individuals aware of HPAP services across the state include providing HPAP information during pharmacy inspections, articles in state professional newsletters, link to HPAP on Board website (we have this), etc.

C. Financial Report

The Board Financial Report was reviewed. Executive Director Shanard-Koenders stated the FY16 revenue is nearly on track in most areas noting expenditures for new office furniture, double rent (due to office space overlap) and computer upgrades. The Board is positioned financially to finish the fiscal year well.

D. Staff Reports

1. Employee Update

Melissa DeNoon filled the open PDMP Director position and started on February 1st. The Board office is currently fully staffed.

2. Inspector Reports

a. Paula Stotz

In the field, Paula reported seeing incomplete and inconsistent biennial inventories being done. She suggested encouraging annual inventories instead of the DEA required biennial inventories. During inspections she noted name and address omissions on prescriptions as well as a pharmacy not entering pseudoephedrine purchases into the reporting database.

b. Bill Vander Aarde

Bill has started his second round of inspections. He also reported the city of Milbank is building a new hospital with a state of the art pharmacy.

c. Gary Karel

Gary spends time talking to the PIC's about USP< 800>, NIOSH 014, and proposed revisions to USP <797>. He also mentioned CMS conditions of participation which were effective October 30, 2015, and inspectors will need to elevate awareness. The following items were one-time occurrences in various pharmacies:

- Hospital key pad access allowed all RNs to enter; prefer key in AMDD (if an option) or FAB to provide better tracking
- Starter packs in hospital from Community Pharmacy included controlled substances which is prohibited
- Media Fill Testing and Finger Tip Testing not completed
- Documentation of cleaning not available in several facilities
- Liquid drawn up into 1ml syringes had wrong BUD
- Found chemo in Positive Pressure room
- Found PIC was taking outdated controlled substances to police department for destruction
- DEA 222 Forms not filled out correctly

A lively discussion regarding the unmet need in the community for a narcotics takeback program occurred. Gary indicated we may want to look at other communities with programs like North Dakota and Iowa's mail back program. He reported the DEA website suggests using kitty litter with carbon or coffee grounds as a disposal method. Lewis Drug successfully uses Rx Destroyer for internal destruction. Hy-Vee also stocks a disposal product; however, each involves an expense to the disposer. Bill Ladwig stated that the police department is an official disposal site but individuals are reluctant to take their medication there. The DEA has tried to urge individuals to use existing programs without success. Diane Dady indicated individuals are shocked when they try to return unused drug to the pharmacy and learn the pharmacy cannot take them back. If individuals cannot afford to buy disposal products and pharmacies are unable to help, the problem goes un-addressed. In some cases, no means of disposal may lead to drug

diversion. In a conversation with Executive Director Shanard-Koenders, Carol Montedonico, from the DEA indicated by law

- no provider can take back a controlled substance and destroy it; and
- a provider can legally destroy the drug together in the presence of the patient with no documentation required

Diane Dady volunteered to investigate the Yellow Jug take back program currently operating in North Dakota. Program is backed by the State's Attorney General and funding raised through increasing wholesale license fees.

Sharp's take back was also discussed. Attendees voiced concerns regarding implementation of any take back program including the expense to pharmacies, risk exposure, legality, documentation/paperwork, and complexity. It was suggested the Board of Pharmacy take this issue on as it is the Board's job to protect the public. Bill Ladwig volunteered to conduct a collection pilot program through Lewis pharmacies.

For the next meeting designated individuals above will gather information on take back programs utilized in other states, and PDMP Director Melissa DeNoon will spearhead the initiative for the Board of Pharmacy.

3. Statistical Reports for December 1, 2015 to February 29, 2016

Shanard-Koenders briefly reviewed both the Activity Report and the License Summary Report noting there were five new full-time pharmacy licenses and 44 new non-resident pharmacy permits issued since the last meeting.

Pharmacist: 1,946 active licenses (9 new licensees),
Pharmacy Interns: 333 currently registered (5 new registrations)
Full-Time Pharmacy permits: 272 (5 new permits)
Part-Time Pharmacy permits: 46 – (0 new permits)
Technician Registrations: 1547 current (48 new registrations)
Wholesale permits: 1,126 (37 new)
Non-Resident pharmacy permits: 741 current (44 new permits)

Bill Ladwig is working with SDSU College of Pharmacy Dean Hedge to address the shortfall and continuing decline in pharmacy technicians. In an effort to increase technician numbers, they have discussed going into high schools to recruit and possibly creating an avenue for individuals to have a career as a technician. Declining technician numbers is a nationwide problem. It is difficult to find high quality people. Jeff Nielsen reiterated that Cigna experiences the same problem in both its South Dakota and Arizona locations. Per Diane Dady, finding and retaining quality technicians in a rural setting presents an even greater challenge. Sue Schaefer questioned if the schools could do something regionally like the Scrub Camp, and in Milbank the high school offers a health program class where individuals learn about health professions. Brenda Jensen stated the available pool of candidates from which to hire technicians may not include the ambitious, hard-working, ethical, high achieving individuals desired.

4. PDMP

Per Melissa DeNoon, PDMP Director, the goals of the Prescription Drug Monitoring Program are 1) to improve patient care, 2) reduce diversion, and 3) increase PDMP user participation and education. PDMP currently has 2589 approved users. Recent Apriss software enhancements included a *Bulk Patient Search function* which significantly increased the Board's efficiency in processing Drug Court requests, as well as doctors' ability to access information for daily patient rosters. On March 3, 2016, the SD Board of Pharmacy PDMP

department partnered with the Department of Criminal Investigation and presented at the SD Academy of Physician's Assistant Conference in Rapid City. A significant increase in requests for data access by physician assistants occurred in the days following. Melissa is currently working on a new Harold Roger's PDMP grant. Funds could potentially be used for integrations with Sanford and Rapid City Regional.

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

1. Closing of Wollman Pharmacy in Lake Andes and changing to Remote Pick Up Site under James Drug, Wagner, Dan Fiebelkorn PIC
2. AMDD, Main Street Pharmacy I Corp, dba Norm's Thrifty White, Norm Kaufman PIC
3. Closing of K-Mart #9273, 100 – 1563 Pierre, transfer files and inventory to Walgreens
4. Closing of K-Mart #4735, 100 – 1539 Mitchell, transfer files and inventory to Walgreens
5. AMDD, Avera St. Mary's, Pierre, Pyxis Machine P&Ps – change brand AMDD
6. Remote Pick Up, Avera St. Michaels Hospital, Bon Homme Pharmacy, Tyndall, Jacklyn Dvoracek – PIC
7. Hoffman Drug 100-0474, CHOW to Tiffany and Brett Maydew, Tiffany Maydew, PIC
8. GE Associates Inc., - 600-2559, Martin, SD
9. Walmart Pharmacy 10-2443, 100-2039, Sioux Falls, Jada Le, PIC
10. Avera Dialysis – Wagner, 100-2040, Glenn Voss, PIC
11. Vilas Pharmacy – 100-2038, Highmore, Telepharmacy, Beth Joachim, PIC
12. Joerns, LLC – 600-2565, Elk Point

F. Variances – The following variances were reported by Shanard-Koenders and approved by Board members.

1. Rapid City Regional LTC Pharmacy, 4 additional drugs added to E-Kit at Prison
2. Rapid City Regional Tech check Tech variance renewal

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

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

1. Hy-Vee #1820-Vermillion: DEA 106
2. Sanford USD Medical Center: DEA 106 X 2
3. Davis Pharmacy: Break in
4. Hy-Vee #1631-Louise Ave in SF: DEA 106
5. Shopko Pharmacy #2101– Arrowhead in SF: DEA 106
6. Hy-Vee #1632 –Minnesota Ave in SF: DEA 106
7. CSRx dba Medicine Shoppe: Complaint
8. Safeway #0581– Rapid City: Attempted Robbery

H. SD Pharmacists Association Update – Sue Schaefer

Sue briefly reviewed items highlighted in the SDPhA Update – Spring, 2016 handout. SDPhA did not sponsor any bills this legislative session. Marijuana continues to remain a hot topic of discussion on the floor. The legislative flu immunization clinic was well attended and will be offered again next year. Insurance policies and paperwork provided too many hurdles, so DakotaMart covered all flu shot costs this year. Immunizations were reported to the registry and primary physician. During Legislative Days, SDPhA covered the cost of hotel accommodations and dinner for SDSU pharmacy students in attendance. The Annual SDPhA meeting held in September included presentations on diversion, pharmacy law updates, SD PDMP, medical review, and immunization requirements.

Financial review – budget is on track, SDPhA received annual funds from SD BOP, and an office downsizing move helped the bottom line.

Sue shared an email with attendees announcing Dean Hedge's installment as SDSU Interim Provost replacing outgoing Provost Nichols. Dr. Jane Mort will assume the position of Acting Dean of Pharmacy.

Attendees discussed the Narcan Bill (HB 1079) sponsored by the Medical Association and backed by SDPhA. Drug is now available in nasal spray form. A family member may have Narcan on-hand for emergent situations but a prescription is required. Concerns were voiced regarding a prescription drug being given to a third party to administer. Pharmacists can administer in emergent situations; however, they do not have prescriptive authority. There must be a protocol in place for this circumstance.

I. Other Reports

1. SDSU College of Pharmacy – Dennis Hedge not in attendance

Per Kari Shanard-Koenders, the South Dakota Board of Pharmacy will approve students to take the NAPLEX and MPJE exams as soon as possible in order to expedite access. Report accompanying minutes.

2. SD Society of Health System Pharmacists – Tadd Helwig not in attendance

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

Report accompanying minutes.

4. HPAP Update – Maria Eining

Appears at beginning of agenda.

J. Old Business

1. FDA Draft MOU – 503A and 503B

No updates to report. SD Board of Pharmacy feels the FDA will force States to complete 503A and 503B facility inspections.

2. Immunization Policy Statement – Protocols

Attendees reviewed Policy Statement Immunization handout and noted the South Dakota law is limited to flu immunizations only except where protocols exist and when prescriptions are used. The Board reviewed an immunization policy statement for posting on the website. Further several excellent protocols were reviewed to provide guidelines including reviewing eligibility before administering immunization, documentation responsibility, and mandatory reporting to SD Immunization and Information System (SDIIS) for everyone not just individuals age 0 – 18. The Department of Health does not require vaccines/immunizations records to be entered into the registry if individual is older than 18 years. Kari Shanard-Koenders asked members to review and provide feedback regarding items they would like to see included in sample protocols placed on the Board website. Basing protocols on ACIP guidelines/standard may result in fewer changes needing to be made.

3. Rapid City Regional Asteres Script Center Update

System is working well; no need to appear before Board

4. DOH Rule Changes 44:75:08:03 Medication therapy Review Hospitals Repeal

Rule was repealed as a result of significant pushback. Documentation component was the largest issued and potentially could have been addressed by modifications.

5. USP <797> Proposed Revisions – Update

Public comment period ended January 31, 2016. The earliest that General Chapter <797> may be published is November 1, 2016 with the earliest official date of May 1, 2017. Based on the comments received, the chapter may be revised, republished, or forwarded to ballot. Gary Karel reviewed USP <797> handout with attendees emphasizing the three risks levels are going to be replaced with two categories.

6. USP <800> - Update

Document was published February 1, 2016. Additionally, the Expert Committee approved a delayed official implementation date of July 1, 2018.

7. DLR and Disciplinary Application Changes to Applications

Kari Shanard-Koenders and Board secretary Beth Windschitl explained the changes made to all pharmacist applications (initial, renewal and reinstatement) as a result of DLR requirements.

K. New Business

1. Downing Labs – Consent Decree by Federal Judge - Recommendations

Downing Labs was issued a cease and desist order for unsafe sterile compounding. Company is still operational on non-sterile side. The Texas Board has not revoked their license. North Dakota Board of Pharmacy did not renew Downing Labs' license due to repeated issues. Board feels that criteria should be established for these types of situations.

2. Office Software Platform RFP – Beth Windschitl

Beth will begin working on an RFP for an E-Licensing software package.

3. Cigna Update – Jeff Nielsen

Cigna has entered into a partnership with Catamaran / Optimum and is moving their dispensing function to a central fill center. All medication will go through the Kansas City facility primary site. Specialty medications and controlled substances will still be dispensed through Cigna in Sioux Falls. Both Cigna and Catamaran's names will appear on the medication label for prescriptions originating from the central fill center. Per Jeff, there is little change to the front end; greatest impact is to Cigna team members on the filling floor. Displaced individuals will transition to other positions within Cigna.

L. Other Business

1. Board Meeting Dates for 2016

- a. June 10, 2016 in Sioux Falls
- b. September 15, 2016 in conjunction with SDPHA in Brookings
- c. December 2, 2016 in Sioux Falls

M. Other Meetings

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

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

No limit to number of Board members who can attend meeting at the expense of the State. NABP offers one scholarship of \$1,500. Anyone who is interested in attending should contact the Board Executive Director by Monday, April 4, 2016. Board members Jeff Nielsen and Lenny Petrik expressed an interest in attending.

There being no further business Lisa Rave made a motion to adjourn. The meeting adjourned at 11:50 a.m.