

SD Board of Pharmacy Meeting Minutes
Thursday, September 12, 2019; 1:00 p.m. MDT
The Roosevelt Room at The Lodge at Deadwood
100 Pine Crest Lane, Deadwood, SD 57732

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

Board Staff Present: Executive Director Kari Shanard-Koenders, Inspectors Tyler Laetsch and Carol Smith, and PDMP Director Melissa DeNoon

Attendees Present: Melissa Gorecki (SDPhA), Beth Sundahl (Safeway), Carrie Gerdeman (Walgreens), Joe Bergsmith (Walmart), Mark Dady (Family Pharmacy), Gary Karel, Craig Olsen (Diamond Pharmacy), Gerald O'Brien (Diamond Pharmacy), Dana Darger (SDPhA), Joseph Berendse (SDSHP), Erica Bukovich (SDPhA), Lori Ollerich (SDPhA and Pharmacy Specialties); by phone Matt Valasek (Diamond Pharmacy); Gina Jules, Dr. Jerry Childs, Steve Epple, and Theresa Lewis (all Armor Correctional Health Services); Monte Roemmich, Mike Duncan, and Jesse Breidenbach (all Sanford Health); Michael Claire (Walgreens Compounding Services).

A. Call to Order and Introductions

At 1:03 p.m. the meeting was called to order by President Dady who read the Board of Pharmacy mission statement. Board Members, Board Staff, and meeting attendee introductions followed. Voice roll call was taken, and a quorum was present.

B. Consent Agenda

The President reviewed the consent agenda noting any items could be removed for discussion. Lisa Rave made a motion to approve the consent agenda; motion was seconded by Dan Somsen. Voice roll call was taken, and motion passed (4-0).

Due to time constraints, item H. 1. was heard at this time; please refer to this section in the minutes for details.

C. Staff Reports

1. Operations Report – Kari Shanard-Koenders, R.Ph., Executive Director
 - a. The Executive Director stated the Board of Pharmacy has successfully implemented its iGov e-licensing platform. Board staff is addressing program glitches as they occur and are answering licensee questions regarding the new platform.
 - b. Administrative Rules § 20:51 red tape clean up and update on compounding practices regarding USP-NF General Chapters <795>, <797>, <800>, and <825> were submitted to Susan Sporrer; she advised the number of revisions included was too large for the November 4, 2019 deadline and therefore the proposed changes have not been sent to Board members to date. The Executive Director will instead proceed with only the compounding practice updates for the November 4 deadline so the chapter will be updated by USP's effect date of December 1, 2019.
 - c. The FBI contacted the Board office to schedule and complete two background check audits. Since the Board only utilizes the paper method, the audits will be less extensive. Beth Windschitl, Senior

Secretary, is handling the first audit visit today and the second audit visit is scheduled for September 24, 2019.

- d. South Dakota will host the 2021 NABP District V Annual Meeting. District V members are IA, MN, NE, ND, SD, and Manitoba and Saskatchewan, Canada. The last time SD was the host state, the meeting was held in Deadwood; looking into holding the 2021 meeting at Custer State Park.

2. Inspector Reports

- a. Carol Smith, Inspector

Reported the following items/observations/occurrences:

- Even though her inspection territory in northeastern SD is geographically small, she is surprised at the number of diversion cases reported to her; one case involved a technician who'd been employed for three years. All schedules are being diverted and she surmises the 'small town mentality' causes PICs to get lax on their controlled substance audits as they know all their staff well and don't think any of them would divert.

- b. Tyler Laetsch, Inspector

Reported the following items/observations/occurrences:

- Finding pharmacy locations with a MedDrop receptacle are not following DEA regulations including not having their 'Collector' status DEA license posted and the receptacle is not 'securely placed'.
- Still seeing confusion regarding how to operate a pharmacy when the pharmacist is not on-site; prescriptions cannot be sold and a sign needs to be placed to inform the public no pharmacy services are available.
- Questions continue from PICs regarding USP-NF General Chapters <795>, <797>, and <800>.
- Questions on what a telepharmacy model looks like for a critical access hospital.
- For pharmacy remodels, provide blueprints to the Board office in a timely fashion as Board staff will help identify missing design requirements.
- Continued focus is needed to input correct information on controlled substance prescriptions.
- This quarter there were many pharmacies that did not meet the time requirements for reporting PIC and employer changes, had technicians not registered with the Board, and had staff without name tags. The Executive Director emphasized the lack of timely PIC change reporting.
- Board Member Dan Somsen asked Tyler a question regarding how remote site pickup, in which no pharmacist is present, differs from the absence of the pharmacist in a retail setting? Tyler answered the Board approves variances for remote pickup sites and patient counseling occurs before pickup at the remote site.

3. PDMP Report

PDMP Director Melissa DeNoon reported the following updates:

- a. New and Current Project Updates

- PMPi Hub sharing set-up with WA, OK, and ME (26 total)
- RxCheck Hub connection live and sharing set-up with UT
- NarxCare live July 15
- Statewide Gateway Integration Project live August 26
- License Integration Project in progress

- MedDrop Program receiving additional DSS grant funding for another expansion round planned for Q4 2019
- SD DOH received a 2019 CDC Overdose Data to Action Grant; funding for the PDMP to continue Prescriber Reports, Clinical Alerts, Masked Data Extracts, and the addition of the PMP Advanced Analytics tool from Appriss Health

b. Presentations Given/Events Attended

- SD State Board of Dentistry Board Meeting PDMP and License Integration Project Presentation - Pierre
- 2019 COAP HR PDMP National Meeting – Washington, DC
- Opioid Abuse Advisory Committee Meeting PDMP Update Presentation – Pierre
- Appriss Health’s PDMP Leadership Summit – Louisville, KY
- Upcoming Events: SDPhA 133rd Annual Convention & 2019 NASCSA Conference

c. Statistics/Visuals Shared

- PDMP utilization – queries via web portal and by SD pharmacists and prescribers through Gateway integrations
- Trending SD patients’ opioid prescriptions
- New NarxCare enhanced PDMP report

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

The following were reported by Tyler Laetsch and Carol Smith and discussed.

1. DEA Form 106 - Avera McKennan Sioux Falls
2. Complaint – Shipping temperature sensitive medications
3. DEA Form 106 – Avera Queen of Peace Mitchell
4. DEA Form 106 – HyVee Watertown
5. DEA Form 106 – Walgreens SF Louise Ave
6. DEA Form 106 – Prairie Lakes Watertown
7. Complaint – Medication Error
8. Complaint – Patient information – specialty medication
9. DEA Form 106 – Avera Long Term Care Corsica
10. Complaint – Dispensing medications to wrong patient
11. Complaint – Pharmacy failure to notify Board Office

E. SD Pharmacists Association – Dana Darger, R.Ph., SDPhA Vice President

1. Activity Report – the following items from the submitted Annual Report were highlighted by Mr. Darger:
 - a. National legislative efforts are outlined for review in the report.
 - b. SDPhA lobbyist update – Margo Northrup will be vacating her lobbyist role as she has been promoted to a judgeship.
 - c. SDPhA board members have presented by-laws updates which will be voted on at the upcoming convention.
 - d. SDPhA continues to actively support SCAPP; this is an important investment in the association’s future.
 - e. Pharmacy Technician University (PTU) – SDPhA is one of the first Associations to offer low-cost access to this online training module and is pleased to report the Therapeutic Research Center – PTU 101 module administered qualifies as a PTCB-Recognized Education/Training Program to meet the new 2020 CPhT requirements.

- f. An Association Management Rotation student is presently with Amanda Bacon, SDPhA Executive Director.
 - g. Executive Director Kari Shanard-Koenders also shared that PTCB is changing and there will be specialty add-ons making the test less comprehensive with less hospital pharmacy questions and reminded that a 'TT', technician-in-training, has 2 years to become certified. Board President Diane Dady added that in rural SD, it's common to lose potentially great technicians due to test anxiety; ED Shanard-Koenders added the ExCPT is a more retail-based certification exam.
 - h. The SDPhA annual convention will be held September 13-14, 2019 at the Deadwood Lodge.
2. Financial Reports were not reviewed.

F. Other Reports

1. SDSU College of Pharmacy – Jane Mort, Pharm.D., Dean and Professor, College of Pharmacy and Allied Health Professions Department (not in attendance, no report)
2. SD Society of Health-System Pharmacists – Joseph Berendse, Pharm.D., BCPS, BCACP, SDSHP President
 - SDSHP is offering a new \$500 grant for a residency project in the state that aligns with SDSHP's strategic plan. Applications will be sent to new residency class.
 - Resident liaison election will take place soon.
 - Congratulations to Tom Johnson, former SDSHP President, for his election as ASHP's new President-elect.
 - Congratulations also to Jodi Sterrett, SDSHP Board of Director's Technician member, for her appointment to the ASHP Pharmacy Technician Forum – Patient Care Quality Advisory Group.
 - The Dakota Night Reception at this year's ASHP Midyear Clinical Meeting in Las Vegas, NV will be on December 9, 2019 at the Excalibur.
3. SD Association of Pharmacy Technicians – Jerrie Vedvei, CPhT, SDAPT President (not in attendance, report submitted for review)

G. Old Business

1. USP <795>; USP <797>; USP <800>: Tyler Laetsch, Pharm.D., Pharmacy Inspector
 - USP 795 and USP 797 published June 1, 2019 for go live date of December 1, 2019.
 - USP 795 clarifications – Flavoring antibiotic suspensions is not compounding, simple reconstitution of antibiotics with water is not compounding; however, combining two creams or preparing a magic mouthwash is compounding and USP 795 must be followed including the restriction for carpet in the compounding area (Board may propose to allow extra time for compliance) and the BUD changes
 - USP 797 – Focus on where compound is prepared, training of employees, completion of monthly surface samples, and BUD changes regarding the use of isolators (glove boxes) unless present in clean room suite.
 - USP 800 – Retail pharmacies are still behind in their preparation. If a final dosage form is on the list and the pharmacy is performing minor manipulations, such as counting, the whole chapter does not need to be followed if an 'Assessment of Risk' is completed. If compounding with drugs on table 1 of the NIOSH Hazardous Drug List or any Active Pharmaceutical Ingredient, API, on the NIOSH Hazardous Drug List tables 2, or 3, the whole chapter must be followed.

- Joe Bergsmith from Walmart asked if the corporate office completes the Assessment of Risk for all their pharmacies, is this acceptable? Tyler answered, yes, if a copy is accessible at store level and the training requirements are met.

H. New Business

1. Diamond Pharmacy Services – Craig Olsen, R.Ph.; Gerald O'Brien; Matt Valasek, R.Ph.; Gina Jules, Pharm.D.; Dr. Jerry Childs, DO; Steve Epple; and Theresa Lewis

Per Craig Olsen, Diamond Pharmacy Services currently holds a SD Wholesale License and a SD Nonresident Pharmacy License. Diamond Pharmacy Services is the pharmacy vendor with Armor Correctional Health Services at the Minnehaha County Jail and currently has an e-kit variance for their SD Nonresident Pharmacy License for emergency/first dose treatment of inmates at the Minnehaha County Jail. The kit does include a small number of controlled drugs. New DEA regulations regarding controlled substances in an e-kit has created the need for Diamond Pharmacy Services to shift to a new provider compliant model and they are thereby requesting a variance for their SD Wholesale License to follow this new model.

This new model has the following license requirements and process:

- The facility provider has a compliant DEA registration in which the registration address reflects that of the facility location and is legally permitted to procure stock controls in SD. The chosen provider may be an MD, DO, PA, or NP as these roles all meet this SD procurement criteria.
- This provider will be sold medication via a wholesale transaction and will be responsible for all stock medication inventory due to the legal nature of the wholesale transaction.
- The wholesaler must also be licensed in SD.

Diamond Pharmacy Services has provided a Policy and Procedure outline handout detailing this model for the variance they are seeking. This model is currently being used successfully in other states they service. Discussion ensued with Diamond representatives clarifying that the DEA has vetted and accepts this model and the current Minnehaha County Jail Medical Director, Dr. Childs, also accepts the change to this new model.

Board member Lisa Rave made a motion to approve the requested variance and Dan Somsen seconded the motion. The floor was opened for discussion and Board member Tom Nelson asked if a time limit for the variance should be added to the motion. Lisa Rave amended her motion to approve the requested variance with no time limit; Dan Somsen seconded the motion. Voice roll call was taken, and motion passed (4-0).

2. Mission Statement – Diane Dady, R.Ph., Board President

Diane stated she would like to shorten our Board's mission statement and referenced the included handout with examples from other states. She asked for suggestions be forwarded to her for discussion at the next Board meeting. Board member Dan Somsen commented that we should add 'patient safety' into our new statement.

3. HyVee Variance Request – Justin Manning, Pharm.D.

Justin was unable to be in attendance, so this item was tabled.

4. Sanford Variance Request – Monte Roemmich, Pharm.D., BCPS; Mike Duncan, Pharm.D.; and Jesse Breidenbach

Per Monte Roemmich, Sanford is requesting a variance to ARSD 20:51:02:11. Sanford provided the policy in place at the Fargo Medical Center and Clinics that allows pharmacists to refill medications per a protocol. Sanford would like to have a similar protocol in place in SD and add to it the ability for pharmacy interns to be part of the process. The variance will address SD’s current rules regarding the pharmacist:intern ratio and direct supervision of the intern by the pharmacist.

Board member Lisa Rave suggested Sanford rewrite the Fargo policy/protocol and resubmit for inclusion in New Business at the next Board meeting. It will be sent via email for board member feedback.

5. Administrative Rules § 20:51 Red Tape Clean Up – Per Kari Shanard-Koenders, R.Ph., Executive Director, this was already addressed in her Operations Report.

I. Other Business

1. Recent Meeting News

- a. 2019 District V NABP/AACP Meeting, August 7-9, 2019 in Duluth, MN – Kari
 - Focus on opioid issues and keynote speakers discussed how they began MAT in their community
 - Kari and Jennifer Ball, Pharm.D., BCACP, BCGP shared how SD is approaching our opioid crisis
 - Also discussed is the move to get rid of state regulations, i.e. ID who now just references federal regulations

2. Future Board Meeting Dates – All meetings held in Board Conference Room unless otherwise noted

- a. December 6, 2019, 8 am – 12 pm CST
- b. April 2, 2020, 8 am – 12 pm CDT, in conjunction with the SDSHP 44th Annual Conference, Sioux Falls
- c. June 5, 2020, 8 am – 12 pm, CDT
- d. September 10, 2020, 1 pm – 5 pm, CDT, in conjunction with the SDPhA 134th Annual Conference, Brookings?

3. Future Meetings

- a. SDPhA, September 13-14, 2019, The Lodge at Deadwood
- b. NABP Interactive Executive Officer Forum, October 1-2, 2019, NABP Headquarters – Kari
- c. FDA Intergovernmental Working Meeting on Drug Compounding, October 11-12, 2019, Silver Spring, MA – Kari and Tyler
- d. NABP Interactive Compliance Officer and Legal Counsel Forum, December 4-5, 2019 - Tyler

J. Public Comment – Board President Diane Dady recognized and thanked Board member Lisa Rave for her three consecutive terms (9 years) on the Board as this is her last Board meeting.

K. Executive Session: per SDCL 1-25-2; Legal Issues (no Executive Session held)

L. Adjourn

Board member Dan Somsen made a motion to adjourn, Lisa Rave seconded the motion, and the meeting adjourned at 4:40pm MDT.

Diane Dady, President

Date

Kari Shanard-Koenders, Ex. Director

Date