

**SD Board of Pharmacy Meeting Minutes**  
**September 24, 2020 1:00 p.m. CST**  
**South Dakota Board of Pharmacy Zoom Conference**  
**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:** Amanda Bacon, Joe Bergsmith, Justin Manning, Lori Ollerich, Lorri Walmsley, Dana Darger, Denise Frank, Jeff Wigfield, Melissa Goff, Christine Burg, Lauren Paul, Rob Geddes, Mike Duncan, Laura Stoebner, Rebecca Wahrmund, Madison Hall, Dan Hansen, Jeremy Daniel, Ron McNamara, Jessica Adams, and Joel Kurzman.

**A. Call to Order and Introductions**

Meeting was called to order at 1:00 p.m. by President Petrik who read the Board of Pharmacy mission statement. Board Members, Board Staff, and meeting attendee introductions followed. Roll was called, and a quorum was in attendance.

**B. Consent Agenda**

The President reviewed the consent agenda noting any items could be removed for discussion. Dan Somsen made a motion to approve the consent agenda; motion was seconded by Cheri Kramer. A voice vote was taken, and motion passed (5-0).

**C. Staff Reports**

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

The Executive Director reported:

- The following Rule changes were passed; 1. Immunization Chapter ARSD 20:51:28 which provided for all immunizations to be completed based upon a protocol or prescription. Immunization certification moved to one-year increments., 2. Dialysate delivery to homes via a prescription by wholesalers as opposed to pharmacies due to high volume pallets which need to be delivered by trucks. 3. Intern ratio increased from one pharmacist to two. LRC is looking for consistency throughout the statutes due to the change in term changes being requested, i.e. Registered. Another rules hearing will be needed. After the legislative session, if 36-11 changes are passed, we will be able to again promulgate.
- FDA has a new M.O.U. on compounding. It has not been finalized and we have one year to sign if the Board agrees. Final version will be out soon. The SD BOP has submitted requested changes through NABP comments. Board member, Cheri Kramer, commented that she thinks that the FDA would like the Pharmacy boards to police 503A compounding. APC is affording opportunity for meeting so that they could explain what the FDA is pursuing.
- Covid-19 updates: Pharmacists and pharmacy staff are now considered front-line workers and in that they would be considered first in terms of receiving a Covid19 vaccination, but not all health care

workers will receive vaccine in Phase 1, which will be quantity dependent. Currently SD has nearly 1000 pharmacists and interns available to administer immunizations.

- Pfizer is first to move ahead with a Covid19 vaccine. Challenges remain with the -70C storage, reconstitution, and two dose requirement. Moderna will likely be second to market with their product which is also a two-dose product, but storage is -20C and it does not require reconstitution. Johnson & Johnson may be next with a single dose vaccine which does not require reconstitution and will be stored at regular refrigerator temperature. They are approaching the Stage 3 clinical trials at present. Astra/Zeneca and many other manufacturers have trails ongoing.
- NABP has been working with the CDC and Department of Defense. The distribution contract was given to McKesson to move vaccines to the chain pharmacies. The state stockpile will receive vaccine which will be distributed to the health systems. Details are at the federal level in terms of who gets vaccines first such as those working in health care and those in long-term care.
- The Tyler, Melissa and I are presenting at the SDPHA Annual Meeting on September 24, 2020.
- This meeting is Board member, Diane Dady's last meeting. Diane was a past board president and board staff have appreciated her good common sense. Diane was thanked for her excellent service. Diane Dady thanked everyone and appreciated the opportunity to serve.

## 2. Inspector Reports

### a. Tyler Laetsch

- Pharmacies partly open/drive through/curb side/ delivery/mail out
- Hours of operation changes
- Vaccinations resuming and changing
- Hydroxychloroquine questions from pharmacies
- Pharmacies and clean room/hood reports, read them and use them as well as staff training
- Several calls about fraudulent calls to pharmacies with Prometh/codeine scripts
- COVID testing, retail and at NH
- Hospital remodels
- Phone calls about provider offices and nonresident pharmacies not formal complaints
- Call and schedule all inspections and constant communication with pharmacists
- 87 virtual inspections, 15 in person inspections spaced out 1 – 2 per week due to contact tracing, ease of changing schedule for both parties, and ease for the pharmacy knowing I have not been at multiple locations during the pandemic.

### b. Paula Stotz, Inspector

Reported the following items:

- During this quarter: 14 Virtual inspections & 10 In person inspections
- 1 pharmacy had a disposable syringe in an open Kenalog vial and reusing for compounding
- Completed several online trainings and webinars
- A few pharmacies are not including controlled substance prescriptions in the Will Call area on their annual or biennial inventory. Several have now begun to include them. Noted that wearing masks with shields is a hot endeavor
- Many pharmacies ensure all the required information is on a controlled substance prescription prior to filing prescriptions away, a few pharmacies are not adding the provider's address on phoned-in controlled substance prescriptions.
- Many pharmacies have begun to implement USP 800 by either labeling the shelving of the hazardous drugs or placed them to a separate area of the pharmacy. Most pharmacies have a dedicated hazardous drug counting tray. A few pharmacies use appropriate hazardous drug agents to deactivate,

decontaminate, and clean the hazardous drug counting tray. Ex: Hydrogen peroxide wipes followed by alcohol wipes, others just using alcohol wipes. Some pharmacies have implemented the use of nitrile gloves when handling hazardous drugs, and others have begun using chemotherapy tested gloves.

c. Carol Smith, Inspector

Reported the following observations/occurrences:

- During this quarter: 9 virtual inspections, 1 Wholesale inspection and 19 in person inspections
- Attended webinars and the 795 & 797 Forum Zoom meeting.
- Many of the pharmacies have not been including the controlled substance prescriptions that have been filled but not yet picked up by patients, in the biennial inventory. It was recommended that if there are not controlled substance prescriptions in the “will call” bin this should be documented on the biennial inventory.
- A suboxone prescription was found that did not include a medical condition.
- Some pharmacies are still only cleaning their NIOSH trays with alcohol and not using an oxygenating agent to decontaminate/deactivate.
- There were four pharmacies where no one was wearing a name tag.
- Several pharmacies are not circling the quantity, signing or initialing and dating the controlled substance invoices. The CII and CIII-V invoices were not filed separately and in chronological order.

3. PDMP Report

Director Melissa DeNoon reported the following updates:

- PMPi Hub sharing set-up with WY and PR (33 total).
- Statewide Gateway Integration Project: 13 HCEs ‘Integration Request Received’, 5 HCEs ‘Credentials Sent’, and 20 HCEs ‘In Production’ including 5 new:
  - o Center for Family Medicine – Sioux Falls
  - o Prairie Lakes Healthcare System – 2 EHR platforms – Watertown
  - o Dunes Surgical Hospital – Dakota Dunes
  - o Center for Neurosciences Ortho Spine – Dakota Dunes
- License Integration Project – test files completed; next steps to begin live uploads.
- MedDrop Drug Take-Back Program: 83 receptacles in place; added HyVee’s remaining 6 SD sites (all in Sioux Falls) to Trilogy’s ‘Automatic Reload’ program.
- SD DOH Opioid Abuse Advisory Committee Virtual Meeting – presented “SD PDMP Update”.
- Trends in 2020 opioid prescriptions dispensed to SD patients reviewed.
- SD PDMP utilization by pharmacists and prescribers via the web portal and Gateway integrations discussed.

**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 106---Loss in Transit from QuVa to Avera McKennan
2. DEA Form 106 – Loss in Transit CVS Louise Ave SF to patient
3. DEA Form 106 – Landmann-Jungman Memorial Hospital Pharmacy employee loss
4. DEA Form 106 – Safeway Mt. Rushmore Rd, miss count
5. DEA Form 106—Regional Home Health Hospice misplaced expired meds where nursing pulled expired meds out of drawer.
6. DEA Form 106—unexplained accounting loss of controls in compounding (nonresident)
7. Complaint 2020-0004---Prescriber E prescribed incorrect Rx to pharmacy and it was filled, patient then called provider to ask and provider stated Rx was prescribed to her in error.
8. DEA Form 106--- Sioux Falls Specialty Hospital employee theft

**D. SD Pharmacists Association** – Lori Ollerich, Pharm D, SDPHA President, Dana Darger, R.Ph., SDPHA President Elect

1. Activity Report – the following items from the SDPhA report were highlighted by Ms. Ollerich:
  - a. Supreme court case; Rutledge V. PCMA is rescheduled for October 6, 2020. Eight justices could be an issue. If Arkansas wins this case, it does not end DIR fees or unfair reimbursement, but it could give states the authority to determine whether these practices are detrimental – saying whether states indeed have the right to regulate PBMs.
  - b. This legislative session will utilize a new communications platform called Voter’s Voice. This tool will allow for communication such as an opt-in for text messages. These messages will contain ready-made tools to quickly communicate with both state legislators and congressional delegation when it matters most. Platform will roll out shortly after convention.

**F. Other Reports**

1. SDSU College of Pharmacy – Interim Dean and Professor Dan Hansen, Pharm D.
  - One third of the way through the first semester. All labs in person. PPE in place. All is working out.
  - 70 new P1 students with a total of 287 students P1-P4. 65 students is the placement goal.
  - 75 students graduated in a virtual ceremony. Dan noted a high residency rate, a continuing trend.
  - In July 2020, the respiratory care program at Dakota State University transitioned to the College of Pharmacy and Allied Health Professions, finding a home in the Department of Allied and Population Health. Currently a 2-year program but will be a 4 year in the future.
  - A Master of Public Health is in development and seeking accreditation.
  - Searching for FT Dean, Educational Coordinator, Program Assistant, Research Associate and Instructor for Respiratory Care Program.
  - Grant funding is up. \$1.6 million spread over 3 departments.
  - Dr. Yen-Ming Huang was selected as the 2020 ACH Healthcare Communication Virtual Research Forum Humanities and Social Sciences Scholarship Award recipient.
  - Philip Jacobson, Hannah Brockmeier, and Zach Muller represented SDSU in the ACCP Clinical Pharmacy Challenge.
2. SD Society of Health System Pharmacists (SDSHP) – Jeremy Daniel, Pharm D, BCPP, BCPS (after break)
  - Adjusting formatting and going virtual: utilizing “Lecture Panda” which will bring in CE from other states.
  - October is Pharmacy Month and planning ‘live’ events such as a Pumpkin Carving Contest.
  - Midyear is coming up with students and residents attending for free and reduced costs for members.
  - Residency grant is open.
  - Considering having annual meeting be virtual.
3. SD Association of Pharmacy Technicians (SDAPT) – John Thorns, CPhT
  - No report. No representation present at board meeting. Kari is presenting at their annual continuing education conference on October 3, 2020

**Break**

- Full Board meeting resumed at 2:25 p.m.

## G. Old Business

### 1. Rules Revisions – Tyler

- October 13<sup>h</sup> is the date that the passed rules go in effect. One: 2 interns to 1 pharmacist. Two: Dialysate Solution from wholesalers. Three: Added 2<sup>nd</sup> section to the Immunization chapter to make the 20hour/CPR required for qualified applicants and change to annual rather than a 2 year with 1 hr CE toward immunizations each year. Added interns may immunize under supervision of a pharmacist that is authorized to immunize as well. We also changed the reporting requirement from mandatory reporting to patient’s primary care provider to now pharmacies must report immunizations to SDIIS.

### 2. COVID-19 Testing Policy Statement Revision—Kari

- Drive through testing has become a newer model for Covid19 testing with Walmart and Walgreens moving towards implementing systems. A policy statement has been created in which to cover all types of pharmacy Covid19 testing. Lorri Walmsley comments that she is glad the board is adding a policy statement because she sees more testing coming. Rob Geddes of Albertsons/Safeway said minimal patient contact when they send out a Covid19 saliva test that has a Fed Ex 1-3 day turn around. A sample is good for 56 hours with a 98% accuracy. Joe Bergsmith with Walmart said that their testing model has specific hours for collecting as to not inundate the primary pharmacist on duty. Board member, Cheri Kramer, asked Joe if there is a plan to dispose of PPE after use. Joe replied that yes that there is a process in place with clear instructions. Joe will send full SOP to the board when ready. Joe added that pharmacists and technicians have stepped forward to provide testing and it is not mandatory of their staff. Kari explained the added changes to the policy in yellow with added input on line 3 to add mailed supplied and ‘if applicable’. Line 5: Joe recommended to add “comfortable”. Other board members concurred. Line 7: Pharmacist/Pharmacy reports changes suggested by Tyler. “The pharmacist or testing vendor must report test results to the South Dakota Health Department at [sd.gov/diseasereport](https://sd.gov/diseasereport)”.
- Board member Dan Somsen made a motion to approve new policy statement as revised and discussed during meeting and Cheri Kramer seconded the motion. Voice call was taken; motion passed (5-0).

## H. New Business

### 1. Variance request for Animal Health International Pharmacy, Jeff Wigfield, Pharm. D. Director of Pharmacy Operations, Patterson Companies, Inc.; Ron McNamara, Operations Manager

- Jeff Wigfield presented the requested variance from Administrative Rule 20:51:29:02 requiring the registration of pharmacy technicians to label product for final verification by a registered pharmacist. The skills and training needed to label stock bottle of veterinary medications does not rise to the level of a registered pharmacy technician and these are mostly warehouse workers. Tyler has inspected the facility and suggested the variance.
- Board member Diane Dady made a motion and Dan Somsen seconded the motion. Voice roll call was taken; motion passed (5-0).

### 2. Variance request Sanford USD Medical Center – Laura Stoebner, Pharm D.; Mike Duncan, Pharm D.

- Document shared to board members. Laura commented that this allows technicians to verify total quantity after filling with prechecked automated device. The pharmacist has previously approved compounded product and allow only CPhT certified technicians approve whether 20 ml or not.
- Board member Dan Somsen made a motion and Tom Nelson seconded the motion. Voice call was taken; motion passed (5-0).

2. Policy statement—Transfer Rules Clarification -Tyler

- This is meant to clarify the transfer of Rx between pharmacists. The discussion that followed focused on The facsimile component of transmission concerns which was cleared up when Tyler shared 20:51:23:02 which states that the transferring pharmacist or intern must contact the pharmacy receiving the fax to obtain the registered pharmacist and information for required record keeping. Tyler added 4<sup>th</sup> line: The transferring pharmacy must contact the pharmacy receiving the fax to record the pharmacy and pharmacist information.
- Board member Cheri Kramer made a motion to approve new policy statement as revised during meeting and Diane Dady seconded the motion. Voice call was taken; motion passed (5-0)

4. Pharmacist Zamulko Discipline Approval

- Document shared via email to board members regarding signed stipulation. No discussion. Board member Cheri Kramer made a motion and Dan Somsen seconded the motion. Voice vote was taken; motion passed (5-0).

**I. Other Business**

1. Recent Meeting News

- i. NABP/AACP 83rd Annual District V, Virtual business Meeting August 7, 2020 – Upcoming meetings will be held in 2021 in Winnipeg, Canada, 2022 in Custer State Park with SD as the host state.
- ii. FDA Intergovernmental Meeting on Compounding September 20-21, 2020 – Tyler and Kari attended with the focus on 503b and some 503a (MOU). Tyler learned about manufacturing process. Board member, Cheri Kramer asked about eye drop availability and Kari said it was not mentioned. Cheri has concerns about product availability.

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

- i. December 11, 2020, 9AM – 1 PM, CST
- ii. April 8, 2021, 1PM-5PM, CDT in coordination with the SDSHP 45th Annual Meeting SF
- iii. June 25, 2021, 8AM-12PM CDT (tentative)
- iv. September 16, 2021 1PM-5PM in coordination with SDPHA, Spearfish

**L. Public Comment** – No one spoke.

**M. Adjourn**

Diane Dady made a motion to adjourn the meeting; Dan Somsen seconded the motion. Voice vote was taken, motion passed (5-0). Meeting adjourned at 3:58 p.m.

Meeting adjourned at 3:58 p.m. CST

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Lenny Petrik, President

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Date

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Kari Shanard-Koenders, Ex. Director

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Date