

AGENDA
NORTH DAKOTA STATE BOARD OF PHARMACY
March 21, 2024
NORTH DAKOTA STATE BOARD OF PHARMACY
1838 East Interstate Ave Suite D-Conference Room-Bismarck, ND

THURSDAY-MARCH 21, 2024

9:30 AM CALL TO ORDER – Shane Wendel, President
Recite: Mission Statement

Review and approval of agenda AGENDA

Review and approval of Minutes of January 11-13, 2024 meeting MINUTES

Assign members to review all paid invoices and Reconciled Bank Statements

9:45 AM Joseph McDonald, PharmD RPh5915 -DUI TAB 1

10:15 AM Hayden Jeanotte, Tech1392 -DUI TAB 2

10:30 AM McCall Zenker RPh5233 -Reinstatement Request TAB 3

11:30 AM Altru- New Facility PHAR180 and PHAR180A TAB 4

12:00 PM LUNCH

1:30 PM Meeting for Legislative Study with Commissioner Nathan Svihovec TAB 5

Discussion Items: TAB 6
-May Exam Preparations
-DSCSA
-Inspection Cycle
-Tech-in-Training online application
-Kratom
-NABP Annual Meeting

Board Member Reports
Executive Director’s Report

Consider approval of all legal action of the Executive Director

Year to date Financials

Vouchers - Adjourn

President Shane Wendel, PharmD called the Board Meeting to order at 9:30 AM on Thursday, March 21, 2024.

Present in the Room were Executive Director Mark J Hardy, PharmD, Pharmacist Shane Wendel, Technician Member Diane Halvorson, RPhTech; Tanya Schmidt, PharmD; Public Member Ron Horner; Tyler Lannoye, PharmD; Howard C Anderson Jr RPh and David Lindell, JD. Also present were Joy Dahlen, Pharm D Candidate on rotation with Pharmacist Tyler Lannoye, Sarah Wirz, Pharm D Candidate on rotation with Pharmacist Shane Wendel, Pharmacist Mike Riepl of the PharmAssist Committee, Technician Mandy Chase representing the Northland Association of Pharmacy Technicians (NAPT)

Present on Zoom were: Pharmacist Carolyn Bodell, Sara Watson from Cardinal Health, Hayden Jeanotte Tech1392 and Tonia Okafor, Pharm D.

President Wendel read the mission statement: *The Board of Pharmacy protects, preserves and promotes the public health and welfare of the citizens of North Dakota by assuring that the highest quality pharmaceutical care is delivered, and that appropriate use of pharmaceuticals is upheld through education, communication, licensing, legislation, regulation, and enforcement.*

It was moved by Pharmacist Steve Irsfeld and seconded by Pharmacist Tanya Schmidt to approve the agenda, as presented. On vote by roll call Pharmacist Carolyn Bodell – Aye- Technician Diane Halvorson -Aye- Pharmacist Tanya Schmidt -Aye- Public Member Ron Horner -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Steve Irsfeld -Aye- Pharmacist Shane Wendel -Aye-. Nays none. The motion carried.

It was moved by Pharmacist Tyler Lannoye and seconded by Public Member Ron Horner to approve the Minutes of the January 10-11-12, 2024 meeting, as printed. On vote by roll call Pharmacist Carolyn Bodell – Aye- Technician Diane Halvorson -Aye- Pharmacist Tanya Schmidt -Aye- Public Member Ron Horner -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Steve Irsfeld -Aye- Pharmacist Shane Wendel -Aye-. Nays none. The motion carried.

President Wendel appointed public member Ron Horner and Technician Diane Halvorson to review the paid invoices and the bank statements.

Hayden Jeanotte Tech1392 was available via Zoom at 9:37 AM. Dr. Hardy reviewed his case briefly and asked him to explain what happened to the Board. Technician Jeanotte works with the Indian Health Service out of Belcourt. He has met with Mike Riepl of the Pharm Assist committee. Pharmacist Riepl said Hayden has been very open about the situation. Mike has reviewed the drug and alcohol evaluation he had done and found it very comprehensive and professional. He is perfectly satisfied with Hayden's situation now, two months after the incident. Hayden stated his family has been very supportive in getting him to work while his license is suspended.

Board members encouraged Hayden to share his story with others to help them avoid similar incidents.

It was moved by Technician Diane Halvorson and seconded by Pharmacist Steve Irsfeld to take no further action on the registration of Hayden Jeanotte, Tech1392, at this time. On vote by roll call Pharmacist Carolyn Bodell – Aye- Technician Diane Halvorson -Aye- Pharmacist Tanya Schmidt -Aye- Public Member Ron Horner -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Steve Irsfeld -Aye- Pharmacist Shane Wendel -Aye-. Nays none. The motion carried.

At 9:50 AM Joseph McDonald, Pharm D, RPh5915 was present in the room to discuss the DUI he had. In 2022 he was involved in a collision. He stated he has learned a lot, changed his life around. He took a short term leave of absence from Sanford, entered treatment on his own in Minneapolis where his family lives. Mike recommended he get a sponsor, attend meetings regularly. He stated that he is abstinent from alcohol for life now and has been clean for five months.

It was moved by Pharmacist Tanya Schmidt and seconded by Technician Diane Halvorson to take no further action against the license of Joseph McDonald, Pharm D, RPh5915 at this time. On vote by roll call Pharmacist Carolyn Bodell – Aye- Technician Diane Halvorson -Aye- Pharmacist Tanya Schmidt -Aye- Public Member Ron Horner -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Steve Irsfeld -Aye- Pharmacist Shane Wendel -Aye-. Nays none. The motion carried.

At 10 AM Board members discussed preparations for the May exam. Pharmacist Steve Irsfeld will come to help with the non-sterile compounding. Executive Director Hardy corresponded with faculty at NDSU to prepare a new sterile compounding video. Technician Diane Halvorson asked to review it prior to the exam. Pharmacist Gayle Ziegler will be invited to help with the exam.

Three students will present two posters at the NABP Annual meeting. Pharmacist Tanya Schmidt and Pharmacist Carolyn Bodell will be preceptors. There seems to be many more poster applications now which explains why only two of ours were chosen.

At 10:20 AM the Drug Supply Chain Security Act (DSCSA) was discussed. Some supply chain participants are waiting until November 2024 when the act will be enforced, to get everything up and running. Others are very active in being ready prior to that date.

At 10:35 AM McCall Zenker RPh5233 joined the Board via Zoom to present her request for reinstatement of her license. McCall now has a sponsor, as requested by the Board and the PharmAssist committee. She has a contract in place with the committee. She is in regular contact with her sponsor, meeting once a week and soon transitioning to two times a week. McCall explained that she and her husband, who is a physical therapist, are opening a treatment business in Mandan, ND. She expects to keep busy there but would like to be able to work part time remotely if things are slow. She has also considered giving vaccinations and injections at the business.

Mike Riepl has obtained permission to talk with McCall's sponsor and to share his findings with the Board. McCall is in compliance with her contract, her urine tests and hair tests have come

back clear. McCall said she is working through the big book, which is a story of recovery, with her sponsor.

Dr. Hardy pointed out there were no questions about McCall's care of patients when she was working.

Technician Diane Halvorson said she still has concerns with allowing McCall to practice Pharmacy, which was echoed by other Board members.

It was moved by Pharmacist Tyler Lannoye to modify the order of McCall Zenker, RPh 5233 to allow her to work remotely, as a mail order Pharmacist or consultant, with no access to drugs including controlled substances. The motion was seconded by Pharmacist Carolyn Bodell. On vote by roll call Pharmacist Carolyn Bodell – Aye- Technician Diane Halvorson -Nay- Pharmacist Tanya Schmidt -Nay- Public member Ron Horner -Nay- Pharmacist Tyler Lannoye -Aye- Pharmacist Steve Irsfeld -Nay- Pharmacist Shane Wendel -Aye-. Ayes three, Nays Four. The motion failed.

President Wendel asked McCall Zenker to follow her current stipulation and order and return to meet with the Board at their May 2024 meeting.

At 11:25 AM Erin Navarro, Pharmacist in Charge at Altru Health Systems in Grand Forks joined the Board via Zoom to review and explain the plans for the new facility. Dr. Hardy pointed out this is a grandfathered pharmacy which will continue to operate the Hospital and outpatient pharmacy under one license. The address of the facility will be the same as it is currently. Many questions were asked by Board members, all answered satisfactorily by Pharmacist Navarro. Pharmacist Navarro indicated their move in date is January 2025.

It was moved by Pharmacist Tanya Schmidt and seconded by Technician Diane Halvorson to approve the plans for the new pharmacy space at Altru Health Systems in Grand Forks (Phar180 and Phar180A). On vote by roll call Pharmacist Carolyn Bodell – Aye- Technician Diane Halvorson -Aye- Pharmacist Tanya Schmidt -Aye- Public Member Ron Horner -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Steve Irsfeld -Aye- Pharmacist Shane Wendel -Aye-. Nays none. The motion carried.

The Board broke for lunch at noon and at 1 PM began a discussion of the planned inspection cycle. The letters have been sent out to pharmacies notifying them of the earlier cycle this year. Dr. Hardy indicated we are ready to go and will plan to include the wholesaler and veterinary retail facilities this year.

Dr. Hardy reported the online technician in training application is getting close to operational with just a few glitches to be ironed out.

Kratom was discussed. There are concerns on its addiction potential, but a large group of producers and sellers do not want it scheduled. Pharmacist Steve Irsfeld related his practice and has worked with 19 individuals wanting to get off opioids with a low dose naltrexone

tapering plan. He has also encountered three individuals asking for help getting off kratom, for which he has not been able to be successful in helping.

Technician Diane Halvorson and Technician Mandy Chase spoke on behalf of NAPT, the plans they have for the Fall Conference.

The upcoming NABP elections were discussed briefly with everyone encouraged to review the candidate profiles and communicate with our registered delegate before the vote.

At 1:30, Dr. Hardy welcomed Labor Commissioner Nathan Svihovec who was with us to clarify a few questions for his final report to the legislature on the Board and Commissions study which legislation from the 2023 session has requested. Carolyn Laird who is working with the Labor Commissioner on the study and had attended a previous meeting of the Board was present via Zoom. All Board members contributed to the clarification of the questions asked. Most of the questions centered on the time it takes to get licensed, reciprocity with other states and continuing education requirements.

Dr. Hardy welcomed Pharmacist Andrew Funk via Zoom, who now works for NABP as a member relations/government affairs. He presented a very good Power Point on the Drug Supply Chain Security Act and answered questions from the Board. He volunteered to send us his presentation for some editing and posting on the Board's website for the use of North Dakota pharmacies wanting to know what they need to do to comply with the act, which will be required as of November 2024. DSCSA compliance centers around a good policy and procedure to verify and document the identity with the licensure of each supplier, and record the check, a plan to quarantine any suspected counterfeit product, and investigate those situations and report it on an FDA 3911 form within one business day of discovery.

Pharmacist Funk volunteered to follow up on Shane Wendel's question about why his stores were getting more than one GLN number and whether stores needed separate GLN numbers for their 340B business.

It was moved by Technician Diane Halvorson and seconded by Public Member Ron Horner to approve the paid invoices and the bank statements as a result of their review. On vote by roll call Pharmacist Carolyn Bodell – Aye- Technician Diane Halvorson -Aye- Pharmacist Tanya Schmidt left the meeting for a family funeral so was absent for this vote. Public member Ron Horner -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Steve Irsfeld -Aye- Pharmacist Shane Wendel -Aye-. Nays none. The motion carried.

Technician Diane Halvorson brought up the support for the NoDak Pharmacy Journal. It is our official publication and since it is going virtual now, we may want to consider our level of support. It was expressed that we should be sure it is going to all licensees who provide contact information to us. Dr. Hardy will visit with Mike Schwab about the distribution plans. Diane departed the meeting due to the snow starting outside.

It was moved by Pharmacist Steve Irsfeld and seconded by Pharmacist Tyler Lannoye to approve all the legal actions of the Executive Director. On vote by roll call

Pharmacist Carolyn Bodell – Aye- Technician Diane Halvorson left the meeting before this vote; Pharmacist Tanya Schmidt left the meeting for a family funeral so was absent for this vote. Public Member Ron Horner -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Steve Irsfeld -Aye- Pharmacist Shane Wendel -Aye-. Five ayes, Nays none. The motion carried.

It was moved by Pharmacist Steve Irsfeld and seconded by Pharmacist Tyler Lannoye to approve the financials as presented. It was noted that there were no journal entries. On vote by roll call Pharmacist Carolyn Bodell – Aye- Technician Diane Halvorson left the meeting before this vote; Pharmacist Tanya Schmidt left the meeting for a family funeral so was absent for this vote. Public Member Ron Horner -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Steve Irsfeld -Aye- Pharmacist Shane Wendel -Aye-. Five ayes, Nays none. The motion carried.

President Wendel called for any further business. There being no further business forthcoming and the meeting was adjourned at 3:30 PM.

President
Shane R. Wendel, PharmD

Technician & Senior Member
Diane M. Halvorson, RPhTech

Member
Tyler G Lannoye, PharmD

Member
Tanya L Schmidt, PharmD

Member
Steven P Irsfeld, RPh

Public Member
Ron J Horner

Member
Carolyn R Bodell, RPh

Executive Director
Mark J. Hardy, PharmD