

**AGENDA**  
**November 19, 2020**  
**Board of Pharmacy Office –**  
**1906 E Broadway Ave - Bismarck, ND**  
**[701-328-9535]**

**Join Zoom Meeting**

<https://us02web.zoom.us/j/81501835392>

**Phone** +1 312 626 6799 US (Chicago)

**Meeting ID:** 815 0183 5392

**8:30 AM** – Call to Order – President Gayle Ziegler, RPh

**AGENDA**

**Recite Mission Statement**

Review and sign September 18, 2020 Board Minutes

**MINUTES**

Sign original Pharmacist and Technician Certificates

**Discussion Items:**

COVID-19 Pharmacy Issues

Update on PCMA-vs – Wilke [formerly Tufte]

2020 Inspection update

2020 Legislative Session

***FDA – Compounding MOU***

2020-2021 Financials to Date

President Gayle D Ziegler, RPh called the meeting to order on Thursday November 19, 2020 at 8:30 AM.

**Present on the Zoom Meeting were:** President Gayle D Ziegler, RPh - Diane M. Halvorson, Technician and Senior Member -Tanya Schmidt, PharmD –Shane Wendel, PharmD, Tyler Lannoye, PharmD, Howard C Anderson, Jr, RPh; Attorney David A. Lindell, JD; John Long RPh Representing CVS Health. NDSU PharmD Student Andrew Buttram doing a rotation with the Board, Carly Meyer, Pharm D, a pharmacy resident at CHI Bismarck, Heather Coleman(Erber) an NDSU Intern and Ethan Meidt a University of MT Intern who are both on rotation with Board Member Tyler Lannoye.

**Present in the Board Conference Room** were Executive Director Mark J Hardy, PharmD and Public Member Fran Gronberg

**Absent** : Steve Irsfeld, R.Ph said he would be a little late and did not arrive on the Zoom call until 9:00AM.

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.*

**It was moved by Technician Member Diane Halvorson and seconded by Pharmacist Tanya Schmidt to approve the agenda with the addition of a review of the FDA Memorandum of Understanding on Compounding. On vote by roll call: Technician Member Diane Halvorson -Aye- Pharmacist Shane Wendel -Aye- Pharmacist Tanya Schmidt -Aye- Pharmacist Tyler Lannoye -Aye- Public Member Fran Gronberg-Aye- Pharmacist Gayle Ziegler -Aye. The motion carried.**

**It was moved by Pharmacist Tanya Schmidt and seconded by Pharmacist Tyler Lannoye to approve the minutes of September 18, 2020 as presented. On vote by roll call; Technician Member Diane Halvorson -Aye- Pharmacist Shane Wendel -Aye- Pharmacist Tanya Schmidt -Aye- Pharmacist Tyler Lannoye -Aye- Public Member Fran Gronberg-Aye- Pharmacist Gayle Ziegler -Aye. The motion carried.**

Executive Director Hardy pointed out we have enough signed certificates for now.

Dr. Hardy began the discussion of Covid-19 pharmacy issues. He provided an update from his efforts in assisting the State and Pharmacies on guidance related to the pandemic. He updated the Board on COVID testing opportunities for pharmacies to serve their communities, including the antibody and antigen tests approved as CLIA waived as well as sample collection for the state's testing efforts.

Andrew Buttram, NDSU PharmD Student and Intern on rotation with the Board Office reported on the vaccine development process and the availability for use soon. The Federal Government has purchased the vaccine and it will be distributed in phases. Phase 1 a. will be for essential health care workers, Phase 1 b. will be for Long Term Care residents and the next phases will include more "at risk" populations. Model of distribution to pharmacies were generally discussed and noted to be still being determined. Many pharmacies have signed up with the State to receive and administer vaccines to their Long-Term-Care patients.

Training and preparation for the receipt and use of the Covid-19 vaccines was discussed and pharmacists are being encouraged to prepare if they wished to participate.

John Long RPh of CVS confirmed Dr. Hardy's explanation of how vaccine shipments would go. Either directly to some chains like CVS, through wholesaler networks to pharmacies and also through the State Health Department to pharmacies signed up with them. Pharmacist Shane Wendel is signed up for his pharmacies. Pharmacist Wendel encouraged all pharmacies to get signed up with the state, work with the State on planning, and also encouraged the Board to mount a Public Information Campaign to make them aware of the availability in their pharmacy.

Executive Director Hardy reported that pharmacists could, with the Federal declaration, vaccinate children down to three years old. He also explained the recent expansion to allow a trained Registered Pharmacy Technician to administer vaccines.

Technician Member Diane Halvorson reported the Northland Association of Pharmacy Technicians has been meeting to discuss this vaccine opportunity and has negotiated a reduced price for the ACPE approved training with CEImpact if enough are interested.

John Long reported that CVS will be rolling out the use of technicians where it is allowed.

Executive Director Hardy reported on the status of the PCMA vs Wilke (formerly Tuft) case. The case has been ruled by the Eighth Circuit Court of Appeals against the State appearing to defer to previous rulings. The State has appealed to the US Supreme Court to reconsider our case due to a similar appeal and arguments from the State of Arkansas dealing with some parallel preemption matters.

Dr. Hardy gave an update on the Remote Virtual Inspection process. It seems to be working but has been hampered by some issues in the programming. Pharmacist Irsfeld and Pharmacist Schmidt have both been inspected and said it was a good process with good questions being asked of the pharmacies after review of the self-inspection.

Executive Director Hardy reviewed our legislation for Controlled Substance updates to Chapter 19-03 to keep up with DEA scheduling.

There will be some legislation introduced by legislators related to drug importation. Board Members encouraged Executive Director Hardy and Senator Anderson to offer the Board of Pharmacy as the agency to handle the development of a program for the state. There will also likely be legislation offered to encourage drug pricing transparency. The Board will continue to work with the Insurance Commissioner to bring information on this legislation to his attention for consideration on appropriate actions.

There has been discussion about initiating legislation allowing for a pharmacist's independent authority to order vaccinations without necessitating working through a protocol. Also, discussion on legislation to provide authority to extend an emergency dispensing of a 30 day supply consistent with the executive order issued by Governor Burgum. Pharmacist Irsfeld brought the issue of counseling on new mail order prescriptions sent through the mail, which the Board spent much time on rulemaking a year ago and never was able to enact.

At 10 AM John Deutsch, PharmD joined the Zoom call for the discussion on the FDA MOU which the FDA has long been working on which relates to inspection and communication protocols

between FDA and the Boards of Pharmacy. The chief benefit to ND pharmacies is the FDA will allow the pharmacies to ship over 5% of their prescription to other states. This will be a benefit to those pharmacies like that of Dr. John Deutsch who are located on the border of the state and others who serve a clientele in other states. There are some opponents advocating that this MOU is an overreach by the FDA. However, given the Federal Law as well as FDA's concerns on harms to patients from compounding problems the discussions have continued to occur. The Boards have until October 26, 2021 to sign the MOU.

Dr. Hardy reviewed the financial reports. There are no journal entries to review.

**It was moved by public member Fran Gronberg and seconded by pharmacist Steve Irsfeld to approve the financials as presented. On vote by roll call; Technician Member Diane Halvorson -Aye- Pharmacist Shane Wendel -Aye- Pharmacist Tanya Schmidt -Aye- Pharmacist Tyler Lannoye -Aye- Public Member Fran Gronberg-Aye - Pharmacist Steven Irsfeld - Aye Pharmacist Gayle Ziegler -Aye. The motion carried.**

The next meeting will be January 7, 2021, a Thursday.

President Ziegler adjourned the meeting.

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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