

A G E N D A - September 21, 2023
NORTH DAKOTA STATE BOARD OF PHARMACY
1838 E Interstate Ave – Conference Room – Bismarck, ND

9:30 AM CALL TO ORDER – Diane Halvorson-Senior Member

Recite: Mission Statement

AGENDA

Review and approval of agenda

Review and approval of Minutes of July 20, 2023

MINUTES

9:30 AM Remodeling: Towner County Medical Center – Pharmacy

TAB 1

10:00 AM Foreign Pharmacist Olugbemi Dickson Akinlosotu- Thrifty White Grand Forks

TAB 2

10:30 AM Follow up - LTC call delegation to Technicians On Call

TAB 3

Review of Comments and Final Adoption

TAB 4

61-01-01 Organization of Board

61-02-01-03 Pharmaceutical compounding standards

61-02-07.1 Pharmacy Technician

61-03-01 Licensure of Pharmacists

61-04-10 CLIA Waived Laboratory Tests

61-04-12 Limited Prescriptive Authority for Naloxone

Exam Schedule – Candidate Russell Janssen

11:30 AM	Roll Call and Orientation of all Candidates - Video
11:45 -12:45 PM	Laboratory Section 1
1:00 - 1:30 PM	Errors and Omissions 1
1:30 - 2:00 PM	Oral Examination - 1

12:00 PM **LUNCH**

1:00 PM Briana Fluhrer, PharmD-Gateway Pharmacy- Central Fill Pharmacy

TAB 5

Discussion Items:

-Pharmacist Reinstatement Application

-DSCSA Delay

-Attorney General Training

-Foreign Graduate Procedures

-Inspections

-Intern Licensing

TAB 6

Board Member Reports

Executive Director's Report

Consider approval of all legal action of the Executive Director

Year to date Financials

Vouchers – Adjourn

Senior Member Technician Diane Halvorson called the Board Meeting to order at 9:30 AM on Thursday September 21, 2023.

Present in the Room were Executive Director Mark J Hardy, PharmD; Technician Member Diane Halvorson, RPh Tech; Tanya Schmidt, PharmD; Carolyn Bodell, RPh; Public Member Ron Horner; Tyler Lannoye, PharmD; Howard C Anderson Jr RPh; and David Lindell, JD.

Present on Zoom were Molly Naumann, Pharm D with Thrifty White, Andy Croxton and Bob Mooney representing the architects doing the work at Towner County Medical Center Pharmacy.

Senior Member Diane Halvorson 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 Tanya Schmidt and seconded by Pharmacist Tyler Lannoye, to approve the agenda with the addition of discussion of intern licensing. On vote by roll call Public Member Ron Horner -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Carolyn Bodell -Aye- Pharmacist Tanya Schmidt -Aye- Technician Diane Halvorson -Aye-. The motion carried.

It was moved by Pharmacist Tanya Schmidt and seconded by Pharmacist Tyler Lannoye, to approve the Minutes of the July 20, 2023, as printed. On vote by roll call Public Member Ron Horner -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Carolyn Bodell -Aye- Pharmacist Tanya Schmidt -Aye- Technician Diane Halvorson -Aye-. The motion carried.

The architects for the Towner County Medical Center Pharmacy remodel joined the board via Zoom. Dr. Hardy asked them to summarize the plans presented. There will be a non-hazardous compounding area with an ante room for use in the hospital. Dr. Hardy expressed that the area seems to be a little small, but the architects feel, based on their previous experience, it will work fine. Pharmacist Carolyn Bodell asked about the buffer room engineering control. She suggested stainless steel for the pass-through window and the architects confirmed it cannot be opened from both sides at once. The architects confirmed the HEPA filters will be in the ceiling and the doors are regular, not sliding, doors. The hoods will be moved six inches from the walls so cleaning can be done behind them. The completion date for the work is scheduled for June 2024.

It was moved by Pharmacist Tanya Schmidt and seconded by Pharmacist Carolyn Bodell to approve the plans for Towner County Medical Center, as submitted. On vote by roll call Public Member Ron Horner -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Carolyn Bodell -Aye- Pharmacist Tanya Schmidt -Aye- Technician Diane Halvorson -Aye-. The motion carried.

Foreign Pharmacist Olugbemi Dickson Akinlosotu joined the board, in person, with Molly Naumann, PharmD, to discuss his application for an intern license. He received the Foreign Pharmacy Graduate Certification in 2011. He later worked in Manitoba and attended school in Winnipeg receiving a degree in Supply Chain Technology. He has been working as a Pharmacy Assistant, equivalent to our Pharmacy Technician, in Winnipeg and since July 2023. He has also been working for Thrifty White in Grand Forks as a Technician-in-Training.

It was moved by Pharmacist Tyler Lannoye, and seconded by Pharmacist Carolyn Bodell to grant an intern license to Olugbemi Dickson Akinlosotu. Pharmacist Tanya Schmidt disclosed that she is a Thrifty White employee for which the new intern will be working. On vote by roll call Public

Member Ron Horner -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Carolyn Bodell -Aye- Pharmacist Tanya Schmidt -Aye- Technician Diane Halvorson -Aye-. The motion carried.

Pharmacist Jeff Shorten of Thrifty White, joined via Zoom to discuss their proposal for LTC call delegation to Technicians On Call. Jeff discussed their proposal with the Board, answered questions about how it would work, and the timeline for the pilot project they proposed. The write up they sent included the term pharmacy manager and North Dakota uses pharmacist in charge. Jeff said he looked at the two terms interchangeably, and that he would modify the document to include the ND language, making them consistent with our rules and laws. There was discussion about moving forward with a rule change, either in the Long Term Care Consulting rules, or in the Telepharmacy rules, but it was felt by most board members, that we should consider the results of the proposed pilot project before moving ahead with any rules. The proposal for Dickinson and Grand Forks will give the pilot about six to seven hundred long term patients, providing a good number to evaluate the results of the pilot.

It was moved by Pharmacist Carolyn Bodell and seconded by Pharmacist Tyler Lannoye to allow Thrifty White to move ahead with a pilot project at their Grand Forks and Dickinson locations (Phar72 and Phar76). The pilot project would use on call technicians when the pharmacy is closed, supervised by pharmacists over computer, audio, and visual links to prepare medications at licensed pharmacies and deliver them to Long Term Care facilities for administration by facility staff to the patients of the facility. Dr. Hardy will reach out to other pharmacies servicing long term care patients in those communities so they understand the proposal and give them the opportunity to submit their own proposal, or wait for the results of the Thrifty White pilot project, which will be delivered by Thrifty White at the January 2024 meeting of the Board. Tanya Schmidt disclosed that she is a Thrifty White employee. On vote by roll call Public Member Ron Horner -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Carolyn Bodell -Aye- Pharmacist Tanya Schmidt -Aye- Technician Diane Halvorson -Aye-. The motion carried.

Senior Member Diane Halvorson moved to the review of comments and final adoption of rules from the hearing held at the last meeting.

61-01-01 Organization of Board

There were no comments offered on this rule change at the hearing.

There were no written comments received during the open comment period.

It was moved by Pharmacist Carolyn Bodell and seconded by Pharmacist Tanya Schmidt, to approve 61-01-01 Organization of Board as originally proposed. On vote by roll call Public Member Ron Horner -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Carolyn Bodell -Aye- Pharmacist Tanya Schmidt -Aye- Technician Diane Halvorson -Aye-. The motion carried.

61-02-01-03 Pharmaceutical compounding standards

There were no comments offered on this rule change at the hearing.

During the open comment period guidance was received from the Food and Drug Administration (FDA) about dispensing drugs received from an outsourcing facility to patients.

This additional language to take advantage of this opportunity for North Dakota patients is suggested.

9. *Compounding for office use.*

- a. *It is acceptable to compound human drug products to be used by North Dakota practitioners in their office for administration to patients provided they are prepared by a facility licensed as an outsourcing facility in accordance to North Dakota Century Code section 43-15.3-13 or by a resident North Dakota pharmacy. It is acceptable for a North Dakota licensed pharmacy to obtain a compounded human drug from a licensed outsourcing facility and dispense it to a patient. It is acceptable for any licensed pharmacy to compound veterinary drug products to be used by veterinarians in their office for administration to client's animals. These compounded office use products may be dispensed to clients for use in a single treatment episode, not to exceed a one hundred twenty-hour supply.*
- b. *Sales to other pharmacies, veterinarians, clinics, or hospitals are manufacturing and are not allowed. It is the responsibility of the pharmacy and pharmacist involved in the compounding to ensure compliance with this section for the products they compound.*

It was moved by Pharmacist Tanya Schmidt and seconded by Pharmacist Tyler Lannoye to approve the changes in 61-02-01-03 Pharmaceutical compounding standards based on the Food and Drug Administration (FDA) guidance received. On vote by roll call Public Member Ron Horner -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Carolyn Bodell -Aye- Pharmacist Tanya Schmidt -Aye- Technician Diane Halvorson -Aye-. The motion carried.

Mike Schwab and Jessie Johnson of the North Dakota Pharmacist's Association joined the Board via Zoom.

61-02-07.1 Pharmacy Technician

In subsection 02, Technician Diane Halvorson suggested we put a period after the reference to accreditation agencies, add in the language that was inadvertently not in the draft and remove the old language, so it reads as below. All Board members agreed.

"Pharmacy Technician in Training" is a person who is enrolled in an academic experiential rotation program of North Dakota state college of science accredited by the American Society of Health Systems Pharmacists (ASHP)/accreditation council for pharmacy education (ACPE). ~~or in an on-the-job self-instructional pharmacy technician study program under the supervision of a licensed pharmacist.~~ A Pharmacy Technician in Training, as they progress through their training program, may perform any of the duties of a registered pharmacy technician at the discretion of the pharmacist in charge and the pharmacist supervising their training program unless otherwise specified in the rules.

Pharmacist Tanya Schmidt suggested we remove the use of dashes between "technician in training" consistently throughout the rules. Board members agreed with this.

Alba Borici asked if the technician in training could be the original filler of the medication but not the final checker, Board members confirmed this to be the intention of the rule change.

Technician Diane Halvorson indicated that the Northland Association of Pharmacy Technicians would be supportive of these changes. Mike Schwab of NDPhA suggested we add "in the rules" to avoid confusion about the language "unless otherwise specified".

It was moved by Public Member Ron Horner and seconded by Pharmacist Tyler Lannoye to approve the changes in 61-02-07.1 Pharmacy Technician, based on the comments received and the clarifying language from Mike Schwab. On vote by roll call Public Member Ron Horner -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Carolyn Bodell -Aye- Pharmacist Tanya Schmidt -Aye- Technician Diane Halvorson -Aye-. The motion carried.

61-03-01 Licensure of Pharmacists

In subsection 01, Technician Diane Halvorson suggested an edit to last sentence for clarity. All Board members agreed.

All applications must be accompanied by affidavits from former employers of graduation and hours of internship, showing that the applicant has met the requirements had the experience required under a licensed pharmacist, as required by of North Dakota Century Code section 43-15-15.

In subsection 02, Dr Hardy recommended deleting the requirement for the school to be a member of the American Association of Colleges of Pharmacy. Board members agreed.

All colleges of pharmacy which are members of the American association of colleges of pharmacy or maintain standards equivalent to those required for membership in that association, and have been accredited by the accreditation council for pharmacy education (ACPE).

Pharmacist Carolyn Bodell recommended deleting the 'or reciprocity' in subsection 04.

Technician Diane Halvorson recommended grammatic changes in (4) (C) of subsection 4. Board members agreed with both.

There were no written comments received during the open comment period.

It was moved by Pharmacist Tanya Schmidt and seconded by Pharmacist Carolyn Bodell to approve the changes in 61-03-01 Licensure of Pharmacists based on the comments received. On vote by roll call Public Member Ron Horner -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Carolyn Bodell -Aye- Pharmacist Tanya Schmidt -Aye- Technician Diane Halvorson -Aye-. The motion carried.

61-04-10 CLIA Waived Laboratory Tests

Board members all agreed that there is no reason that we should require notification to the Board of Pharmacy when a pharmacy is engaging in CLIA waived testing and agreed to eliminate that section. (61-04-10-05)

There were no written comments received during the open comment period.

It was moved by Pharmacist Tanya Schmidt and seconded by Pharmacist Tyler Lannoye to approve the changes in 61-04-10 CLIA Waived Laboratory Tests based on the comments received. On vote by roll call Public Member Ron Horner -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Carolyn Bodell -Aye- Pharmacist Tanya Schmidt -Aye- Technician Diane Halvorson -Aye-. The motion carried.

61-04-12 Limited Prescriptive Authority for Naloxone-

There were no comments offered on this proposed rule change at the hearing.

There were no written comments received during the open comment period.

It was moved by Pharmacist Tanya Schmidt and seconded by Pharmacist Tyler Lannoye to approve 61-04-12 Limited Prescriptive Authority for Naloxone as originally proposed. On vote by roll call Public Member Ron Horner -Aye- Pharmacist Tyler Lannoye -Aye- pharmacist Carolyn Bodell -Aye- pharmacist Tanya Schmidt -Aye- technician Diane Halvorson -Aye-. The motion carried.

At 11 AM Candidate Russell Janssen joined the Board in person and the Board began prepping him for the North Dakota pharmacist licensure exam.

The Board broke for lunch while candidate Janssen continued with the exam. They finished the exam.

Briana Fluhrer Pharm D of Gateway Pharmacy joined the Board in person to discuss the Gateway Pharmacy proposal for a central fill site at 1838 E Interstate Ave Suite C. to serve their four locations in Bismarck-Mandan. Discussion ensued, policies were suggested, advice was given and Dr. Fluhrer was invited to make a license application to the board.

Dr. Hardy presented a revised reinstatement application based on the newly adopted rule. All agreed it was proper to utilize.

Dr. Hardy reviewed the FDA advisory for delay in enforcement of the new Drug Supply Chain Security Act (DSCSA). He does plan to have the inspectors discuss the upcoming FDA implementation at their visits this year, so pharmacies are prepared for final implementation.

Dr. Hardy discussed the Attorney General training to be held this November and invited any board member wishing to attend to make it known to him and he will put them on the list.

Foreign Graduate licensing procedures were discussed. We are getting more inquiries, likely due to the workforce shortage, seeking licensure in North Dakota. We want to be sure the individuals have adequate education to allow them to sit for the exams before granting them an intern license, and we need to be sure they are eligible before granting licensure.

Dr. Hardy reported that the inspectors are out working. Bonnie Thom has asked to retire as her husband is also retiring from farming. Tom Simmer, R.Ph. has been hired to replace Bonnie and is working in the western part of the state.

Technician Diane Halvorson reported on the upcoming technician fall conference on September 30th, 2023. They have 72 registered attendees and 16 or 17 of them plan to take the specific immunization training.

Technician Diane Halvorson asked about our policy on when a student can obtain an intern license. The Board last clarified the requirement in 2019 to, after the first year of the pre-pharmacy program, but she wondered, with the changes in the school early admission policy, if we should look at it again. It was agreed to place it on the agenda for the January meeting when we have the representation, at the college, with the Board.

Dr. Hardy commented on the upcoming inspections, a process the office will use to find any deceased individuals, and the interim legislative committee agenda relative to pharmacy.

The proposed pharmacy technician project at NDSU was brought up. Northland Community College at East Grand Forks is looking to discontinue their program and we are at risk for not having a training program in that area. NDSU and NDSCS plan to meet again to explore some possible collaboration.

It was moved by Pharmacist Tanya Schmidt and seconded by Pharmacist Tyler Lannoye to approve all legal actions of the Executive Director. On vote by roll call Public Member Ron Horner -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Carolyn Bodell -Aye- Pharmacist Tanya Schmidt -Aye- Technician Diane Halvorson -Aye-. The motion carried.

Dr. Hardy reviewed the financials. He reported on some money he has placed in CDs to take advantage of the high short-term interest rate. He also discussed his ongoing inquiry into a scholarship or loan repayment program for those returning to or agreeing to stay and work in North Dakota.

It was moved by Pharmacist Tyler Lannoye and seconded by Pharmacist Tanya Schmidt to approve the financial reports as presented and noted there were no journal entries to consider. On vote by roll call Public Member Ron Horner -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Carolyn Bodell -Aye- Pharmacist Tanya Schmidt -Aye- Technician Diane Halvorson -Aye-. The motion carried.

It was moved by Public Member Ron Horner and seconded by Pharmacist Carolyn Bodell to adjourn the meeting. On voice vote all present voted aye and Senior Member Diane Halvorson adjourned the meeting at 3 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