

SD Board of Pharmacy Meeting Minutes
Friday, June 5, 2020; 8:00 a.m. CST
South Dakota Board of Pharmacy Virtual Meeting
4001 W. Valhalla Blvd Suite 202, Sioux Falls, SD 57106

Board Meeting was held via Zoom Conference

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

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

Attendees Present: Chad Sherard, Amanda Bacon, Bob Mercer, Joe Bergsmith, Justin Manning, Lauren Berton, Sarah McGill, Jessica Strobl, Kaylee Amundson, Bill Ladwig, Jane Mort, Lori Oellrich, Lorri Walmsley, Dana Darger, Matt Toennies, Haylee Allen, Bill VanCamp, and Emily Haugh.

A. Call to Order and Introductions

Meeting was called to order 8:02 a.m. by President Petrik who read the Board of Pharmacy mission statement. Board Members, Board Staff, and meeting attendee introductions followed. A 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. Tom Nelson made a motion to approve the consent agenda; motion was seconded by Dan Somsen and roll call vote taken and motion was approved (5-0).

C. Staff Reports

1. Staff Reports - Kari Shanard-Koenders, R.Ph., Executive Director

The Executive Director reported:

- Work from home was March 16 – June 1 via board tablets. License applications of all types continued to be processed daily by board staff.
- No staff changes.
- Spoke with SDSU P2 Pharmacy students with Tyler Laetsch.
- Participated in Hydroxychloroquine committee.
- NABD support has been good during COVID19. Pearson testing sites were closed mid-March – April and May were half capacity. Pharmacists are essential test takers. SDSU test site to open in June with remote option in July. NABP has taken on the transcript repository role however they may take a week to 10 days to post to site. Test scores are not released until transcript is available.
- EO 2020-16 has provided suspension of several rules. ASHP has extended licensure time to January 1, 2021. Several other extensions are also in place such as background checks being waived, and intern ratio suspended.
- ASHP has extended licensure time to January 1, 2021.
- PPE has arrived. KN95 masks are in request by SD pharmacies. Tyler made a delivery of PPE to the Yankton area on Thursday. Some packages will be mailed out and in other instances pharmacies are picking up PPE at the office.

2. Inspector Reports

a. Tyler Laetsch

- 2 days with P4 class learning hospital rules/law.
- Questions about chemo compounding and hazardous drugs
- Virtual inspections
- COVID questions, immunization questions
- Pharmacy renewals have begun
- PPE Distribution
- Control inventories of missing items, signature, date or time of day.

b. Paula Stotz, Inspector

Reported the following items:

- Completed a couple of virtual inspections.
- Attended webinars
- Sewed 186 masks
- Answered question regarding immunizations via phone calls.
- Noted that wearing masks with shields is a hot endeavor

c. Carol Smith, Inspector

Reported the following observations/occurrences:

- Participated in the USP 800 live 7-hour webinar.
- Received Certification in Sterile Compounding for Inspectors (CSCI)
- Attended numerous webinars, touched base with PICS in the northeast part of SD to discuss pandemic.

3. PDMP Report

Director Melissa DeNoon reported the following updates:

- PMPi hub data sharing set up with NH; currently share with 31 other PDMPs.
- Statewide Gateway Integration Grant Project Update: 8 healthcare entities (HCEs) have submitted an integration request, 8 HCEs are in the integration process, and 15 HCEs have live integrations.
- License Integration Project is in progress.
- MedDrop Drug Take-Back Program Update: 45 sites added in the most recent expansion bringing total to 83 sites which are present in 43 SD counties.
- Zoom webinar on the SD PDMP held for the SDSU College of Pharmacy P2 class on April 9, 2020.
- PMP AwarxE's Clinical Alerts enhancement 2018 and 2019 data shared; decreases were seen across all three alert thresholds and in the total number of alerts to all prescribers and the total number of prescribers that received alerts.
- MedDrop Program Monthly Bundle Report chart shared; total aggregate weight returned for destruction from program inception in 2017 through April 2020 is 8,020 lbs.
- Listing of all 83 MedDrop sites shared.

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

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

1. DEA Form 107 – Lewis Southgate – robbery - pseudoephedrine
2. DEA Form 106 – Walgreen's Rapid City Mountain Rd. -robbery
3. DEA Form 106 – Boyd's East – burglary

E. SD Pharmacists Association – Amanda Bacon, SDPhA

1. Activity Report – the following items from the SDPhA report were highlighted by Ms. Bacon:
 - a. Created COVID website resource page for Pharmacist to refer to. Updated Facebook page.
 - b. Working with NAFDA on a weekly basis and has been going well.
 - c. Continuing to pursue legislation efforts
 - d. Planning on in-person Annual Convention for September 25-6, 2020 in Brookings, however it is a fluid situation due to COVID19.
 - e. Pharmacy Technician University (PTU) has had a total of 70 enrolled in program since inception 2.5 years ago. Currently, 6 are scheduled for Fall.
 - f. Supreme court case; Rutledge V. PCMA is rescheduled for October 2020.
2. Financial Report
 - a. Working frugally with budget especially during COVID19. The executive director concurred that Amanda has contributed greatly during COVID19.
3. Annual Funding Discussion per SDCL 36-11-6
 - a. Voted on by board. Dan Somsen made a motion to continue funding and Tom Nelson seconded the motions. Voice roll call was taken; motion passed (5-0).

F. Other Reports

1. SDSU College of Pharmacy – Jane Mort, Pharm D., Dean and Professor, College of Pharmacy and Allied Health Professions Department
 - Thanked BOP for aiding in graduates this Spring due to COVID19. 75 graduates participated in virtual hooding which is available on YouTube.
 - 289 accepted overall for Fall 2020 with 70 P1's. Fee increases approved for Fall as well.
 - Students are phasing back to campus with face to face on August 19, 2020 going through Thanksgiving. No Labor Day or Veteran's Day holiday breaks and online final testing after Thanksgiving. APPE starts July 13 and goes 5 weeks and then Fall session. IPPE is working on schedules.
 - Respiratory care program coming on board. DSU is in the process of accreditation and this is moving to the SDSU College of Pharmacy and Allied Health professions and will issue an Associate and B.S. degrees in Population Health degree.
 - Dan Hansen is Interim Dean will National Search is underway for Jane Mort's replacement.
 - Bernie Hendricks continues to work at 45% capacity
 - Recipients of recent awards were noted such as Theresa Seefelt, teacher of the year.
 - Well wishes extended to Jane Mort in her retirement.
2. SD Society of Health System Pharmacists (SDSHP) – Haylee Broderson, Pharm D, BCPS, BCPP
 - Beginning to plan for next meeting to get residents to present at SDS on 4/9/2021.
 - Kari added that SDSHP has been added to the board mailing list.
3. SD Association of Pharmacy Technicians (SDAPT) – John Thorns, CPhT
 - No report. No representation present at board meeting.

G. Break

- Full Board meeting, with all parties, resumed at 9:30 a.m

H. Old Business

1. Baxter Wholesaler Shipping to Patient Variance Renewal – Bill Van Camp, Jr., J.D.
 - Bill Van Camp requested another year extension on behalf of Baxter. Currently working on a rule re-write so to ease restrictions on shipping of dialysate to renal patients and due to the ongoing lobbying for this change, an extension of shipping direct to patient is asked of the board.
 - Diane Dady made a motion to extend Variance for another year and Tom Nelson seconded the motion. Voice roll call was taken; motion passed (5-0).
2. Avera Specialty Report on Drug Repository Pilot and Variance Renewal – Matt Toennies, Pharm D., CSP
 - The executive director prefaced with explaining that a subcommittee group is adding a “Practice Act” which would have allowance for drug repository.
 - Matt Toennies explained that is why we have a pilot program to experiment with complexities of the gathering and reissue of meds. Reference of other states programs aids in building the program.
 - Board Member Somsen made a motion to extend the variance for no longer than one year. Board member Diane Dady suggested a substitute motion, Avera will be provided an extension on the variance for up to one year and as Avera begins to use other enterprise pharmacies to distribute repository drug, in their discharge planning, they should report to the Board prior to the one-year extension. Dan Somsen seconded the motion. Voice roll call was taken; motion passed (5-0).
3. Rules Revisions – Tyler Laetsch
 - The executive director provided rules revisions to the board.
 - Open for discussion: 260 Hour intern requirement. Possibly waive as other states do not require.
 - Discussion of the term(s) “Registered Pharmacist vs. Licensed Pharmacist”. The executive director acknowledged that ‘clean-up’ of titles is warranted.
 - Board member Diane Dady made a motion that board staff send out rules to stakeholders for a pre-comment period and Tom Nelson seconded the motion. Voice roll call was taken; motion passed (5-0).
4. Mission Statement – Kari Shanard-Koenders
 - The executive director explained that the request to amend the mission statement was first initiated by Diane Dady when she held the title of president of the board and that possible statements have been drafted.
 - Seven mission statements were presented previously to the board staff per Diane’s **instructions**, and the top three were presented for final selection. Mission statement number one was edited as follows during the board meeting: **The mission of the South Dakota Board of Pharmacy is to protect and promote the health and safety of the public by supporting pharmacists and pursuing the highest quality pharmaceutical care thru education, communication, licensing, legislation, regulation and enforcement.**
 - Board member Diane Dady made a motion to approve the mission statement and Dan Somsen seconded the motion. Voice roll call was taken; motion passed (5-0).
5. COVID-19 Emergency Rule Suspension Update
 - The Emergency Rules did not proceed because EO 2020-16 is in part a result of the recommendation the SD BOP proposed during the April Board Meeting.
6. Antimalarials Policy Statement Revision – Kari Shanard-Koenders
 - A Policy statement was passed by the board at its April meeting. After a discussion of the current state of Hydroxychloroquine use, a motion was made by Diane Dady to rescind the April 4, 2020 policy statement. The motion was seconded by Dan Somsen. Voice roll call was taken; motion passed (5-0).

I. New Business

1. COVID-19 updates and guidance on board of pharmacy website
 - The executive director discussed that there are many resources on the SD BOP website in the COVID19 resources section of the website.
2. Policy Statement Approval – COVID-19 Testing by Pharmacists
 - A Policy Statement for COVID19 testing was previously shared with board members for review.
 - In reference to the Cares Act a referral is needed for further testing
 - A Clinical Laboratory Improvement Amendment (CLIA) waiver is needed to do diagnostic testing unless sending to a separate laboratory.
 - Report all positive and negative results.
 - Bill Ladwig said serology will shape the direction of COVID19. Public wants to know about the validity of anti-body testing.
 - One small edit was requested, a pharmacist may not be conducting testing while in a dispensing role as these need to be separate. A motion was made by board member Cheri Kraemer to approve the Policy Statement as amended which was seconded by Tom Nelson. Voice roll call was taken; motion passed (5-0).

K. Other Business

1. Recent Meeting News
 - i. NABP Annual Meeting May 14, 2020
 - Paula and Kari attended the one-day online meeting. New Officers elected and Resolutions passed:
 - Resolution 116-1-20 was passed which directed state boards of pharmacy that 483 observations from FDA inspections cannot be the sole basis for facility discipline. Some boards are disciplining based on the Form 483 without determining their own findings. We would inspect an FDA in risky situations. The reciprocal discipline happens regularly. Resolution Passed on the use of Biologics: Drug Manufacture received blood and final sent to patient. At this point we have not prohibited. The FDA / NABP allows to ship. NABP getting on board with this.
 - Resolution 116-3-20 which passed, requests NABP to investigate and report on whether Criminal Background checks could be in the NABP e-Profile Connect for all states to use in the future.
 - Resolution 116-4-20 which passed, requests that NABP convene a Task Force to review the best mechanisms to be able to transfer lifesaving unused medications to assist patients. New NABP board members noted for 2020-21. The newly elected officers of the NABP Executive Committee are President-elect Caroline D. Juran. Timothy D. Fensky, assumed the office of NABP president and Jack W. "Jay" Campbell, assumed the position of chairperson of the Executive Committee. Reggie Dillard is the Treasurer along with several Executive Committee members.
 - NABP District V Meeting, which is hosted by the South Dakota has now been moved to 2022 due to the COVID-19 changes which prohibited the meeting from being held in Canada this year. The meeting will be held August 1-3, 2022 at Custer State Park.
2. Future Board Meeting Dates - all held in Sioux Falls Board Room unless otherwise noted
 - i. September 24, 2020 – 1PM-5PM CDT, in conjunction with the SDPhA 134th Annual Conference, Swiftel Center, Brookings, Location TBD
 - ii. December 11, 2020, 9AM – 1 PM, CST
 - iii. April 8, 2021, 1PM-5PM, CDT in coordination with the SDSHP 45th Annual Meeting on April 9-10, 2021
 - iv. June 25, 2021, 8AM-12PM CDT (tentative)

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 (5-0). Meeting adjourned at 11:35 a.m.

Meeting adjourned at 11:35 AM CST

DRAFT