

SD Board of Pharmacy Meeting Minutes

Friday, June 10, 2016 at 8:00 AM

Pharmacy Specialties and Clinic Conference Room
2333 W. 57th Street, Building Lobby 1st Floor
Sioux Falls, SD 57108

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 and Paula Stotz, and Beth Windschitl, Senior Secretary

Attendees Present: Brenda Jensen (Compounding Consultants); Cheri Kraemer (Pharmacy Specialty Clinic); Bill Ladwig (Lewis Drug); Justin Manning (Hy-Vee); Jodi Heins (SDSU); Jane Mort (SDSU); Reed Reuman (SDSU Student); Eddy Ekobena (Walgreens); Bruce Jorgensen (Cardinal Health); and Dana Darger (RC Regional Health)

A. Call to Order

The meeting was called to order by President Lisa Rave at 8:00 AM CST and attendees welcomed.

B. Approval of Board Minutes

President Rave asked for a motion to approve the April 1, 2016 meeting minutes as written. Motion was made by Board member Dady and seconded by Board member Nelson, motion carried.

C. Election of Officers

President Rave opened the floor for nominations for Board President and Vice-President positions. She nominated current Board members Diane Dady for President and Lenny Petrik for Vice-President. The nominations were seconded by Board member Tom Nelson and confirmed unanimously. President Elect Dady assumed the responsibility for leading the meeting.

D. Financial Report

The Executive Director reviewed the Current Expenditures through June 4, 2016, Revenue Report by Month, as well as the License Summary and Activity Report (section E 3). In addition, Shanard-Koenders introduced Eddy Ekobena, a new pharmacist and 2016 South Dakota State University graduate now employed with Walgreens. Meeting attendees introduced themselves.

E. Staff Reports

1. Employee Update

Board office is fully staffed; however, Bill Vander Aarde, inspector for the Northeast quadrant of South Dakota has submitted his resignation. Efforts are underway to retain him. If that fails, position will be posted soon.

2. Inspector Reports

a. Paula Stotz

Annually the SD BOP contracts with the Consumer Product Safety Commission (CPSC) to execute a defined number of Safety Cap Check inspections in South Dakota. Paula

completed five CPSC inspections in May. It was determined, that when the pharmacy places an asterisk behind the patient's name in the pharmacy profile; this is not the best way to indicate that the patient would not like safety caps on their prescriptions. Most pharmacies now obtain a signature from the patient to signify that the patient would like non-safety caps on their prescriptions. The signature is not a requirement of the CPSC, but a good practice. Paula also expressed her concern regarding increasing instances of controlled substance diversions in the State, as well as the need for more controlled substance monitoring. Some pharmacies do a great job completing monthly random controlled substance audits, while others fail to see the necessity of such audits.

b. **Bill Vander Aarde** – Provided by Gary Karel

During inspections, Bill continues to make individuals aware of technician certification requirements, the deadline for achieving certification, and discusses new law regarding technician ratios. The number of grandfathered status technicians continues to decline as most technicians are working toward certification. Bill has seen a rise in random pharmacy audits with focus on schedule II medications. Some PICs do this on a schedule (usually monthly). This is a good improvement over last year. Diversion concerns are being taken seriously.

c. **Gary Karel**

Updates - Sanford Vermillion Hospital has a new pharmacy with a new IV Room; upon inspection discovered IV Room did not have cove molding. Situation has been corrected. PharMerica's remodeled IV room is very nice. Gary completed eight CPSC inspections in May.

The following items were occurrences in various pharmacies:

- Found outdated Epinephrine and/or Benadryl in emergency kits in two locations
- Remote drop off sites – two locations have the word "Drug" or "Pharmacy" on name of business. See 20:51:06:05
- Observed technician preparing non-hazardous IV product without proper garb
- Combat meth certificate outdated-in one location
- PIC could not locate controlled substance biennial inventory for C3 – C4
- Upon review of a report from Hood Testing Company, found comment in report that "Testing indicates CFU biological safety cabinet exceeded USP 797 criteria as noted on Viable Particulate Test report." PIC was not aware of findings.

Gary Karel (SD BOP), Brenda Jensen (Compounding Consultants) and Tony Lee (AT Analytical, event sponsor) were presenters at the USP 797 & USP 800 Workshop held May 10 – 11 at the University Center in Sioux Falls, South Dakota. Workshop topics included Common Rx Protocols, Rx Inspection Mistakes, Clean Room Layouts & Testing, USP 800 Room Requirements.

3. Statistical Reports for March 1, 2016 to May 31, 2016

Shanard-Koenders briefly reviewed both the Activity Report and the License Summary while discussing the Financial Reports (section D of agenda). She noted we are in the license renewal period for South Dakota full-time and part-time pharmacies as well as non-resident pharmacies. License statistics since the last meeting:

Pharmacists: 1,958 current (11 new licensees),
Pharmacy Interns: 350 current (13 new registrations)
SD Full-Time Pharmacies: 269 current (5 new permits)
SD Part-Time Pharmacies: 50 current (4 new permits)
Technicians: 1642 current (74 new registrations)
Wholesale Distributors: 1,171 current (40 new permits)
Non-Resident Pharmacies: 762 current (29 new permits)

4. PDMP

PDMP Director Melissa DeNoon reviewed program statistics with attendees highlighting an increase in total program users (2,706) as well as noted the program attained a milestone of 3252 prescriber queries (3,252) in April. Pharmacist queries continue to outpace prescriber queries. The top prescribed controlled substance in South Dakota remains Hydrocodone / Acetaminophen combination products (20,338); interestingly, number 3 and 4, Zolpidem and Lorazepam, were separated by 1 prescription.

In April, Melissa completed and submitted an application for the Harold Rogers Prescription Drug Monitoring Program Implementation and Enhancement Grant. Funding, if awarded, will support two projects: integration of SD PDMP data into Sanford Health's Electronic Health Record and implementation of a SD Drug Take-Back Program. Details of the proposed Yellow Jug Take Back program are delineated in meeting handout material. Grant funds would cover the cost for a lockable, secure container and monthly fee for 78 pharmacies for 12 months. Attendees discussed other drug take back / disposal options and products currently available to consumers. Per the BOP Executive Director, the Yellow Jug program was used for grant purposes only. If funds are received, all drug disposal options available will be reviewed to determine the best method for use in South Dakota. Bill Ladwig shared that parties in Washington DC are discussing mandating by law drug takeback / disposal programs in all 50 states.

The Avera Integration rollout with PDMP and Meditech occurred on May 25th. Lisa Rave, Avera Clinical Integration Pharmacist, has received positive feedback. When Avera team members access patient online records, they can access patient PDMP information at the same time without having to log into the PDMP platform separately. Upon opening a patient's online record, a PDMP button appears on the patient record screen. Clicking on the button/icon brings up the patient's PDMP drug history within five seconds.

Updates - Melissa continues to work with Appriss (PDMP vendor) to address recurring issues that arise as a result from other states using different drug monitoring software programs and system limitations. In mid-May, both Cigna and MedVantx mail order pharmacies began reporting controlled substance prescription data to the PDMP central repository.

F. Approvals/Information – The following was reported by Shanard-Koenders.

1. Lewis Drug and Lewis Family Drug, All Stores, Return of UD for Credit from LTCF; Lewis continues to work toward developing/implementing one unified, blanket return med policy
2. Closing of Kmart #4813, License # 100-1559, Yankton, May 4, 2016
3. Closing of Kmart #9184, License # 100-1538, Huron, May 4, 2016; Kmart erroneously informed the Board they were closing on May 4, 2016. The Board learned, indirectly, Kmart was still operating after the closure date due to difficulty transferring patient records to other pharmacies. Officially, they will close June 14, 2016.
4. Remote Pick-Up Site, Geddes Medical Clinic, Hoffman Drug, Platte, Tiffany Maydew PIC
5. Sanford Hospital USD Medical Center – Sioux Falls, AMDD Vendor Change from Pyxis to Aesynt (Accudose)

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

1. Diamond Pharmacy Services, Minnehaha County Jail E-kit (same as previous)
2. Renewal, Lead Deadwood Regional Hospital, frequency of pharmacist visits
3. Renewal, Vilas Faith and Eagle Butte, frequency of pharmacist visits
4. Renewal, Alixa Rx frequency of pharmacist visits

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

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

1. Avera McKennan Hospital-Sioux Falls: DEA 106 X 2
 - Two RNs diverting meds at different times; individuals were identified by internal review team that combs through data looking for standard deviations among employees on similar/same work shifts, documentation, and wastage.
2. Walgreens Pharmacy-Spearfish: DEA 106
 - Patient had a prescription for name brand Norco; pharmacy location did not keep the Norco in a locked C2 cabinet. Pharmacist noticed upon reorder that it was missing and technician was identified from camera video as individual diverting medication.
3. Mylan: DEA 106 X 5
 - Mylan shipments are being stolen/diverted during the manufacturer to wholesaler chain of custody
4. Walgreens Pharmacy-Cliff Ave in Sioux Falls: DEA 106, missing methylphenidate 10 mg #100. Not resolved.
5. Walgreens Pharmacy-Sycamore Ave in Sioux Falls: Break in
 - Person chipped a hole in the pharmacy drive-thru window, gained access to the store but did not take anything before police arrived. Victim arrested in Hy-Vee parking lot.
6. Lewis Family Drug-Chamberlain: DEA 106
 - Missing 100 hydrocodone / APAP 5-325. Not resolved.
7. Tienda Salvadorena Mexican Grocery in SF: Complaint
 - Received an official complaint from City Health Department employee who was inspecting the grocery store. Store had a list of medications posted in Spanish. List was forwarded to SD Board of Pharmacy who contacted the FDA in Wisconsin and requesting they follow up. Gary was informed by the City Health Department the store is closing.

I. SD Pharmacists Association Update – Sue Schaefer (see meeting material for report)

J. Other Reports

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

The Board of Regents has approved renaming the College of Pharmacy to the College of Pharmacy and Allied Health Professions. Change reflects the programs within the College and includes the Medical Lab Science program, administrative oversight of the Masters in Public Health, and campus support to the SDSU-Avera Radiologic Technology program articulation agreement.

College of Pharmacy Statistics:

- 76 students graduated with their PharmD on May 6, 2016
- 73 of 76 currently have jobs; expect 100% placement by end of summer
- 18 graduates have taken residencies (23.7%); 75% of applicants were placed

Faculty Updates:

- May 16, 2016, Dennis Hedge assumed the role of SDSU Interim Provost and Jane Mort became the Acting Dean for the College
- May 23, Dr. Barry Dunn was appointed SDSU President following the retirement of President David Chicoine and appointment of Provost Nichols as President of the University of Wyoming
- College of Pharmacy faculty member Dr. Joshua Reineke was awarded the SD Research Team Development award and SD Board of Regents Competitive Research Grant; Dr. Tummala were awarded a Sanford-Profile grant.

Per Dr. Mort, the College of Pharmacy budget model is decentralized meaning tuition dollars flow back to the department which is self-sustaining and directly impacted by enrollment

fluctuations. Enrollment has varied over the last several years. Pharmacy tuition is comparable to other university departments/programs.

Dr. Mort opened the floor for questions. Jeff Nielsen asked her to impart her forecast/outlook regionally and nationally for pharmacy graduates. She sees a growth in the use of sign-on bonuses of 5-6 percent to attract graduates. Kari Shanard-Koenders stated full-time jobs are tougher to get, individuals in profession a few years or no PharmD degree. Pharmacist employment demand is for relief coverage.

2. **SDSU College of Pharmacy** - Assistant Department Head/Professor, Jodie Heins

Professor Heins presented a brief overview of E*Value, the software used by the College of Pharmacy to document and track students' curriculum, intern activity (IPPE & APPE hours, preceptors, etc.). Prior to having the software, all pharmacy student records and tracking of activities for years P1 through P4 were documented manually. The SD Board of Pharmacy supports this effort by contributing \$18, 000 yearly and may have access to several of the software platform components.

3. **SD Society of Health System Pharmacists** – Rhonda Hammerquist, Pharm D, (see meeting material for report)

K. Old Business

1. **Immunization Policy Statement** – Posted

Per Kari Shanard-Koenders, the policy has been posted to the SD BOP website and responses from industry and pharmacies have been favorable. Attendees discussed the impact immunizing will have on pharmacist coverage (i.e. the need for more pharmacists at a location due to time spent immunizing and pharmacists taking on a more clinical role especially for individual without primary care provider.

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

Almost 9,000 comments on the new document are posted on the USP.org website. The Expert Committee is reviewing the comments and met face-to-face in April, 2016 to discuss the comments reviewed. All public comments received will be reviewed. USP does not have an anticipated date for publication.

3. **USP <800>** - Update – Gary Karel

Changes in the USP 800 document must be implemented by July 1, 2018. People continue to exit the compounding business because it is too costly to comply with all of the requirements/regulations.

4. **Controlled Substances Take Back Program** – Update Melissa DeNoon (see section E 4)

5. **DSCSA** - Several Board of Pharmacy staff attended a webinar on when to suspect drug diversion in the supply chain. The presenter discussed many prosecuted cases of supply chain diversion where millions of dollars of misbranded product made it into the supply chain through what appeared to be legitimate secondary (does not buy directly from the manufacturer) wholesalers. The buyer is responsible for examination of the 3T of a transaction: Transaction History, Transaction Statement, and Transaction Information (which must be provided with each transaction). This is particularly important if multiple secondary wholesalers are involved as that is a sign that there could be issues. In some cases the product is not what it purported to be but no one reported to FDA. No major wholesaler drug distributors were involved. Report such cases to the FDA.

6. **Former President Rave** asked for a status update regarding the E-Licensing RFP. Beth Windschitl stated there has been no additional activity on the RFP as the Board of Pharmacy

is in the renewal licensing cycle for non-resident, full-time, and part-time pharmacies as well as updating the pharmacist license renewal online platform (Launchpad) to incorporate Department of Labor data collection requirements.

L. New Business

1. Hy-Vee New Business Model presentation and request for approval– Justin Manning, Regional Supervisor

Justin Manning came before the Board to request a variance (from 20:51:29:22) allowing certified pharmacy technicians and interns to complete the final verification for the accuracy of a filled prescription or medication order. According to Mr. Manning, the Tech check Tech model will enhance and expand pharmacist clinical services and allow the pharmacist more face-to-face time with patients as well as greater availability because it decreases the pharmacist's workload. The model is not new and has been pilot program at Hy-Vee in Fort Dodge, Iowa for over two years. The policies and procedures used in Iowa plus incorporated learnings/improvements will be the foundational basis for the proposed Tech check Tech model trial at the Hy-Vee Marion Road and 26th Street location. The model is predicated on using participants (pharmacist and experienced, certified technicians) who are at the top of their skill set with the goals of increasing patient safety, services, and counseling. Findings have shown no error rate differences when comparing Tech check Tech model versus pharmacist final check. One caveat, most of the model research data available is from institutional settings not retail. Mr. Manning explained the steps executed in the Tech check Tech process, the training requirements, and program evaluation parameters.

At the conclusion of the presentation, the floor was opened for questions and comments.

- a. System Access – All system access is role based and tied to the individual. Tracking capabilities include system requirements (initialing and time stamping) as well as observation by pharmacy security cameras.
- b. Evaluations – Lisa Rave expressed concern regarding the phase-in timeline; not comfortable with double checking technician performance for only one week. She encouraged a longer phase-in period possibly one month with reporting back to the Board. This also would provide an opportunity to gather performance strong data for statistical analysis, as performance studies/figures supporting the model are not as robust as the Board would like to see.
- c. Final Visualization - Paula Stotz inquired if final visualization step of what's in the bottle could occur earlier in the prescription fulfillment process. Jeff Nielsen, from Cigna, stated there is no other place to put it in the process.
- d. Consumer Notification – Stotz also asked if pharmacy customers would be informed (via posted notice or other means) that Hy-Vee uses the Tech check Tech process to fill prescriptions. Is an explanation of the process necessary?
- e. Refills and New Prescriptions – Diane Dady inquired about both types of prescriptions. Justin clarified that the Tech check Tech model is used to fulfill new scripts and refill scripts. Hy-Vee identifies/lists the specific medications that can be processed using the Tech check Tech model. Prescription drugs that cannot be filled using the model will be filled by the pharmacist.
- f. Impact to Pharmacists – Per Justin Manning, Pharmacists who are not part of a Tech check Tech program are concerned it is being implemented in an effort to decrease labor cost, reduce jobs. Hy-Vee is not trying to reduce the number of pharmacists in the workforce and does not view the model a labor reducing method.
- g. Error Reporting – Melissa DeNoon and Diane Dady raised several questions. Who is responsible party for Tech check Tech oversight/performance? Staff pharmacists will be involved in the process not only the pharmacy Pharmacist-In-Charge (PIC). If an error occurs, the PIC assumes the responsibility/liability against their license. Therefore, the PIC needs to be comfortable with the abilities and skill set of a technician performing the Tech check Tech role.

Per Justin Manning, Amy Huntimer the PIC at the 26th & Marion Road Hy-Vee proposed pilot location plans to initially limit participants in the Tech check Tech program to P3 and P4

interns only. Each pharmacy PIC has full control over determining if the program will be implemented in their pharmacy and which pharmacy employees will participate in the program. The full-time technician at the pilot location does not feel she is ready to do the Tech check Tech process.

The Board would like to:

- Determine the data collection points (to possibly encompass scanning accuracy, amount of scripts processed, amount of errors) as well as track increases in other services being provided as a result of the Tech check Tech practice (i.e. increases in immunizations, number of clients counseled, etc.)
- Determine the timeframes for program implementation, rollout (to include time from initial training to operational), and variance length.

Board member Tom Nelson asked the Executive Director and Board President for clarification regarding the meaning of the terms “variance” versus “waiver” as these words appear to be used interchangeably within the documentation provided by Mr. Manning. He also posed the question as to whether or not the Board has the authority to grant a variance to an existing law or administrative rule. This question was not definitively answered and needs to be investigated further.

The Board agreed to table the variance/waiver request from Hy-Vee and will revisit it at the next quarterly meeting. They also requested Justin Manning provide additional statistics from the Hy-Vee pharmacy that currently uses the Tech check Tech model.

2. Opioid Insurance Coverage Quantity Limits – Board Member Jeff Nielsen

Jeff Nielsen posed the following question to meeting attendees, “should we be dispensing 90- or 120-day supplies of medications, should prescribing guidelines change?” As a Board, should we be looking forward and advocating for dispensing no more than a 30-day supply to prevent large quantities from being available for diversion? Would supply quantity restrictions apply to C2 medications only or all controlled substances? Interest in and discussions about prescription quantities will continue to increase in the future as the focus on opioid addiction increases.

In an effort to be proactive, should we look at what other states are doing to impact the problem, examine what limitations exist today in other states, and pose the question to SD Pharmacy Association members to obtain their perspective on the topic? Several questions were raised for consideration: Where do you focus? Should the scope be broad or narrow as most people do not have an opioid issue? Is legislation necessary or is an individualized approach warranted? Should the focus be on impacting the handful of prescription writers who provide 90- and 120-day scripts?

3. Regional Scriptcenter Pro Request – Dana Darger

Dana Darger, from Rapid City Regional Hospital, provided an update on Regional's Scriptcenter Pro Request an automated medication dispensing center used by Regional Hospital employees only. To date, over 6,000 prescriptions have been dispensed without an error. The system allows employees to pick up their prescription from the kiosk which reduces foot traffic in the hospital pharmacy and helps increase bedside counseling delivery. Per Dana, the only complaint is employees want to be able to pick-up all of their prescriptions from the kiosk not just refills as is the current protocol.

Dana asked the Board to consider changing the scope of the Scriptcenter Pro protocol to allow employees to obtain “new” prescriptions via the kiosk. The employee would receive a text telling them they have a (new) prescription and need to call the pharmacy to release the hold on the med and complete the counseling function before it can be dispensed. Jeff Nielsen made a motion to allow new prescriptions to be dispensed from the Scriptcenter kiosk; motion was seconded by Lisa Rave. Motion carried.

4. E* Value – (See section J 2)

5. NABP Newsletter on line?

SD Board of Pharmacy pays \$1030 per quarter for NABP newsletter printing and mailing costs. To achieve a cost savings and utilize technology, Kari Shanard-Koenders suggested moving to an online platform at a cost of \$620 a year. This would align with the method current used by the SDPhA. Attendees agreed to an online format for the NABP newsletter with a link on the SD BOP website.

M. Other Business

1. Board Meeting Dates for 2016

- a. September 15, 2016 in conjunction with SDPHA in Brookings
- b. December 2, 2016 in Sioux Falls; Jeff Nielsen to provide site
- c. March 10, 2017 in Sioux Falls TBD

2. Report on NABP 112th Annual Meeting, May 14-17, 2016

Kari Shanard-Koenders, Jeff Nielsen, and Lenny Petrik attended the 112th NABP Annual Meeting held in San Diego, California. Technician training was one a major topic of the meeting. In 2020, PTCB will not allow a person to take the certification test unless the technician has completed an “approved” technician education program. In South Dakota, educating technicians may present a burden for rural pharmacies. Per Bill Ladwig, SDSU is considering an associate degree developing a technician career path. Both an education and testing components are necessary to create a profession. Attendees discussed NABP assuming a bigger role in the process (i.e. how technicians get from point A to B, education, cost, pay...). Low wages and attracting quality individuals continue to be hurdles in the development of a technician career path. Kari meet with a PTCB representative, at NABP meeting, who indicated PTCB has a summit scheduled to discuss the technician training going forward.

N. Other Meetings

1. NABP/AACP District V Meeting, Lincoln NE, August 4-6, 2016

Registration information is now posted on the SD BOP website. Registration dates are August 4 – 6, 2016.

2. SDPHA Annual Meeting, Brookings, September 16-17, 2016

O. Adjourn