

AGENDA
March 21, 2019

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

9:30 AM – Call to Order - Tanya L Schmidt PharmD, President

AGENDA

Recite Mission Statement

Review and sign January 7-9, 2019 Board Minutes

MINUTES

Sign Pharmacist and Technician Certificates

** Collaborative Agreements – Shane Wendel

CE Credit Teresa Gerbig – RPh4871 – Clinical Endocrinology Fall Symposium
 “*American Academy of Anti-Aging Medicine (A4M)*”

New Pharmacy: In Hornbachers grocery store in West Fargo - Sheila Nudell, RPh4446

Remodeling: Carrington Drug Phar162 – Matthew Paulson, RPh4567

Relocation: The Prescription Shop Inc Phar98 – West Fargo - Tim Holland, RPh

Stipulation and Settlement Agreements:

Complete Pharmacy & Medical Solutions - Miami Lakes, FL

TAB 1

Imprimis NJOF – Ledgewood, NJ

TAB 2

Review Proposed Rule Changes:

TAB 3

- 61-01-01-01 Organization of Board of Pharmacy - removes out-dated email address
- 61-02-01-03 Pharmaceutical Compounding Standards – update to Compounding of
 Drugs to USP 795-797-800 standards
- 61-02-02-01 Building Standards for Pharmacies – updates Drug Storage areas
- 61-02-04-02 Handling of Hazardous Drugs (USP800) new section
- 61-02-06-02 Computer Pharmacy Regulations –adds electronic tracking of prescriptions
- 61-02-07.1-03 Pharmacy Technician Education preparation – clarifies Certification Requirements
- 61-02-07.1-04 Pharmacy Technician – adjusts the ratio of Pharmacists to Technicians
- 61-02-07.1-10 Pharmacy Technician Continuing Education –removes paper tracking requirements
- 61-03-02-04 Consultant Pharmacist Regulations for LTC Facility- addresses controlled substance drug
 destruction process
- 61-03-03.1-01 Internship – clarifies educational requirements for eligibility
- 61-03-04-02 Pharmacist Continuing Education - removes paper tracking requirement
- 61-03-04-04 CE Advisory Board - repeal
- 61-04-03-01 Destruction of Controlled Substances – update to DEA standards
- 61-08-01-08 Out-of-State Pharmacy – modifies Administrative Inspection requirements
- 61-08-01-09 Out-of-State Pharmacy – Prescription Records availability
- 61-12-01-03 Prescription Drug Monitoring Program [PDMP] – Operation of Program
- 61-12-01-04 Prescription Drug Monitoring Program [PDMP] – use for certain dispensing situations
- 61-13-01-03 Controlled Substances Schedules – Remove codified substances scheduled in NDCC 19-03
 by legislature in the 63rd assembly.

12:00 Lunch Break

Legal update: PCMA -vs- Tuft (potential executive session)

Legislative Update

TAB 4

Discussions: May 20-22, 2019 Meeting preparations [draft Agenda]

TAB 5

NABP Resolution on CBD from hemp

TAB 6

PDMP update – consequences of CDC Grant

TAB 7

NABP Annual Meeting plans

Take Back Program update

Year to date Financial Report - Budget comparisons

BUDGET TAB

2017-2018 Draft Audit Report - Widmer Roel [hand out]

Investigative Committee

THURSDAY - March 21, 2019 Exam Schedule - 1

Candidates

Ross Martin Derozier Alves – foreign graduate

12:30 PM Roll Call and Orientation of all Candidates - Video

1:00 - 2:00 PM Laboratory Section 1

2:15 - 2:45 PM Errors and Omissions 1

2:45 - 3:25 PM Oral Examination - 1

Board Minutes:

President Tanya Schmidt, PharmD called the meeting to order on Thursday March 21, 2019 at 9:30 AM in the Board of Pharmacy Office – 1906 E Broadway Ave - Bismarck, ND.

Present were: President Tanya Schmidt, PharmD - Shane Wendel, Pharm D, Diane M. Halvorson, R.Ph. Tech, Public Member Fran Gronberg - Steven Irsfeld, RPh - Gayle D Ziegler, R.Ph. – Executive Director Mark J Hardy, PharmD, Board Attorney David A. Lindell, JD , PharmD Students Tanner Upton, on rotation with Board Member Halvorson and Macey Llewellyn on rotation with Board Member Wendel and Compliance Officer Dennis DelaBarre, RPh.

Absent: Tyler Lannoye, PharmD

President Schmidt 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.*

Executive Director Hardy detailed the additions to the Agenda for the meeting: A Stipulated Agreement from Complete Pharmacy & Medical Solutions; A Stipulated Agreement from Imprimis NJOF – Ledgewood NJ; Modified Collaborative Agreements between: CHI St Alexius Carrington and Central Pharmacy in Carrington; CHI St Alexius New Rockford and Central Pharmacy in New Rockford; A draft Audit Report from Widmer Roel for the 2017-2018 fiscal year; discussion of a CDC grant and potential implications for PDMP. The request for CE Credit from Teresa Gerbig – RPh4871 was withdrawn.

It was moved by Pharmacist Ziegler and seconded by Technician Halvorson to approve the agenda with the reported modifications. On vote by roll call Pharmacist Wendel - aye; Technician Halvorson - aye; Public Member Gronberg – Aye; Pharmacist Ziegler-Aye; Pharmacist Irsfeld – aye; Pharmacist Schmidt – Aye. The motion carried.

It was moved by Pharmacist Irsfeld and seconded by Public Member Gronberg to approve the minutes of the January 7-9, 2019 meeting as printed. On vote by roll call Pharmacist Wendel - aye; Technician Halvorson - aye; Public Member Gronberg - Aye; Pharmacist Ziegler-Aye; Pharmacist Irsfeld - aye; Pharmacist Schmidt - Aye. The motion carried.

The Board reviewed of the Application for Pharmacy Permit, floor plans and lease agreement for a new Class A pharmacy named Medical Pharmacy Sheyenne planned in the Hornbachers grocery store at 2050 Sheyenne Street in West Fargo submitted by Pharmacist Sheila Nudell RPh4446.

It was moved by Pharmacist Ziegler and seconded by Technician Halvorson to approve the floor plans, lease agreement and Application for a Class A Pharmacy Permit to be issued to Medical Pharmacy Sheyenne planned in the Hornbachers at 2050 Sheyenne Street in West Fargo. On vote by roll call Pharmacist Wendel - aye; Technician Halvorson - aye; Public Member Gronberg - Aye; Pharmacist Ziegler-Aye; Pharmacist Irsfeld - aye; Pharmacist Schmidt - Aye. The motion carried.

The Board Members reviewed the floor plans for the remodeling of Carrington Drug Phar162 located at 415 Main Street in Carrington ND submitted by Matthew Paulson RPh4567.

It was moved by Pharmacist Ziegler and seconded by Public Member Gronberg to approve the floor plans for the remodeling of Carrington Drug permit number Phar162. On vote by roll call Pharmacist Wendel - aye; Technician Halvorson - aye; Public Member Gronberg - Aye; Pharmacist Ziegler-Aye; Pharmacist Irsfeld - aye; Pharmacist Schmidt - Aye. The motion carried.

Pharmacist Tim Holland RPh4035 submitted floor plans for the relocation of Phar98 The Prescription Shop Inc from 1210 Sheyenne Street to within the Sanford Clinic currently under construction on the corner of 13th Ave and Sheyenne Street in West Fargo, with an anticipated completion date of September or October 2019. It was noted that it would be a large increase in space for the pharmacy in the new location.

It was moved by Pharmacist Wendel and seconded by Pharmacist Irsfeld to approve the floor plans submitted by Pharmacist Tim Holland for the relocation of The Prescription Shop Inc permit number Phar98 to within the Sanford Clinic, the specific address to be provided at a later date in West Fargo. On vote by roll call Pharmacist Wendel - aye; Technician Halvorson - aye; Public Member Gronberg - Aye; Pharmacist Ziegler-Aye; Pharmacist Irsfeld - aye; Pharmacist Schmidt - Aye. The motion carried.

Executive Director Hardy and Board Attorney David Lindell gave an understanding of the Stipulated Agreements for Complete Pharmacy & Medical Solutions in Miami Lakes FL and Imprimis NJOF in Lidgewood, NJ. It was noted that the violations charged to both facilities were found to be consistent. Both locations were found to be engaging in 503B facility [Outsourcing] activities to medical locations within North Dakota without proper licensure under North Dakota Wholesale statutes.

It was moved by Pharmacist Irsfeld and seconded by Public Member Gronberg to approve the Stipulated Agreement for Complete Pharmacy & Medical Solutions in Miami Lakes, FL. On vote by roll call Pharmacist Wendel - aye; Technician Halvorson - aye; Public Member Gronberg - Aye; Pharmacist Ziegler-Aye; Pharmacist Irsfeld - aye; Pharmacist Schmidt - Aye. The motion carried.

It was moved by Pharmacist Wendel and seconded by Pharmacist Ziegler to approve the Stipulated Agreement for Imprimis NJOF in Ledgewood, NJ. On vote by roll call Pharmacist Wendel - aye; Technician Halvorson - aye; Public Member Gronberg - Aye; Pharmacist Ziegler-Aye; Pharmacist Irsfeld - aye; Pharmacist Schmidt - Aye. The motion carried.

Pharmacist Wendel described the request for modifications in collaborative agreements previously approved by the Board between pharmacies he owns in Carrington and New Rockford. He indicated the Medical Board requested modifications in three of the agreements he has brought for the Board's review and approval.

It was moved by Public Member Fran Gronberg and seconded by Pharmacist Steve Irsfeld to approve collaborative agreements between Pharmacist Shane Wendel and Dr. Michael Page for Carrington, ND. These agreements include: Hypertension Management Protocol, Rapid Group A Streptococcal Pharyngitis Protocol and Rapid Influenza A & B, Pharmacist Wendel recused himself from the vote. On vote by roll call Technician Halvorson - aye; Public Member Gronberg - Aye; Pharmacist Ziegler-Aye; Pharmacist Irsfeld - aye; Pharmacist Schmidt - Aye. Nays none. The motion carried.

It was moved by Pharmacist Gayle Ziegler and seconded by Pharmacist Steven Irsfeld to approve collaborative agreements between Pharmacist Kody Lura and Dr. Michael Page for New Rockford, ND. These agreements include: Hypertension Management Protocol, Rapid Group A Streptococcal Pharyngitis Protocol and Rapid Influenza A & B, Pharmacist Wendel recused himself from the vote. On vote by roll call Technician Halvorson - aye; Public Member Gronberg - Aye; Pharmacist Ziegler-Aye; Pharmacist Irsfeld - aye; Pharmacist Schmidt - Aye. Nays none. The motion carried.

The Board Members reviewed and discussed the proposed rule changes for the public hearing scheduled for Saturday April 6th, 2019 at the NDPhA Convention scheduled to be held in the New York New York Room at the Radisson Inn of Bismarck, ND. It was noted that the meeting room would be modified and proper notification would be given at the location to move down the hall at the hotel to the Manhattan Room to accommodate the Continuing Education Seminar that will be held later in the New York New York Room.

Executive Director Hardy walked through the current drafts that will be presented at the rule hearing and reported on comments received to date.

Executive Director Hardy reported on the Legislative updates from the Bill Tracking list that the Board has been following at this time. It was noted that much of the legislative work has been concluded. However, there are a few issues that are outstanding and being debated, which we are hopeful will conclude in a positive manner. He mentioned that HB1113 Rescheduling of Controlled Substances has been passed and is awaiting the signature of the Governor and would likely be accomplished in the next couple of weeks. The Board will then communicate the scheduling change on Gabapentin that would be incurred.

At 11:45 AM the Board Meeting recessed for lunch which was brought in and served at this time.

At 12:15 PM President Schmidt reconvened the meeting to discuss preparation for the May 20-21-22, 2019 Board Meeting and Examinations schedule. No recommendations to change or varyiate from the examination schedule established last year were made.

At 12:30 PM examination candidate Ross M Derozier Alves arrived at the meeting and was introduced to the Board Members. The afternoon examination process began.

Executive Director Hardy provided a draft resolution that requested the Board review for potentially moving forward at the 115th Annual NABP Meeting to be held on May 16-18, 2019 in Minneapolis, Minnesota. It was noted that the resolution had been received from Attorney Ned Milenkovich and its goal is to align the various Boards of Pharmacy on a path that would permit pharmacies to sell the Hemp derived CBD over the counter in a consistent regulatory approach.

The Board Members had a vigorous and spirited discussion about the proposed resolution and while they were generally in support of the prospect of pharmacies being able to carry CBD products, there was much discussion on the uncertainty of how the FDA will ultimately regulate and the legal requirements involved. All agreed that having medical professionals, including pharmacists, helping patients navigate substances like CBD would be in their best interest. However, the Board Members were not fully comfortable supporting the resolution as presented. They felt it would be better to have a task-force and an open discussion as more clarity develops in the federal regulatory strategies. It was noted that with the passage of the Controlled Substance Bill, this should open up a legal pathway for North Dakota locations to carry hemp derived products when it becomes finalized. The Board Members directed Executive Director Hardy to communicate their decision to Mr. Milenkovich and thank him for his work on this subject.

Executive Director Hardy gave a review of the implications of a CDC opioid PDMP grant, including the unfortunate special conditions that the CDC has placed in the grant mandate for the PDMP. The conditions would negatively impact the PDMP and the interstate sharing system through PMP InterConnect that North Dakota and 48 other states are currently using, as well as the potential loss of control of the PDMP data. The Board Members expressed alarm and concern by these conditions that the CDC put on the grant process and directed Executive Director Hardy to move forward in educating and advocating for removal of the special conditions in question. They noted the progress made in the opioid crises, and credited the PDMP for much of it and the PMP InterConnect for the opportunities it has created.

Executive Director Hardy provided an update on the "Take Back" program and discussed the issue of Sharps Invoices sent to some pharmacies, which was addressed.

The Board Members completed the exam protocols for Mr. Ross M Derozier Alves and tallied his score.

At this time Board Member Wendel exited the meeting for a prior engagement.

It was moved by Public Member Fran Gronberg and seconded by Technician Halvorson to approve the financials as presented. On vote by roll call Technician Halvorson - aye; Public Member Gronberg - Aye; Pharmacist Ziegler-Aye; Pharmacist Irsfeld - aye; Pharmacist Schmidt - Aye. The motion carried.

Executive Director Hardy presented and reviewed the draft Audit Report provided by Widmer Roel, noting that it might be prudent for the Board to discuss considering a motion to set aside more than one year operating expenses as designated assets and designated reserves based on the legal obligations of the Board. The Board Members reviewed the draft Audit Report, they had no further guidance and had no concerns.

It was moved by Technician Halvorson and seconded by to Pharmacist Ziegler to approve the draft Audit Report provided by Widmer Roel. On vote by roll call Technician Halvorson - aye; Public Member Gronberg - Aye; Pharmacist Ziegler-Aye; Pharmacist Irsfeld - aye; Pharmacist Schmidt - Aye. The motion carried.

President Schmidt called for any further business, none was forth coming - the meeting adjourned at 4:00 PM on Thursday March 21, 2019.

The Investigative Committee met to review the pending cases that have transpired since the last meeting.

President
Tanya L Schmidt, PharmD

Senior Member
Gayle D. Ziegler, RPh.

Technician Member
Diane M. Halvorson, RPhTech

Member
Steven P Irsfeld, RPh.

Public Member
Fran Gronberg

Member
Shane R. Wendel, PharmD

Member
Tyler G Lannoye, PharmD

Executive Director
Mark J. Hardy, PharmD