AGENDA September 19, 2019 Board of Pharmacy Office – 1906 E Broadway Ave - Bismarck, ND

9:30 AM - Call to Order - Gayle D Ziegler, RPh President[701-328-953AG	5] ENDA
Recite Mission StatementReview and sign July 18, 2019 Board MinutesMINSign original Pharmacist and Technician Certificates	IUTES
10:00 AM Rule Hearing :61-02-07.1Technician Registration for members of the Military or their spouse of Military61-03-04-04Pharmacist Licensure for members of the Military or their spouse of Military61-04-08Limited Prescriptive Practices61-04-11Administration of Medications & Immunization	TAB 1 Ty
Request for Class K addition:The Bowman Drug Company Phar62 Matthew C. DeGree, PharmDThrifty White Pharmacy #084 [North Cashwise] Phar869 Deidre M. Hahn, PharmDThrifty White Pharmacy #065 [Grafton] Phar643 Heidi Jeongha Chung, PharmD	
Remodeling / Relocation Plans: St Alexius Medical Center Pharmacy Phar190 Bismary Carrington Medical Center Phar191 Mercy Hospital Pharmacy Phar179 Devils Lake Lisbon Health Services Pharmacy Phar582 Trinity Hospital Pharmacy Phar211 Minot Oakes Community Hospital Phar206 Mercy Hospital of Valley City Phar174	ck
	AB 2

12:00 Lunch Break

Discussion Items:	
Update on PCMA-vs - Tufte	
Inspection Process Update	
Record Retention Schedule	TAB 3
Grandfathered Pharmacy Permits	TAB 4
Interim Health Reform Committee Meeting	TAB 5

THURSDAY - September	r 19, 2019 Exam Schedule - 1	Candidates
	<u> Jesse J McCormick – Pacific University in OR</u>	
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	

2018-2019 Year End Financial Report 2019-2020 Financials to Date President Gayle D Ziegler, RPh called the meeting to order on Thursday September 19, 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 - Tyler Lannoye, PharmD initially by phone and later arrived in person with his three interns-Tanya Schmidt, PharmD – Public Member Fran Gronberg - Shane Wendel, PharmD; Executive Director Mark J Hardy, PharmD; Howard C Anderson, Jr, RPh and three Intern PharmD Students: Taylor Deters; Nisha Patel and Dimphy Sohel on rotation with Board Member Lannoye at IHS.

Absent: Steven Irsfeld, RPh

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 Pharmacist Wendel and seconded by Public Member Gronberg to approve the agenda with additions of a Jamestown Hospital Pharmacy request to fill ambulatory chemotherapy pumps, the Interim Health Reform Committee Meeting under the discussion items and a CE request for attendance at the NAPT Fall Conference held in Bismarck on September 13 – 14, 2019. On vote by roll call: Technician Diane Halvorson-Aye- Pharmacist Tyler Lannoye-Aye- Pharmacist Tanya Schmidt-Aye- Public Member Fran Gronberg-Aye-Pharmacist Shane Wendel-Aye - Pharmacist Gayle Ziegler-Aye. The motion carried.

It was moved by Pharmacist Schmidt and seconded by Pharmacist Wendel to approve the minutes of July 18, 2019 as printed. On vote by roll call Technician Member Halvorson-Aye-Pharmacist Lannoye-Aye- Pharmacist Schmidt-Aye- Public Member Gronberg-Aye-Pharmacist Wendel-Aye - Pharmacist Ziegler-Aye. The motion carried.

It was moved by Pharmacist Schmidt and seconded by Public Member Gronberg to grant nine(9) hours of continuing education credit to Melissa Halvorson, Pharm D, as requested, for her attendance at the Northland Association of Pharmacy Technicians conference September 13 and 14, 2019. Others pharmacists requesting credit can receive up to ten hours of CE credit per their request. On vote by roll call: Technician Diane Halvorson-Aye- Pharmacist Tyler Lannoye-Aye- Pharmacist Tanya Schmidt-Aye- Public Member Fran Gronberg-Aye-Pharmacist Shane Wendel-Aye - Pharmacist Gayle Ziegler-Aye. The motion carried.

It was moved by Technician Member Halvorson and seconded by Pharmacist Wendel to grant a Subclass K permit to Bowman Drug Company Phar62 so the pharmacy could be supervised via telepharmacy on weekends or in emergencies when the pharmacist cannot be available during medical situations or weather emergencies. The Class A license held by Bowman Drug Company Phar62 includes the expectation that a pharmacist will be present five days per week to serve the patients of the pharmacy. On vote by roll call: Technician Member Halvorson-Aye- Pharmacist Lannoye-Aye- Pharmacist Schmidt-Aye- Public Member Gronberg-Aye-Pharmacist Wendel-Aye - Pharmacist Ziegler-Aye. The motion carried.

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There was a long discussion relative to the two requests by Thrifty White Pharmacy #084 [North Cashwise] Phar869 and Thrifty White Pharmacy #065 [Grafton] Phar643 to provide telepharmacy supervision to Phar503 White Drug #53-Cavalier. Discussion centered on the fact that this pharmacy has a Class A permit which implies the expectation a pharmacist should be on site five days per week. The subclass K permit was granted in September 2016 *"to allow operation on Saturdays via Telepharmacy and thus continue to provide service on those days, when business is slow, but clinics are still open for emergencies"*.

Executive Director Hardy disclosed that he was from the Cavalier area and had previously worked in the Thrifty White Pharmacy there. It appears there was a significant extension of Telepharmacy services beyond the approval given over the last few months. Currently, the approval of the Subclass K was to be through supervision from Thrifty White #61 in Fargo. Board Members express their dismay in this decision to remove a pharmacist from Thrifty White Pharmacy #053 in Cavalier, beyond the approval granted. Board Member Wendel indicated that allowing a model like this for a telepharmacy, where access to a pharmacist is not an issue, along with the knowledge that the location is a really busy pharmacy, not at risk of closing, would be a dangerous precedent to allow. Board Members directed Executive Director Hardy to investigate further the decision and actions involved.

It was moved by pharmacist Shane Wendel and seconded by technician Diane Halvorson to table the requests from Thrifty White Pharmacy #084 [North Cashwise] Phar869 and Thrifty White Pharmacy #065 [Grafton] Phar643 to supervise White Drug #53 in Cavalier until the November 2019 meeting and direct Executive Director Hardy to work with Thrifty White to resolve the issue of possible non-compliance with their Class A permit, within 30 days. On vote by roll call Technician Member Halvorson-Aye - Pharmacist Lannoye-Aye- Pharmacist Tanya Schmidt asked to be recused since she works for Thrifty White - Public Member Gronberg-Aye-Pharmacist Wendel-Aye-Pharmacist Ziegler-Aye. The motion carried.

Brian Ament, PharmD of Jamestown Hospital Pharmacy Phar173 arrived to explain his Request to fill ambulatory Chemotherapy pumps for patients of their Outpatient Oncology Infusion Center which is owned by the hospital and considered part of the hospital operations. Patients come into the center to get their infusion started and must return each time the infusions need to be repeated. Once the infusion is restarted they return home with the pump running and return to have it disconnected again. The infusion needs to be prepared in a USP 800 environment and it would be a 200 mile round trip for the patient to go to another facility.

It was moved by Technician Member Halvorson and seconded by Pharmacist Lannoye to approve the refilling of the patient infusion as part of the Jamestown Hospital service for their Class B pharmacy permit. On vote by roll call: Technician Halvorson-Aye- Pharmacist Lannoye-Aye- Pharmacist Schmidt-Aye- Public Member Gronberg-Aye-Pharmacist Wendel-Aye - Pharmacist Ziegler-Aye. The motion carried.

Public Hearing on Rule Changes

I am Gayle Ziegler, President of the Board of Pharmacy and I will be acting as hearing officer for this public hearing.

It is now 11:00 AM on Thursday, September 19, 2019 in the Conference Room of the Board Office at 1906 East Broadway Ave in Bismarck, North Dakota 58501

A registration sheet is being circulated; I ask that everyone present please sign this sheet before they leave.

<u>Board Members present were</u>: President Gayle D Ziegler, RPh. -Tanya Schmidt, PharmD - Shane Wendel, Pharm D, Diane M. Halvorson, RPh. Tech, Public Member Fran Gronberg - Tyler Lannoye, PharmD – Executive Director Mark J Hardy, PharmD Absent: Steven Irsfeld, RPh.

This public hearing has been called for the purpose of allowing all interested individuals an opportunity to submit information concerning:

61-02-07.1 Technician Registration for members of the Military or the spouse of Military
61-03-04-04 Pharmacist Licensure for members of the Military or the spouse of Military
61-04-08 Limited Prescriptive Practices
61-04-11 Administration of Medications & Immunization

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Information gathered at this hearing will be used by the Board of Pharmacy for its deliberation and final decision.

The Executive Director of the Board of Pharmacy is taking minutes of this meeting, and it is being recorded, so please identify yourself for the record before you speak.

Everyone present will be given an opportunity to speak. If you have a prepared statement, a written copy of your statement is appreciated and will be helpful.

At this point, I open the hearing for comments. We will begin with:

61-02-07.1 Technician Registration for members of the Military or the spouse of Military No comments were received.

61-03-04-04 Pharmacist Licensure for members of the Military or the spouse of Military Board Members reviewed the National Association of Boards of Pharmacy [NABP] comment and agreed to add language requiring application to be processed through eLTP system to ensure disciplinary actions are checked.

61-04-08 Limited Prescriptive Practices No comments were received.

61-04-11 Administration of Medications & Immunization No comments were received.

CLOSING

Thank you all for coming. The Board of Pharmacy will use all the information gathered at this hearing, in making their decision.

The record will be held open for written comment through October $12^{th} 2019$ At this point, I will close the hearing on:

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

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

61-04-08 Limited Prescriptive Practices

61-04-11 Administration of Medications & Immunization

A registration sheet is being circulated; I ask that everyone present please sign this sheet before they leave.

President Gayle Ziegler closed the hearing at 11:30 AM.

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Mr Jesse J. McCormick, Pharm D a Pacific University of Oregon graduate arrived at the meeting for the ND examination, was oriented and began work on his assigned patient case.

The board reviewed several remodeling plans from our hospitals seeking remodeling approval to comply with USP 800 requirements. The Board's suggestions relative to all the plan submissions centered around three issues which will be communicated to the pharmacist in charge along with their approval letter.

- The Board suggests that doors entering a positive pressure room be designed to open outward and doors to a negative pressure room be designed to open inward. This minimizes air turbulence when the doors are opened.
- A segregated compounding area is permissible but requires a beyond use date to be adjusted according to USP Standards.
- The surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters and cabinets in the classified area must be smooth, impervious, free from cracks and crevices, and non-shedding so they can be cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.

It was moved by Pharmacist Schmidt and seconded by Public Member Gronberg to approve the remodeling plans for St Alexius Medical Center Pharmacy Phar190 Bismarck contingent on review by Compliance Officer Dennis Delabarre of their USP 797 and 800 compliance. On vote by roll call: Technician Member Halvorson-Aye- Pharmacist Lannoye-Aye- Pharmacist Schmidt-Aye- Public Member Gronberg-Aye- Pharmacist Wendel-Aye - Pharmacist Ziegler-Aye. The motion carried.

It was moved by Technician Member Halvorson and seconded by Pharmacist Schmidt to approve the remodeling plans for Carrington Medical Center Phar191. On vote by roll call: Technician Halvorson-Aye- Pharmacist Lannoye-Aye- Pharmacist Schmidt-Aye- Public Member Gronberg-Aye-Pharmacist Wendel-Aye - Pharmacist Ziegler-Aye. The motion carried.

It was moved by Pharmacist Schmidt and seconded by Technician Member Halvorson to approve the remodeling plans for Mercy Hospital Pharmacy Phar179 Devils Lake. On vote by roll call: Technician Halvorson-Aye- Pharmacist Lannoye-Aye- Pharmacist Schmidt-Aye-Public Member Gronberg-Aye-Pharmacist Wendel-Aye - Pharmacist Ziegler-Aye. The motion carried.

It was moved by Technician Member Halvorson and seconded by Pharmacist Wendel to approve the remodeling plans for Lisbon Health Services Pharmacy Phar582. On vote by roll call: Technician Halvorson-Aye- Pharmacist Lannoye-Aye- Pharmacist Schmidt-Aye- Public Member Gronberg-Aye-Pharmacist Wendel-Aye - Pharmacist Ziegler-Aye. The motion carried.

It was moved by Pharmacist Lannoye and seconded by Pharmacist Schmidt to approve the remodeling plans for Oakes Community Hospital Phar206. On vote by roll call: Technician Halvorson-Aye- Pharmacist Lannoye-Aye- Pharmacist Schmidt-Aye- Public Member Gronberg-Aye-Pharmacist Wendel-Aye - Pharmacist Ziegler-Aye. The motion carried.

It was moved by Pharmacist Schmidt and seconded by Technician Member Halvorson to approve the remodeling plans of Mercy Hospital of Valley City Phar174. On vote by roll call: Technician Halvorson-Aye- Pharmacist Lannoye-Aye- Pharmacist Schmidt-Aye- Public Member Gronberg-Aye-Pharmacist Wendel-Aye - Pharmacist Ziegler-Aye. The motion carried. September 19, 2019 Board of Pharmacy Conference Room - Bismarck, ND

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It was moved by Pharmacist Schmidt and seconded by Public Member Gronberg to approve the plans for the new Trinity Hospital Pharmacy Phar211 in Minot contingent on Executive Director Hardy receiving the physical measurements he has requested. On vote by roll call: Technician Halvorson-Aye- Pharmacist Lannoye-Aye- Pharmacist Schmidt-Aye- Public Member Gronberg-Aye-Pharmacist Wendel-Aye - Pharmacist Ziegler-Aye. The motion carried.

The Board was asked to give approval review to the off-site location of the Trinity Oncology Center compounding plans. We do not license this location but it will be supervised by Trinity pharmacists and if Registered Pharmacy Technicians are to work in this facility they must be supervised by North Dakota licensed pharmacists. Should Trinity want an inspection by our USP 797 and USP 800 Inspector they can request that of the Board Office. The Board felt the area complied with USP Standards in regards to the space.

The Board took time to administer the oral examination to Exam Candidate Jesse McCormick, PharmD.

Board Member Shane Wendel left the meeting for another commitment and Public Member Fran Gronberg because she was not feeling well.

Executive Director Hardy updated the board on the PCMA-vs-Tufte law suit, saying the 8th Circuit Court date will be October 15th and indicated that he plans to attend.

The online inspection process is up and running with information out to the stores to do their online self-inspection and our inspectors in the field making visits to pharmacies.

It was moved by Technician Member Halvorson and seconded by Pharmacist Schmidt to approve the updated records retention policy presented by Executive Director Hardy. On vote by roll call: Technician Halvorson-Aye- Pharmacist Lannoye-Aye- Pharmacist Schmidt-Aye-Public Member Gronberg-Aye-Pharmacist Wendel-Aye - Pharmacist Ziegler-Aye. The motion carried.

It was moved by Pharmacist Schmidt and seconded by Technician Member Halvorson to insert the following paragraph in the minutes to give notice that some information on the Board's web site has changed and give notice of that change.

Grandfathered Pharmacy License Dates:

We reviewed our grandfathered licenses to ensure the pharmacy permits listed were still active and in good standing. Upon review we discovered that the license issuance date in the verification section of the Board's website was not always consistent with the date listed on the original permit. These dates have been updated to reflect the date the permits were originally issued. We changed the issuance date of the permit for these pharmacies to June 30^{th} of the original year. The information for the changes was obtained from the annual reports published during the time the permits were originally issued. On vote by roll call: Technician Halvorson-Aye- Pharmacist Lannoye-Aye- Pharmacist Schmidt-Aye- Pharmacist Ziegler-Aye. The motion carried.

Executive Director Hardy reviewed for the Board two bill drafts shared at the recent Interim Health Reform Committee meeting. These bills may affect the Board of Pharmacy operations. We will continue to monitor their progression. It was moved by Technician Member Halvorson and seconded by Pharmacist Schmidt to approve the financial reports for the 2018-2019 fiscal year. On vote by roll call: Technician Halvorson-Aye- Pharmacist Lannoye-Aye- Pharmacist Schmidt-Aye- Pharmacist Ziegler-Aye. The motion carried.

President Ziegler called for any further business, none was forth coming - the meeting adjourned at 3:30 PM on Thursday September 19, 2019.

President Gayle D. Ziegler, RPh. Technician Member & Senior Member Diane M. Halvorson, RPhTech

Member Steven P Irsfeld, RPh

Public Member Fran Gronberg

Member Tyler G Lannoye, PharmD Member Tanya L Schmidt, PharmD

Member Shane R. Wendel, PharmD

Executive Director Mark J. Hardy, PharmD