	AGENDA September 16, 2021 Board of Pharmacy Office – 1906 E Broadway Ave - Bismarck, ND [701-328-9535] Join Zoom Meeting: https://us02web.zoom.us/j/85049836281 Meeting ID: 850 4983 6281 +1 312 626 6799	
9:30 AM – Call to Ord	der – Tyler Lannoye, PharmD - President A	GENDA
Seating of New Mem	bers : Pharmacist Member Carolyn Bodell, RPh, and Public Member Ron Horner	
Recite Mission State	ment	
0,	0	IINUTES
9:40 AM RPh608	38 Karter Trontvet, PharmD	
10:00 AM Stipulate	d Agreement : Hazen Drug PHAR156 & Michael RJ Chase RPh3470	Tab 1
	e ms: .ity Hospital Pharmacy (grandfathered permit) – Retail Pharmacy ans - Carolyn Seehafer, RPh PIC	Tab 2
	Is and Final Adoption Y Pharmacy Technician Registration Requirements Licensure Transfer Unprofessional conduct Administration of Medications and Immunizations Limited Prescription Authority for Immunizations Limited Prescription Authority for Tobacco Cessation Therapies	Tab 3
12:00 Lunch Break		
Discuss Prescription Out]	n Protocol for Immunization and Tobacco Cessation Therapies	[Hand
-	1A-vs – Wehbi [was Tufte] ral Board member orientation/training	Tab 4

2021-2022 Financials to Date

Review of State's settlement of opioid related claims

Budget Tab

Tab 5

President Tyler Lannoye called the meeting to order on Thursday September 16, 2021, at 9:30 AM.

Present in the Board Conference Room were Executive Director Mark J Hardy, PharmD, Board Members: Tyler Lannoye, PharmD; Technician Member Diane Halvorson; Tanya Schmidt, PharmD; Shane Wendel, PharmD; Public Member Ron Horner; Carolyn Bodell, RPh; Attorney David A. Lindell, JD; Howard C Anderson, Jr, RPh, Senior Compliance Officer; and NDSU PharmD Student Shae Mehring on rotation with Pharmacist Wendel.

Present on the Zoom Meeting: Jesse Johnson, Michael Schwab of the North Dakota Pharmacists Association and the Pharmacy Service Corporation, Hannah Scheetz, NDSU PharmD Student, Karter Trontvet, PharmD; Loralee Feininger, PharmD and Carolyn Seehafer, RPh, Pharmacistin-Charge of Trinity Hospital Pharmacy, Minot

Absent: Steven Irsfeld, RPh

President Lannoye 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 Tyler Lannoye and seconded by Pharmacist Shane Wendel to seat newly appointed Board Members Carolyn Bodell, R.Ph. and Public Member Ron Horner. On vote by roll call Pharmacist Tanya Schmidt -Aye- Pharmacist Shane Wendel -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye-Carolyn Bodell and Ron Horner both abstained. The motion carried and President Lannoye declared the two members seated on the Board of Pharmacy and welcomed them.

President Lannoye asked each person present to introduce themselves and give a little background about themselves to establish the group before moving forward.

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

It was moved by Pharmacist Tanya Schmidt and seconded by Technician Diane Halvorson to approve the minutes of the July 15, 2021, as printed. On vote by roll call: Pharmacist Carolyn Bodell- Aye Pharmacist Tanya Schmidt -Aye- Public Member Ron Horner- Aye -Pharmacist Shane Wendel -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye-The motion carried.

Board Members signed certificates to be used for new registrants and licensees.

RPh6088 Karter Trontvet. PharmD was present virtually. Dr. Hardy briefed the Board on Dr. Trontvet's self-report to the Board and asked him to visit with the Board about the incident. He stated he drove home after a party and drove into a tree when parking at home. A police officer observed him and cited him. This occurred in February of 2021. He has met with Pharmacist Tim Carlson of the PharmAssist committee who recommended no treatment beyond his DUI course. Technician Halvorson pointed out critical thinking is important in his work as a pharmacist. Pharmacist Schmidt stated we expected him to make good decisions as would be expected of him in his practice. Pharmacist Wendel said he trusted he has learned from his poor decision and hoped he could be an advocate for others to steer them clear of similar situations.

It was moved by Pharmacist Tanya Schmidt and seconded by Pharmacist Carolyn Bodell to take no further action in the case of Karter Trontvet, PharmD RPh6088 at this time. On vote by roll call: Pharmacist Carolyn Bodell- Aye Pharmacist Tanya Schmidt -Aye- Public Member Ron Horner- Aye - Pharmacist Shane Wendel -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye-The motion carried.

<u>Michael RJ Chase RPh3470 Pharmacist-In-charge at Hazen Drug Phar156</u> arrived at the meeting. Dr. Hardy reviewed the four counts in the complaint along with Allyson Hicks Special Assistant Attorney General, present virtually. Attorney Hicks said Pharmacist Chase was very cooperative, did not contest any of the facts stated in the complaint, was not represented by an attorney, and signed the stipulation, which is before the Board.

A long discussion followed between Board members and Pharmacist Chase about the reasons for and the possible solutions to the problems identified in the complaint.

Pharmacist Chase volunteered there were some process problems involved in the long-term care issues, where the Medication Administration Record (MAR) was used to verify orders. Faxes are received from the nursing home but checking the MAR has been their practice.

Technician Diane Halvorson asked if other Pharmacists were involved with some of the errors to which Pharmacist Chase responded, yes.

Technician Diane Halvorson followed up with a question about the Quality Assurance process used at Hazen Drug to which Pharmacist Chase responded they have just started a QA process involving meeting weekly to resolve issues.

Pharmacist Tyler Lannoye pointed out Hazen Drug needs a process which promotes improvement. Pharmacist Chase responded he meets Monday mornings and Fridays at 5 PM with the nursing home keeping a booklet recording problems and solutions to those items identified.

Pharmacist Shane Wendel pointed out the need for a legal order from the nursing home. The MAR does not meet that standard.

Pharmacist Tanya Schmidt asked about staffing at Hazen Drug. Pharmacist Chase responded they had lost some technicians but were now at full staff with two people filling and one checking. They are back at full staff with two Pharmacists and two Technicians-In-Training.

Pharmacist Tanya Schmidt read from the nursing home report which shows many errors to which Pharmacist Chase responded the med errors were mostly resolved now. Knife River care center seems to know the MAR is not a legal prescription. Pharmacist Tanya Schmidt suggested a longterm care consultant was needed to resolve the process problems identified. Pharmacist Tanya Schmidt asked Pharmacist Chase "*are you confident the stipulation will move you to full compliance and the patient safety you and the Board expects*" to which Pharmacist Chase seemed unsure and asked that a consultant might be found to help.

Pharmacist Tyler Lannoye stated he was a bit uncomfortable with the operation of Hazen Drug at present.

Dr. Hardy and Attorney Hicks reviewed the proposed stipulation with the Board.

It was moved by Pharmacist Shane Wendel and seconded by Pharmacist Tanya Schmidt to approve the stipulation as signed by Pharmacist Chase. On vote by roll call: Pharmacist Carolyn Bodell- Aye Pharmacist Tanya Schmidt -Aye- Public Member Ron Horner- Aye -Pharmacist Shane Wendel -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye-The motion carried.

It was moved by Technician Diane Halvorson and seconded by Pharmacist Carolyn Bodell to direct Executive Director Hardy to review the correction process, help direct Pharmacist Chase in finding a long-term care consultant for Hazen Drug and send an Inspector to Hazen Drug within one month and repeat as necessary. On vote by roll call: Pharmacist Carolyn Bodell- Aye Pharmacist Tanya Schmidt -Aye- Public Member Ron Horner- Aye - Pharmacist Shane Wendel -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye-The motion carried.

Carolyn Seehafer, RPh PIC at <u>Phar211</u> Trinity Hospital Pharmacy Phar211 (grandfathered permit) –joined the Board virtually to present floor plans for a retail pharmacy . Plans were reviewed, questions asked and answered. Board member Carolyn Bodell, R.Ph. disclosed that she works for Trinity Hospital and intended to vote unless there were any objections, none were voiced.

It was moved by Technician Diane Halvorson and seconded by Public Member Ron Horner to approve the floor plans for the relocation of their Class B Hospital Pharmacy Permit to 2305 37 Avenue SW in Minot and to grant a subclass A Out-Patient to Trinity Hospital Pharmacy Permit Phar211 at this new location. On vote by roll call: Pharmacist Carolyn Bodell after disclosing her employment with Trinity Hospital voted- Aye - Pharmacist Tanya Schmidt -Aye- Public Member Ron Horner- Aye - Pharmacist Shane Wendel -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye-The motion carried.

Review of Comments and Final Adoption: Rules were reviewed individually, and any comments received considered. Changes have been made based on previous comments received before, during or after the rule hearing. The Consideration of Comments are attached, included at the end of these minutes.

It was moved by Pharmacist Tanya Schmidt and seconded by Technician Diane Halvorson to approve 61-02-07.1-07 Pharmacy Technician Registration Requirements as presented. On vote by roll call: Pharmacist Carolyn Bodell- Aye Pharmacist Tanya Schmidt -Aye- Public Member Ron Horner- Aye - Pharmacist Shane Wendel -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye-The motion carried.

It was moved by Pharmacist Shane Wendel and seconded by Pharmacist Carolyn Bodell to approve 61-03-01-04 Licensure Transfer as presented. On vote by roll call: Pharmacist Carolyn Bodell- Aye Pharmacist Tanya Schmidt -Aye- Public Member Ron Horner- Aye -Pharmacist Shane Wendel -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye-The motion carried.

It was moved by Pharmacist Tanya Schmidt and seconded by technician Diane Halvorson to approve 61-04-04-01 Unprofessional conduct as presented. On vote by roll call: Pharmacist Carolyn Bodell- Aye Pharmacist Tanya Schmidt -Aye- Public Member Ron Horner- Aye -Pharmacist Shane Wendel -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye-The motion carried. **September 16, 2021**

It was moved by Technician Diane Halvorson and seconded by Pharmacist Tanya Schmidt to approve 61-04-11 Administration of Medications and Immunizations with the changes made as a result of the comments received. On vote by roll call: Pharmacist Carolyn Bodell-Aye Pharmacist Tanya Schmidt -Aye- Public Member Ron Horner- Aye - Pharmacist Shane Wendel -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye-The motion carried.

It was moved by Pharmacist Tanya Schmidt and seconded by Pharmacist Shane Wendel to approve 61-04-14 Limited Prescription Authority for Immunizations with the changes made as a result of the comments received. On vote by roll call: Pharmacist Carolyn Bodell-Aye Pharmacist Tanya Schmidt -Aye- Public Member Ron Horner- Aye - Pharmacist Shane Wendel -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye-The motion carried.

Board Members felt it needed to be made clear that Tobacco included Electronic Nicotine Delivery Systems and other alternative nicotine products in the definition of *"statewide protocol"*.

It was moved by Technician Diane Halvorson and seconded by public member Ron Horner to approve 61-04-15 Limited Prescription Authority for Tobacco Cessation Therapies with the changes suggested by the Board members and the comments received. On vote by roll call: Pharmacist Carolyn Bodell- Aye Pharmacist Tanya Schmidt -Aye- Public Member Ron Horner- Aye - Pharmacist Shane Wendel -Aye- Technician Member Diane Halvorson -Aye-Pharmacist Tyler Lannoye -Aye-The motion carried.

The Board recessed for lunch and came reconvened to discuss the Tobacco Cessation Protocol led by Brody Maack Pharm D, who joined the Board virtually. Several suggestions were made and Dr. Maack will make changes and we will review the protocol again at the November meeting.

Elizabeth Skoy, Pharm D joined the Board virtually to discuss the immunization protocol she has been working on. Some suggestions were made and Dr. Skoy will revise the draft and it will be considered again at the November meeting.

Dr. Hardy reviewed the PCMA vs (now) Wehbi case and explained it was again heard by the Eighth Circuit Court of Appeals panel where arguments have been presented. We expect their determination this fall.

Technician Diane Halvorson reported on the Northland Association of Pharmacy Technicians (NAPT) fall conference. It was an excellent meeting with ten very good speakers and a successful auction where funds were raised for pharmacy technician scholarships. The Pharmacy Technician Certification Board (PTCB) has developed four practice certification modules the completion of all of which will allow a technician to apply for an Advanced Technician Certification. Many states are trying to catch up with North Dakota relative to Pharmacy Technician training requirements and are thinking about a two-tiered system for their technicians.

Dr. Hardy reviewed the balance sheet and year to date financials with the Board. There have been no journal entries since the last approval.

It was moved by Pharmacist Tanya Schmidt and seconded by public member Ron Horner to approve the financials as presented and recognize that there have been no journal entries. On vote by roll call: Pharmacist Carolyn Bodell- Aye Pharmacist Tanya Schmidt -Aye- Public Member Ron Horner- Aye - Pharmacist Shane Wendel -Aye- Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye-The motion carried. Attorney David Lindell reviewed a request from the North Dakota Attorney General for authority to act on behalf of the Board to release all claims related to the recent opioid settlement.

It was moved by Pharmacist Tanya Schmidt and seconded by Technician Diane Halvorson to authorize Executive Director Mark Hardy to sign on behalf of the Board of Pharmacy a document granting the Attorney General, Wayne Stenehjem, the authority to release any and all claims that the State Board of Pharmacy has against Janssen and the other Released Entities that directly or indirectly are based on, arise out of, or in any way relate to or concern the Covered Conduct in the proposed settlement agreement. On vote by roll call: Pharmacist Carolyn Bodell- Aye Pharmacist Tanya Schmidt -Aye- Public Member Ron Horner- Aye - Pharmacist Shane Wendel -Aye- Technician Member Diane Halvorson -Aye-Pharmacist Tyler Lannoye -Aye-The motion carried.

Technician Diane Halvorson asked if we could discuss the possible remodeling of our rented office space, to expand the size of the meeting room to accommodate the Board more easily and those who may attend to hear what is being discussed. Discussion followed about costs of remodeling, alternate office location, handicapped accessibility, and office space for interns. Executive Director Hardy will explore some alternatives for the Board's consideration.

It was moved by Pharmacist Shane Wendel and seconded by Pharmacist Tanya Schmidt to adjourn. All present voted aye and President Lannoye adjourned the meeting at 3:15 PM.

President Tyler G Lannoye, PharmD

Member Steven P Irsfeld, RPh

Member Shane R. Wendel, PharmD

Member Carolyn R Bodell, RPh Technician Member & Senior Member Diane M. Halvorson, RPhTech

Member Tanya L Schmidt, PharmD

Public Member Ron J Horner

Executive Director Mark J. Hardy, PharmD

Board of Pharmacy July 15th Hearing Record and Consideration of Comments:

At 10:30 AM on July 15, 2021 President Tyler Lannoye opened the scheduled rule hearing. I am <u>Tyler Lannoye</u>, President of the Board of Pharmacy and I will be acting as hearing officer for this public hearing.

It is now 10:00 AM on Thursday, July 15, 2021 in the Conference Room of the Board of Pharmacy Office at 1906 East Broadway Ave in Bismarck, North Dakota 58501.

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

<u>Board Members</u> present were: President Tyler Lannoye, PharmD - Shane Wendel, PharmD, Diane M. Halvorson, RPh. Tech, Steven Irsfeld, RPh(remotely) – Tanya Schmidt, PharmD

Also present were Executive Director Mark J Hardy, PharmD - Chief Compliance Officer Howard C Anderson, Jr, RPh – Board Attorney David Lindell, JD - Technician Adelle Casavant, Vice President for the Northland Association of Pharmacy Technicians - Pharm D Students Hannah Scheetz and Madilyn Bommersbach

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

61-02-07.1-07	Pharmacy Technician Registration Requirements
61-03-01-04	Licensure Transfer
61-04-04-01	Unprofessional conduct
61-04-11	Administration of Medications and Immunizations
61-04-14	Limited Prescription Authority for Immunizations
61-04-15	Limited Prescription Authority for Tobacco Cessation Therapies

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, and it 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. We will begin with

<u>61-02-07.1-07</u> Pharmacy Technician Registration Requirements No comments were received on the above rule changes.

61-03-01-04 License Transfer

No comments were received on the above rule changes.

61-04-04-01 Unprofessional conduct

Executive Director Hardy explained the updated language, based on the discussions and direction of the Board during the May 2021 Meeting.

No comments were received on the above rule changes.

61-04-11 Administration of Medications and Immunizations

Pharmacist Tanya Schmidt suggested we include gluteal administration specifically. However, it was determined that intramuscular included those injections in the gluteal muscle, so no change is necessary.

Pharmacist Howard Anderson suggested that the "ordered by the supervising authorized pharmacist was too restrictive and perhaps "delegated by the authorized pharmacist" would be better to include administration ordered by other practitioners as well. Also add "authorized" before pharmacist for clarity.

Pharmacist Steve Irsfeld suggested we divide (1.) into two parts and use language that could include Telepharmacy sites where supervision of the qualified pharmacy technician is available by way of the audio and video link.

In subsection (2.) Technician Member Halvorson suggested we use "training approved by the board" instead of, to the reference to ACPE as the technician programs or colleges of pharmacy who develop acceptable programs and might not be ACPE providers.

The Board agrees with the changes detailed above.

Pharmacist Brett Barker of Nucara provided the following comment by email: Thank you for the opportunity to provide input. NuCara would absolutely support the ability for technicians to administer immunizations in a telepharmacy setting. We believe that would greatly impact public access and that it can be done safely in telepharmacy settings with proper training and supervision. The pharmacist can easily provide clinical oversight and patient counseling remotely. Obviously, the primary hurdle would be how to handle emergency situations, so it would be important to have a pharmacy specific SOP for this. In Iowa, we have the pharmacist available via video and also partner with the local clinics (which luckily we have never had to utilize). The technicians should be trained in basic life saving and on the anaphylaxis protocols and able to administer medications per the protocol upon instruction by the pharmacist. Without the ability to provide remote supervision for immunizations in a telepharmacy setting, our ability to provide vaccines in those communities would likely be limited to 1-2 days per month. I am happy to provide any additional feedback you think would be helpful to the board.

The Board agrees with Pharmacist Barker and thus modified the language to allow supervision by audio and video link to clearly allow for administration to happen remotely under the authorized pharmacist's discretion.

<u>61-04-14</u> Limited Prescriptive Authority for Immunizations

In 61-04-14-01 (3.) Use "vaccination" as an equivalent for "Immunization".

In 61-04-14-01 (4.) Add a "the" before Board.

In 61-04-14-02 (1.) Remove the second "authorized" in the first reference.

61-04-14-02 (1)(a, b, c, & d) Molly A. Howell MPH, Immunization director for the State Department of Health suggested these were redundant and language referencing (a. & e.) would be adequate. Board Members agreed with this clarification.

61-04-14-02 (2.) Remove the extra "be" between "must and meet"

61-04-14-02 (3.) Modify language to "...appropriateness for receiving a vaccination prior to ordering..."

61-04-14 02 (4.) Ms. Howell also suggested we modify this subsection to say, "Prior to ordering and administration of an immunization pursuant to the statewide immunization protocol, the authorized pharmacist shall consult and review the statewide immunization registry. The Authorized Pharmacist or their designee must report any immunization ordered and administered to the state immunization registry. The pharmacist may provide the patient with a record of the vaccine administered." Board Members agreed with this clarification. **Board members concurred to the adjustments listed above.**

Sandra Kay Guckian, IOM, MS, RPh, Vice President, State Relations for the National Association of Chain Drug Stores provided the following comments/recommendation based on the changes agreed by Board from the rule hearing:

Among ACIP's vaccine specific recommendations, they have recommendations for different travel vaccines – although per the CDC website, those recommendations are published in MMR vs. being on a "schedule".

Because the language references an "approved vaccine schedule", we suggest the following:

1. Authorized Immunizations authorized. The immunizations authorized to be ordered and administered pursuant to a statewide protocol to patients ages 3 or older shall include<u>an</u> <u>immunization recommended by ACIP in its approved vaccination schedule and any</u> <u>other emergency immunization in response to a public health emergency</u> and an <u>immunization recommended by CDC for international travel</u>:

a<mark>. An immunization recommended by ACIP in its approved vaccination schedule for</mark> adults

b. An immunization for influenza

c. An immunization recommended by CDC for international travel

<mark>d. A Tdap (tetanus, diphtheria, acellular pertussis) vaccination in a booster application</mark> e. Any other emergency immunization in response to a public health emergency

Board members concurred with this clarification on travel related immunizations.

<u>61-04-15</u> Limited Prescriptive Authority for Tobacco Cessation Therapies

61-04-15-01 (3.) Add a "the" between by and Board.

61-04-15-02 (2.) (a.) Use "approved by the Board" instead of "accredited by ACPE"

61-04-15-02 (5.) - Change "reasonable" to "reasonably"

– Remove "and shall advise the patient to consult a practitioner"

Board members concurred to the adjustments above.

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

The record will be held open for written comment through July 28th, 2021

At this point, I will close the hearing on:

61-02-07.1-07	Pharmacy Technician Registration Requirements
61-03-01-04	Licensure Transfer
61-04-04-01	Unprofessional conduct
61-04-11	Administration of Medications and Immunizations
61-04-14	Limited Prescription Authority for Immunizations
61-04-15	Limited Prescription Authority for Tobacco Cessation Therapies

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

President Tyler Lannoye, PharmD closed the public hearing at 11:45AM.