

AGENDA
September 18, 2020
Board of Pharmacy Office –
1906 E Broadway Ave - Bismarck, ND
[701-328-9535]

Join Zoom Meeting
<https://us02web.zoom.us/j/87236594861>
 Phone +1 312 626 6799
 Meeting ID: 872 3659 4861

8:30 AM – Call to Order – Gayle D Ziegler, RPh President	1
AGENDA	
<u>Recite Mission Statement</u>	2
Review and approve July 16, 2020 Board Minutes	3
Arrange to Sign original Pharmacist and Technician Certificates	
** 8:45 AM Abby Keller Tech1312 – Stipulated and Settlement Agreement	
9:00 AM CE Credit Request: Articles published by Michael Riepl, RPh3819	4
9:30 AM Rena Synek - Tech1627	5
10:00 AM National Coalition for Drug Quality & Security Recognition of QAS Accreditation [held over from July 16 th Meeting]	6
10:30 AM	
New Pharmacy RxE2 LLC – Class J [office practice] in Fargo – Gerald E Finken, RPh	7
Remodeling / Relocation Plans:	
Donna Bieri, PharmD - TAT White Shield Telepharmacy – Roseglen, ND Phar777	8
Shane Wendel, PharmD - Pharmacist Associates LLC dba Northwood Drug Phar514	9
Laurie Thompson, RPh - Presentation Medical Center – Rolla Phar199	10
Jerome Schmidt, RPh – Cooperstown Medical Center Pharmacy – new building plans Phar320	
11:00 AM Cole Peterson – P3 NDSU PharmD Program – Academic Misconduct	11
Discussion Items:	
COVID testing and vaccines	
Update on PCMA-vs – Tufte -----	12
Inspection Process Update	
Legislative Session -----	13
** January Meeting Date	
2018-2019 Year End Financial Report - motion on Audit	14
2020-2021 Financials to Date & General Journal Entries	15

President Gayle D Ziegler, RPh called the meeting to order on Friday September 18, 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 – Steve Irsfeld, R.Ph. ;Howard C Anderson, Jr, RPh; Pharmacist Michael Riepl, Technician Rena Synek, Denise Frank and Sumeet Singh of the National Coalition for Drug Quality and Security – Quality and Security [QAS]; John Long R.Ph Representing CVS Health, Jessica Adams of Telepharm and Dennis Pathroff of Kermit, Zuger and Smith. NDSU PharmD Student Kayla Briggs doing a rotation with the Board, Donna Bieri, Pharm D, Chris Albertson and Cole Peterson pharmacy Intern were on the Zoom call. **Present in the Board Conference Room** were Executive Director Mark J Hardy, PharmD; Attorney David A. Lindell, J.D.

Absent was Public Member Fran Gronberg who called in sick today.

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 Diane Halvorson and seconded by Pharmacist Tanya Schmidt to approve the agenda with the addition of the review of the Stipulated Settlement Agreement signed by Abby Keller Tech1312 and review of the date and plan for the January 2021 meeting. On vote by roll call, Pharmacist Shane Wendel -Aye Technician Diane Halvorson -Aye- Pharmacist Tanya Schmidt -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Steve Irsfeld -Aye- Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

It was moved by Pharmacist Tanya Schmidt and seconded by Pharmacist Shane Wendel to approve the minutes of the July 16, 2020 Board Meeting as printed. Pharmacist Tyler Lannoye abstained as he was not present at the meeting and the other five board members presented voted Aye. Nays None. The motion carried.

Dr. Hardy arranged with Board Members to get certificates signed as he, or they, traveled around the state.

At **8:45 AM** Dr. Hardy asked Attorney David Lindell to explain the case of Abby Keller Tech1312 – and the Stipulation and Settlement Agreement which she has signed. She is currently working with Kim Essler, R.Ph. of the PharmAssist committee and does desire to get her Technician Registration reinstated once she has been approved by the Board.

It was moved by Pharmacist Tanya Schmidt and seconded by Pharmacist Steve Irsfeld to approve the Stipulation and Settlement Agreement as signed by Abby Keller, RPh Tech1312. On vote by roll call, Pharmacist Shane Wendel -Aye-Technician Diane Halvorson -Aye-Pharmacist Tanya Schmidt -Aye-Pharmacist Tyler Lannoye -Aye-Pharmacist Steve Irsfeld -Aye-Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

President Ziegler asked Mike Riepl, RPh. to address his request for Continuing Education credit for the eight articles he has written on compounding and gotten published in journals.

There was much discussion and many questions answered by Pharmacist Riepl. It was clear that board members appreciated very much the contributions Pharmacist Riepl has added to the practice of compounding and several said they liked the articles very much. However, the board does not want to get into the position of reviewing every article pharmacists or technicians might publish for continuing education.

It was moved by Pharmacist Tyler Lannoye and seconded by Pharmacist Shane Wendel to deny the request of Michael Riepl, RPh3819 for continuing education credit for published articles. On vote by roll call, Pharmacist Shane Wendel -Aye-Technician Diane Halvorson -Aye-Pharmacist Tanya Schmidt -Aye-Pharmacist Tyler Lannoye -Aye-Pharmacist Steve Irsfeld -Aye-Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

Rena Synek, Tech1627 was present to discuss her self-report of a DUI arrest she had as a result of a poor decision she made to drive home after some drinking she did after the break-up of a 10 year relationship she had. Technician Synek currently works in the Inpatient Pharmacy at Sanford. She has been evaluated by Pharmacist Michael Riepl of the PharmAssist Committee who reviewed her evaluation from Heartview. Both the PharmAssist Committee and Heartview recommend no further action is need in the case of Technician Rena Synek.

It was moved by Pharmacist Shane Wendel and seconded by Technician Diane Halvorson to take no further action in the case of Rena Synek, Tech1627. On vote by roll call, Pharmacist Shane Wendel -Aye-Technician Diane Halvorson -Aye-Pharmacist Tanya Schmidt -Aye- Pharmacist Tyler Lannoye -Aye-Pharmacist Steve Irsfeld -Aye-Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

Denise Frank from the National Coalition for Drug Quality & Security Recognition – Quality and Security [QAS] Accreditation program was on the call and President Ziegler asked her to update the Board on this accreditation program. They just marked their first year of the program which grants wholesaler distribution accreditation. She compared QAS to with the Verified Accredited Wholesale Distributor (VAWD) program of the National Association of Boards of Pharmacy (NABP). QAS has accredited 14 companies to date and have another six in the process. Many questions were asked and answered by Denise Frank. There was discussion of the ownership of the company, the process facilities undergo to obtain their accreditation and the process for QAS to withdraw a facility's accreditation.

It was moved by Pharmacist Tanya Schmidt and seconded by Pharmacist Steve Irsfeld to table further consideration of acceptance of the QAS Accreditation program until the January 2022 meeting. On vote by roll call, Pharmacist Shane Wendel -Abstained as he is an Executive Committee Member of NABP- Technician Diane Halvorson -Aye- Pharmacist Tanya Schmidt -Aye- Pharmacist Tyler Lannoye -Aye-Pharmacist Steve Irsfeld -Aye- Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

CEO Chris Albertson, along with Dr. Cordy, Medical Director, of Presentation Medical Center was present to explain the plans to move and remodel the pharmacy at Presentation Medical Center in Rolla. He indicated the new location will increase space and get the pharmacists to the medical/surgical floor to enhance collaboration with the other practitioners. The sterile preparation room is down the hall from the proposed location and will remain in place.

It was moved by Pharmacist Tanya Schmidt and seconded by Pharmacist Shane Wendel to approve the move and remodeling plans for Presentation Medical Center Pharmacy as presented. On vote by roll call, Pharmacist Shane Wendel -Aye-Technician Diane Halvorson -Aye-Pharmacist Tanya Schmidt -Aye-Pharmacist Tyler Lannoye -Aye-Pharmacist Steve Irsfeld -Aye-Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

Donna Bieri, Pharm D was present to present the plans for Phar777 the Telepharmacy within the new Three Affiliated Tribes clinic planned in White Shield. It may not be started until spring, but Pharmacist Bieri would like to get the plans approved now. There is a walk-up window planned and, after discussion, board members suggested the window plan be moved from the counseling room to the adjacent wall to the pharmacy just outside the work area to avoid disrupting counseling sessions in process when delivering medications through the window. This is one facility which has seen the need with the COVID Pandemic for the walk-up window service.

It was moved by Pharmacist Tanya Schmidt and seconded by Pharmacist Steve Irsfeld to approve the plans for Phar777 Class G Pharmacy issued to TAT White Shield Telepharmacy with a request to move the walk-up window to the wall adjacent to the pharmacy just outside the work area to avoid disrupting counseling sessions in process and ensure security of the window location. On vote by roll call, Pharmacist Shane Wendel -Aye-Technician Diane Halvorson -Aye-Pharmacist Tanya Schmidt -Aye-Pharmacist Tyler Lannoye -Aye-Pharmacist Steve Irsfeld -Aye-Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

Gerald Finken, RPh was present to discuss his application for a Class J Office Practice Pharmacy in Fargo. The pharmacy is planned to have a global reach and will operate through contracted pharmacists and pharmacies to counsel patients in clinical trials with the goal of reversing the 9 out of 10 failure rate of medication trials. The pharmacy will employ Kristina Schlecht, PharmD RPh4760 and will have online access to clinical information and counsel patients through virtual access tools.

It was moved by Technician Diane Halvorson and seconded by Pharmacist Steve Irsfeld to approve the application of Gerald Finken, R.Ph. for a Class J Office Practice Pharmacy called RxE2, LLC at 4302 13th Ave S # 4326 Fargo, ND 58103. On vote by roll call, Pharmacist Shane Wendel -Aye-Technician Diane Halvorson -Aye-Pharmacist Tanya Schmidt -Aye-Pharmacist Tyler Lannoye -Aye-Pharmacist Steve Irsfeld -Aye-Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

President Ziegler asked Cole Peterson an Intern in the P3 PharmD program at NDSU to explain the situation around his academic misconduct charges. He said that he and two other students had collaborated on some testing conducted through technology during their courses. The college has put them on academic probation, failed them in the courses and this has cost them a year of additional time to finish their program. Intern Peterson wishes to put this incident behind him and be a model student and pharmacist from now on.

It was moved by Pharmacist Shane Wendel and seconded by Pharmacist Tanya Schmidt to reinforce what NDSU School of Pharmacy has done to require retaking of courses and assist in helping fellow students avoid similar temptations by keeping Cole Peterson -current INT99493 licensed as an intern through his completion of his academic program. On vote

by roll call, Pharmacist Shane Wendel -Aye-Technician Diane Halvorson -Aye-Pharmacist Tanya Schmidt -Aye-Pharmacist Tyler Lannoye -Aye-Pharmacist Steve Irsfeld -Aye-Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

At 11:30 President Ziegler asked Shane Wendel PharmD to explain the plans for the former Paul J Bilden Pharmacy to be remodeled and now known as Pharmacist Associates LLC dba Northwood Drug.

It was moved by Pharmacist Tyler Lannoye and seconded by Pharmacist Steve Irsfeld to approve the remodeling plans for Class A Phar514 Northwood Drug at 10 North Main Street in Northwood, ND 58267. On vote by roll call, Pharmacist Shane Wendel -Abstained- Technician Diane Halvorson -Aye- Pharmacist Tanya Schmidt -Aye- Pharmacist Tyler Lannoye -Aye- Pharmacist Steve Irsfeld -Aye- Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

Dr. Hardy asked Kayla Briggs, currently working as an Intern with the Board of Pharmacy to explain the work and process for pharmacists to do screening for Covid 19. Mike Schwab of NDPhA, Mark Hardy and Elizabeth Skoy at the college have worked closely to develop the program and to make sure the training and supplies pharmacists need are available. Mayo Pharmacy and Churchill Pharmacy in Bismarck have been the pilot pharmacies. All the information has been placed on the board web site developed by Dr Skoy and we are ready to recruit other pharmacies to participate.

Dr. Hardy explained the plans to prioritize the distribution of COVID vaccines when available. Some will require ultra-cold chain handling at minus 80 degrees which is currently beyond most capabilities. Others will require different storage and handling depending which are approved and available for use by the public.

Dr. Hardy gave an update on the PCMA vs Tuftes lawsuit where the 8th Circuit has reversed the District Court and appears to be awaiting the US Supreme Court ruling on the Arkansas case.

Dr. Hardy updated Board Members on the inspection process wherein pharmacies are doing their self-inspection via the online program where the inspectors can access it, follow up by telephone and finalize the Inspection, given the unique year of the Pandemic.

Dr. Hardy gave an update on Legislation planned by the Interim Health Care Committee. One bill deals with biosimilars and another with transparency of manufacturer and PBM pricing practices. He is working with the Insurance Commissioner on a joint approach to violations in the legislation where the Board will provide some investigative work and the insurance commissioner will make the final decision on hearings. There will likely be a bill to be sure ND laws are ready to allow importations from other countries if the FDA gets rules in place.

There were questions from Board Members asking about what seems to be the impediment to collaborative practice such as prescribing of smoking cessation products and some other products that other states have authorized pharmacists to prescribe.

It was moved by Pharmacist Tanya Schmidt and seconded by Technician Diane Halvorson to move the January 2021 meeting to January 7th, 2021. On vote by roll call, Pharmacist Shane Wendel -Aye-Technician Diane Halvorson -Aye-Pharmacist Tanya Schmidt -Aye- Pharmacist Tyler Lannoye -Aye-Pharmacist Steve Irsfeld -Aye-Pharmacist Gayle Ziegler -

Aye. Nays none. The motion carried.

The auditor’s draft report was reviewed at a previous meeting. Since then we have instituted a review of journal entries by the board member and some password change suggestions have been instituted.

It was moved by Pharmacist Shane Wendel and seconded by Technician Diane Halvorson to accept and approve the draft auditor report provided by Schmitz-Holmstrom LLP. On vote by roll call, Pharmacist Shane Wendel -Aye-Technician Diane Halvorson -Aye-Pharmacist Tanya Schmidt -Aye-Pharmacist Tyler Lannoye -Aye-Pharmacist Steve Irsfeld -Aye-Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

Dr. Hardy reviewed the financial report and the journal entries.

It was moved by Pharmacist Tanya Schmidt and seconded by Technician Diane Halvorson to approve the financial reports and journal entries as presented. On vote by roll call, Pharmacist Shane Wendel -Aye-Technician Diane Halvorson -Aye-Pharmacist Tanya Schmidt -Aye-Pharmacist Tyler Lannoye -Aye-Pharmacist Steve Irsfeld -Aye-Pharmacist Gayle Ziegler -Aye. Nays none. The motion carried.

Concurrent actions were taken by drug manufactures on eligibility to 340B programs and contract pharmacies. Many of our critical access hospitals, disproportionate share hospitals and rural pharmacies rely on the discounts offered through the 340B program to make ends meet. Drug companies are pushing back and asking that the eligible entities use just one contract pharmacy to better determine that only eligible patients get the discounted drugs.

It was moved by Pharmacist Shane Wendel and seconded by Technician Diane Halvorson to adjourn the meeting. All board members present voted aye and the meeting was adjourned.

President
Gayle D. Ziegler, RPh.

Technician Member & Senior Member
Diane M. Halvorson, RPhTech

Member
Steven P Irsfeld, RPh

Member
Tanya L Schmidt, PharmD

Public Member
Fran Gronberg

Member
Shane R. Wendel, PharmD

Member
Tyler G Lannoye, PharmD

Executive Director
Mark J. Hardy, PharmD