

A G E N D A
MAY 15-16-17, 2023

Monday – May 15, 2023 *Club House Hotel & Suites - 4400 15th Ave South – Regency 2 Room*
Fargo ND 58103 (1-701-282-5777)
<https://us02web.zoom.us/j/84019321848>

10:30AM - CALL TO ORDER – Steven Irsfeld, President

Recite: Mission Statement

Sign Original Certificates: RPh & Tech

Review and Approval of Agenda

Review & Approval of Meeting Minutes of: March 16, 2023

AGENDA TAB
MINUTE TAB

10:45 AM Progress report - Brayden Trontvet RPH6231

11:00 AM Kpah C Matadi – Intern Int398

Tab 1

Remodeling Plans: Velva Drug Phar523

Tab 2

Relocation: Medicine Shoppe Fargo Phar135

Tab 3

Lunch: Lucky 13's

Meeting dates 2023-2024 fiscal year

Tab 4

Discussion items: Administrative Rule Changes

Inspection cycle 2023-2024 – Focuses and Direction

District V Meeting

Legislative Update

*Portfolio Discussion

*Tech-in-Training Survey

*NABP Meeting Recap

Tab 5

Budget and Financials

BUDGET TAB

Executive Director Contract

Consider Approval of the actions of the Executive Director

Election of President for the July 1, 2023 – June 30, 2024 year

Appoint two Board Members to review: All paid expenses & Bank Account Reconciliations

Appoint Audit Committee and representative for PDMP Advisory Board

Investigational Committee case reviews

Review Candidate Files (53)

Candidate TAB

Review Intern Portfolios

Make final preparations for practical exam

Investigative Committee

**TUESDAY-MAY 16, 2023 EXAMINATION SCHEDULE - Sudro Hall/Aldevron Tower NDSU -
1401 Albrecht Boulevard Fargo, ND 58102**

ALL	7:45 – 8:15	AM	Roll Call and Orientation View Sterile Compounding Video	ALL Candidates	ROOM 27
	8:45 – 9:30	AM	Errors and Omissions	Section 1	Aldevron Room 350
	9:30 - 10:15	AM	Errors and Omissions	Section 2	Aldevron Room 350
	10:15– 11:00	AM	Errors and Omissions	Section 3	Aldevron Room 350
	8:30 – 9:30	AM	Laboratory	Section 1	Concept Pharmacy
	9:45 -10:45	AM	Laboratory	Section 2	Concept Pharmacy
	11:00 -12:00	AM	Laboratory	Section 3	Concept Pharmacy
	1:00 – 2:00	PM	Laboratory	Section 4	Concept Pharmacy
	2:15 – 3:15	PM	Laboratory	Section 5	Concept Pharmacy
	3:30 - 4:30	PM	Laboratory	Section 6	Concept Pharmacy

**WEDNESDAY - MAY 17, 2023 -ORAL EXAMINATION SCHEDULE- Club House Hotel & Suites - 4400 15th
Ave South Fargo ND 58103 (1-701-282-5777)**

8:20	AM	SECTION	1	To Room:	<u>Board Room</u>
8:40	AM	SECTION	2	To Room:	<u>Regency 2</u>
9:00	AM	SECTION	3	To Room:	<u>Regency 3</u>
9:20	AM	SECTION	4		
9:40	AM	SECTION	5		
10:00	AM	SECTION	6		
10:20	AM	SECTION	7		
10:40	AM	SECTION	8		
11:00	AM	SECTION	9		
1:00	PM	SECTION	10		
1:20	PM	SECTION	11		
1:40	PM	SECTION	12		
2:00	PM	SECTION	13		

Final Scoring of Exams
Approval of all Paid expenses
Other business
Complete Vouchers

ADJOURNMENT

President Steven Irsfeld, RPh called the Board Meeting to order at 10:30 AM on Monday May 15, 2023.

Present in the Room were Executive Director Mark J Hardy, PharmD, President Steven Irsfeld, RPh; Technician Member Diane Halvorson, RPhTech; Tanya Schmidt, PharmD; Carolyn Bodell, RPh. Public Member Ron Horner; Shane Wendel, PharmD; Tyler Lannoye, PharmD; Howard C Anderson Jr RPh and Attorney David A. Lindell, JD.; Karley Westra, Pharm D, doing a residency with Board member Tyler Lannoye, was in attendance.

Present on Zoom: None at the start of the meeting.

President Irsfeld 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 Technician Member Diane Halvorson and seconded by Pharmacist Tanya Schmidt to approve the Agenda with the addition of discussion of portfolio reviews, a report from Technician Member Halvorson on the Technician-in-Training Survey and NABP Meeting Recap. On vote by roll call Pharmacist Shane Wendel -Aye- Pharmacist Carolyn Bodell -Aye- Technician Diane Halvorson -Aye - Pharmacist Tyler Lannoye -Aye- Pharmacist Tanya Schmidt -Aye - Public Member Ron Horner -Aye-Pharmacist Steve Irsfeld -Aye- Nays none. The motion carried.

It was moved by Pharmacist Tanya Schmidt and seconded by Pharmacist Shane Wendel to approve the Minutes of the March 16, 2023 meeting, as printed. On vote by roll call Pharmacist Shane Wendel -Aye- Pharmacist Carolyn Bodell -Aye- Technician Diane Halvorson -Aye - Pharmacist Tyler Lannoye -Aye- Pharmacist Tanya Schmidt -Aye - Public Member Ron Horner -Aye-Pharmacist Steve Irsfeld -Aye- Nays none. The motion carried.

Executive Director Hardy brought up a picture of a license using electronic signatures. Discussion followed with the Board Members seeming to be comfortable with either signing in person or using electronic signatures.

At 10:45 AM Brayden Trontvet, Pharm D, RPh6231, joined the Board Meeting via Zoom to report to the Board on his progress since being before the Board. He is now employed at Wall's Long Term Care Pharmacy in Grand Forks. A note to Executive Director Hardy from PharmAssist Committee Member Tim Carlson RPh. confirmed he is doing well. President Irsfeld, on behalf of the Board of Pharmacy, wished him continued success.

The visit with Dr. Trontvet reminded Board Member Halvorson of the session at the recent NABP Annual meeting stressing a "*just culture*" in disciplinary matters. She said we always need to balance that with the protection of the public. She suggested an expert, perhaps from our PharmAssist Committee, come and discuss with the Board at a future meeting.

Kpah C. Matadi Int398 3rd Year in the NDSU PharmD Program appeared before the Board to discuss the DUI he received in November of 2022. After taking three shots of an alcoholic

beverage, he went to drive home and was picked up for DUI. He has completed the court ordered activities and met with the PharmAssist Committee. PharmAssist Committee Member Kelly Brodsho, PharmD is with him today and reports he is doing well. He has met with Dr. Friesner at the college, as well.

It was moved by Technician Diane Halvorson and seconded by pharmacist Tyler Lannoye to take no further action against the intern license of Kpah C. Matadi. On vote by roll call Pharmacist Shane Wendel -Aye- Pharmacist Carolyn Bodell -Aye- Technician Diane Halvorson -Aye - Pharmacist Tyler Lannoye -Aye- Pharmacist Tanya Schmidt -Aye - Public Member Ron Horner -Aye-Pharmacist Steve Irsfeld -Aye- Nays none. The motion carried.

It was moved by Technician Member Diane Halvorson and seconded by Pharmacist Carolyn Bodell to approve the remodeling plans for Velva Drug Company Phar523, located at 16 Main St. N, in Velva ND 58790. On vote by roll call Pharmacist Shane Wendel -Aye- Pharmacist Carolyn Bodell -Aye- Technician Diane Halvorson -Aye - Pharmacist Tyler Lannoye -Aye- Pharmacist Tanya Schmidt -Aye - Public Member Ron Horner -Aye-Pharmacist Steve Irsfeld -Aye- Nays none. The motion carried.

It was moved by Pharmacist Tanya Schmidt and seconded by Pharmacist Tyler Lannoye to approve the plans, lease and relocation of The Medicine Shoppe Fargo, Phar135 from 1605 South University Drive to a new location at 2301 South University Drive. On vote by roll call Pharmacist Shane Wendel -Aye- Pharmacist Carolyn Bodell -Aye- Technician Diane Halvorson -Aye - Pharmacist Tyler Lannoye -Aye- Pharmacist Tanya Schmidt -Aye - Public Member Ron Horner -Aye-Pharmacist Steve Irsfeld -Aye- Nays none. The motion carried.

The Board Members went to Lucky 13 for lunch, returning at 1 PM.

Dr. Elizabeth Skoy and Gayle Ziegler, RPh, Board Compliance Officer/Inspector, joined the board at 1 PM.

Dr. Skoy asked about the scope of a Registered Pharmacy Technician in collecting and processing CLIA waived samples for laboratory tests. After discussion, the board felt that a rule change to clearly outline the technician’s ability to assist an authorized pharmacist would be necessary. Board members directed a rule change be proposed by Executive Director Hardy in consultation with Dr. Skoy.

It was moved by Technician Member Halvorson and seconded by Pharmacist Tanya Schmidt to approve the meeting dates for 2024 as:

January 10-12, 2024	<i>Club House Hotel & Suites</i>	Fargo	If Requested
March 21, 2024	Board Office	Bismarck	If Requested
May 20-22, 2024	<i>Club House Hotel & Suites</i>	Fargo	May 21-22, 2024
July 18, 2024	Board Office	Bismarck	If Requested
September 19, 2024	Board Office	Bismarck	If Requested
November 21, 2024	Board Office	Bismarck	If Requested

On vote by roll call Pharmacist Shane Wendel -Aye- Pharmacist Carolyn Bodell -Aye- Technician Diane Halvorson -Aye - Pharmacist Tyler Lannoye -Aye- Pharmacist Tanya Schmidt -Aye - Public Member Ron Horner -Aye-Pharmacist Steve Irsfeld -Aye- Nays none. The motion carried.

A Representative from Cardinal Health joined the meeting via Zoom.

Executive Director Hardy reviewed drafts of potential rule changes for comments by Board Members and interested parties, as follows:

61-01-01 Organization of Board-Revising the Board’s purpose and contact information

61-02-01-03 Pharmaceutical compounding standards-Update to adopt revised USP 795 & 797 chapters

61002-07.1 Pharmacy Technician-revisions to tech-check-tech, posting of registration and reinstatement process for technicians.

61-03-01 Licensure of Pharmacists-Create Canadian license transfer process and posting of registration

61-04-10 CLIA Waived Laboratory Tests-Changes per previous discussion to allow delegation to Registered Pharmacy Technicians.

61-04-12 Limited Prescriptive Authority for Naloxone-Make section product agnostic.

Dr. Hardy explained these potential changes may go to a hearing in July and comments would be requested at that time.

Executive Director Hardy asked if there was interest in moving to prescriptive authority for buprenorphine and there did not seem to be interest at this time.

It was suggested that an Agenda item for the July 20th, 2023 Meeting should be a “*scope of practice of a licensed intern*”.

Compliance Officer Gayle Ziegler, RPh participated with the Board in a discussion of the upcoming inspection cycle and the focus of those inspections.

Board Minutes suggested that the focuses of this year’s inspection be:

- The Drug Supply Chain Security Act (DSCSA) Ask pharmacies how they would respond to a suspect product investigation.
- The new USP 797 and 795 standards and the changes they will require for compounders.
- Continued focus on counseling especially on new prescriptions. Warning notices need to be written for those clearly out of compliance.
- Continuous Quality Improvement (CQI) policies. How the quality related events are recorded and analyzed for improvement.

Compliance Officer Ziegler suggested we modify our question on the self-inspection form to clearly ask how you identify and prevent internal diversion.

It was moved by Pharmacist Lannoye and seconded by Pharmacist Schmidt to discontinue portfolio reviews as part of the Board Exam for the next year. On vote by roll call Pharmacist Shane Wendel -Aye- Pharmacist Carolyn Bodell -Aye- Technician Diane Halvorson -Aye -

Pharmacist Tyler Lannoye -Aye- Pharmacist Tanya Schmidt -Aye - Public Member Ron Horner -Aye-Pharmacist Steve Irsfeld -Aye- Nays none. The motion carried.

Dr. Hardy reviewed the plans for the upcoming District V NABP/AACP meeting in Medora. He encouraged everyone to secure their room reservations as the block may fill up soon.

Technician Diane Halvorson reviewed the recently completed NAPT Survey about Technician-in-Training employment needs.

The recent NABP meeting was discussed by those attending. It was a very good meeting with some timely and important topics discussed by experts.

It was moved by Pharmacist Tanya Schmidt and seconded by Pharmacist Carolyn Bodell to approve the balance sheet and financials as presented and recognize there were no journal entries. On vote by roll call Pharmacist Shane Wendel -Aye- Pharmacist Carolyn Bodell -Aye- Technician Diane Halvorson -Aye - Pharmacist Tyler Lannoye -Aye- Pharmacist Tanya Schmidt -Aye - Public Member Ron Horner -Aye-Pharmacist Steve Irsfeld -Aye- Nays none. The motion carried.

It was moved by Pharmacist Shane Wendel and seconded by Technician Diane Halvorson to approve the 2023-2024 budget as presented. On vote by roll call Pharmacist Shane Wendel -Aye- Pharmacist Carolyn Bodell -Aye- Technician Diane Halvorson -Aye - Pharmacist Tyler Lannoye -Aye- Pharmacist Tanya Schmidt -Aye - Public Member Ron Horner -Aye-Pharmacist Steve Irsfeld -Aye- Nays none. The motion carried.

It was moved by Technician Diane Halvorson and seconded by Pharmacist Tanya Schmidt to approve the contract with Dr. Mark Hardy, as Executive Director for the upcoming year. On vote by roll call Pharmacist Shane Wendel -Aye- Pharmacist Carolyn Bodell -Aye- Technician Diane Halvorson -Aye - Pharmacist Tyler Lannoye -Aye- Pharmacist Tanya Schmidt -Aye - Public Member Ron Horner -Aye-Pharmacist Steve Irsfeld -Aye- Nays none. The motion carried.

It was moved by Pharmacist Shane Wendel and seconded by Pharmacist Tyler Lannoye to approve all of the legal actions of the Executive Director since this was last done. On vote by roll call Pharmacist Shane Wendel -Aye- Pharmacist Carolyn Bodell -Aye- Technician Diane Halvorson -Aye - Pharmacist Tyler Lannoye -Aye- Pharmacist Tanya Schmidt -Aye - Public Member Ron Horner -Aye-Pharmacist Steve Irsfeld -Aye- Nays none. The motion carried.

President Irsfeld opened nominations for Board President for the upcoming term. Pharmacist Tanya Schmidt, Pharmacist Carolyn Bodell and Pharmacist Shane Wendel were nominated. On the third ballot Pharmacist Shane Wendel was declared the President for the 2023-2024 Board year.

President Irsfeld appointed Pharmacist Tanya Schmidt and Pharmacist Carolyn Bodell to review all paid expenses and bank account reconciliations.

President Irsfeld appointed Technician Diane Halvorson and Pharmacist Tanya Schmidt to the Audit Committee.

President Irsfeld appointed Pharmacist Tyler Lannoye to serve as the Board representative on the Prescription Drug Monitoring Program Advisory Committee.

Public Member Ron Horner, Attorney David Lindell, Senior Compliance Officer Howard C Anderson and Executive Director Hardy separated themselves to serve as an Investigating Committee to review complaints.

The Board Members then reviewed 52 candidate files, for the next two days of examinations and made final preparations for the exams in a working dinner.

The Board Members met at NDSU Sudro Hall/Aldevron Tower NDSU, 1401 Albrecht Boulevard, Fargo ND at 7:30 AM on May 16th to begin the exam process for the candidates.

The Board Concluded the oral exams Wednesday May 17th. President Irsfeld called for any further business. There being no further business forthcoming and the meeting was adjourned at 3:15 PM.

President
Steven P Irsfeld, RPh

Technician Member & Senior Member
Diane M. Halvorson, RPhTech

Member
Tyler G Lannoye, PharmD

Member
Tanya L Schmidt, PharmD

Member
Shane R. Wendel, PharmD

Public Member
Ron J Horner

Member
Carolyn R Bodell, RPh

Executive Director
Mark J. Hardy, PharmD