

**AGENDA****November 19, 2015****Board of Pharmacy Office – 1906 E Broadway Ave - Bismarck, ND**

**10:00 AM** – Call to Order – and Review of Mission Statement of Board of Pharmacy  
Public Member Fran Gronberg, President

**AGENDA**

Review and sign September 17, 2015 Board Minutes

**MINUTES**

Sign original Pharmacist and Technician Certificates

Review the Consideration of Comments received for the final Rule Adoption

Adoption of :

**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 - REVISED
Prescriptive Authority for Naloxone	Chapter 61-04-12

**10:45 AM** Jayme Wolf – RPh5459

**11:00 AM** Curtis Waldvogel, PharmD - Reciprocity from IL *Disciplinary Actions*

**11:30 AM** Advit Shah - Foreign graduate from University of Manitoba

**TAB 2**

**CE Request** UND “Antipsychotics and QTc Interval” - Amy Werremeyer, PharmD  
Sanford “Diabetes Symposium” – Sandra Offutt, R.Ph.

**Collaborative Agreement:** Bismarck Sanford Anticoagulation Clinic–John Savageau, RPh  
CHI St Alexius – Mandan Clinic Anticoagulation - LeNeika Roehrich, PharmD  
Altru Anticoagulation Clinic – Grand Forks - Melanie Cairns, PharmD [renewal]

**12:00 Lunch Break** [order in]

**Record Retention** – Board of Pharmacy Policy proposal

**TAB 3**

Year to date Financial Report - Budget comparisons

**BUDGET TAB**

**New Pharmacy:** Horizon Pharmacy - Bismarck - Lucas Hoechst, PharmD

**THURSDAY – November 19, 2015 Exam Schedule - # Andrew Holm**

**Candidates**

1:15 - 1:30 PM	Roll Call and Orientation of Candidates
1:30 - 2:30 PM	Laboratory Section
2:30 - 3:00 PM	Errors and Omissions
3:30 - 4:15 PM	Oral Examination

**Investigative Committee**

President Fran Gronberg called the meeting to Order at 10:00 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 - Gary Dewhirst, RPh - Diane M. Halvorson, RPhTech - Steven Irsfeld, RPh -Shane Wendel, PharmD. – Tanya L. Schmidt, PharmD; Executive Director Mark J Hardy, PharmD – Howard C Anderson, Jr. R.Ph., Chief Compliance Officer; Also present were: PharmD Student Tyler Hewitt Walker, on rotation with Board Member Wendel and PharmD Student Kristy Schwanke on rotation with Board Member Schmidt.

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 pharmaceuticals is upheld through education, communication, licensing, legislation, regulation, and enforcement.*”

***It was moved by Technician Member Halvorson and seconded by Pharmacist Dewhirst to approve the Agenda with the addition of; discussion by Inspector Dennis DelaBarre of hospital pharmacy inspections results, extension of the North Dakota State College of Science (NDSCS) technician program to a cohort group at Bismarck State College (BSC), progress on the Yellow Jug Old Drugs program sign up, timing of inspections of retail pharmacies, the registration of technicians in training who are in a remedial program at NDSCS and removal of the 11:30 meeting with foreign pharmacy graduate Mr. Advit Shah who contacted Executive Director Hardy to say he would not make the meeting because of the adverse weather they were experiencing in Canada at this time. All Board Members voted Aye - the Motion carried.***

The Board Members signed original certificates and reviewed the minutes from September 17<sup>th</sup>, 2015. A question was asked about David Leedah, Pharm D. and his return to explain conversations with NDSU about CE for the Sanford programs. Executive Director Hardy explained that he has been asked to present on the January agenda.

***It was moved by Technician Member Halvorson and seconded by Pharmacist Schmidt to approve the September 17<sup>th</sup>, 2015 minutes as presented. All Board Members voted Aye - the Motion carried.***

The Board reviewed all the Comments received and considered the final Rule Adoption of:

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 – Revised accordingly
Prescriptive Authority for Naloxone	Chapter 61-04-12

Comments which needed review were received only on proposed changes to NDAC 61-04-10 CLIA Waived Tests:

***It was moved by Pharmacist Ziegler and seconded by Pharmacist Irsfeld to approve: Chapter 61-02-01-19 Pharmacy Quality Improvement as published; Chapter 61-03-01- Licensure of Pharmacists as published; Chapter 61-04-08- Limited Prescriptive Practices as published; Chapter 61-04-10- CLIA Waived Tests as revised due to changes made after consideration of comments, which are attached; and to approve Chapter 61-04-12- Prescriptive Authority for***

***Naloxone as published. 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 10:45 AM Pharmacists Thomas Simmer and John Savageau from Bismarck Sanford Health arrived and joined the meeting. It was explained by Executive Director Hardy and discussed that future collaborative agreements can be between the medical director and the pharmacist in charge due to legislation effective as of August 1, 2015.

***It was moved by Pharmacist Wendel and seconded by Technician Member Halvorson to approve the collaborative agreement as presented by John Savageau, Pharm.D of Sanford Health Bismarck. All board members voted aye, nays none, the motion carried.***

***It was moved by Pharmacist Dewhirst and seconded by Pharmacist Schmidt to approve the collaborative agreement proposed by LeNeika Roehrich, Pharm D of CHI-Mandan Clinic Anticoagulation as the first to be approved outside of an institution, as access to the medical records is available electronically at the clinic. All board members voted aye, nays none, the motion carried.***

***It was moved by Pharmacist Schmidt and seconded by Pharmacist Irsfeld to approve the Altru Anticoagulation Clinic collaborative agreement renewal presented by Melanie Cairns, PharmD, under the new four year renewal provision. All board members voted aye, nays none, the motion carried.***

At approximately 10:50 Pharmacist Jayme Wolf – RPh5459 arrived, apologized for being tardy and reported that the roads were slick from sleet and snow which caused her delay. Dr. Wolf explained her progress since meeting with the board previously. She thanked the board for granting her the ability to work 20 hours per week as that has been very therapeutic for her. Pharm-Assist Committee member, Agnes Harrington has contacted Dr. Hardy and communicated that Dr. Wolf was doing well. She did recommend that Dr. Wolf schedule marriage counseling with or without her husband attending.

***It was moved by Pharmacist Wendel and seconded by Pharmacist Schmidt to allow ND RPh5459 - Jayme Wolf, Pharm D to work up to 24 hours per week, require that she follow through with the recommendations of the counselor and Pharm-Assist Committee; that she return to the Board meeting in January to report on her progress. Pharmacist Ziegler disclosed that she works for Sanford where Dr. Wolf is employed and intends to vote. Six board members voted aye, one nay, the motion carried.***

***It was moved by Pharmacist Schmidt and seconded by Pharmacist Irsfeld to grant one hour of continuing education credit for the UND program “Antipsychotics and QTc Interval” to Amy Werremeyer, PharmD. All board members voted aye, nays none, the motion carried.***

***It was moved by Pharmacist Irsfeld and seconded by Pharmacist Ziegler to grant Sandra Offutt, R.Ph. six hours of continuing education credit for attendance at the Sanford “Diabetes Symposium” and also include any other attendees who make a specific request for the program credit. Board Member Gayle Ziegler disclosed that she works for Sanford. All board members voted aye, nays none, the motion carried.***

Dr. Hardy reviewed the reciprocity application of Curtis Waldvogel, Pharm D from Illinois, as he has some previous disciplinary action on his record.

***It was moved by Technician Member Halvorson and seconded by Pharmacist Dewhirst to grant Executive Director Hardy and Board Member Wendel the authority to approve the reciprocity of Curtis Waldvogel, PharmD after they conduct a telephone interview with him. All board members voted aye, nays none, the motion carried.***

The board made final preparations for today's exam to be given to candidate Andrew Holm, PharmD.

Board members broke for lunch, during where they discussed:

The meeting past Executive Director Howard Anderson and current Executive Director Mark Hardy had with the provost at Bismarck State College and the President, Provost and Dean of Health sciences at North Dakota State College of Science about extending their technician program to a cohort group at BSC with registration to be ready to begin for the fall 2016 semester. Career and Technician Education (CTE) initiatives were also discussed. The CTE programs are possible with the help of the Department of Public Instruction and the CTE regional consortiums and are delivered at high schools which choose to participate.

Compliance Officer Anderson reported that we have 29 pharmacies signed up for the Yellow Jugs Old Drugs program and another 40 who have promised to sign up in the next week or so. We plan to roll this program out in conjunction with the Attorney General's office by the first of the year.

Pharmacist Wendel indicated he has heard from several pharmacists that they would appreciate the inspection cycle be completed by the end of September, if possible.

Discussion about the registration of technicians in training while they are taking a remedial course through NDSCS was answered by Dr. Hardy, indicating that he felt we should register them during this time if they are actually enrolled at NDSCS.

Mark Hardy presented the records retention policy prepared by PharmD Student Jennelle Holt and said it was still a draft for review and would be ready for potential Board approval at a future meeting.

Mark Hardy reviewed the financial report with the board.

***It was moved by Pharmacist Wendel and seconded by Technician Member Halvorson to approve the financial report once the net income figures were reconciled between the income statement and the balance sheet. 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 1:15PM Candidate Andrew Holm arrived and was administered the practical exam by the board members.

At 1:30 PM Lucas Hoechst, PharmD arrived at the meeting to discuss his Application for a new Class-A Retail Pharmacy Permit for Horizon Pharmacy, located at 4535 Northern Sky Drive Suite 3 in Bismarck, ND 58503.

***It was moved by pharmacist Gary Dewhirst and seconded by pharmacist Gayle Ziegler to approve the plans, lease and pharmacy permit of Lucas Hoechst, PharmD for Horizon Pharmacy, located at 4535 Northern Sky Drive Suite 3 in Bismarck, ND 58503. All board members voted aye, nays none, the motion carried.***

Executive Director Hardy took advantage of Inspector Howard Anderson and free board members to do some investigative committee work.

Compliance Officer Dennis DelaBarre, RPh was present and reported on what he was finding on his sterile product pharmacy inspections. Progress is being made, although some pharmacies have a ways to go to meet USP 797 standards.

Compliance Officer DelaBarre also discussed the issues encountered regarding hazardous drug compounding in some of our critical access hospitals and the changes with new USP 800 Standards, which may affect future operations of these locations. Compliance Officer DelaBarre indicated that most of the critical access hospitals are compliant with the first-dose review rule, with just a couple of outliers, which are currently implementing telepharmacy services to ensure compliance. He remarked that the positive impact of this in the medication delivery in those facilities which do not have a pharmacist on staff at all times. Board Members thanked Pharmacist DelaBarre for his time and efforts during his first round of hospital inspections.

Executive Director Hardy discussed the recent FDA Meeting that he had attended in Washington, DC between the various states, with the topic being the FDA's implementation of the Drug Quality and Security Act. Much of the discussion at the meeting involved the states providing feedback on the new FDA regulatory standards on compounding set forth in the new federal law and the memorandum of understanding between the FDA and all the states. Executive Director Hardy indicated that there had been a very lengthy discussion on the memorandum of understanding and the issues it created for each individual jurisdiction. The FDA was very unclear as to what level of inspections they would be providing over the new outsourcing facilities and compounding pharmacies. It was noted that the FDA was very firm, that the Drug Quality and Security Act would not allow for office use compounding by a traditional pharmacy location any longer.

Executive Director Hardy discussed the Drug Supply Chain Security Act implementation and the feedback that the states provided to FDA on clarifications of a number of items; including licensure standards for states for wholesale distributors and third-party logistics providers. Over all the meeting left a lot of unanswered questions about how the FDA intended to implement and enforce the various provisions. Certainly more information is necessary as to what the effects will be for the Boards and our licensees.

Technician Member Halvorson reported on the Accreditation Council on Pharmacy Education meeting she attended to consider criteria for the accreditation of technician training programs. She pointed out that delegates commented that costs should be kept reasonable for providers of the programs and criteria reasonable so as not to erect barriers to accreditation which diminish the availability of the accredited programs available to potential technicians. Continuous Professional Development (CPD) was discussed as an alternative to continuing education programs now taken by both pharmacists and technicians. CPD is intended to focus on an individual's area of practice. There was discussion on whether the participant, ACPE or the employer should control the choice of the programs.

At 4:30 PM president Gronberg adjourned the meeting.

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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

## Consideration of Comments for September 17, 2015 rule hearing.

1. **Revise N.D. Admin. Code Chapter 61-02-01 to add a Continuous Quality Improvement and Policy and Procedure Requirement for retail pharmacies.**

No Comments Received

2. **Revise N.D. Admin. Code Chapter 61-03-01 Licensure of Pharmacists to transfer a license or license reciprocity**

No Comments Received

3. **Revise N.D. Admin Code Chapter 61-04-10 CLIA Waived Laboratory Tests**

Lauren Berton: CVS Health in support of the revised proposed language which expands current practice standards for pharmacists performing CLIA waived laboratory tests. We do ask that the board consider further expansion to allow a pharmacist designee under supervision, such as a technician or intern, to perform these tests. I have included suggested changes to language in blue below to 61-04-10-01(3), 61-04-10-02 and 61-04-10-03 to allow a pharmacist designee to perform these tests. We also request that the board add language to 61-04-10-06(1) specifically allowing LDL cholesterol testing.

### PROPOSED LANGUAGE

**61-04-10-01. Definitions.** For purposes of this chapter:

3. "Portfolio review" means a review by the board of a pharmacist's Pharmacy's records of ~~proficiency testing training logs~~, control testing logs, and records of patient tests performed to determine that a ~~pharmacist pharmacy~~ is continuously and consistently providing a service in a quality and competent manner.

**61-04-10-02. Education requirements ~~for pharmacists to perform CLIA waived laboratory tests.~~**

~~A pharmacist~~ An individual licensed or registered by the Board must meet the following requirements in order to perform CLIA waived laboratory tests authorized by North Dakota Century Code section 43-15-25.3 or added to the list as allowed by ~~that~~ section 61-04-10-06:

**61-04-10-03. Minimum quality standards required.** ~~Pharmacists~~ Pharmacies performing CLIA waived laboratory tests must meet the following standards:

61-04-10-06. Exempt tests and methods. An individual licensed or registered by the board, performing the following food and drug administration-waived tests and using the following methods, is exempt from the provisions of North Dakota Century Code chapter 43-48:

1. Total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides test by any accepted method

Jeff Lindoo: Thrifty White believes it is essential that pharmacists be allowed to delegate these tasks.

- These tests are CLIA-waived, because it has been determined that they do not require the education and training of a laboratory technician to do the test. In fact, these are tests that consumers can do themselves.
- We cannot expand pharmacy practice toward pharmacists truly serving as a health care practitioner if we saddle pharmacists with requirements to perform tasks that can be delegated individuals with much less education and training and at a much lower salary level. We don't require pharmacists to count pills and put them in bottles, because we have realized that is not good use of their education & training. I believe this is the same thing.

**Board Response:**

The Board agrees with the addition of “LDL Cholesterol” in 61-04-10-06 (1). Because this is already listed in the current law, so should be included in the rule

The Board discussed the topic of delegation and the following is from the minutes during the September 24<sup>th</sup> public hearing.

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.

Regarding Interns, we would maintain the intern can conduct the tests as long as it is done under a supervising pharmacist who is able to conduct the specific test and the intern is properly trained to conduct the test. This is a consistent stance on other duties interns are able to perform under pharmacist supervision.

Joel Kurzman: NACDS supports the proposed rules that expand the types of CLIA-waived tests that pharmacists can provide to their patients without having to comply with requirements of North Dakota Century Code chapter 43-48. This rule change will enable pharmacists and pharmacies to offer additional healthcare services that are currently provided by pharmacists and pharmacies in other states. Elsewhere in the country, pharmacists and pharmacies increasingly offer this public health service to promote prevention, early detection, and disease management. Given that millions of Americans lack adequate and timely access to primary health care, eliminating barriers to pharmacist-provided services such as CLIA-waived tests will allow pharmacists to assist physicians and other healthcare providers in meeting increased patient demand for basic healthcare services in North Dakota.

**Board Response:** The Board would agree with the comment.

Bridget Weidner: Staff in our office [North Dakota Department of Health] have reviewed the proposed North Dakota Board of Pharmacy rule changes to Chapter 61-04-10 CLIA Waived Laboratory Tests. We have a concern with section 61-04-10-06. Exempt tests and methods. The rule states that an individual licensed by the board, performing the following food and drug administration-waived tests and using the following methods, is exempt from the provision of the North Dakota Century Code chapter 43-48. Included in the lists of tests is Vitamin D blood test by any accepted method and genomic testing by any accepted method. These two tests are not currently food and drug administration waived tests. Since these tests are not food and drug administration waived tests, the pharmacy would not be able to perform this testing under a CLIA Certificate of Waiver.

**Board Response:** The Board would agree with the comments that since these two tests are not included as CLIA waived test that we will remove Vitamin D blood test and the genomic test from 61-04-10-06.

Sandra Matthey: On behalf of the North Dakota Board of Clinical Laboratory Practice, I am writing a letter of concern regarding your change to Administrative Rule § 61-04-10-06 which would allow licensed Pharmacists to perform waived laboratory testing. The Clinical Laboratory Administrative Rule § 96-02-10-01 already has a list of waived exempt tests which can be performed by non-laboratory personnel under the supervision of someone licensed by the ND

Board of Clinical Laboratory Practice. The Board of Clinical Laboratory Practice carefully screens each of these tests to ensure that they are indeed waived tests and that the public is safe to have these tests performed by non-laboratory personnel. Many of the tests in § 61-04-10-06 are not waived, the testing process is not simple, and the language is very nonspecific. In fact, the term “by any accepted method” is very broad and may lead to unsafe laboratory testing



since these methods are not vetted by the Board of Clinical Laboratory Practice. We respectfully ask that you consider these concerns and perhaps defer to the language of the Administrative Rule § 96-02-10-01. The Board would be willing to discuss this with the Board of Pharmacy at your convenience.

**Board Response:** The Board appreciates the efforts which the Board of Clinical Laboratory Practice has put into the list in their Administrative Rules. Our Board crafted our lists of tests specifically from 96-02-10-01 Administrative Rule. There are a few key additions of tests made to the list in 61-04-10-06 which the Board felt are safe and reasonably simple to administer. Pharmacists are increasingly being called upon and educated to conduct these simple point of care tests which often are purchased at their pharmacies. We have made the following modifications to the list of tests which differ from the tests outlined in 96-02-10-01 and NDCC 43-15-25.3.

- ~~13. Nicotine or cotinine test by any accepted method urine~~
- ~~14. Thyroid stimulating hormone blood test by any accepted method. blood~~
- ~~15. Vitamin D blood test by any accepted method~~
- ~~16. Bone mass and bone mineral density test by any accepted method~~
- ~~17. Genomic testing by any accepted method~~
- ~~18. Drug screening tests by any accepted method urine~~

**4. Revise N.D. Admin. Code Article 61-04 to add N.D. Admin. Code Chapter 61-04-12 Limited Prescriptive Authority for Naloxone**

Joel Kurzman: Pharmacists and pharmacies have an important role to play in facilitating access to naloxone for overdose prevention purposes. Pharmacists are recognized medication experts and are oftentimes the most readily accessible healthcare provider in local communities. By enabling pharmacists to prescribe and dispense Naloxone rescue kits in accordance with a written protocol approved by the board, the proposed rules will serve to eliminate barriers that can otherwise deter individuals from obtaining naloxone for use in overdose prevention scenarios. We commend the Board for promulgating regulations that clarify and streamline the process by which pharmacists can obtain limited prescriptive authority for naloxone for this purpose.

**Board Response:** The Board would agree with the comment.

**5. Revise N.D. Admin. Code Chapter 61-04-08 Limited Prescriptive Practices**

No Comments Received