

AGENDA March 23, 2017
Board of Pharmacy Office – 1906 E Broadway Ave - Bismarck, ND

9:30 AM – Call to Order – recite Mission Statement
President Shane Wendel, PharmD

AGENDA

Review and sign January 9-11, 2017 Board Minutes **MINUTES**

Sign original Pharmacist and Technician Certificates

CE Credit Request: Sandra Offutt – ND RPh4235
Janel M Agnes – ND RPh4415

New Pharmacy - Lifescript Pharmacy PLLC – 4305 58th Street S – Fargo
Lance D LeClair, PharmD
Embrace Pharmacy - Grand Forks
Samantha Buck, PharmD

10:00 AM Discussion Items: Proposed Rule Changes **TAB 1**
61-04-13 Patient consultation requirements
61-08-01-10 [Out-of-State] Counseling Services

Collaborative Agreement @ Spirit Lake Health Center – Fort Totten, ND
1) Anticoagulation
2) Asthma Clinic
3) Tobacco Cessation

Remodeling: Innovis Health Pharmacy LLC % Essentia Health MBR - Fargo
Family Medicine Residency Pharmacy - Altru UND Grand Forks

Professional Program Students Immunization Certificates **TAB 2**

12:00 Lunch Break

Legislative Update – Executive Director Hardy

1:00 PM – Jayme L Wolf ND RPh5459 update

2:00 PM Widmer Roel 2015-2016 Audit Report

Department of Health – Tuberculosis prevention & control program **TAB 3**

Funding Request - NDSU Project Proposal **TAB 4**

Year to date Financial Report - Budget comparisons **BUDGET TAB**

Discussions: May 2017 Meeting
NABP Meeting

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President Shane Wendel, PharmD called the meeting to order on Thursday March 23, 2017 at 9:31 AM in the Conference Room of the Board of Pharmacy Office, 1906 East Broadway in Bismarck, ND.

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.*

Present in addition to President Wendel were: Public Member Fran Gronberg -Gary W. Dewhirst, R.Ph. - Tanya L. Schmidt, PharmD - Diane M. Halvorson, R.Ph. Tech, - Steven P. Irsfeld, R.Ph. - Gayle D Ziegler, R.Ph. -Executive Director Mark J Hardy, PharmD and Board Attorney David Lindell.

Also present: Jackie Hjelle PharmD, who is a resident working with Board Member Tanya Schmidt; Dennis McAlister, Pharm D, RP. and John Ward, JD representing Express Scripts; John Long RPh with CVS Caremark and LuGina Mendez-Harper, PharmD representing Prime Therapeutics.

The Board Members signed Original Certificates for Pharmacists and Pharmacy Technicians to be used at a later date.

It was moved by Public Member Gronberg and seconded by Technician Member Halvorson to approve the minutes of January 9-11, 2017 as printed. On vote by roll call: Pharmacist Dewhirst - Aye Public Member Gronberg - Aye Technician Halvorson - Aye Pharmacist Irsfeld - Aye Pharmacist Schmidt - Aye Pharmacist Wendel - Aye Pharmacist Ziegler - Aye Nays none - the motion carried.

At about 9:35 AM Pharm-Assist Committee Member Agnes Harrington called into the Board meeting to discuss the upcoming appearance of Jayme L Wolf ND RPh5459. The Board asked her to call back once Dr. Wolf arrived at the meeting.

Executive Director Hardy distributed an NABP Survey dated March 9th, 2017 on the value of an NABP Association Membership. It was noted that the benefit was much higher than what the ND Board of Pharmacy actually pays for membership.

It was moved by Public Member Gronberg and seconded by Technician Member Halvorson to approve a request by Pharmacist Sandra Offutt, ND RPh4235 for 6.25 continuing education hours for attendance at Sanford Diabetes Symposium held November 10th, 2016 in Fargo, ND. On vote by roll call: Pharmacist Dewhirst - Nay Public Member Gronberg - Aye Technician Halvorson - Aye Pharmacist Irsfeld - Aye Pharmacist Schmidt - Aye Pharmacist Wendel - Aye Pharmacist Ziegler - Aye - the motion carried.

It was moved by Pharmacist Irsfeld and seconded by Public Member Gronberg to approve a request by Pharmacist Janel M Agnes, ND RPh4415 for 11 continuing education hours for attendance at two conferences on the Billings Ovulation Method Association [BOMA] held June 3-4, 2016 in Tampa FL and an extension course held August 11-14 in Bismarck, ND. On vote by roll call: Pharmacist Dewhirst - Nay Public Member Gronberg - Aye Technician Halvorson - Aye Pharmacist Irsfeld - Aye

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Pharmacist Schmidt – Aye Pharmacist Wendel – Aye Pharmacist Ziegler – Aye – the motion carried.

Technician Member Halvorson asked Executive Director Hardy to explain the recent meeting with NDSU School of Health Professionals relative to their continued American Colleges Pharmaceutical Education [ACPE] accreditation as a Continuing Education Provider [CPE]. Executive Director Hardy gave an overview of the discussion and summarized by reporting that NDSU was considering relinquishing their CPE accreditation status through ACPE due to budgetary considerations, along with options he felt were appropriate going forward. The Board Members felt it was an unfortunate decision, but understands it is a NDSU decision and interested parties in the profession have time to discuss potential solutions on this important matter.

It was moved by Pharmacist Ziegler and seconded by Pharmacist Irsfeld to approve the floor plans, lease agreement and Application for Class A Out-patient Retail Pharmacy Permit to LifeScript Pharmacy PLLC, located at 5670 38th Ave S, Unit A in Fargo, ND 58104. The PLLC is owned by Pharmacist Lance LeClair ND RPh5751. On vote by roll call: Pharmacist Dewhirst – Aye Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Irsfeld – Aye Pharmacist Schmidt – Aye Pharmacist Wendel – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

It was moved by Public Member Gronberg and seconded by Pharmacist Dewhirst to approve the floor plans, lease agreement and Application for Class A Out-patient Retail Pharmacy Permit to Embrace Pharmacy Inc, located at 2424 32nd Ave South Suite 101B in Grand Forks, ND 58201. The corporation is owned by Pharmacist Samantha Buck ND RPh5368. On vote by roll call: Pharmacist Dewhirst – Aye Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Irsfeld – Aye Pharmacist Schmidt – Aye Pharmacist Wendel – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

At 10:15 AM the Board turned their attention to the proposed rule changes that had been tabled from the previous meeting. Executive Director Hardy gave a summary of the discussion, including the comments received since the last meeting. President Wendel opened the discussion to all present to give their comments regarding the final version of:

61-04-13 Patient consultation requirements

61-08-01-10 [Out-of-State] Counseling Services

Dr. Mendez-Harper of Prime Therapeutics felt that the change to require a “reach out” to the patient on new prescriptions sent by mail was burdensome and that the issues under discussion were essentially customer service issues, not patient safety. Dr. Dennis McAllister stated that he believed the model that Express Scripts utilizes works and that the tenets to require a phone attempt for consultation in the rule was excessive and inappropriate. John Long RPh, MBA with CVS Caremark indicated he really appreciated the open and honest dialogue that the interest parties were allowed to have with the Board Members, which was unique from his experiences with other regulatory Boards. He also felt that there was a lack of added support for the proposed changes and discussed the revisions recommended from their company.

Pharmacist Irsfeld discussed the process he utilizes when mailing a new prescription from his pharmacy, including requiring his staff to try and contact the patient to provide consultation. Pharmacist Schmidt related the importance of the provision in these rules to allow a “reach out” to the patient, but if not successfully contacted, to continue to process

the prescription and allow the company to ship the medication so as not to interrupt or delay their therapy.

The discussion progressed to “*specialty mail order medications*” and their standards for consultation on these types of prescriptions. All present indicated their pharmacies do have a higher level of reach out to patients on new “specialty medications:”

Executive Director Hardy explained the intent of the rule to ensure that we are educating patients on new prescriptions. This provision will make a positive step in educating patients on utilizing their prescriptions. The Board feels this will ensure positive outcomes and raise the expectations for providing education to patients. As complex therapies become more common, the influence that the pharmacist must play to ensure the patient is educated and informed of their regimen is even more crucial.

Public Member Fran Gronberg expressed her perspective as a member of the public on the receiving end of this and her expectations as a patient utilizing a pharmacy and the Board’s responsibility to protect the public.

Past Executive Director, Senator and Senior Compliance Officer Howard C Anderson, Jr, RPh was able to join the meeting and discussed some of the history of consultation in the state and his desires to raise compliance.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Irsfeld to approve the final adoption of NDAC 61-04-13 Patient consultation requirements as follows:

61-04-13. Patient consultation requirements. Each prescription dispensed by a pharmacy serving patients in the state and each out-of-state pharmacy providing prescriptions by mail to patients in the state must provide the following in regard to consultation:

- 1. Provide consultation by a pharmacist or intern on each new prescription dispensed.**
- 2. Provide consultation by a pharmacist or intern on each refill prescription dispensed. Pursuant to NDAC 61-02-07.1-05, screening a patient for consultation on a refilled prescription can be completed by a registered technician.**
- 3. Counseling can be provided to the patient or their agent.**
- 4. For a refilled prescription, when the patient or their agent is not available at the time of dispensing, the pharmacy must supply written or electronic materials and a toll free phone number for the patient or their agent to contact the pharmacist.**
- 5. For a new prescription being dispensed by mail to a patient, an attempt to reach the patient or their agent must be made for a consultation on the prescription, however if the patient or their agent is not available at the time of dispensing, the pharmacy must supply written or electronic materials and a toll free phone number for the patient or their agent to contact the pharmacist**
- 6. This section does not apply to prescriptions for patients exempted in NDCC 43-15-31.2**
- 7. Failure to provide proper consultation under this section is considered unprofessional conduct by the pharmacy and pharmacist under NDAC 61-04-04-01(9) and is subject to disciplinary action**

On vote by roll call: Pharmacist Dewhirst – Aye Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Irsfeld – Aye Pharmacist Schmidt – Aye Pharmacist Wendel – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

Senior Board Member Dewhirst stated that this is not a Board of Pharmacy verses mail-order issue. The Board after extension conversations wants to ensure the best patient care and really believes this will create improvements in pharmaceutical care across the state of

North Dakota. This may be a starting point and there may be innovations that can be laid for future compliance and improvements made in future rules.

It was moved by Pharmacist Ziegler and seconded by Pharmacist Irsfeld to approve the final adoption of NDAC 61-08-01-10 [Out-of-State] Counseling Services as follows:

61-08-01-10. Counseling services. Out-of-state pharmacies shall provide accessible telephone counseling service for patients' drug inquiries with a licensed pharmacist during regular working hours. Available telephone counseling service must be provided that is consistent with the standard of due care. The pharmacies' telephone number will be prominently identified and affixed on the prescription container label. Guidelines for counseling services shall be consistent with professional practice counseling guidelines set in NDAC 61-04-13.

On vote by roll call: Pharmacist Dewhirst – Aye Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Irsfeld – Aye Pharmacist Schmidt – Aye Pharmacist Wendel – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

Board Members expressed that there was an authentic need for the public to be educated through counseling on their medications.

Executive Director Hardy thanked those that had continuously attended the various Board Meetings to provide their opinions and input throughout the Rule Hearing process and that he appreciated the understanding and cooperation through the lengthy process on these rules. All input was both welcomed and valued.

It was moved by Pharmacist Schmidt and seconded by and Public Member Gronberg to approve the Anticoagulation Collaborative Agreement submitted by Spirit Lake Health Center in Fort Totten, ND Pharmacists and practitioners:

Lynde Monson, PharmD	Jeffrey Vaagen, MD
Tana Triepke, PharmD	Roxanne Jonas, MD
Jennifer Stubson, PharmD	Jennifer Simhai, FNP-C

On vote by roll call: Pharmacist Dewhirst – Aye Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Irsfeld – Aye Pharmacist Schmidt – Aye Pharmacist Wendel – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

It was moved by Technician Member Halvorson and seconded by and Pharmacist Irsfeld to approve the Asthma Collaborative Agreement submitted by Spirit Lake Health Center in Fort Totten, ND Pharmacist and practitioners:

Tana Triepke, PharmD	Cheryl Hefta, WHNP-C	Roxanne Jonas, MD
	Jeffrey Vaagen, MD	

On vote by roll call: Pharmacist Dewhirst – Aye Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Irsfeld – Aye Pharmacist Schmidt – Aye Pharmacist Wendel – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

It was moved by Pharmacist Ziegler and seconded by and Pharmacist Irsfeld to approve the Tobacco Cessation Collaborative Agreement submitted by Spirit Lake Health Center in Fort Totten, ND Pharmacist and practitioners:

	Tana Triepke, PharmD			
Cheryl Hefta, WHNP-C	Roxanne Jonas, MD	Jennifer Simhai, FNP-C	Jeffrey Vaagen, MD	

On vote by roll call: Pharmacist Dewhirst – Aye Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Irsfeld – Aye Pharmacist Schmidt – Aye Pharmacist Wendel – Aye Pharmacist Ziegler – Aye Nays none – the motion carried. March 23, 2017 Board Office - 1906 E Broadway Ave - Bismarck, ND Page 6
At noon, Lunch was delivered.

It was moved by Pharmacist Dewhirst and seconded by Technician Member Halvorson to approve the submitted remodeling plans for ND Pharmacy Permit Phar522 - Innovis Health Pharmacy LLC % Essentia Health MBR located at 3000 32 Ave SW in Fargo, ND. On vote by roll call: Pharmacist Dewhirst – Aye Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Irsfeld – Aye Pharmacist Schmidt – Aye Pharmacist Wendel – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

It was moved by Technician Member Halvorson and seconded by Pharmacist Ziegler to approve the remodeling expansion plans submitted by ND Pharmacy Permit Phar477 Altru Family Medicine Residency Pharmacy located at 725 Hamline Street in Grand Forks, ND. On vote by roll call: Pharmacist Dewhirst – Aye Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Irsfeld – Aye Pharmacist Schmidt – Aye Pharmacist Wendel – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

Executive Director Hardy gave an update on the Legislation the Board introduced. SB No 2096–Controlled Substances rescheduling and HB No 1099 which adds gabapentin, brand name Neurontin, as a reportable drug to the PDMP. Both bills have been passed and signed by Governor Burgum. He explained HCR 3026 which would ask for a study of the membership and the immunity provisions relating to the administrative boards in the State of North Dakota. Dr. Hardy expounded on the importance of staying involved in the legislative process to ensure the proposed supervision is appropriate for the Boards and to help educate on the unfortunate inferences made by some based on the North Carolina Dental Board vs the FTC case are clarified and understood. The goal is to have regulatory boards respond effectively to protect the public. He went on to expound on the Medical Marijuana provision and the needle exchange program legislation and the two recently heard pieces of legislation the ND Pharmacist Association sponsored relative to specialty pharmacy and Pharmacy rights. He went on to explain that it has been a busy session, especially recently. However, he expects things to settle down now.

Board Members asked several questions on the ND Pharmacist Association legislation and the impact it would have on the Board, relative to what is contained within the bill.

At 1:00 PM Jayme L Wolf ND RPh5459 appeared before the Board. Pharmacist Wolf presented a letter from her current employer, the Kelly Inn, where she has been working as a housekeeper since January 27th. She indicated that she enjoyed the experience and thanked the Board for requesting that she move in this direction. However, she felt mentally and physically ready to get back into a pharmacy and requested the removal of the restriction from a non-dispensing pharmacy role currently in her Order.

Pharmacist Ziegler indicated she was aware of the tight job market and that Pharmacist Wolf may encounter difficulties obtaining employment given the surplus of professionals in the Fargo area.

Pharm-Assist Committee Member Agnes Harrington joined the meeting via telephone and reported that she thought Ms. Wolf was doing great in her recovery.

Technician Member Halvorson indicated she believed required Controlled Substances Audits would be an important provision in allowing Ms. Wolf to transition into a dispensing role as a pharmacist.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Irsfeld to amend the Order of Pharmacist Jayme L Wolf ND RPh5459 to allow her to practice in a ND Pharmacy in a dispensing role. The pharmacy that employs Pharmacist Wolf must conduct a minimum of monthly Schedule II Controlled Substance Audits and report discrepancies to the Board. On vote by roll call: Pharmacist Dewhirst – Aye Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Irsfeld – Aye Pharmacist Schmidt – Aye Pharmacist Wendel – Aye Nays none – the motion carried. Pharmacist Ziegler recused herself due to her previous employment with Pharmacist Wolf.

Board Members reviewed the NDSU School of Pharmacy and Health Professions project proposal submitted by Heidi Eukel, PharmD and Mark Strand relative to the “*Pharmacists Engagement in the Community to Target Opioid Abuse Prevention.*” Executive Director Hardy explained his understanding of the proposal, in which they requesting a grant from the Fargo/Moorhead Area Foundation. They are also seeking a \$3,000 grant from the Board of Pharmacy to defray additional costs associated in this proposed project. The Board Members reviewed the submitted project budget and perspective impact of the proposal and although it was not clear how the \$3,000 funding would be spent, they felt the project was well within the need of the profession to be involved in Naloxone delivery and providing information and consultation on the risks of opioids. It was a consensus that the NDSU School of Pharmacy individuals would provide data back to the Board the results of this project.

It was moved by Public Member Gronberg and seconded by Pharmacist Dewhirst to grant the request of \$3,000 with the requirement that they provide the results to the Board and that Executive Director Hardy obtain more details relative to the expenditures and budget. On vote by roll call: Pharmacist Dewhirst – Aye Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Irsfeld – Aye Pharmacist Schmidt – Aye Pharmacist Wendel – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

At 2:00 PM Ms. Jodi Myrvik, UND Center for Family Medicine, Bismarck, Ms Dee Pritschet and Lindsey VanderBusch of the ND Department of Health appeared before the Board to discuss the Department of Health’s proposal on Tuberculosis prevention and control program. Ms. VanderBusch provided an overview of the Department of Health’s role in Tuberculosis prevention and control within the State of North Dakota, including their desire for a pharmacist to dispense these medications to ensure the individual is provided the same level of safety and support that any patient would receive in the dispensing of medications. They indicated that they had put a request for proposals to the pharmacies but only received a response from the UND Center for Family Medicine locations. The Board Members asked how many cases were anticipated. To which Ms. VanderBush replied they treat between 500 to 700 latent Tuberculosis cases and last year had 22 active cases treated. Medications would be delivered to patients and consultation would occur with the

pharmacist involved. Executive Director Hardy explained that in order for UND Center for Family Medicine pharmacies to serve these patients, it would be an extension of what they are currently allowed to do under their permitted Class H Government pharmacy. The Board thought this was an important extension of services that was needed for the State and important that pharmacists be involved in the care of these individuals, and in many cases the medications being provided free of charge or through a 340B program are not available at all pharmacies in the state.

It was moved by Public Member Gronberg and seconded by Pharmacist Dewhirst to allow the UND Family Medicine Pharmacies in Bismarck and Minot to serve these patients and be the participating pharmacies specifically for the Tuberculosis prevention and control program for the ND Department of Health. It was noted that any future programs being developed would need to be presented to the Board. It was also noted that the patient retains their right to choose whichever pharmacy they would like to utilize when obtaining these medications. All in attendance agreed that would be the case. On vote by roll call: Pharmacist Dewhirst – Aye Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Irsfeld – Aye Pharmacist Schmidt – Aye Pharmacist Wendel – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

Executive Director Hardy presented the year-to-date financials for the Board to review.

It was moved by Pharmacist Schmidt and seconded by Pharmacist Irsfeld to accept the financial statements as presented. On vote by roll call: Pharmacist Dewhirst – Aye Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Irsfeld – Aye Pharmacist Schmidt – Aye Pharmacist Wendel – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

The May 2017 meeting was discussed and it was noted that the meeting would start on Monday with the Exams on Tuesday and Wednesday. The Board expressed interest in adding a few discussion items such as Rule Changes, Technician Training processes and USP 800 Inspections, along with the focus of the 2017 Inspection / Compliance visit cycle.

Beth Stockdill, CPA of Widmer Roel PC arrived to discuss the Board of Pharmacy's July 1, 2015 to June 30th, 2016 Audit Report. The Board asked questions of Ms. Stockdill and it was noted that the additional requirement of the pension audit required for Government Audits was included in the Audit. The Board Members felt the pension provision was a burdensome requirement to compile with and they requested that the office allow Widmer Roel help come up with the financial numbers for this purpose and are willing to accept a deficiency on the audit for this. Ms. Stockdill explained the other deficiencies which were consistent in previous years, relative to having limited staff.

It was moved by Pharmacist Schmidt and seconded by Public Member Gronberg to approve the findings of the July 1, 2015 to June 30th, 2016 Audit Report conducted by Widmer Roel. On vote by roll call: Pharmacist Dewhirst – Aye Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Irsfeld – Aye Pharmacist Schmidt – Aye Pharmacist Wendel – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

President Wendel requested any further business, none forthcoming. He adjourned the meeting at 3:30 PM.

President
Shane R. Wendel, PharmD.

Gary W. Dewhirst, RPh.
Senior Member

Member
Diane M. Halvorson, RPhTech.

Member
Gayle D. Ziegler, RPh.

Public Member
Fran Gronberg

Member
Steven P Irsfeld, RPh.

Member
Tanya L Schmidt, PharmD

Executive Director
Mark J. Hardy, PharmD