

**AGENDA**  
**July 18, 2019**  
**Board of Pharmacy Office –**  
**1906 E Broadway Ave - Bismarck, ND**  
**[701-328-9535]**

**9:30 AM** – Call to Order – Gayle D Ziegler, RPh President **AGENDA**

**Recite Mission Statement**

Review and sign May 18-20, 2019 Board Minutes **MINUTES**

Sign original Pharmacist and Technician Certificates

**10 AM Hearing:** Yasmin Awad – Tech 1281 **TAB 1**

**Remodeling Plans:** Dakota Precision Rx Bismarck Phar428 USP 800 Lab floor Plans  
Irsfeld Pharmacy Dickinson Phar143  
Mercy Hospital Pharmacy Williston Phar176 Clean Room Plans

2018-2019 Year End Financial Report **Budget Tab**  
2019-2020 Financials to Date

**Discussion Items:**

Rule Changes finalized at May Meeting – update **TAB 2**

Update on PCMA-vs - Tufte

NABP/AACP District V Meeting Duluth MN

Inspection Process Update

\*\*\* ***Exam Competencies***

***Guidance on Tobacco Cessation prescriptive authority***

***Rule adjustments for new ND Departmental of Environmental Quality citation***

**Proposed Rule Changes**

61-02-04-02 Handling of Hazardous Drugs (USP800) new section **TAB 3**

61-02-07.1 Technician Registration for members of the Military or their spouse of Military

61-03-04-04 Pharmacist Licensure for members of the Military or their spouse of Military

61-04-08 Limited Prescriptive Practices

61-04-11 Administration of Medications & Immunization

New Prescription Adaptation -

**12: 00 Lunch Break**

**THURSDAY - July 18, 2019 Exam Schedule - 3**

**Candidates**

11:30 PM Roll Call and Orientation of all Candidates - Video

11:45 - 12:45 PM Laboratory Section 1

1:00 - 1:30 PM Errors and Omissions 1

1:30 – 2:00 PM Oral Examination - 1

President Gayle D Ziegler, RPh called the meeting to order on Thursday July 18, 2019 at 9:30 AM in the Board of Pharmacy Office – 1906 E Broadway Ave - Bismarck, ND.

**Present were:** President Gayle D Ziegler, RPh - Steven Irsfeld, RPh - Diane M. Halvorson, Technician and Senior Member - Tyler Lannoye, PharmD- Tanya Schmidt, PharmD – Public Member Fran Gronberg - Shane Wendel, PharmD; Executive Director Mark J Hardy, PharmD; Howard C Anderson, Jr, RPh and PharmD Students: Tyler A Maanum, on rotation at the Board Office; Bailey Johnson on rotation with Board Member Schmidt; Ifeoluwa Olamijulo on rotation with Board Member Lannoye and brand new Pharmacist, as of yesterday, Abby Wilder, PharmD also with Board Member Lannoye and Bret Carlson on rotation with Board Member Wendel.

President Ziegler 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.*

As there were so many guests today President Ziegler asked everyone to introduce themselves, which was done.

***It was moved by Pharmacist Schmidt and seconded by Public Member Gronberg to approve the agenda with additions of the hearing for Yasmin Awad-Tech1281, a review of oral questions used for the exam (Gayle Ziegler), discussion of pharmacist's prescriptive authority for tobacco cessation products (Tyler Lannoye) and an adjustment to accommodate changes made by the legislature in moving the radiological health section to the Department of Environmental Quality. On vote by roll call: Pharmacist Irsfeld –Aye- Technician Member Halvorson –Aye- Pharmacist Lannoye –Aye- Public Member Gronberg –Aye- Pharmacist Schmidt –Aye- Pharmacist Wendel –Aye- Pharmacist Ziegler-Aye. The motion carried.***

***It was moved by technician Diane Halvorson and seconded by pharmacist Tanya Schmidt to approve the minutes of the May 18-20, 2019 meeting as printed. On vote by roll call: Pharmacist Irsfeld –Aye- Technician Member Halvorson –Aye- Pharmacist Lannoye –Aye- Public Member Gronberg –Aye- Pharmacist Schmidt –Aye- Pharmacist Wendel –Aye- Pharmacist Ziegler-Aye. The motion carried.***

Board members signed original certificates for future use as the meeting progressed.

Executive Director Hardy reported and showed Board Members some statistics on the PDMP after a question on usage of the PDMP.

PharmD Student Tyler Maanum on rotation at the Board Office provided an update on a Pharmacy Technician CE Audit he is assisting the Board to conduct.

Pharmacist Steve Irsfeld explained the plans for Irsfeld Pharmacy in Dickinson Phar143 and answered questions from board members relative to his plans for compliance with USP 800 standards for compounding with hazardous substances. He is, of course, owner of Irsfeld Pharmacy.

***It was moved by pharmacist Tanya Schmidt and seconded by pharmacist Tyler Lannoye to approve the remodeling plans for Irsfeld Pharmacy [Phar143] in Dickinson. On vote by roll call: Pharmacist Irsfeld –recused himself from voting- Technician Member Halvorson –Aye- Pharmacist Lannoye –Aye- Public Member Gronberg –Aye- Pharmacist Schmidt –Aye- Pharmacist Wendel –Aye- Pharmacist Ziegler-Aye. The motion carried.***

Pharmacist Kevin Oberlander and Registered Pharmacy Technician Darcy Triplett representing Dakota Precision Rx in Bismarck arrived at the meeting to discuss the floor plans they submitted. The plans were explained by Pharmacist Oberlander and Technician Triplett to bring them into compliance with USP 800 compounding standards for compounding hazardous substances.

***It was moved by pharmacist Tanya Schmidt and seconded by public member Fran Gronberg to approve the remodeling plans for Dakota Precision Rx in Bismarck [Phar428] to bring them into compliance with USP 800 On vote by roll call: Pharmacist Irsfeld -Aye- Technician Member Halvorson -Aye- Pharmacist Lannoye -Aye- Public Member Gronberg -Aye- Pharmacist Schmidt -Aye- Pharmacist Wendel -Aye- Pharmacist Ziegler-Aye. The motion carried.***

Pharmacist Dave Sandberg was contacted by telephone to explain the plans for remodeling at Mercy Hospital Pharmacy Williston Phar176. The clean room plans are intended to bring their hospital into compliance with USP 800.

***It was moved by technician Diane Halvorson and seconded by pharmacist Steve Irsfeld to approve to plans for Mercy Hospital Pharmacy Williston [Phar176]. On vote by roll call: Pharmacist Irsfeld -Aye- Technician Member Halvorson -Aye- Pharmacist Lannoye -Aye- Public Member Gronberg -Aye- Pharmacist Schmidt -Aye- Pharmacist Wendel -Aye- Pharmacist Ziegler-Aye. The motion carried.***

At 10:30 AM President Ziegler called the hearing for Yasmin Awad Tech1281 to order. Technician Awad is not present and had not responded to recent communications from the Board. Dr. Hardy reviewed her case file for the Board. She misrepresented her compliance with our requirement to be currently certified by PTCB on her last two renewals.

***It was moved by public member Fran Gronberg and seconded by pharmacist Shane Wendel to revoke the registration of Yasmin Awad Tech1281 as a North Dakota pharmacy technician and to assess her costs of the complaint and hearing as determined by Attorney Lindell and Dr. Hardy. On vote by roll call: Pharmacist Irsfeld -Aye- Technician Member Halvorson -Aye- Pharmacist Lannoye -Aye- Public Member Gronberg -Aye- Pharmacist Schmidt -Aye- Pharmacist Wendel -Aye- Pharmacist Ziegler-Aye. The motion carried.***

Dr. Hardy reported that the rule changes finalized at the May meeting will be heard at the Administrative Rules committee meeting on September 4<sup>th</sup>, 2019 and are expected to be effective October 1, 2019 except for the USP referenced rules on compounding which will be effective December 1, 2019 as that is the date the USP chapters become effective. It was noted all revisions from the May Rule Hearing were approved and the Attorney General's Opinion had been received.

Dr. Hardy explained that we do not yet have a date for the 8<sup>th</sup> Circuit case on PCMA vs Tufte as it has not been scheduled by the court.

The NABP/AACP District V meeting in Duluth will be attended by several board members.

Dr. Hardy reviewed the efforts in progress to get our inspection process online. He demonstrated a tablet with a Verizon hot spot built in which the inspectors will use in the field to affirm the self-inspection completed online by our pharmacies. He expects to have the software upgrade working within the next two weeks and compliance visitations started soon after.

President Ziegler discussed the progress in updating the exam competencies with oral questions. She agreed to assist correlating each Board Member's competency questions into a single document.

The Board broke for lunch and began the examinations for the three candidates.

The proposed rule changes were reviewed.

Executive Director Hardy gave an understanding on the recent information provided by US Pharmacopeia on the applicability of the USP Chapter 800. He played a video created by USP on this topic. It was noted that USP Chapter 800 is applicable when referenced in USP 795 and 797 and thus would be enforceable in pharmacies conducting compounding. However, they would not be enforceable on pharmacies *NOT* engaged in compounding. This validated the, seemingly, new information and perspective USP provided the Boards at the NABP Annual Meeting.

***It was moved by Pharmacist Schmidt and seconded by Pharmacist Lannoye not to move forward with 61-02-04-02 the new section on handling of hazardous drugs (USP 800). On vote by roll call: Pharmacist Irsfeld -Aye- Technician Member Halvorson -Aye- Pharmacist Lannoye -Aye- Public Member Gronberg -Aye- Pharmacist Schmidt -Aye- Pharmacist Wendel -Aye- Pharmacist Ziegler-Aye. The motion carried.***

Intern Tyler Maanum explained the revision he made to NDAC Section 61-05-01 – Radiopharmaceutical Services, which referenced the Department of Health as the state authority for radiological health as that authority has been moved to the new Department of Environmental Quality. Therefore these changes will be made at our request by the Legislative Council. No rule change process will be necessary.

***It was moved by Technician Member Halvorson and seconded by Pharmacist Irsfeld to ask Legislative Council to make these changes to 61-05-01 to the new Department of Environmental Quality. On vote by roll call: Pharmacist Irsfeld -Aye- Technician Member Halvorson -Aye- Pharmacist Lannoye -Aye- Public Member Gronberg -Aye- Pharmacist Schmidt -Aye- Pharmacist Wendel -Aye- Pharmacist Ziegler-Aye. The motion carried.***

The rules on provisional licensure for members of the military and their spouses, Administration of Medications and the repeal of Limited Prescriptive Practices was reviewed and discussed. It was noted that a Public Hearing will be set for these Rule Changes at the September 19, 2019 meeting.

Dr. Hardy suggested that the new section on Prescription Adaptation not be pursued at this time as it appears, we need some legislation to clear up the authority of the board for such a move.

Pharmacist Lannoye discussed a pilot project envisioned by a colleague pharmacist to prescribe smoking tobacco cessation products in the same format as was done with naloxone. Executive Director Hardy responded that we would need to have legislative changes for such authority. Pharmacists can do this now within a collaborative agreement, but the hope is to allow all pharmacists who have the proper training to participate in this public health service.

President Ziegler asked Dr. Hardy to review the 2018- 2019 year end financials and the 2019-2020 financials to date report.

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

President Ziegler called for any further business, none was forth coming - the meeting adjourned at 4:00 PM on Thursday July 18, 2019.

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President  
Gayle D. Ziegler, RPh.

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Technician Member & Senior Member  
Diane M. Halvorson, RPhTech

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Member  
Steven P Irsfeld, RPh

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Member  
Tanya L Schmidt, PharmD

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Public Member  
Fran Gronberg

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Member  
Shane R. Wendel, PharmD

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Member  
Tyler G Lannoye, PharmD

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Executive Director  
Mark J. Hardy, PharmD