

September 15, 2016

Board Office Conference Room

Bismarck, ND

AGENDA

September 15, 2016

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

10:00 AM – Call to Order – Shane R Wendel, PharmD, President

AGENDA

Recite Mission Statement

10:00 AM Hearing – Tech108 Renee Jangula

TAB 1

Review and sign July 14, 2016 Board Minutes

MINUTES

Sign original Pharmacist and Technician Certificates

Request for CE Credit:

1. ND Immunization Conference – State Health Department – Alvin W Schwindt, RPh3290
2. Opioid Symposium: Preparing Professionals to Confront the Opioid Crisis
Fargo and Bismarck Attendees presenting Certificate of Completion 6 ½ hours
3. Nutri-Dyn – Great Plains Conference
4. Quality Health Associates Annual Quality Forum – Sara Vaagene, RPh4405
5. Spirit Lake Pharmacists Immunization Program

****Addition = NAPT Recruitment Video**

11:00 AM John Pemberton – Reciprocity Request

11:30 AM Continuation on discussion for transition of Sanford Health – Fargo **TAB 2**

Noon Lunch Break

1:00 PM Rule Changes from April 30th, 2016- Hearing – NDPhA Convention **TAB 3**

61-02-01-03 Compounding Standards

61-02-07.1-05 Tasks Technicians *MAY* perform

61-04-12 Patient consultation requirements

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

Technician to Pharmacist Ratio – continued discussion and drafts **TAB 4**

Request for a subclass K to be added for supervision of Class K Telepharmacy: TAB 5

Phar339 White Drug #63 – Devils Lake to monitor Phar218 White Drug #57 –Maddock

Phar603 White Drug #71 – Linton to monitor Phar673 White Drug #66 – Ashley

Phar78 White Drug #40 – Minot to monitor Phar702 White Drug #62 – Mohall

Phar461 White Drug #50 – Rugby to monitor Phar219 White Drug #58 – Rolette

Request subclass K to be added to Class A – monitored by Phar404 White Drug #61 Fargo

Phar503 White Drug #53 – Cavalier Phar511 White Drug #55 – Hettinger

Phar966 White Drug #72 in Lisbon

THURSDAY – September 15, 2016 Exam Schedule - Joseph R McDonald Candidates

1:15 - 1:30 PM Roll Call and Orientation of Candidates- all

1:30 - 2:30 PM Laboratory Section 1

2:30 - 3:00 PM Errors and Omissions 2

3:30 - 4:15 PM Oral Examination - all

2016-2017 Financial Report

Budget Tab

President Shane Wendel, PharmD called the meeting to order on Thursday September 15, 2016 at 10:00 AM in the Conference Room of the Board of Pharmacy Office, 1906 East Broadway in Bismarck, ND.

Present in addition to President Wendel were: Gary W. Dewhirst, R.Ph., Diane M. Halvorson, RPhTech, - Steven P. Irsfeld, R.Ph. - Gayle D Ziegler, R.Ph. –Executive Director Mark J Hardy, PharmD; Board Attorney David Lindell, JD; and Howard C Anderson, Jr, R.Ph. Senior Compliance Officer

Also present: PharmD Student Intern Savannah D. Miller; Michael Riepl, RPh of the PharmAssist Committee, new PharmAssist Committee Member Chantal Weisenburger, RPhTech and Technician Renee Jangula; NAPT President Amanda Olauson, RPhTech; John Long R.Ph., MBA. with CVS Caremark; Patrick Ward J.D. represented Express Scripts; Abigail Stoddard, LuGina Mendez-Harper, Pharm D, Jack McDonald J.D. representing Prime Therapeutics and Dennis K. McAllister, R.Ph., FASHP for Express Scripts. Arriving at 11:00 AM was Rod St Aubyn representing the Pharmaceutical Care Management Association;

Board Members absent were: Public Member Fran Gronberg and Tanya L. Schmidt, PharmD.

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.*

It was moved by Technician Diane Halvorson and seconded by Pharmacist Steve Irsfeld to approve the agenda with the addition of the Telepharmacy Permit requests from Thrifty White Pharmacy, viewing of the Northland Association of Pharmacy Technicians (NAPT) video and the request for CE credit for the Spirit Lake immunization course. All board members present voted aye. Nays none. The motion carried.

It was moved by Pharmacist Gayle Ziegler and seconded by Technician Diane Halvorson to approve the minutes of July 14, 2016 as printed. All board members present voted aye. Nays none. The motion carried.

At 10 AM President Wendel asked Technician Renee Jangula to move up to the head of the table, Dr. Hardy introduced her and indicated she was here due to a complaint and she has signed a stipulation. Dr Hardy asked her to explain what occurred to the board. She said the pharmacist had observed her taking some promethazine with codeine from the pharmacy shelf and refilling her bottle, for which she had a prescription, but without authorization of a pharmacist. Board Attorney David Lindell explained the stipulation and Technician Jangula answered several questions from the board. She explained that she has a contract with the PharmAssist Committee and is doing well in her recover from her identified alcohol use disorder. She is 60 days sober, completed outpatient treatment at Heartview and is now in aftercare. Pharm-Assist Committee Member Mike Riepl confirmed her success in recovery. Gayle Ziegler asked if she was ready to go back to work and she said, "yes, part time".

It was moved by Pharmacist Steve Irsfeld and seconded by Pharmacist Gary Dewhirst to approve the stipulation signed by Technician Renee Jangula, Tech108. All board members present voted aye. Nays none. The motion carried.

It was moved by Pharmacist Steve Irsfeld and seconded by Pharmacist Gayle Ziegler to award Amy Werremeyer, Pharm D. and any others who submit their Certificate of Completion, 6.5 hours of North Dakota Continuing Education for the Opioid Symposium put on by the Department of Human Services and the opioid coalition. Four board members voted aye. Pharmacist Gary Dewhirst voted Nay explaining that he felt we should accept only ACPE accredited CE as they have the system in place to validate the programs. The motion carried.

It was moved by Pharmacist Steve Irsfeld and seconded by Pharmacist Gayle Ziegler to award 0.5 hours of North Dakota Continuing Education for each session attended of the Spirit Lake Immunization Conference to all who request credit. The education was administered by ND Department of Health. Four board members voted aye. Pharmacist Gary Dewhirst voted Nay explaining that he felt we should accept only ACPE accredited CE as they have the system in place to validate the programs. The motion carried.

It was moved by Pharmacist Gayle Ziegler and seconded by Pharmacist Steve Irsfeld to table consideration of the consideration of CE for the Nutri-Dyn program until after the program so we can review the materials and get feedback from attendees of any commercial bias of specific sessions. All board members present voted aye. Nays none. The motion carried.

It was moved by Pharmacist Steve Irsfeld and seconded by Pharmacist Gayle Ziegler to award 5 hours of North Dakota continuing education credit to Sara Vaagene, R.Ph. for attendance at the Quality Health Associates Annual Quality Forum. Four board members voted aye. Pharmacist Gary Dewhirst voted Nay explaining that he felt we should accept only ACPE accredited CE as they have the system in place to validate the programs. The motion carried.

It was moved by Pharmacist Steve Irsfeld and seconded by Pharmacist Gayle Ziegler to award Alvin W. Schwindt, R.Ph and others who furnish prove of attendance, up to 11.25 hours of North Dakota Continuing Education for attendance at the 2016 ND Immunization Conference held by the State Health Department. Four board members voted aye. Pharmacist Gary Dewhirst voted Nay explaining that he felt we should accept only ACPE accredited CE as they have the system in place to validate the programs. The motion carried.

At 10:50 the board watched the Video prepared by Pharmacist Joel Aukes for NAPT highlighting the various roles a technician can play in a pharmacy. The video addressed Hospital Pharmacy, Retail Pharmacy, Telepharmacy, sterile and non-sterile compounding. Amanda Olauson, RPh.Tech. was present to explain the development process which was partly sponsored by the Board of Pharmacy. Another video will be prepared focusing on promotion of technician training options.

At 11:00 AM Reciprocity Candidate John Pemberton appeared before the Board to explain the disciplinary actions on his record. He had a sanction from the Washington Board for filling internet prescriptions while employed as a Pharmacist at a Washington pharmacy.

It was moved by Pharmacist Gary Dewhirst and seconded by Technician Diane Halvorson to allow John Pemberton to reciprocate off of his Washington license, which is now unencumbered. All board members present voted aye. Nays none. The motion carried.

At 11:30 AM Pharmacist Robert (Bob) Biberdorf, Enterprise Vice President of Pharmacy for Sanford Health joined the meeting by telephone. Discussion with the board followed on the proposed Memorandum of Understanding developed by Dr. Hardy and Attorney Lindell between the Board and Sanford Health to allow 18 months for Sanford to transition the current outpatient pharmacy, the Mills Avenue portion of the Grandfathered Hospital Pharmacy permit Phar315. Sanford plans to move to their new location 5225 23rd Ave S in Fargo, as soon as construction is complete. Pharmacist Biberdorf said he would rather have two or three years, but felt this timetable would put the onus on Sanford to expedite the consolidation of the Mill Avenue pharmacy with their Broadway Pharmacy. They will apply for a new Class B Hospital Pharmacy permit for their current 801 Broadway North location, which will not be a Grandfathered permit.

It was moved by Technician Diane Halvorson and seconded by Pharmacist Steve Irsfeld to approve the Memorandum of Understanding in its current form be presented to Sanford Health, which is made a part of these minutes. The purpose is to allow a transition of care for Sanford as they move services to their new location. On vote by roll call, Technician Member Diane Halvorson, Pharmacist Steve Irsfeld, Pharmacist Gary Dewhirst and Pharmacist Shane Wendel voted aye. Pharmacist Gayle Ziegler recused herself, as she works for Sanford. The motion carried.

Pharmacist Jeff Shorten of Thrifty White joined the board at 11:45 AM to explain the requests by Thrifty White for Sub Class K, Telepharmacy permits to allow for supervision of their Telepharmacy sites by pharmacists at stores, where extra time is available, and thus to allow the Central Consultation site to focus more on providing Medication Therapy Management. Also Sub Class K permits are being requested for some pharmacies to allow operation on Saturdays via Telepharmacy and thus continue to provide service on those days, when business is slow, but clinics are still open for emergencies.

It was moved by Pharmacist Steve Irsfeld and seconded by Pharmacist Gayle Ziegler to grant a subclass K permit for Phar339 White Drug #63 – Devils Lake to monitor Phar218 White Drug #57 –Maddock. All board members present voted aye. Nays none. The motion carried.

It was moved by Pharmacist Gayle Ziegler and seconded by Technician Diane Halvorson to grant a subclass K permit for Phar603 White Drug #71 – Linton to monitor Phar673 White Drug #66 – Ashley. All board members present voted aye. Nays none. The motion carried.

It was moved by Technician Diane Halvorson and seconded by Pharmacist Steve Irsfeld to grant a subclass K permit for Phar78 White Drug #40 – Minot to monitor Phar702 White Drug #62 – Mohall. All board members present voted aye. Nays none. The motion carried.

It was moved by Pharmacist Gayle Ziegler and seconded by Technician Diane Halvorson to grant a subclass K permit for Phar461 White Drug #50 – Rugby to monitor Phar219 White Drug #58 – Rolette. All board members present voted aye. Nays none. The motion carried.

It was moved by Pharmacist Gayle Ziegler and seconded by Pharmacist Steve Irsfeld to grant a subclass K to Phar503 White Drug #53-Cavalier's Class A permit to allow it to be monitored by Phar404, White Drug #61 in Fargo. All board members present voted aye. Nays none. The motion carried.

It was moved by Pharmacist Steve Irsfeld and seconded by Technician Diane Halvorson to grant a subclass K to Phar511 White Drug #55-Hettinger's Class A permit to allow it to be monitored by Phar404, White Drug #61 in Fargo. Pharmacist Gary Dewhirst disclosed that he has worked at this pharmacy and has an interest in the building it occupies, but intends to vote. All board members present voted aye. Nays none. The motion carried.

A request for a subclass K permit for Phar966 White Drug #72 in Lisbon was tabled until the other pharmacy in the community can be consulted and a potential Memorandum of Understanding can be considered.

The board broke for lunch at 12:10 PM and prepared the exam for this afternoon.

At 1 PM Exam candidate Joseph R. McDonald arrived, was oriented and began the examination protocol.

At 1:30 PM Dr. Hardy began the review of the Rules, upon which the Hearing has been held, but which have not been acted upon for final approval by the Board.

Proposed changes to NDAC 61-02-01-03 Compounding Standards were discussed. Dr. Hardy reported that he and Pharmacist Steve Irsfeld attended the North Dakota Veterinary Association in August 2016 and discussed the changes with them. Many did not realize that it was currently a violation for veterinarians to dispense products compounded from pharmacies for resale. The veterinarians asked that we lengthen the time allowed to dispense an emergency supply of office use compounded products to 5 days, as this would cover long weekends and holidays when the products cannot be obtained.

It was moved by Pharmacist Gayle Ziegler and seconded by Pharmacist Gary Dewhirst for final adoption of the changes in NDAC 61-02-01-04 Compounding Standards with inclusion of 120 hours in subsection 9. b. All board members present voted aye. Nays none. The motion carried.

Proposed changes to NDAC 61-02-07.1-05 Tasks Technicians may Perform will be held until the November meeting to allow discussion at the Fall Conference of NAPPT.

Proposed changes to NDAC 61-04-12 Patient Consultation Requirements were reviewed by Dr. Hardy one subsection at a time. Written comments submitted in the last few days are included in the notebooks and have been reviewed by Board Members.

From: April C. Alexander for the Pharmaceutical Care Management Association.

LuGina Mendez-Harper, RPh., Pharm.D. for Prime Therapeutics

John Long, RPh, MBA for CVSHealth

Lorri Walmsley, RPh for Walgreens

Dennis K. McAllister, R.Ph., FASHP for Express Scripts

A summary of these comments centers around their provision of mail service and specialty pharmacy services with most saying that their pharmacists are available 24/7 via a phone call from the patient and requirements to reach out to the patient before providing service are only 20% to 25% effective, might slow down service to the patient, are unnecessarily expensive and that the written materials currently provided. The option for the patient to call and reach a pharmacist has served patients well for decades. They contend that they and boards of pharmacy receive very few complaints about their service.

Subsection 1. No changes were suggested.

Subsection 2. No changes were suggested, but depends on adoption of the technician rules tabled until after the fall Technician Conference.

Subsection 3. No changes were suggested.

Subsection 4. No changes were suggested.

Subsection 5. The language, "an attempt to reach the patient or their agent should be made for a consultation on the prescription" drew a great deal of discussion.

Dennis McAllister stated that calling before dispensing slows down the patient getting their medication. The "Attempt" costs money and slows the process. The current process of dispensing the prescription, sending written material with it and allowing the patient to call and reach the pharmacist 24/7 has worked well for them for decades. Additionally, Express Scripts currently makes 40,000 calls per week to clarify prescriptions or get patient information when needed. Their model of care is different and they advocate for creating an exemption similar to what is in the Century Code for Long-Term-Care patients and hospital patients.

LuGina Mendez-Harper echoed the inefficiencies of the "attempt to contact" language.

John Long and Pat Ward pointed out that there seemed to be no problems with mail service pharmacy, so why make the change.

Board Members felt that there was a need to better educate patients receiving new prescriptions from any pharmacy with a consultation while certainly not creating a delay in care, which is what is meant in making the "attempt to contact". Medications are becoming more complex and having educated patients is important in an evolving model of health care.

Subsection 6. Also drew many comments. Although Dennis McCallister and some others said they had no problem with this section, as all their patients must be enrolled before they dispense a prescription, others did have problems with it and suggested it belonged elsewhere and not as a part of patient counseling regulations. Rod St Aubyn, and others, pointed out that this subsection 6. Seems to conflict with NDCC 43-15-31.2. David Lindell and Jack McDonald explained that a rule is intended to clarify or provide more detail of what a statute allows, but cannot conflict with it.

President Wendel mentioned that this issue arose during our July meeting and participants were asked to come up with language that would work for them. Abigail Stoddard and several other participants said their legal departments could suggest no language that would accomplish the board's purpose and suggested the language be stricken.

It was moved by Pharmacist Gayle Ziegler and seconded by Pharmacist Gary Dewhirst to remove subsection 6. All board members present voted aye. Nays none. The motion carried.

Subsection 7. Depends on the language in NDCC 43-15-31.2 and needs not be changed.

Subsection 8. Received no suggestions for change.

With no resolution to subsection 5 along with the need for concurrent passage of the technician changes, action on this rule was deferred until future Board meeting. Interested parties departed the meeting and all thanked the Board for being very open in its deliberation concerning these new rules.

Proposed changes to NDAC 61-08-01-10 out-of-State Counseling Services depends upon the resolution of the previous rule, so it was deferred until future Board meeting.

Discussion moved to the technician to pharmacist ratio and Dr. Hardy presented three possible drafts of NDAC 61-02-07.1 Pharmacy Technician. Eliminate the ratio section altogether, specify it will be left up to the pharmacist’s discretion, or move to a 4 to 1. This item will be deferred until it has been discussed at the NAPT Conference in October.

The Federal law change to allow partial filling of a schedule II prescription up to a maximum of the original quantity or 30 days from the date written was discussed. It is hoped that this will reduce the amount of unused medication in medicine cabinets and thus reduce the diversion and misuse of these medications. North Dakota has no prohibitions in our laws or rules which would prevent partial filling of these prescriptions, therefore the change can be implemented here immediately.

President Wendel asked Dr. Hardy to review the financials for the Board.

Dr. Hardy pointed out that we have paid for the next batch of Take Back containers for our pharmacies and they should be shipped by the end of the month. President Wendel stated that it is our intention to cover the cost of this program for our pharmacies and that we could explore adjusting the Manufacturer licensing fee if needed.

Technician Diane Halvorson announced that Amanda Olauson, RPh Tech has been recognized as one of the PTCB spotlight technicians for the year and that Technician Diane Halvorson is a finalist for the PTCB Technician of the Year.

It was moved by Pharmacist Gary Dewhirst and seconded by Pharmacist Steve Irsfeld to adjourn the meeting. All board members present voted aye. Nays none. The motion carried and the meeting was adjourned.

President
Shane R. Wendel, PharmD.

Gary W. Dewhirst, R.Ph.
Senior Member

Member
Diane M. Halvorson, RPhTech.

Member
Gayle D. Ziegler, R.Ph.

Public Member
Fran Gronberg

Member
Steven P Irsfeld, R.Ph.

Member
Tanya L Schmidt, PharmD

Executive Director
Mark J. Hardy, PharmD