AGENDA September 27, 2018

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

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

AGENDA

Recite Mission Statement

Agenda - Review and Approve

Review and sign July 19, 2018 Board Minutes

MINUTES

Sign original Pharmacist and Technician Certificates

CE Request: Amy Simon, PharmD RPh5082

James L Roerig, PharmD RPh5100

Remodeling Plans: Forman Drug – Nathan Schlecht, RPh **Revised Plans:** Sanford Broadway Phar309 Fargo

Relocation Northwest Human Service Center Phar608 Williston

Collaborative Agreement: Sanford Anticoagulation Clinic – Fargo

Heather Strawsell, PharmD - Allison Frank, PharmD

Family HealthCare Pharmacy, NDSU

Susan Wolf Nelson, RPh

10:45 Nathaniel Berglind – 4th Year PharmD Candidate

Tab 1

11:30 Dennis Johnson, RPh – Red River Behavioral Health Systems – Grand Forks

Tab 2

Discussion on access to Medications

12:00 Lunch Break

Budget and Financial Reports

Budget Tab

1:00 PM Roll Call and Orientation of all Candidates - Video

Candidates

Tab 3

- 1) Jashandeep K Walia August NDSU Grad
- 2) Gregory L Fondong August NDSU Grad

Discussion Items:

Update on ROMA-vs - Cufte [Rotential Executive Session]

US 2 800 Task Force

ACSCR/ACRG Rharmacy Technician Rrogram changes

State action related to FCO-vs-NO Dental Board

Regislative Session

Home Dialysis Distribution - Eaxter

Tab 4

President Tanya Schmidt, PharmD called the meeting to order on Thursday September 27, 2018 at 9:30 AM in the Conference Room of the Board of Pharmacy Office, 1906 East Broadway in Bismarck, ND.

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.

<u>Present were</u>: President Tanya Schmidt, PharmD - Diane M. Halvorson, R.Ph. Tech, - Tyler G Lannoye, PharmD. - Shane Wendel, Pharm D, Gayle D Ziegler, R.Ph. – Executive Director Mark J Hardy, PharmD, Howard C Anderson, R.Ph. Senior Compliance Officer.

<u>Also present</u>: PharmD Student Interns: Vanessa E Ryberg on rotation with Technician Member Halvorson and Tafadzwa [Eleck] Bhobho on rotation with Board Member Wendel and new Pharmacist Melissa M Halvorson, PharmD.

Absent: Public Member Fran Gronberg and Steven Irsfeld, RPh

The Board Members present signed Technician Registration Certificates for use in the future. Arrangements will be made to get the signatures of the two absent Board Members.

It was moved by Pharmacist Gayle Ziegler and seconded by Technician Diane Halvorson to approve the agenda with the addition of a Report on a recent meeting attended by Executive Director Hardy held with the FDA on Compounding and a discussion for future agendas to accommodate candidate testing in the late morning. On vote by roll call: Gayle D Ziegler, RPh.-Aye; Diane M. Halvorson, R.Ph. Tech- Aye; Tyler G Lannoye, PharmD. -Aye; Shane Wendel, Pharm D, - Aye; Tanya Schmidt, PharmD - Aye. Nays none - the motion carried.

It was moved by Technician Diane Halvorson and seconded by Pharmacist Shane Wendel to approve the minutes of the July 19, 2018 Board Meeting as printed. On vote by roll call: Gayle D Ziegler, RPh.-Aye; Diane M. Halvorson, R.Ph. Tech- Aye; Tyler G Lannoye, PharmD. – Aye; Shane Wendel, Pharm D, - Aye; Tanya Schmidt, PharmD – Aye. Nays none – the motion carried.

It was moved by Technician Diane Halvorson and seconded by Pharmacist Shane Wendel to approve 11.25 hours of CE for Amy Simon, Pharm D. RPh5082, and any other attendee completing the 2018 ND Immunization Conference put on by the State Health Department and requesting CE credit. On vote by roll call: Gayle D Ziegler, RPh.-Aye; Diane M. Halvorson, R.Ph. Tech- Aye; Tyler G Lannoye, PharmD. –Aye; Shane Wendel, Pharm D, - Aye; Tanya Schmidt, Pharm D – Aye. Nays none – the motion carried.

It was moved by Pharmacist Gayle Ziegler and seconded by Pharmacist Tyler Lannoye to request more information regarding the actual courses James L. Roerig, Pharm D RPh5100 attended and reconsider his request for 40 hours of CE credit for attendance at the American Psychiatric Association 2018 Annual meeting at the November 2018 Board meeting. On vote by roll call: Gayle D Ziegler, RPh.-Aye; Diane M. Halvorson, R.Ph. Tech-Aye; Tyler G Lannoye, PharmD. -Aye; Shane Wendel, Pharm D, - Aye; Tanya Schmidt, PharmD - Aye. Nays none - the motion carried.

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It was moved by Pharmacist Tyler Lannoye and seconded by Pharmacist Shane Wendel to approve 0.5 hours of CE for the Sanford Health Pharmacogenomics Program presented by

Sanford Imagenetics, as it was only a 15 to 20 minute video program. On vote by roll call: Gayle D Ziegler, RPh.-Abstained as she works for Sanford; Diane M. Halvorson, R.Ph. Tech-Aye; Tyler G Lannoye, PharmD. -Aye; Shane Wendel, Pharm D, - Aye; Tanya Schmidt, PharmD - Aye. Nays none - the motion carried.

The remodeling plans submitted by Nathan Schlecht, RPh for Phar19 Forman Drug currently located at 330 Main Street South in Forman, North Dakota were reviewed and discussed.

It was moved by Technician Diane Halvorson and seconded by Pharmacist Gayle Ziegler to approve the remodeling floor plans submitted by Pharmacist Nathan Schlecht for Phar19 Forman Drug located at 330 Main Street South in Forman, ND. On vote by roll call: Gayle D Ziegler, RPh.-Aye; Diane M. Halvorson, R.Ph. Tech- Aye; Tyler G Lannoye, PharmD. –Aye; Shane Wendel, Pharm D, - Aye; Tanya Schmidt, PharmD – Aye. Nays none – the motion carried.

Board Member reviewed and discussed the submitted revised floor plans for the remodeling of Sanford Pharmacy Broadway– Phar309 located at 737 Broadway Ave in Fargo, ND. It was noted a desire by Sanford to expand the existing location rather than centrally relocating at the downtown campus.

It was moved by Technician Diane Halvorson and seconded by Pharmacist Tyler Lannoye to approve the revised remodeling plans for Sanford Broadway Pharmacy, Phar309 at 737 Broadway Ave in Fargo. Gayle Ziegler disclosed that she works for Sanford but intends to vote. On vote by roll call: Gayle D Ziegler, RPh.-Aye; Diane M. Halvorson, R.Ph. Tech- Aye; Tyler G Lannoye, PharmD. –Aye; Shane Wendel, Pharm D, - Aye; Tanya Schmidt, PharmD – Aye. Nays none – the motion carried.

Plans for the Northwest Human Service Center – Phar608 currently located at 316 2nd Ave West to relocate to the 4^{th} floor of the Metro Center Building at this same address in Williston were reviewed and discussed.

It was moved by Pharmacist Shane Wendel and seconded by Technician Diane Halvorson to approve the plans for the relocation of the Northwest Human Service Center – Phar608 within the building they are currently located at 316 2nd Ave West to relocate to the 4th floor of the Metro Center Building in Williston. On vote by roll call: Gayle D Ziegler, RPh.-Aye; Diane M. Halvorson, R.Ph. Tech-Aye; Tyler G Lannoye, PharmD. –Aye; Shane Wendel, Pharm D, - Aye; Tanya Schmidt, PharmD – Aye. Nays none – the motion carried.

At about 10:25 AM NDSU PharmD Intern Nathaniel Berglind arrived to address the Board Members relative to his disciplinary action and to request reinstatement of his ND Intern License Int65713 which had been suspended in March 2018. Board Members reviewed the communication sent on behalf of Mr. Berglind to satisfy the requests of the Board during the May Meeting. Mr. Berglind expressed remorse for his decision and indicated he made a mistake and will be moving forward understanding the implications of decisions made when dealing with the public.

It was moved by Pharmacist Shane Wendel and seconded by Technician Diane Halvorson to approve the reinstatement of NDSU PharmD Student Nathaniel Berglind's ND Intern September 27, 2018 Board of Pharmacy Office Bismarck, ND Page 4

License, Int65713 effective today until May 31, 2019. On vote by roll call: Gayle D Ziegler, RPh.-Aye; Diane M. Halvorson, R.Ph. Tech- Aye; Tyler G Lannoye, PharmD. –Aye; Shane Wendel, Pharm D, - Aye; Tanya Schmidt, PharmD – Aye. Nays none – the motion carried.

It was moved by Pharmacist Tyler Lannoye and seconded by Pharmacist Shane Wendel to approve the updated Sanford Anticoagulation Clinic- Fargo Collaborative Agreement. Gayle Ziegler disclosed that she works for Sanford but intends to vote. On vote by roll call: Gayle D Ziegler, RPh.-Aye; Diane M. Halvorson, R.Ph. Tech- Aye; Tyler G Lannoye, PharmD. –Aye; Shane Wendel, Pharm D, - Aye; Tanya Schmidt, PharmD – Aye. Nays none – the motion carried.

It was moved by Pharmacist Gayle Ziegler and seconded by Technician Diane Halvorson to approve the updated collaborative agreement for Family HealthCare Pharmacy-NDSU requested by Susan Wolf Nelson, RPh, which includes their multiple locations in Fargo and West Fargo. On vote by roll call: Gayle D Ziegler, RPh.-Aye; Diane M. Halvorson, R.Ph. Tech-Aye; Tyler G Lannoye, PharmD. -Aye; Shane Wendel, Pharm D, - Aye; Tanya Schmidt, PharmD - Aye. Nays none - the motion carried.

Pharmacists Dennis Johnson and Ross Nygaard of Wall's LTC Pharmacy Inc in Grand Forks arrived to discuss Long-Term-Care Dispensing Devices [Class L Pharmacy Permit] for the Wall's RRBH Hospital Pharmacy at Red River Behavioral Health Systems. There was much discussion and advice offered on policies and procedures to prevent diversion, facility patient safety and assure pharmacist control in the medication delivery. The Board felt the law allowed the Class L permit to be used for a facility give the language in NDAC 61-02-01-01 subsection 4 (I). Dr Hardy reported the DEA would be willing to register as a LTC Dispensing Device as well based on the conversations with the regional office.

It was moved by Technician Diane Halvorson and seconded by Pharmacist Tyler Lannoye to grant a Class L Pharmacy Permit to Wall's RRBH Hospital Pharmacy at 1451 44th Ave S Unit A in Grand Forks, ND, to be used to supply medications through Omnicell Machines. On vote by roll call: Gayle D Ziegler, RPh.-Aye; Diane M. Halvorson, R.Ph. Tech- Aye; Tyler G Lannoye, PharmD. –Aye; Shane Wendel, Pharm D, - Aye; Tanya Schmidt, PharmD – Aye. Nays none – the motion carried.

Lunch arrived and was distributed. While eating lunch Board Members discussed the afternoon examination schedule for the two August 2018 NDSU Grads – Mr. Gregory L Fondong, Pharm D and Ms. Jashandeep K Walia Pharm D.

At 1:00 PM Gregory L Fondong, Pharm D and Jashandeep K Walia, Pharm D arrived at the meeting for the Examination Orientation and addressed the Board as the Examination process began.

Barbara Lacher, RPhTech retired director of the NDSCS Technician Program and current member of the ASHP/ACPE Accreditation Board, involved in rewriting the technician accreditation standards for technician training programs, arrived at the meeting. She explained the consensus conference recommended ASHP/ACPE approved standards for a two tiered technician program accreditation standard. There will be an entry level program and an advanced program for which programs can seek accreditation. NDSCS will take the board's recommendation for whether North Dakota will recognize both levels, or choose one level for registration in ND. After consideration and review of the standards the board took no action to change the current language in the rules which will make both levels eligible for registration in ND and will leave to the employers whether to seek technicians with the advanced degree for their employment needs.

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President Schmidt asked to put the issue on future agendas for continued monitoring along with other requirements for pharmacy technicians.

Dr. Hardy reviewed the financial reports at 2:50 PM.

It was moved by Pharmacist Gayle Ziegler and seconded by Technician Diane Halvorson to approve the financial reports as presented. On vote by roll call: Gayle D Ziegler, RPh.-Aye; Diane M. Halvorson, R.Ph. Tech- Aye; Tyler G Lannoye, PharmD. –Aye; Shane Wendel, Pharm D, - Aye; Tanya Schmidt, PharmD – Aye. Nays none – the motion carried.

Board Members conducted the Oral examinations of the candidates and finalized the exam scores.

Attorney David Lindell arrived at the meeting. Dr. Hardy reviewed the status of the PCMA vs Tufte case for the board, including the decision by the District Judge and the decision of PCMA to appeal. Attorney Lindell explained the timeline of the cases and the 8th circuit court and PCMA's decision to appeal.

The USP Task force chaired by Steve Irsfeld is being put on hold as most compounders in ND will be required by accreditation agencies to comply. Discussion followed about using a consultant to develop some simple policies pharmacies can use to comply with the requirements and move forward with a rule on USP 800 Compliance.

State action in response to the FTC vs North Carolina Dental Board was discussed. There is a meeting on October 30th which David Lindell, Howard Anderson and perhaps Public Member Fran Gronberg will attend.

There were discussions of possible legislative changes. Updating of the controlled substance act will be necessary. Decisions will need to be made at the November meeting to make the deadline for introduction of agency bills.

Baxter International Home Dialysis distribution model for patients with End Stage Renal Disease (ESRD) was discussed. Board members felt that Baxter's model was allowable under the law if they hold an Out-of-State pharmacy license through their subsidiary, RTS Americas in Deerfield, IL, where patient's orders are processed, and patient education occurs for the peritoneal dialysate drugs and devices for which they distribute. Due to the nature of the large volume product, Baxter Healthcare wholesale distribution centers, located throughout the United States and ultimately delivers the peritoneal dialysate drugs and devices to the ESRD patients, shall be required to be licensed under the wholesaler statutes.

President Schmidt adjourned the meeting at 4:10 PM and the investigating committee began their work.

President	Senior Member
Tanya L Schmidt, PharmD	Gayle D. Ziegler, RPh.
Technician Member	Member
Diane M. Halvorson, RPhTech	Steven P Irsfeld, RPh.
Public Member	Member
Fran Gronberg	Shane R. Wendel, PharmD
Member	Executive Director
Tyler G Lannoye, PharmD	Mark J. Hardy, PharmD