

SD Board of Pharmacy Meeting Minutes
Thursday, April 2, 2020, 1:00 PM – 5:00 PM
South Dakota Board of Pharmacy
4001 W. Valhalla Blvd, STE 206, Sioux Falls, SD 57106

Board Meeting was held via Zoom Conference

Board Members Present: President Lenny Petrik; Members Diane Dady, Dan Somsen, Tom Nelson, and Cheri Kraemer.

Board Staff Present: Executive Director Kari Shanard-Koenders, PDMP Director Melissa DeNoon, Inspectors Tyler Laetsch, Paula Stotz and Carol Smith, and administrative staff Rhea Kontos and Beth Windschitl.

Attendees Present: Christine Burg, Justin Manning, Lori Ollerich, Amanda Bacon, Andrea Darr, Chad Sherard, Jane Mort, John Thorns, Lauren Paul, Joel Kurzman, David McVey, and Justin Williams.

A. Call to Order and Introductions

Meeting was called to order 1:02 p.m. by President Petrik who read the Board of Pharmacy mission statement. Board Members, Board Staff, and meeting attendee introductions followed.

B. Consent Agenda

The President reviewed the consent agenda noting any items could be removed for discussion. Tom Nelson made a motion to approve the consent agenda; motion was seconded by Dan Somsen. A motion to approve the consent agenda was made by Tom Nelson and seconded by board member Dan Somsen. A voice roll call was taken, a quorum present, and motion was approved (5-0).

C. Staff Reports

1. Operations Report – Kari Shanard-Koenders, R.Ph., Executive Director

The Executive Director reported:

- a. Due to COVID-19, there will be one Board staff member in the office each day to provide services to the public and answer the phone. Remaining staff members are working remotely from home using the tablets recently purchased for Board members.
- b. The Board has been working closely with NABP in the development of a new program called "Passport". Due to the closure of Pearson Vue testing centers, Passport allows licensed health professional from other state to obtain a temporary South Dakota license in order to assist in the event staffing shortages occur due to COVID-19.

Justin Williams, Legal Counsel for South Dakota Department of Health and liaison for other DOH boards, stated Executive Order 2020-01, recognizes the license of any one from another state and under (36-11) any pharmacist or pharmacy who holds a license in another state can work in South Dakota for a duration of an emergency order. The Emergency Medical Assistance Compact (EMAC) operates under the same tenant and applies to compact members in all 50 states.

- c. The Board's online licensing platform has not been impacted by COVID-19 events. License applications of all types continue to be processed daily by board staff.

- d. Board is fielding many questions regarding COVID-19 and is developing informational materials and polices specific to hydroxychloroquine to share with pharmacists and pharmacies.
- e. SDBOP continue to stay in close contact with South Dakota State University academic staff discussing the ongoing challenges staff and student face as a result of COVID-19.

Discussion diverted to topic J. 1. Proceed to that section of agenda for information

2. Inspector Reports

All inspections have ceased. Staff continue to reach out to pharmacies, to serve as a resource, review all materials pertaining to COVID-19, and share information when appropriate.

- a. Paula Stotz, Inspector
Reported the following inspection items/observations/occurrences and since inspections have been postponed, calls to pharmacies to see how they are doing:
 - Many SD pharmacies are adjusting hours, stepping up cleaning efforts, adding plexiglass shields at pick-up points, not requiring signatures, creating zones of separation, and are encouraging the use of drive-ups where available.
- b. Carol Smith, Inspector
Reported the following inspection items/observations/occurrences:
 - Working on Critical Point recertification models
 - Pharmacies are collecting homemade masks, ordering extra inhalers and hydroxychloroquine
 - Reported on the DEA COVID-19 Emergency rule changes on schedule II controlled substances
- c. Tyler Laetsch, Inspector
 - Pharmacies moving to drive thru use, stepping up cleaning measures
 - Board received a verbal complaint; written complaint was never received
 - One independent pharmacy closed for financial reasons
 - Most pharmacies have implemented USP 800
 - Compounding records need improvement; better records
 - Continue to see issues with individuals not signing logbooks; same offenders year over year
 - USP 795 and 797 go to expert committee for BUD provisions review
 - USP 800 appeal was denied

3. PDMP Report

PDMP Director Melissa DeNoon reported the following updates:

- a. New and Current Project Updates
 - Added Pennsylvania to PMPi Hub sharing
 - Statewide Gateway Integration Project: six healthcare entities (HCEs) in production with 27 total HCEs in the integration process
 - The number of MedDrop program sites in South Dakota expanded to 80; through December 2019, 5,818 pounds have been collected and returned for destruction
- b. Presentations Given/Events Attended
 - 2020 COAP Grant National Meeting in Washington DC

- PDMP presentation to USD Med School first year students
- Annual PDMP report to SD Legislature's Senate and House Health and Human Services Committees

c. Upcoming Events

- PDMP Webinar to SDSU P2 pharmacy students

d. Statistics/Visuals Shared

- Noted decreases in all three opioid parameters tracked
- Started trending county specific data (top patient counties by opioid prescription count). Numbers show a downward trend three years in a row (2017 – 2019)
- The top ten most prescribed controlled substances to SD patients for years 2017, 2018, and 2019 were shared with year-to-year changes discussed

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

The following were reported by Tyler Laetsch and discussed.

1. DEA Form 106—Cigna loss in transit to patient
2. DEA Form 106—Boyd's Drug RxExpress robbery
3. DEA Form 106—Boyd's Drug East Robbery
4. Complaint-2020-001 Multiple errors by pharmacy reported by clinic
5. DEA Form 106—Avera Grasslands, resolved
6. DEA Form 106—Boyd's Drug East Robbery
7. Complaint-2020-0002 Pharmacist taking noncontrolled medications from hospital pharmacy stock
8. Complaint-2020-0003 Pharmacy filling prescription with multiple strengths of medication
9. DEA Form 106—Avera McKennan Hospital medication was misplaced in trash
10. DEA Form 106—Avera McKennan nurse
11. DEA Form 106—Avera on Louise Inpatient Pharmacy nurse

E. SD Pharmacists Association – Amanda Bacon, SDPhA Executive Director

1. Activity Report – the following items from the SDPhA report were highlighted by Ms. Bacon:
 - a. SDPhA staff is focused on COVID-19: fielding phone calls, reaching out to pharmacies and pharmacists, developing resources, and working closely with SD BOP on joint issues.
 - b. The 2020 legislative session has concluded; key bills, from the 95th session, regarding pharmacy practice (HB 1057 and HB 1234).
 - c. A dozen legislators participated in the Legislative Flu Shot Clinic sponsored by SDPhA.
 - d. Added a special COVID-19 resource page on the SDPhA website and link to SD BOP website
 - e. Dates for Spring District meeting and SDPhA annual meeting are posted on the website
 - f. Meeting Updates – cancellations, delivery channel changes:
 - APHA Annual Meeting – participation by ZOOM conference
 - NCPA Congressional Pharmacy Summit – cancelled
 - DEA Take-Back Event - postponed
 - g. Per SDPhA Executive Director Bacon, there is a lot of COVID-19 information circulating in the profession, community, and government. As such, we need greater focus and an effort toward clarify.
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
 - With the exodus of students from campus, the College of Pharmacy and Allied Health Professional is busy making the conversion to online instruction and went live on 4/24/2020. Only essential personnel are on campus and those in attendance change daily.
 - Lab instruction has presented some challenges. ACPE continues to provide additional guidance.
 - P4 pharmacy students are heading into block # 9 and provision for most students to work remotely established
 - Faculty updates – New hires Erin Miller and William Anderson; open position – experiential coordinator
2. SD Society of Health System Pharmacists (SDSHP) – Jordon Baye, Pharm.D., SDSU Assistant Professor
(Not in attendance, no report)
3. SD Association of Pharmacy Technicians (SDAPT) – John Thorns, CPhT, SDAPT President
 - John is the newly elected president of SDAPT. He has been a technician in South Dakota for eight years.
 - The association is doing well financial and currently working on arrangements for the annual conference which will be held in three locations – Pierre, Rapid City, and Sioux Falls.

G. Break and Executive Session

- Diane Dady made a motion to move to Executive Session; motion was seconded by board member Cheri Kraemer. A voice roll call was taken, and motion passed (5-0). Board members retired to Executive Session at 2:28 p.m.
- Full Board meeting, with all parties, resumed at 2:57 p.m.

H. Discipline Approval

1. 17-014 – Technician Jaysie Witkop CPhT-3093
 - Dan Somsen made a motion to revoke technician Witkop's registration; motion was seconded by Cheri Kraemer. Voice roll call was taken, and motion passed (5-0)
2. 17-018 – Technician Cassandra Haubris –TT-5119
 - Cheri Kraemer made a motion to revoke technician Haubris' registration; motion was seconded by Tom Nelson. Voice roll call was taken, and motion passed (5-0)
3. 18-006 – Non-Resident Distinguished Pharmacy, Houston, TX – 400-1227
 - Dan Somsen made a motion to revoke the nonresident license (400-1227) of Distinguished Pharmacy, Houston, TX. Motion was seconded by Cheri Kraemer. Voice roll call was taken, and motion passed (5-0)
4. 18-008 – Technician Mark Gbalenchey – TT-5742
 - Cheri Kraemer made a motion to revoke technician Gbalenchey's registration; motion was seconded by Tom Nelson. Voice roll call was taken, and motion passed (5-0)
5. 18-009 – Pharmacist Christopher Sonnenschein - Stipulation Probation 5089
 - Tom Nelson made a motion to place pharmacist Sonnenschein on probation. Cheri Kraemer seconded the motion. Voice roll call was taken, and motion passed (5-0)

6. Non-Resident Licensure Denial IWO Pharmacy, TX
 - No action taken

I. Old Business

1. Rules Revision Update, Tyler Laetsch, Board Inspector
 - A very preliminary revision of rules is complete and ready to release to the public (associations and groups) for consideration and comments. Revisions should be considered a starting point for discussions.
 - Tyler Laetsch, stated the number associated with each impacted rule and provided a brief synopsis of the proposed change to each rule in (20:51) Pharmacy and Pharmacist
2. Mission Statement – Diane Dady, Board Member
 - September, December and April agendas have allotted time to discuss the development of a new board mission statement. Diane Dady requested the topic be tabled due to the full agenda and suggested topic be moved to next meeting.
3. After Hours Remote Pharmacy Services (AHRPS) – Board Policy Statement

At the December 2019 board meeting, Andrea Darr (Avera e-Care) asked for clarification regarding off-site after-hours hospital pharmacy services and the board's stance/guidance on its policy statement #18 - the central pharmacy pharmacist located out-of-state must be licensed in the state of South Dakota. The topic was tabled and moved to April's agenda.

Today Andrea Darr again comes before the board to 1) seek clarification from the board regarding the current discrepancy in the existing rule, and to 2) receive definite direction regarding how to apply and follow the rule. Must all pharmacists working at an out-of-state central pharmacy providing after hours services in South Dakota required to be licensed in South Dakota or only the pharmacist of final review? Our policy statement states that all pharmacists working in AHRPS must be licensed in the state, but we do not require this for non-resident license holders.

Avera's San Antonio team provides after-hours hospital pharmacy services to South Dakota entities reviewing, verifying, and approving orders before medication is released from a Pyxis machine as well as serving as a resource.

Discussion followed and included after-hours standard being applied differently, medication errors and accountability, credentialing requirements for individuals and facilities, insurance coverage, access to electronic medical records (EMR), and recordkeeping data. It was felt that if this pharmacist is accessing all of this and releasing a medication on behalf of the facility that the pharmacist is more like an employee of the hospital and needs to be credentialed like others.

The Executive Director suggested that if we table the topic and take no action regarding the Board Policy Statement at this time, we would need to provide Avera e-care guidance on its San Antonio pharmacists license.

Board member Tom Nelson made a motion to enforce the current after-hours policy statement as written (which requires AHRPS pharmacists to be licensed in South Dakota.) Cheri Kraemer seconded the motion. Voice roll call was taken; motion passed (5-0).

J. New Business

1. COVID-19 Emergency Rules/Proclamation/Rule Suspension – Kari Shanard-Koenders

Emergency Rule Making Authority, will there be potential issues in the current environment that will make it difficult for potential licensees and new graduates to fulfill licensing requirements?

- Reviewed COVID-19 Suspension of Rules Sd Board of Pharmacy document (handout).
- Per Justin Williams, Governor Noam's office thinks all requirements of licensure can still be met without implementing emergency rule making authority. In addition, the Governor is examining some rules to determine if suspension of specific rules is required at this point in time but thinks the EMAC compact will be sufficient to meet evolving needs. Per Justin William, the Governor does not want the Board to begin the emergency rule making process.
- Per Justin William, the Department of Health (DOH) does not support any emergency rule making at this time. He strongly encouraged the Board not to implement emergency rules.
- Board can initiate suspend existing rules but cannot independently implement new rules. The Board Policy Statement applies to new prescriptions and restricts supply to 14-days only. For patients who are long-term users of hydroxychloroquine for RA and Lupus, obtaining refills for existing prescriptions may be difficult.

The Executive Director suggested, if board wished that topic be tabled to allow time for review and perhaps establish another meeting in the future to specifically address topic. Board member Tom Nelson made a motion to approve the COVID-19 Emergency Suspension of Rules for a duration of 90 days. Dan Somsen seconded the motion. Voice roll call was taken; motion passed (5-0).

2. Listserv – Tyler Laetsch, Inspector

The Board of Pharmacy now has Listserv capabilities. Two types of lists are available.

- One list will be managed internally by the SD BOP, for South Dakota licensed pharmacists only, and will be used to communicate information regarding diversion, shoppers, etc. Individuals cannot subscribe to this Listserv
- The second list, is open to the general public, allows anyone to subscribe, and will communication pharmacy practice general information.

3. Closing of a Pharmacy

- Inspectors researched and produced a document, with an emergency worst case scenario perspective, which will be posted to the Board website.

K. Other Business

1. Recent Meeting News

- i. 2020 NABP Interactive Board Member Forum, January 28-29, 2020 – Cheri Kremer reported that the meeting was excellent

2. Future Board Meeting Dates – all held in Sioux Falls Board Room unless otherwise noted

- i. June 5, 2020 – 8AM – 12PM CDT
- ii. September 24, 2020 – 1PM-5PM CDT, in conjunction with the SDPhA 134th Annual Conference, Swiftel Center, Brookings, Location TBD
- iii. December 11, 2020, 8PM – 12pm, CST

3. Upcoming Meetings –

- i. Cancellation of NABP Annual Meeting will move to online business meeting only
- ii. District V Meeting in Winnipeg may move to business only meeting. Either that or Winnipeg meeting will move to 2021 and South Dakota will host in 2022. District V survey being taken.

L. Public Comment (none)

M. Adjourn

Dan Somsen made a motion to adjourn the meeting; Cheri Kraemer seconded the motion. Voice roll call was taken, motion passed (4-0). Meeting adjourned at 5:19 p.m.