

AGENDA
July 23, 2015

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

10:00 AM – Call to Order – Public Member Fran Gronberg, President **AGENDA**

Mission Statement of Board – proposal [hand-Out]

Review and sign: May 26-29, 2015 Board Minutes **MINUTES**

Sign original Pharmacist and Technician Certificates

Discussion Items **TAB 1**

Pharmacy Quality Improvement	Chapter 61-02-01-19
Pharmacy Compounding Standards	Chapter 61-02-01-03
Technician Screening Patients	Chapter 61-02-07.1
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

District V Meeting August 6-8, 2015 – Board involvement [hand-Out]

Yellow Jug Old Drugs Program roll out [hand-Out]

10:45 AM NuCara Pharmacy Long-Term-Care #2 [NuCara #32] request to add Subclass K – Telepharmacy to permit **TAB 2**

11:00 AM Peter Lee – MDD Contract Packaging – VAWD requirement **TAB 3**

Collaborative Agreement: St Alexius Pharmacists & Bone & Joint – Bismarck **TAB 4**

New Owner – Glen Ullin Pharmacy – Daniel Churchill, PharmD – Class K Telepharmacy and add subclass K for Churchill Pharmacy in Bismarck

12: 00 Lunch Break

Relocation – Mercy Hospital – Devils Lake – Kimberly Hurley, PharmD - PIC

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

~~**1:00 PM** – **New Pharmacy** – 3rd Street Clinic – Fargo – Judith Swisher, R.Ph~~ postponed

THURSDAY - July 23, 2015 Exam Schedule - #5-6 **Candidates**

1:15 - 1:30 PM	Roll Call and Orientation of Candidates- all 6
1:30 - 2:30 PM	Laboratory Section 1
2:30 – 3:30 PM	Laboratory Section 2
1:30 - 2:00 PM	Errors and Omissions 1
2:30 - 3:00 PM	Errors and Omissions 2
3:30 - 4:15 PM	Oral Examination - all

Thursday July 23, 2015

Board of Pharmacy Conference Room

Bismarck, ND

President Fran Gronberg called the meeting to order at 10:20 AM in the Board of Pharmacy conference meeting room in Bismarck, North Dakota. The delay was due to road construction that various Board Members had run into in traveling to Bismarck and within Bismarck.

Present were: Gary W. Dewhirst, R.Ph. - President Fran Gronberg -Diane M. Halvorson, RPhTech - Steven P. Irsfeld, R.Ph. - Shane Wendel, PharmD. - Executive Director Mark J Hardy, PharmD. and PharmD Student Mikayla A Fick, on rotation at the Board Office. Present via telephone conference was Gayle D Ziegler, R.Ph.

Also present was Compliance Officer Judy Swisher and Pharmacist Peter Lee.

Absent was Laurel Haroldson, R.Ph. who has graciously continued to serve until the Governor appoints a new Board of Pharmacy Member.

It was moved by Pharmacist Wendel and seconded by Pharmacist Irsfeld to approve the Agenda as presented. All Board Members present voted Aye - the Motion carried.

Executive Directory Hardy explained the desire for the Board of Pharmacy to develop a Mission Statement. Executive Director Hardy then presented a proposed Mission Statement for the Board's consideration.

It was moved by Pharmacist Wendel and seconded by Pharmacist Irsfeld to approve the Mission Statement as presented by Executive Director Mark J. Hardy, PharmD - as printed below:

Mission Statement

Of the

North Dakota State Board of Pharmacy

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 the appropriate use of the pharmaceuticals is upheld through education, communication, licensing, legislation, regulation, and enforcement.

All Board Members present voted Aye - the Motion carried.

It was moved by Pharmacist Wendel and seconded by Pharmacist Irsfeld to approve the Minutes of the May 26-29, 2015 Board Meeting after the typo correction to the 4th paragraph on page 5 to read "795" not 785 as written. All Board Members present voted Aye - the Motion carried.

Pharmacist Peter Lee of MDD Contract Packaging was present to discuss his operation of a repackaging facility in Fargo, North Dakota for pharmacies serving nursing homes and a possible exemption to the VAWD accreditation as currently required in NDCC 43-15.3. He expressed the current initiative to have good manufacturing practices at his facility to meet the requirements for an approved Food and Drug Administration [FDA] Registration. Furthermore, with the passage of the new federal legislation on pedigrees, he discussed the need to have proper documentation on the transportation of the medications, which he would be repackaging for pharmacies to utilize for their long-term-care patients. Pharmacist Lee pointed out probable duplications in VAWD in regards to his need to meet the federal pedigree requirements and the cost of having to acquire both.

Pharmacist Lee requested an exemption to the VAWD Requirement for MDD Contract Packaging, as currently required by North Dakota Century Code [NDCC] 43-15.3.

Board Members held a lengthy discussion on the potential implications on current standards of creating such an exemption for Pharmacist Lee. They did feel, as a pharmacist, he would be accountable; however, there would be issues with other repackagers and other facilities seeking an exemption to the VAWD requirement based on the Board's action of exemption made for Pharmacist Lee.

It was the consensus of the Board to observe and obey the current requirements in the statutes regarding VAWD accreditation and that we are not in a position to create an exemption for Pharmacist Lee and his facility.

At this time Pharmacist Dewhirst asked to be excused for a short time as he was committed to a conference call with the National Association of Boards of Pharmacy [NABP] that he would take in another room.

Executive Director Hardy gave a review of the administrative rules currently under discussion for a proposed rule hearing; having revised them based on comments made at previous Board Meetings.

Compliance Officer Judy Swisher, RPh addressed Chapter 61-02-07.1 - Technician Screening Patients and how that may be utilized, and the effect on the practice of pharmacy.

Executive Director Hardy asked if the Board Members were in favor of moving forward with a formal rule hearing on some of these rules at the September 17th, 2015 Board meeting. With the exception of Chapter 61-02-07.1 - Technician Screening Patients, which they determined needed more discussion and information gathered, possible at the next NDPhA convention, the Board Members agreed to move forward with a hearing on:

Pharmacy Quality Improvement	Chapter 61-02-01-19
Pharmacy Compounding Standards	Chapter 61-02-01-03
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

Executive Director Hardy presented an update on the planning for the District V NABP/ AACP Meeting North Dakota is hosting, scheduled for August 6-8, 2015 in Fargo and asked the Board for their assistance with the Friday entertainment and supper. He asked who was planning to attend and indicated he would provide more information upon their arrival in Fargo on August 6th.

Executive Director Hardy presented an update on the planning for the controlled substances disposal program through Yellow Jug Old Drugs and the potential roll out to participating pharmacies within the next month. He distributed a draft letter that would be sent to the pharmacies within North Dakota explaining participation along with materials on the requirements and proper request for a Yellow Jug Old Drugs disposal container.

Executive Director Hardy presented a communication received that morning from Angela Thompson, PharmD, Pharmacist-in-Charge of NuCara LTC #2 located at 979 Central Ave N in Valley City, North Dakota and holds ND Pharmacy Permit # Phar842 relative to their request for a subclass K – Telepharmacy permit. This communication states that the request is made with the intention of supervising / overseeing the telepharmacy location in Enderlin. After review of the documentation and discussion:

It was moved by Pharmacist Irsfeld and seconded by Pharmacist Dewhirst to approve a subclass K – Telepharmacy to NuCara LTC #2 – ND Pharmacy Permit # Phar842 located at 979 Central Ave N in Valley City, for the sole purpose of supervising / overseeing the NuCara #35 telepharmacy operation located in Enderlin, North Dakota. All Board Members present voted Aye - the Motion carried.

It was moved by Pharmacist Irsfeld and seconded by Pharmacist Wendel to approve the remodeling plans that indicates the addition of a consultation room and video/audio link equipment and the Application for a subclass K – Telepharmacy Permit submitted for Glen Ullin Pharmacy located at 113 South Main in Glen Ullin, ND submitted by new owner Daniel Churchill, PharmD. All Board Members present voted Aye - the Motion carried.

It was moved by Pharmacist Dewhirst and seconded by Technician Member Halvorson to approve the relocation plan submitted for Mercy Hospital Pharmacy – ND Pharmacy Permit #Phar179 located at 1031 7th Street East in Devils Lake, North Dakota. All Board Members present voted Aye - the Motion carried.

President Gronberg recessed the meeting for lunch which had arrived. During lunch the Board Members reviewed the candidate files and preparations for the afternoon's examination schedule and Pharmacist Ziegler left the meeting via ending her call.

At 1:15 four candidates presented for orientation and exams:

Jason Bruel – Ryan Platz – Adam Stubson and Jennifer Pieper Wang

The Board Examinations were completed and all four candidates were successful and on their way to licensure in North Dakota. The Board wished them well in all their endeavors.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Wendel to approve the financials as presented in the year-to-date reports provided by Executive Director Hardy. On a vote by Roll Call: Pharmacist Dewhirst – Aye President & Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Irsfeld – Aye Pharmacist Wendel – Aye Nays none – the motion carried.

Executive Director Hardy provided an update on the new legislation, NDCC 43-15-31.4 regarding Collaborative Agreements and asked PharmD Student Mikayla A Fick to present a document she created. PharmD Student Fick distributed a guidance document for new agreements and how personnel changes were to be handled for review and discussion.

A Collaborative Agreement submitted by St Alexius Pharmacists & Bone & Joint Clinic Physicians in Bismarck was presented to the Board. Executive Director Hardy explained that this is a personnel modification to the already approved Collaborative Agreement and thus did not require the full Board's support, per the new legislation.

After the Board Members reviewed NDCC 43-15-31.4 and agreed that once the Board of Medicine reviews and agrees to the guidance document, that it should be utilized by those interested parties entertaining a collaborative agreement and that the guidance document should be posted on our website for direction.

It was also the consensus of the Board that Executive Director Hardy should deal with the A Collaborative Agreement submitted by St Alexius Pharmacists & Bone & Joint Clinic Physicians in Bismarck, in this manner as it was a personnel modification. He will write a letter acknowledging the receipt and to approve the personnel modification.

It was moved by Pharmacist Dewhirst and seconded by Technician Member Halvorson to approve the Guidance Document for Administrative Process for Collaborative Agreements as created by PharmD Student Mikayla A Fick. All Board Members present voted Aye - the Motion carried.

Executive Director Hardy will submit this guidance document to the Board of Medicine for their review and agreement.

Executive Director Hardy paid the Board Member Invoices and President Gronberg adjourned the meeting at 3:45 PM.

President – Public Member
Fran Gronberg

Gary W. Dewhirst, R.Ph.
Senior Member

Member
Diane M. Halvorson, RPhTech.

Member
Gayle D. Ziegler, R.Ph.

Member
Shane R. Wendel, PharmD.

Member
Steven P Irsfeld, R.Ph.

Member
Laurel A. Haroldson, R.Ph.

Executive Director
Mark J. Hardy, PharmD