

AGENDA
November 21, 2019
Board of Pharmacy Office – [701-328-9535]
1906 E Broadway Ave - Bismarck, ND

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

Recite Mission Statement

Review, Amend and Approve Agenda

AGENDA

Review and sign September 19, 2019 Board Minutes

MINUTES

Sign original Pharmacist and Technician Certificates

Request for Class K addition: withdrawn

Thrifty White Pharmacy #053 - discussion

Request for CE Credit: Shawnel Decker, RPh4509

Remodeling: In Health Specialty Pharmacy – Fargo Phar570 submitted by
John Deutsch RPh5205 - Jason Cossette RPh5363 Pharmacist-in-Charge

Temporary Location for Remodel Mercy Hospital in Valley City

10:00 AM Final Rule Adoption:

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

10:30 Christiana Roach License Transfer from IL – request

12: 00 Lunch Break

Discussion Items:

Update on PCMA-vs - Tufte

Inspection Process Update

Interim Health Reform Committee Meeting

Practical Exam

**** addition** Review Enacted Legislation HB 1382

2019-2020 Financials to Date

Budget Tab

THURSDAY - November 21, 2019 Exam Schedule - None

President Gayle D Ziegler, RPh called the meeting to order on Thursday November 21, 2019 at 9:30 AM in the Board of Pharmacy Office – 1906 E Broadway Ave - Bismarck, ND.

Present were: President Gayle D Ziegler, RPh - Diane M. Halvorson, Technician and Senior Member - Tanya Schmidt, PharmD – Public Member Fran Gronberg - Shane Wendel, PharmD; Tyler Lannoye, PharmD present by phone; Executive Director Mark J Hardy, PharmD; Howard C Anderson, Jr, RPh and three NDSU Intern PharmD Students: Board Intern Kylee N. Nelsen; Intern Kenneth J Gillies on rotation with Board Member Lannoye and Intern Samantha J. Rogelstad on rotation with Board Member Wendel

Absent: Steven Irsfeld, RPh – Board Attorney David Lindell

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.*

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

It was moved by Technician Member Halvorson and seconded by Pharmacist Schmidt to approve the agenda with the addition of a discussion of HB 1382. On vote by roll call Technician Diane Halvorson-Aye- Pharmacist Tanya Schmidt-Aye- Public Member Fran Gronberg-Aye- Pharmacist Shane Wendel-Aye- Pharmacist Tyler Lannoye [via phone]-Aye- Pharmacist Gayle Ziegler-Aye. The motion carried.

It was moved by Public Member Gronberg and seconded by Technician Halvorson to approve the minutes of September 19, 2019 as printed. On vote by roll call Technician Diane Halvorson-Aye- Pharmacist Tanya Schmidt-Aye- Public Member Fran Gronberg-Aye- Pharmacist Shane Wendel-Aye- Pharmacist Tyler Lannoye [via phone]-Aye- Pharmacist Gayle Ziegler-Aye. The motion carried.

Executive Director Hardy explained the reasons behind the withdrawal of the requests for a subclass K permit for two Thrifty White locations to supervise Thrifty White Pharmacy # 053 in Cavalier, ND. After the last meeting a letter was generated explaining the Board had authorized only a sub class K for this pharmacy and operating it as a Class K did not appear in the best interest of the community as well as the Board's approval. A new Pharmacist-in- Charge is on-site in this pharmacy and it is operating in compliance with the intentions intended by the Board. Board Members reviewed the responses provided by Thrifty White and were happy with the swift action taken.

It was moved by Pharmacist Schmidt and seconded by Public Member Gronberg to grant 15.5 hours of continuing education credit to Pharmacist Shawnel Decker, RPh4509, for completion of the program, Bio-identical Hormone Replacement Therapy accredited for Continuing Medical Education sponsored by the American Academy of Anti-Aging medicine through George Washington School of Health Sciences. On vote by roll call Technician Diane Halvorson-Aye- Pharmacist Tanya Schmidt-Aye- Public Member Fran Gronberg-Aye- Pharmacist Shane Wendel-Aye- Pharmacist Tyler Lannoye [via phone]-Aye- Pharmacist Gayle Ziegler-Aye. The motion carried.

It was moved by Technician Halvorson and seconded by Pharmacist Schmidt to approve the remodeling plans for In Health Specialty Pharmacy, Pharm570, of Fargo to add a USP800 non-sterile compounding area. On vote by roll call Technician Diane Halvorson-Aye-

Pharmacist Tanya Schmidt-Aye- Public Member Fran Gronberg-Aye- Pharmacist Shane Wendel-Aye- Pharmacist Tyler Lannoye [via phone]-Aye-Pharmacist Gayle Ziegler-Aye. The motion carried.

It was moved by Pharmacist Schmidt and seconded by Pharmacist Wendel to approve the plans for the temporary location of Mercy Hospital in Valley City to be used during remodeling of their pharmacy to meet USP 800 standards. On vote by roll call Technician Diane Halvorson-Aye- Pharmacist Tanya Schmidt-Aye- Public Member Fran Gronberg-Aye- Pharmacist Shane Wendel-Aye- Pharmacist Tyler Lannoye [via phone]-Aye-Pharmacist Gayle Ziegler-Aye. The motion carried.

It was moved by Pharmacist Wendel and seconded by Technician Halvorson to adopt the revision to 61-02-07.1 Technician Registration for members of the Military or their spouse of Military. It was noted that no comments had been received. On vote by roll call Technician Diane Halvorson-Aye- Pharmacist Tanya Schmidt-Aye- Public Member Fran Gronberg-Aye- Pharmacist Shane Wendel-Aye- Pharmacist Tyler Lannoye [via phone]-Aye-Pharmacist Gayle Ziegler-Aye. The motion carried.

It was moved by Pharmacist Schmidt and seconded by Public Member Gronberg to adopt the revision to 61-03-04-04 Pharmacist Licensure for members of the Military or their spouse of Military with the addition of language to ensure candidates go through the NABP e-LTP review of any disciplinary action. On vote by roll call Technician Diane Halvorson-Aye- Pharmacist Tanya Schmidt-Aye- Public Member Fran Gronberg-Aye- Pharmacist Shane Wendel-Aye- Pharmacist Tyler Lannoye [via phone]-Aye-Pharmacist Gayle Ziegler-Aye. The motion carried.

It was moved by Pharmacist Wendel and seconded by Pharmacist Schmidt to repeal the rule 61-04-08 Limited Prescriptive Practices. It was noted that no comments had been received. On vote by roll call Technician Diane Halvorson-Aye- Pharmacist Tanya Schmidt-Aye- Public Member Fran Gronberg-Aye- Pharmacist Shane Wendel-Aye- Pharmacist Tyler Lannoye [via phone]-Aye-Pharmacist Gayle Ziegler-Aye. The motion carried.

It was moved by Technician Halvorson and seconded by Pharmacist Schmidt to adopt the revision to 61-04-11 Administration of Medications & Immunization. It was noted that no comments had been received. On vote by roll call Technician Diane Halvorson-Aye- Pharmacist Tanya Schmidt-Aye- Public Member Fran Gronberg-Aye- Pharmacist Shane Wendel-Aye- Pharmacist Tyler Lannoye [via phone]-Aye-Pharmacist Gayle Ziegler-Aye. The motion carried.

Pharmacist Christiana Roach called in by phone to discuss her application to reciprocate her pharmacist license from Illinois to North Dakota. She was licensed in California and lost that license because of a substance use disorder, failed recovery there, moved back home to Illinois and worked with the Illinois Health Professional Recovery Program and is now in recovery with her Illinois license in good standing. She volunteered that it helped that her job is in telepharmacy with no access to controlled substances. However, she feels she has progressed in her recovery and has no concerns on working in a retail or hospital pharmacy again.

It was moved by Pharmacist Wendel and seconded by Technician Member Halvorson to approve Christiana Roach's license transfer application allowing her to sit for the ND MPJE and obtain eventual licensure as a ND Pharmacist. On vote by roll call Technician Diane Halvorson-Aye- Pharmacist Tanya Schmidt-Aye- Public Member Fran Gronberg-Aye- Pharmacist Shane Wendel-Aye- Pharmacist Tyler Lannoye [via phone]-Aye- Pharmacist Gayle

Ziegler-Aye. The motion carried.

At 10:45 AM president Ziegler moved to the discussion items on the agenda.

Executive Director Hardy gave an update on the PCMA vs Tuft case. The hearing has been held before the three Judge panel of the eighth circuit where good questions were asked from both sides. We now await the decision from the panel which is expected to take over six months.

Dr. Hardy reported that three of the inspectors were nearly done with their work. Compliance Officer Bonnie Thom is ready to begin her work in the northwest. The new electronic process seems to be working well. Pharmacist Tanya Schmidt said the new process is easy to use and a good experience.

In response to Board Member's inquiry Executive Director Hardy stated that Compliance Officers have noted consultation seems to be much improved with technicians providing the screening as the recent rule allows.

Pharmacist Gayle Ziegler asked how follow-up works when inspectors note something on the inspection or if a warning is written. Chief inspector Anderson responded that the inspector may require missing information such as inventories or lapsed registrations be reported to them or the office within the time they have set, e.g. 30 days. Dr. Hardy responded that if a warning is issued the office follows up to ensure compliance within a reasonable time. If a second warning is issued, we proceed to the investigating committee and likely to a hearing.

Dr. Hardy reported on the recent meeting of the interim health care reform committee of the legislature. He presented their draft bills related to transparency and drug pricing transparency and Interchangeability of Biosimilars. The Board had no concerns on either and asked to continue to monitor as the next session approaches.

Executive Director Hardy explained new enacted legislation HB 1382 from the 2019 Session, effective January 1st, requiring patient consent or two notifications, by different means, before a refill is sent to the patient. Board Members agreed mailing each refill via an auto fill agreement would still require the prior consent of the patient or would require two attempts to contact the patient.

Dr. Hardy invited board members to consider attendance at the NABP member forum coming up early next year. Technician Diane Halvorson indicated she would like to attend again if no other board members could go.

It was moved by Pharmacist Schmidt and seconded by Public Member Gronberg to approve the financial reports as printed. On vote by roll call Technician Diane Halvorson-Aye- Pharmacist Tanya Schmidt-Aye- Public Member Fran Gronberg-Aye- Pharmacist Shane Wendel-Aye- Pharmacist Tyler Lannoye [via phone]-Aye-Pharmacist Gayle Ziegler-Aye. The motion carried.

The Board broke for lunch.

The interns attending were excused while the board discussed the practical exam competencies and associated questions which past director and Senior Compliance Officer Howard Anderson has prepared for their review. Confidentiality of the exam was discussed. The work will be placed on the January agenda for continuation of work to have a final working document ready for the May exams.

President Ziegler called for any further business, none was forth coming - the meeting 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