

A G E N D A - July 20, 2023
NORTH DAKOTA STATE BOARD OF PHARMACY
1838 E Interstate Ave Suite D – Conference Room – Bismarck, ND

Join Zoom Meeting: <https://us02web.zoom.us/j/86445335392>

THURSDAY – JULY 20, 2023

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

Recite: Mission Statement

Review and approval of agenda **AGENDA**

Review and approval of Minutes of May 16-17, 2023 **Minutes**

Sign Pharmacist and RPhTech Original Licenses

10:15 AM Public Rule Hearing **TAB 1**

- 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

11:30 AM Thrifty White LTC On Call Options Jeff Shorten, PharmD **TAB 2**

Exam Schedule - **Candidates**

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

Discussion Items: Scope of practice of a licensed intern **TAB 3**

 District V Annual Meeting – Medora, ND – August 9-11, 2023 **TAB 4**

 PDMP Usage

 DSCSA

 CE Audit Report

Board Member Reports

Executive Director’s Report

Consider approval of all legal action of the Executive Director

Year to date Financials **Budget Tab**

Vouchers – Adjourn

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President Shane Wendel, PharmD called the Board Meeting to order at 9:30 AM on Thursday July 20, 2023.

Present in the Room were Executive Director Mark J Hardy, PharmD, President; Shane Wendel, PharmD; Steven Irsfeld, RPh; Technician Member Diane Halvorson, RPhTech; Tanya Schmidt, PharmD; Carolyn Bodell, RPh. Public Member Ron Horner; Tyler Lannoye, PharmD; Howard C Anderson Jr RPh, Kpah C. Matadi, Intern #298 on rotation with Shane Wendel, Pharm D and NDSU PharmD Student Charles [Marcus] Tademy on rotation with the Board;

Present on Zoom: S. Botnick representing Wedgewood Pharmacy in New Jersey, Alba Borici a Purdue University student and Danielle DiCiolla representing Cardinal Health. There were two others who did not wish to identify themselves for the record.

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 Tanya Schmidt and seconded by Technician Diane Halvorson to approve the agenda with the additions of discussion on the PDMP usage by pharmacists, the DSCSA taking effect this fall, and a report on the CE audits. On vote by roll call Pharmacist Tanya Schmidt -Aye- Pharmacist Tyler Lannoye-Aye-Pharmacist Carolyn Bodell-Aye-Public member Ron Horner -Aye- Technician Diane Halvorson -Aye- Pharmacist Steve Irsfeld- Aye- Pharmacist Shane Wendel -Aye- The motion carried.

It was moved by Pharmacist Carolyn Bodell and seconded by Technician Diane Halvorson to approve the Minutes of the May 15-17, 2023 meeting, as printed. On vote by roll call Pharmacist Tanya Schmidt -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Carolyn Bodell -Aye- Public Member Ron Horner -Aye- Technician Diane Halvorson -Aye- Pharmacist Steve Irsfeld-Aye- Pharmacist Shane Wendel -Aye- The motion carried.

The template signatures used on the license and registration certificates were reviewed. All board members thought this a good method for getting signed certificates to licensees and registrants in a timely manner.

Pharmacist Carolyn Bodell asked about the PDMP review required of the pharmacists who filled the prescriptions written by the two Nurse Practitioners who lost their licenses for over prescribing of controlled substances. Dr. Hardy said he had looked at the case when it was before the Board of Nursing and although there may have been some concerns in decisions, he could see nothing that warranted a disciplinary matter.

Intern Marcus Tademy reviewed the continuing education audits he has assisted with. He indicated CE audits were conducted by two PharmD students for the two-year period from March 1st, 2021 to March 1st, 2023; one audit for registered pharmacists and one audit for registered pharmacy

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technicians. A total of 67 pharmacists were audited and 63 of those were found to be compliant, while four were initially found to be non-compliant. Upon follow-up with the four non-compliant pharmacists, three were found to be short hours and one was able to provide proof of compliance. This audit is considered complete, and no further follow-up is warranted.

A total of 46 pharmacy technicians were audited and 41 of those were found to be compliant, while five were initially found to be non-compliant. Upon follow-up, two technicians have responded with proof of CE hours completion, one responded without enough hours and has paid a fine, and we are awaiting responses from the final two technicians. This audit remains open, pending the responses from the two technicians.

Board members expressed a desire to deviate from the previous process of a prorated fine, according to credits short, to a flat fine for any noncompliance which currently would be \$250 for a technician and \$500 for a pharmacist. They also directed Executive Director Hardy to require remediation credits for any individual determined to be short within a reasonable time with any administrative resolution. They agreed with the approach to offer the opportunity for a hearing if a licensee determined they wanted to go that route.

President Wendel opened the rule hearing at 11:15 AM.

I am Shane Wendel, President of the Board of Pharmacy and I will be acting as hearing officer for this public hearing.

It is now 11:15 AM on Thursday, July 20th 2023 in the Board Room at the Board of Pharmacy, 1838 E Interstate Avenue.

This public hearing has been called for the purpose of allowing all interested individuals an opportunity to submit information concerning:

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

The comments received at this hearing will be considered with any written comments that are received through August 4, 2023. Information gathered at this hearing will be used by the Board of Pharmacy for its deliberation and final decision.

The Executive Director of the Board of Pharmacy is taking minutes of this meeting; this hearing is being recorded, so please identify yourself for the record before you speak.

Everyone present will be given an opportunity to speak. If you have a prepared statement, a written copy of your statement is appreciated and will be helpful.

At this point, I open the hearing for comments.

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61-01-01 Organization of Board

There were no comments offered on this rule change.

61-02-01-03 Pharmaceutical compounding standards

There were no comments offered on this rule change.

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.

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 member 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.

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).~~

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Pharmacist Carolyn Bodell recommended to delete the 'or reciprocity' in subsection 04. Technician Diane Halvorson recommended grammatical changes in (4) (C) of subsection 4. Board members agreed with both.

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)

61-04-12 Limited Prescriptive Authority for Naloxone-

There were no comments offered on this proposed rule change.

Thank you all for coming. The Board of Pharmacy will use all of the information gathered at this hearing, in making their decision.

The record will be held open for written comment through August 4, 2023.

At this point, I will close the hearing on:

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

A registration sheet is being circulated; I ask that everyone present please sign this sheet before they leave.

Jeff Shorten, Pharm D, joined the board by Zoom to discuss the Thrifty White request for an On Call Option to use with Long Term Care Facilities when medication is needed after the provider pharmacy has closed for the day. He asked if a technician could go to the store, prepare the needed medication, have it approved by a pharmacist at a Minnesota 24-hour pharmacy and then be delivered to the LTC facility by the technician for administration by the nursing staff there.

Dr. Shorten was asked to prepare a written policy and procedure for review by the Board and consideration at their September meeting. Dr. Hardy stated it should include licensure of the participating pharmacists in North Dakota. He asked the write-up be received in time for him to have it considered by potential competitors before the September meeting. The Board will then consider whether it can be allowed as a pilot project or would need a potential change for consideration.

Candidates Chapleur Vang and Libby Wirth began the exam process which was administered during lunch. Both candidates passed the Board examinations.

The Scope of Practice of Pharmacy Interns was discussed. This centered around the tech check tech activity, considering whether the intern can be the final checker in this activity. The rules currently say

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the pharmacist must perform verification of the intern before the medication is dispensed. Otherwise, the intern can do whatever the pharmacist working with them authorizes them to do.

The Drug Supply Chain Security Act was discussed. It currently is scheduled to take effect in November of this year. There are many unanswered questions which NABP and the Boards are trying to answer. How will small manufacturers comply? How do you handle the merchandise if you buy an existing store? How are store to store transfers of merchandise to be accounted for? How are compounded products handled when transferred from a compounder to another store for final dispensing? How will product bought before the act takes effect to be accounted for?

Dr. Hardy and President Wendel reviewed the plans for the District V meeting August 9-11, 2023 hosted by North Dakota in Medora.

In the Board Member reports, Technician Diane Halvorson reported on her visit to the new Trinity Hospital facility in Minot. They seem to be fully staffed in the technician area, with some technicians in training, as well.

Technician Diane Halvorson also inquired about the status of the NDSU Technician In Training program. Dr. Hardy responded that the idea is going slow, with the need to address it with the Board of Higher Education.

Dr. Hardy reported on the new space and asked Board Members how they felt about the facility and if they had any suggestions for improvement. Signage was mentioned. The new signs are on order. A better microphone system in the conference room was suggested so Zoom participants can hear the board's conversations better.

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

It was moved by Technician Diane Halvorson and seconded by Pharmacist Carolyn Bodell to approve the financials and journal entries as presented. On vote by roll call Pharmacist Tanya Schmidt -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Carolyn Bodell -Aye- Public Member Ron Horner -Aye- Technician Diane Halvorson -Aye- Pharmacist Steve Irsfeld -Aye- Pharmacist Shane Wendel -Aye- The motion carried.

Dr. Hardy broached the topic of the board using the extra funds which might be built up to provide loan forgiveness for students staying in North Dakota. More research will be done on the idea.

President Wendel called for any further business. There being no further business forthcoming at 3:38 PM.

It was moved by Pharmacist Tanya Schmidt and seconded by Public Member Ron Horner to adjourn. The motion carried on a voice vote and the meeting was adjourned.

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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

