

A G E N D A
MAY 17-18-19, 2021

Monday – May 17, 2021 WINGATE INN 4429 19th Ave S - Fargo ND 58103
Meadowlark Room (1-701-281-9133)

Zoom Link - <https://us02web.zoom.us/j/87412578984>

10:30AM - Call to Order – Gayle Ziegler, RPh - President

Recite: Mission Statement

Sign Original Certificates: RPh & Tech

Review and Approval of Agenda

AGENDA TAB

Review & Approval of Meeting Minutes of: March 18, 2021

MINUTE TAB

10:45 Tristan Houle NDSU Intern
Steven P Kawulok, RPh5533

11:30 Loren M Podoll RPh5192 Reinstatement

Tab 1

Review Stipulated Agreement: Morgan C Wampler, RPhTech Tech1658

Tab 2

Remodel - Relocation Plans: Valley View Pharmacy Phar645 Bismarck

Meeting dates 2021-2022 fiscal year

Tab 3

Lunch: Lucky 13's

Proposed Rule Changes and New Rules

Tab 4

61-02-07.1 (13) Pharmacy Technician Registration Requirements

61-03-01-04 Licensure Transfer

61-04-04-01 (22) Definition of unprofessional conduct

61-04-11 Administration of Medications and Immunizations [Pharmacy Technicians]

61-04-14 Limited Prescription Authority For Immunization

61-04-15 Limited Prescription Authority For Tobacco Cessation

Discussion items: Inspection cycle 2021-2022 – Focuses and Direction
Update on PCMA vs Tufto [potential Executive Session]
Recap of 2021 Legislative Session
FDA Compounding Memorandum of Understanding

Budget and Financials

BUDGET TAB

Executive Director Contract

Consider Approval of the actions of the Executive Director

Election of President for the July 1, 2021 – June 30, 2022 year

Appoint two Board Members to review:

All paid expenses.

Review Bank Account Reconciliations

Appoint Audit Committee and representative for PDMP Advisory Board
Investigational Committee case reviews

Review Candidate Files = **58**

Candidate TAB

Review Intern Portfolios

Make final preparations for tomorrows exams

TUESDAY-MAY 18, 2021 EXAMINATION SCHEDULE - Sudro Hall NDSU

ALL	7:15 - 7:45	AM	Roll Call and Orientation	ALL Candidates	ROOM 24
			View Sterile Compounding Video		
	8:00 - 9:00	AM	Laboratory	Section 1	Concept Pharmacy
	8:15 - 9:00	AM	Errors and Omissions	Section 1	Room 21
	9:00 - 9:45	AM	Errors and Omissions	Section 2	Room 21
	9:45 - 10:30	AM	Errors and Omissions	Section 3	Room 21
	10:30 -11:15	AM	Errors and Omissions	Section 4	Room 21
	9:15 -10:15	AM	Laboratory	Section 2	Concept Pharmacy
	10:30 -11:30	AM	Laboratory	Section 3	Concept Pharmacy
	12:30 - 1:30	PM	Laboratory	Section 4	Concept Pharmacy
	1:45 - 2:45	PM	Laboratory	Section 5	Concept Pharmacy
	3:00 - 4:00	PM	Laboratory	Section 6	Concept Pharmacy
	4:15 - 5:15	PM	Laboratory	Section 7	Concept Pharmacy

WEDNESDAY - MAY 19, 2021 -ORAL EXAMINATION SCHEDULE- Wingate Inn - 4429 19th Ave S
701- 281-9133

8:20	AM	SECTION	1	To Room:	<u>Board Room</u>
8:40	AM	SECTION	2	To Room:	<u>Flickertail</u>
9:00	AM	SECTION	3	To Room:	<u>Meadowlark Room</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		
11:20	AM	SECTION	10		
1:20	PM	SECTION	11		
1:40	PM	SECTION	12		
2:00	PM	SECTION	13		
2:20	PM	SECTION	14		
2:40	PM	SECTION	15		
3:00	PM	SECTION	16		

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

ADJOURNMENT

President Gayle D Ziegler, RPh called the meeting to order on Monday May 17, 2021 at 10:30 AM.

Present at the Wingate in the Meadowlark Room were:

President Gayle D Ziegler, RPh, Board Members; Diane M. Halvorson, Technician Member; Shane Wendel, PharmD; Tyler Lannoye, PharmD; Executive Director Mark J Hardy, PharmD, and Howard C Anderson, Jr, RPh, Senior Compliance Officer. Also present was Pharmacist Lance LeClair.

Present on the Zoom Meeting were: Steven Irsfeld, RPh and David A. Lindell, JD, Board Attorney - John Long R Ph. representing CVS was present remotely.

Absent: Tanya Schmidt, PharmD who arrived after lunch and Fran Gronberg, Public Member, who has not been reappointed by the Governor.

President Ziegler 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 Tyler Lannoye to approve the agenda as printed. On voice vote all present voted aye. The motion carried.

It was moved by Pharmacist Shane Wendel and seconded by Pharmacist Steve Irsfeld to approve the minutes of March 18, 2021 meeting as printed. On voice vote all present voted aye. The motion carried.

Tristan Houle NDSU P1 Int383, having recently become a P2 intern joined the Board along with Kelly Brodsho and Agnes Harrington of the PharmAssist Committee. Intern Houle explained he received a DUI citation and he was charged with a Class B Misdemeanor for actual physical control due to sitting in his car while it was running, on March 7th, 2020. He has completed his required evaluation, 20 hours of community service and has met with Agnes Harrington several times and attended a couple of AA meetings. Ms. Harrington and Pharmacist Brodsho voiced no concerns about Intern Houle as this time.

Diane Halvorson stated, "you showed the critical thinking we are looking for by not driving and trying to contact someone to drive you home". The Board encouraged Intern Houle to share his story with other students to help them avoid similar situations.

It was moved by Technician Member Diane Halvorson and seconded by Pharmacist Shane Wendel to take no further action against the intern license of Tristan Houle, NDSU P2 Int383 at this time. On vote by roll call Pharmacist Steve Irsfeld -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Shane Wendel -Aye- Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

Steven P. Kawulok, RPh5533 discussed with the Board his DUI and disturbing the peace citation he received in October of 2020. He admittedly drank too much, drove home and was arrested in his driveway where he resisted the officer and thus the charge was filed. He has been meeting with Agnes Harrington and Kelly Brodsho of the PharmAssist Committee. He is thinking of attending a BE (Beginning Experience) group. Ms Harrington and Pharmacist Brodsho expressed no concerns with him at this time.

It was moved by Technician Member Diane Halvorson and seconded by Pharmacist Tyler Lannoye to take no further action against the license of Steven P. Kawulok, RPh5533. On vote by roll call Pharmacist Steve Irsfeld -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Shane Wendel -Aye- Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

It was moved by Technician Member Diane Halvorson and seconded by Pharmacist Tyler Lannoye to approve the stipulated agreement with Morgan C. Wampler, RPhTech-Tech1658 as presented by Dr. Hardy and Attorney David Lindell JD. On vote by roll call Pharmacist Steve Irsfeld -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Shane Wendel -Aye- Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

The request for reinstatement of Pharmacist Loren M. Podoll, RPh5192 was reviewed by Dr. Hardy. Pharmacist Podoll had some actions against him in Oregon related to his work as Pharmacist-in-Charge of a CVS Pharmacy in Oregon. Pharmacist Podoll is a 2008 graduate of NDSU and wishes to reinstate his North Dakota Pharmacist License to work remotely with patients.

It was moved by Pharmacist Tyler Lannoye and seconded by Pharmacist Steve Irsfeld to approve the reinstatement of Pharmacist Loren M. Podoll, RPh5192. On vote by roll call Pharmacist Steve Irsfeld -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Shane Wendel -Aye- Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

Board Members reviewed the plans for relocation of Valley View Pharmacy Phar645 currently located at 2425 Hillview Ave in Bismarck. Daniel Churchill, PharmD was contacted by telephone and answered questions from Board Members relative to the sterile compounding anticipated at the pharmacy. It being a Long-Term-Care pharmacy, only compounding for immediate use is anticipated.

It was moved by Pharmacist Shane Wendel and seconded by Pharmacist Tyler Lannoye to approve the floor plans for the new location of Valley View Pharmacy Phar645 as presented. On vote by roll call Pharmacist Steve Irsfeld -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Shane Wendel -Aye- Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

The Board discussed the schedule of meetings for 2022 and decided to think about it over lunch. The Board broke for lunch at Lucky 13's.

Pharmacist Tanya Schmidt joined the meeting at 1:45 PM after their lunch break.

It was moved by Pharmacist Steve Irsfeld and seconded by Pharmacist Tanya Schmidt to approve the 2022 schedule of meetings as printed and presented by Dr. Hardy. On vote by roll call Pharmacist Steve Irsfeld -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tanya Schmidt -Aye Pharmacist Tyler Lannoye -Aye- Pharmacist Shane Wendel -Aye- Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

2022 Meeting Dates**EXAMS**

January 12-14 , 2022	Wingate by Wyndam	Fargo, ND	If Requested
March 17, 2022	Board Office	Bismarck, ND	If Requested
NABP is May 19-21, 2022	AZ	No Exams	
<i>Graduation is: <u>May 13th</u></i>			
May 16-18, 2022	Wingate by Wyndam	Fargo, ND	May 17- 18, 2020
July 21, 2022	Board Office	Bismarck	If Requested
September 15, 2022	Board Office	Bismarck	If Requested
November 17, 2022	Board Office	Bismarck	If Requested

Proposed Rule Changes and New Rules were reviewed by Dr. Hardy and discussed by the board.

61-02-07.1 (13) Pharmacy Technician Registration Requirements - This change is to come into compliance with recently passed legislation, Senate Bill 2175, to allow members of the military to receive a provisional registration.

61-03-01-04 Licensure Transfer

This change is to come into compliance with recently passed legislation, Senate Bill 2175, to allow members of the military to receive a provisional license.

61-04-04-01 (22) Definition of unprofessional conduct

Lance LeClair RPh5751 was present and discussed his pharmacy's perspective on the proposed addition. He is Pharmacist-In-Charge at Phar567 LifeScript Pharmacy PLLC in Fargo which does extensive marketing to potential patients. Pharmacist LeClair indicated they have changed processes on marketing due to concerns raised by complaints.

Pharmacist LeClair stated - *"Now when a consumer responds to an advertisement, he/she is called by a marketer. If the consumer expresses interest s/he is referred to a pharmacist. The pharmacist reaches out to the now patient and determines if a prescription might help the patient's stated health condition. If deemed appropriate by the pharmacist, the pharmacist reaches out to the patient's provider with a suggestion for a prescription to help the patient. If the prescriber responds with a prescription, it is filled and sent out to the patient by the pharmacy. A confirmation call is made to the patient before shipping of the medication."*

It was noted that the Board experiences many complaints from the public and health professionals with concerning marketing strategies.

Upon questioning by the Board, Board Members directed Executive Hardy to revise the language to make it clear what the Board expects to happen by pharmacists in these cases to assure good patient care.

61-04-11 Administration of Medications and Immunizations [Pharmacy Technicians]

This new section would implement Senate Bill 2279 and provide the framework for Registered Pharmacy Technicians to assist the Pharmacist in administering immunizations. Board Members deliberated on the desire of the Board to allow for remote supervision of administrations by Technicians, as well as allowing Registered Pharmacy Technicians to administer other injections under the approval of the Pharmacist. They directed Executive Director Hardy to broaden the ability to include other medications, given subcutaneously or intramuscularly, as Technician Member Halvorson stated - *"training is provided in the Educational Programs for Technicians"*.

61-04-14 Limited Prescription Authority for Immunization

Executive Director Hardy explained the framework of implementation of the ability of Pharmacists to have limited prescriptive authority for immunizations, in compliance with Senate Bill 2221, Pharmacists to have limited prescriptive authority for immunizations. Pharmacists are now allowed to order and administer immunizations for individuals older than three years of age. He explained the approach in the rule, indicating that he had researched the states that have implemented this ability and followed a model similar to Iowa. This would allow the Board to set forth the parameters for the standard of care in a rule and further develop a statewide protocol that would explicitly outline the process for pharmacists to follow. This protocol would have to be updated on a regular basis. Executive Director Hardy indicated a desire to leverage professionals and experts within the NDSU School of Pharmacy, to assist the Board in developing the protocol. All Board Members present approved of this approach.

61-04-15 Limited Prescription Authority for Tobacco Cessation

Executive Director Hardy walked through the proposed rule for limited prescriptive authority for tobacco cessation, similar to the immunization authority. The parameters are set forth in the rule and a defined specific statewide protocol would be developed. Again, we hope for the assistance of the experts within NDSU School of Pharmacy and other tobacco cessation experts in developing this protocol for the Board to consider and approve.

The Board Members then discussed the Inspection cycle 2021-2022 and set the following focuses:

- Review of how the pharmacy conducts their own controlled substance audits
- The technician's role in a pharmacy.
- Proper identification of professionals in the pharmacy and on phone calls.

Dr. Hardy provided an update on PCMA vs Tuft. The case has been remanded to the 8th circuit. We have gotten the first brief filled by PCMA and are in process of developing the State's brief.

Executive Director Hardy recapped the 2021 Legislative Session. Overall, the session was positive for the profession of pharmacy, with some practice related legislation being broadly supported, approved and signed into law. On the drug pricing front, there will be a drug pricing study moving forward in the interim, studying various initiatives that had been considered by the legislative body, as well as a deeper dive into PBM impacts on drug pricing. He indicated that the drug price transparency bill did pass, that will cause the Insurance Commissioner to implement this information collection. The Board of Pharmacy will be required to raise the fees on certain Wholesale Licenses, up to \$1,000 fee for the 2022 licensure and renewal cycle with \$600 of that going to the State Treasurer for use by the Insurance Commissioner in implementing this legislation. He expressed a concern to the Board Members of the fiscal impact that may result on existing licenses based on those that will drop their licenses. Therefore, the Board will need to consider the financial impact this may have going forward.

The Board discussed the FDA Compounding Memorandum of Understanding, based on information that had been provided at the NABP Virtual Annual Meeting. It was noted that so far only one state had signed the MOU, with a deadline of October for states to sign. NABP has requested for the deadline to be extended out. We will continue the discussion at the future meetings.

It was moved by Pharmacist Tanya Schmidt and seconded by Technician Member Diane Halvorson to approve the 2021-2022 budget and the Executive Director Contract as presented. On vote by roll call Pharmacist Steve Irsfeld -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tanya Schmidt -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Shane Wendel -Aye- Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

There were no Journal entries to review.

It was moved by Pharmacist Shane Wendel and seconded by Technician Member Diane Halvorson to expand the authority of NDSU School of Pharmacy to use the \$20,000 support granted last year to request the School to assist the Board with the development of prescriptive authority protocols. On vote by roll call Pharmacist Steve Irsfeld -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tanya Schmidt -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Shane Wendel -Aye- Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

It was moved by Technician Member Diane Halvorson and seconded by Pharmacist Tanya Schmidt to approve all legal actions of the Executive Director since the last such action. On vote by roll call Pharmacist Steve Irsfeld -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tanya Schmidt -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Shane Wendel -Aye- Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

It was moved by Technician Member Diane Halvorson and seconded by Pharmacist Tyler Lannoye to approve the financial report and balance sheet as presented. On vote by roll call Pharmacist Steve Irsfeld -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tanya Schmidt -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Shane Wendel -Aye- Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

President Ziegler opened nominations for President of the Board for the 2021-2022 year. Pharmacist Tyler Lannoye was nominated by Pharmacist Steve Irsfeld.

It was moved by Pharmacist Steve Irsfeld and seconded by Pharmacist Shane Wendel to cease nominations and cast a unanimous ballot for Pharmacist Tyler Lannoye. On vote by roll call Pharmacist Steve Irsfeld -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tanya Schmidt -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Shane Wendel -Aye- Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

President Ziegler appointed Pharmacist Tanya Schmidt and Technician Diane Halvorson to review the paid invoices and bank statements.

President Ziegler appointed Pharmacist Tanya Schmidt and Technician Member Diane Halvorson to the audit committee for the 2021-2022 year.

President Ziegler appointed Pharmacist Tyler Lannoye to again represent the Board of Pharmacy on the Prescription Drug Monitoring Program Advisory Committee.

Board Members broke for dinner then reconvened to work on finishing portfolio reviews and selecting the exam assignments for tomorrow's exams.

It was moved by Pharmacist Tanya Schmidt and Technician Diane Halvorson to approve the paid invoices and bank statements. On vote by roll call Pharmacist Steve Irsfeld -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tanya Schmidt -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Shane Wendel -Aye- Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

The Board reconvened on Tuesday at 7:15 AM at NDSU Sudro Hall Room 24 for the Candidate Orientation.

The Board then administered the practice examinations throughout the day and prepared for the Wednesday Oral Examinations.

The Board reconvened on Wednesday May 19th at the Wingate Inn in the Meadowlark Room to begin the Oral Examinations. After the oral examinations were complete the Board Members met to finalize the scoring – all candidates passed.

President Ziegler called for any further business; none were forthcoming she adjourned the meeting at 3:45 PM.

President
Tyler G Lannoye, PharmD

Technician Member & Senior Member
Diane M. Halvorson, RPhTech

Member
Steven P Irsfeld, RPh

Member
Tanya L Schmidt, PharmD

Public Member

Member
Shane R. Wendel, PharmD

Member

Executive Director
Mark J. Hardy, PharmD