

**AGENDA**  
**September 17<sup>th</sup> , 2015**

**Board of Pharmacy Office – 1906 E Broadway Ave - Bismarck, ND**

**9:30 AM** – Call to Order – Public Member Fran Gronberg, President **AGENDA**

**Recite: Mission Statement**

Seat new Board Member – Tanya Schmidt, PharmD – administer Oath of Office

Review and sign July 23<sup>rd</sup>, 2015 Board Minutes **MINUTES**

Sign original Pharmacist and Technician Certificates

**10:00 AM** RULE HEARINGS on **TAB 1**  
 Pharmacy Quality Improvement Chapter 61-02-01-19  
 Licensure of Pharmacists [terminology] Chapter 61-03-01  
 Limited Prescriptive Practices Chapter 61-04-08  
 CLIA Waived Tests Rule Chapter 61-04-10  
 Prescriptive Authority for Naloxone Chapter 61-04-12

**11:00 AM** David Leedah, PharmD CE Provider for Sanford Health **Tab 2**

**11:30 AM** **New Pharmacy** - floor plans – St Alexius – Minot Medical Plaza

**11:45 LUNCH**

**12:30 PM** Foreign Graduate: Kshipra Pachauri Sharma **Tab 3**

**1:00 PM** **New Pharmacy** – 3<sup>rd</sup> Street Clinic – Grand Forks – Judith Swisher, R.Ph.  
 Dakota Clinic Pharmacy – Innovis Hospital - S Fargo

**1:30PM** ASHP Pharmacy Technician education accreditation requirement –  
 Thrifty White Drug Pharmacies

**2:00 PM** – Isaac Aasen, PharmD RPh5260 **Tab 4**

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

Discussion items:

- Update Yellow Jug Old Drug Program – drug disposal
- Law Book revisions
- FARB training – August 28<sup>th</sup>
- Implementation of 2015 Legislation

President Fran Gronberg called the meeting to Order at 9:30 AM in the Conference Room of the Board of Pharmacy Office located at 1906 East Broadway in Bismarck, North Dakota.

Present were: President Fran Gronberg -Diane M. Halvorson, RPhTech - Shane Wendel, PharmD. – Tanya L. Schmidt, PharmD; Executive Director Mark J Hardy, PharmD – Howard C Anderson, Jr, Chief Compliance Officer; Also present were: PharmD Student Kyle Walker, on rotation at the Board Office and PharmD Student Micah Bender on rotation with Board Member Wendel; Gabe Lautenschlager, PharmD, Pharmacist-in-Charge at CVS North in Bismarck.

Absent were: Gary W. Dewhirst, RPh and Steven P. Irsfeld, RPh

President Gronberg read the *Board of Pharmacy 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 the pharmaceuticals is upheld through education, communication, licensing, legislation, regulation, and enforcement.*

Executive Director Hardy asked that the proposed Stipulated Agreement with Pharmacist Jayme Wolf be added to the current Agenda at 2:30 PM, and announced that the 11:30 AM item will be deleted, as the plans for the Minot Medical Plaza pharmacy are not ready.

***It was moved by Technician Halvorson and seconded by Pharmacist Wendel to approve the Agenda with the addition of the Stipulated Agreement review and removal of the 11:30 item. All Board Members present voted Aye - the Motion carried.***

President Gronberg administered the Oath of Office to new Board Member: Tanya L Schmidt, PharmD and presented her with her name tag.

***It was moved by President Gronberg and seconded by Pharmacist Ziegler to Seat Tanya L. Schmidt, Pharm.D on the Board of Pharmacy. All Board Members present voted Aye - the Motion carried.*** Dr. Schmidt was welcomed by all present.

***It was moved by Pharmacist Ziegler and seconded by Technician Halvorson to approve the Minutes of the July 23, 2015 Board Meeting as printed. All Board Members present voted Aye. The Motion carried.***

Original Pharmacist and Pharmacy Technician Certificates were passed around for signature by those Members present.

President Gronberg asked for reports on the Federation of Associations of Regulatory Boards (FARB) attended by Fran Gronberg, Diane Halvorson, Attorney David Lindell and Dr. Hardy and sponsored by our board and others for the benefit of all boards in North Dakota. The training was presented by Dale Atkinson, Executive Director of FARB. Many of the attendees from small boards thanked us for sponsoring the session, as their budgets would not have allowed such training. There were 30 to 40 attendees.

Important items of discussion were the essential element of separating our own job from protecting the public, concern about using private computers for board business, as that might open up your private e mail to open records requests. The retention of emails by Board Members and staff was discussed, including mechanisms to address their concerns.

Dr. Hardy stated that pertinent emails regarding Board Business which go to a majority of the board could be sent to our contact list as well, which includes the press.

Another discussion item related to the FTC vs North Carolina Dental Board; the cease and desist orders issued by Boards when there is not a clear authority to regulate, for example, unlicensed individuals or companies. Our Board authority is clear, that we do regulate those individuals and entities, but others may not.

At this time Michael Schwab, Vice President of the ND Pharmacist Association joined the meeting to discuss the proposed rule changes; and LaVaye Dressen, RPh of the VA in Bemidji, MN - who is attending to comply with the requirements of her PharmD Program at University of Florida.

### **PUBLIC HEARING FORMAT**

I am Fran Gronberg, 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, September 17, 2015 in the Conference Room of the Board of Pharmacy Office at 1906 East Broadway Ave in Bismarck, North Dakota 58501.

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

1. Pharmacy Quality Improvement Chapter 61-02-01-**19**
2. Licensure of Pharmacists [terminology] Chapter 61-03-01
3. Limited Prescriptive Practices Chapter 61-04-08
4. CLIA Waived Tests Rule Chapter 61-04-10
5. Prescriptive Authority for Naloxone Chapter 61-04-12

Information gathered at this hearing will be used by the Board of Pharmacy for their 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.

Executive Director Hardy reported that no written comments have been received at this time. He gave a description of each of the proposed rules and their changes, which the Board Members discussed and asked questions; PharmD Student Kyle Walker pointed out a few non-substantial grammatical or typo changes, such as or should be of – as to at in the printed proposed rules.

In discussions regarding changes to the CLIA waived Tests rules, Dr Hardy explained a past comment received from Pharmacist Jeffrey Lindoo on the involvement of Pharmacy Technicians in conducting CLIA waived Tests. Board Members agreed that while technicians certainly can assist a pharmacist in preparing the patient for the test, the actual test must be

conducted by the pharmacists. There was no feeling that any language would need to be changed to account for this consensus.

Mike Schwab commented that it was a desire of the State Pharmacy Associations, to streamline the approval of collaborative agreements by the boards, as this sometimes slows the process of serving patients. He had no objections to the current revisions in improving the process, however.

CLOSING - 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: October 5, 2015 At this point, I will close the public hearing on:

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|---|---------|-------------|
| 1. Pharmacy Quality Improvement           | Chapter | 61-02-01-19 |
| 2. Licensure of Pharmacists [terminology] | Chapter | 61-03-01    |
| 3. Limited Prescriptive Practices         | Chapter | 61-04-08    |
| 4. CLIA Waived Tests Rule                 | Chapter | 61-04-10    |
| 5. Prescriptive Authority for Naloxone    | Chapter | 61-04-12    |

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

Mark Hardy suggested that future rules may address technician responsibilities to include the expansion of duties into assessing the need for pharmacist counseling on refills, revision of the compounding rules to more closely align with USP chapters 795 and 797, perhaps by referencing them directly.

At 11:00 AM David Leedah, PharmD, CE Provider for Sanford Health joined the meeting by phone. Dr. Leedah was approved as a provider of continuing education for programs developed at Sanford Health in Fargo one year ago with an agreement to reassess at this meeting. Dr. Hardy presented a list of several programs he has approved and Dr. Leedah said that 7 to 15 attend each session.

**It was moved by Technician Halvorson to approve David Leedah, Pharm D, clinical director at Sanford Health in Fargo, as a CE provider for North Dakota for one more year. Programs will be provided to the Board office five business days prior to delivery of the program. Dr. Leedah will consult with NDSU about ACPE accreditation for these programs. Pharmacist Gayle Zeigler announced that she would not vote, as she works for Sanford. Three board members voted aye, one nay. The motion carried.**

At this time Pharmacist Judith Swisher entered the meeting room to be present for the discussion of the 3<sup>rd</sup> Street Clinic, a proposed new pharmacy she is considering opening. Since she was available the Board agreed to address her request at this time. Pharmacist Swisher explained the floor plans for the proposed pharmacy. She will own eight of the fifteen membership units with the 3<sup>rd</sup> Street Clinic (TSC) non-profit owning the remaining balance.

***It was moved by Pharmacist Schmidt and seconded by Pharmacist Ziegler to approve the floor plans for TSC Pharmacy, LLC [Third Street Clinic] located at 360 Division Ave in Grand Forks, ND with the modification to the counseling room access so patients are not able to access the***

***drug or prescription storage areas. This approval is contingent on receipt and approval by Dr. Hardy of revised plans, a lease, Member Control Agreement, Operating Agreement and financial agreement for the company, if these documents are drawn. All five board members present voted aye, the motion carried.***

Shane Wendel stated, “Judy, you are truly an inspiration for the work you do and the time and expertise you commit to this project, and others.”

At 12:25 Ms. Kshipra Sharma arrived at the meeting. Ms. Sharma is a foreign pharmacy graduate and currently registered as a Pharmacy Technician. She appeared before the Board of Pharmacy to request licensure as a Pharmacy Intern. NABP is granting Ms. Sharma authorization to complete the Foreign Pharmacy Graduate Equivalency Examination Certificate.

***It was moved by Pharmacist Schmidt and seconded by Pharmacist Ziegler to grant Ms. Sharma an intern license so she can begin accumulating her 1500 hours of internship. All board members present voted aye. The motion carried.***

At 12:50 Laura Morris, PharmD was reached by phone to discuss the new pharmacy plans submitted for Dakota Clinic Pharmacy 32<sup>nd</sup> to be located at 3000 32<sup>nd</sup> Ave South in the Innovis Hospital in Fargo, ND. This location would be a new pharmacy under the same ownership structure as the existing Dakota Clinic Pharmacy – Phar114.

***It was moved by Public Member Gronberg and seconded by Pharmacist Ziegler to approve the floor plans for Dakota Clinic Pharmacy 32<sup>nd</sup> to be located at 3000 32<sup>nd</sup> Ave South in the Innovis Hospital in Fargo, ND. This approval is contingent upon receipt and approval by Dr Hardy of a lease, completed Application for Pharmacy Permit and affidavit of ownership. All members presented voted aye – the motion carried.***

At 1:00 PM Pharmacist Kenneth Strandberg and Barbara Lacher, RPhTech from the Technician Program at NDSCS; and Ms. Tanya Rene, Human Resource Manager and Pharmacist Timothy Weipert of Thrifty White Drug Pharmacies all arrived at the meeting.

Pharmacist Tim Weippert stated the problems Thrifty White Drug Pharmacies are having with 50 technician openings for their 29 North Dakota stores. Pharmacist Lautenschlager of CVS North in Bismarck stated they have similar problems. Ms. Rene reported to the Board the amount of money they spend yearly to provide tuition to their employees for technician training. Pharmacist Weippert stated that he felt some alternate system of program approval might be sought. The *Pharmacist's Letter* is seeking accreditation for their program through ACPE and once accredited this would be another method for training. With tuition/ fees of \$4,571 for each year of on-campus or online program at NDSCS, \$2,825 for the cost of the PATSIM program, Ms. Rene stated “it gets pretty expensive when they have 50 people in the program”.

The Board pledged to explore expanding a Technician program to the **Bismarck State College** and other state schools as well as work to get the training options as workable as possible. Dr. Hardy, Fran Gronberg and Howard will meet with President Skogen as soon as practical.

Dr. Hardy reported that 29 pharmacies were signed up for the Yellow Jug Old Drugs program, that 50 more containers would be ordered soon. Dr Hardy and Inspector Anderson would meet with the Attorney General next week to discuss consolidating their program with the Board's new Yellow Jug Old Drugs program.

David A. Lindell, JD, special assistant attorney general arrived at the meeting.

At 2:00 PM Isaac Aasen, PharmD – RPh5260 appeared before the Board to discuss the potential purchase of a licensed Pharmacy and request a modification of his Order. Accompanying Pharmacist Aasen was his father, Pharmacist Randall Aasen. Isaac Aasen, PharmD discussed an opportunity to purchase Skip's Budget in Grand Forks and his desire to be Pharmacist in Charge (PIC). A letter from Pharm-Assist committee member Tim Carlson spoke highly of Isaac's adherence to his treatment plan and attendance at recovery meetings. Attorney Lindell reviewed Isaac's order with the board and although he is still under probation there is nothing which would prevent him from purchasing a pharmacy and being PIC. Board members thanked Pharmacist Isaac Aasen for coming and wished him well in his new venture.

At 2:30 PM Jayme Wolf, PharmD – ND RPh5459 appeared before the Board to answer questions relative to her recent complaint and discuss the Stipulated settlement she has signed.

Gayle Ziegler indicated she was Pharmacist Wolf's supervisor and would not participate in the discussion of her case, or vote.

***It was moved by Technician Halvorson and seconded by Pharmacist Wendel to approve the stipulation as signed by Jayme Wolf -RPh5459. On vote by roll call Gayle Ziegler, RPh abstained, Public Member Fran Gronberg, Technician Member Diane Halvorson, Tanya Schmidt, PharmD and Shane Wendel, PharmD - all voted Aye. The stipulation was approved.***

***It was moved by Technician Halvorson and seconded by Pharmacist Schmidt to give Executive Director Mark Hardy authority to approve Pharmacist Wolf to return to work up to 20 hours per week under supervision of another pharmacist, upon approval of her counselor and Agnes Harrington of the Pharm-Assist committee. Pharmacist Wolf must return at the November 19<sup>th</sup>, 2015 meeting to report to the board. Board members Public Member Fran Gronberg, Technician Member Diane Halvorson, Tanya Schmidt, PharmD and Shane Wendel, PharmD - all voted Aye. Gayle Ziegler, RPh. did not vote. The motion carried.***

Publication of the Pharmacy law book revisions to include all the legislative changes implemented has been contracted out to a Microsoft word specialist and is moving forward.

Implementation of 2015 session legislation will be accomplished as soon as the rules heard today become effective.

Executive Director Hardy paid the Board Member Invoices and President Gronberg adjourned the meeting at 4:30 PM.

The Investigative Committee met to discuss current complaints and cases.

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President – Public Member  
Fran Gronberg

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Gary W. Dewhirst, R.Ph.  
Senior Member

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Member  
Diane M. Halvorson, RPhTech.

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Member  
Gayle D. Ziegler, R.Ph.

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Member  
Shane R. Wendel, PharmD.

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Member  
Steven P Irsfeld, R.Ph.

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Member  
Tanya L Schmidt, PharmD

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Executive Director  
Mark J. Hardy, PharmD