

AGENDA
September 21, 2017

Board of Pharmacy Office – 1906 E Broadway Ave - Bismarck, ND

10:00 AM – Call to Order – Steven Irsfeld, RPh - President

Recite Mission Statement

Review and approval of agenda

AGENDA TAB

Review and sign July 13, 2017 Board Minutes

MINUTES

Sign original Pharmacist and Technician Certificates

10:00 AM Hearing Oakes Drug Phar217 - Michael Spiese, RPh4393

TAB 1

10:30 AM Hearing Scott J Maves, RPh4259

Relocation plans ND Pharmacy Inc Phar35 – Dickinson, ND

Remodel / relocation 1st Care Health Center – Park River Phar202
Roger Maris Cancer Center – Sanford in Fargo

Collaborative Agreement: Jesse Rue, PharmD @ Carrington Med Center /CHI St Alexius
Brandi Ollerman, PharmD – Point of Care – Dr Robert Bathurst, MD
The Medicine Shoppe in Dickinson
Matthew Perkins, PharmD – Point of Care – Dr Robert Bathurst, MD
The Medicine Shoppe in Jamestown

Legal update: PCMA -vs- Tufte (potential executive session)

Sponsorship Request: For CE for Pharmacists on Dementia Care
Marketa Marvanova - Associate Professor - NDSU

TAB 2

Discussion item: State discussion on Opioid abuse / overdose
Transferring / Forwarding EPCS Prescriptions
USP 800

TAB 3

NDSU Portfolio feedback - Teri Udem, RPh

TAB 4

TAB 5

Noon Lunch Break

2017-2018 Year to date Financial Report

Budget Tab

Exam Schedule - Ronald Davison , Jr, PharmD – Drew T Pentland PharmD

Candidates

THURSDAY – November 21, 2017 Exam Schedule - [2]

Candidates

Ronald Davison , Jr, PharmD – Drew T Pentland PharmD

1:15 - 1:30 PM Roll Call and Orientation of Candidates- all

1:30 - 2:30 PM Laboratory Section 1

2:30 - 3:00 PM Errors and Omissions 2

3:30 - 4:15 PM Oral Examination - all

President Steven Irsfeld called the meeting to order on Thursday September 21, 2017 at 10:00 AM in the Conference Room of the Board of Pharmacy Office, 1906 East Broadway in Bismarck, ND.

President Irsfeld 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.*

Present in addition to President Irsfeld were: Public Member Fran Gronberg -Gary W. Dewhirst, R.Ph. - Tanya L. Schmidt, PharmD - Diane M. Halvorson, R.Ph. Tech, - Gayle D Ziegler, RPh - Shane Wendel, PharmD -Executive Director Mark J Hardy, PharmD and Board Attorney David Lindell.

Also present: Compliance Officer Rick Detwiller, Alex Petterson, PharmD Student on rotation at the Board Office; Patricia Minihan, a resident with Board Member Tanya Schmidt; and Melissa Halvorson, PharmD Student on rotation with Board Member Shane Wendel. Also present were: Pharmacists Michael and Walter Spiese; their Attorney Bruce Quick and Pat Ward, JD representing Express Scripts

Executive Director Hardy reported the following additions to the Agenda:

- The change of a Hearing to a Stipulated Agreement for Oakes Drug Phar217
- The floor plans for the remodeling of Roger Maris Cancer Center - Sanford in Fargo
- Collaborative Agreements for *The Medicine Shoppe* Point of Care testing with Dr. Robert Bathurst, MD:
 - 1) Brandi Ollerman, PharmD - Ronald Davison, PharmD - Lisa Brennan, RPh at The Medicine Shoppe in Dickinson
 - 2) Matthew Perkins, PharmD - John Fugleberg, RPh - Karen Sinner, RPh - Lori Graves, RPh. At The Medicine Shoppe in Jamestown
 - 3) LaNell Hagen, PharmD - Karl Krenz, PharmD - Kyle Hilleren, PharmD at The Medicine Shoppe in North Fargo
 - 4) LaNell Hagen, PharmD - Karl Krenz, PharmD - Kyle Hilleren, PharmD at The Medicine Shoppe in South Fargo

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Schmidt to approve the Agenda as amended. On a vote by roll call: Pharmacist Ziegler - Aye Technician Halvorson - Aye Pharmacist Schmidt - Aye Public Member Gronberg - Aye Pharmacist Wendel - Aye Pharmacist Dewhirst - Aye Pharmacist Irsfeld - Aye Nays none - the motion carried.

It was moved by Technician Member Halvorson and seconded by Pharmacist Ziegler to approve the Minutes of the July 13th, 2017 Board Meeting as printed. On a vote by roll call: Pharmacist Ziegler - Aye Technician Halvorson - Aye Pharmacist Schmidt - Aye Public Member Gronberg - Aye Pharmacist Wendel - Aye Pharmacist Dewhirst - Aye Pharmacist Irsfeld - Aye Nays none - the motion carried.

President Irsfeld requested Pharmacist Michael Spiese and his Attorney Bruce Quick come forward to address the Board relative to their Stipulated Agreement. Board Attorney David Lindell read the proposed Complaint, Statement of Charges and the proposed Stipulated Agreement that was reached by Pharmacist Spiese and Executive Director Hardy. Executive Director Hardy provided the Board Members the details of the full investigation; including the

complaint and report by Board Compliance Officers Howard C Anderson, Jr, RPh and Rick Detwiller, RPh and the admission of Pharmacist Michael Spiese of the misconduct cited in the complaint.

Pharmacist Michael Spiese addressed the Board, giving his perspective and remorse for his actions and the situation. He indicated he was ready to be held accountable for the situation he put himself in and would accept the Board's reprimands. He answered the Board Member questions and put forth his plans to move forward in the pharmacy and deal with the financial consequences of his actions. Board Members consulted with Compliance Officer Detwiller on whether he felt it was a fair Stipulated Agreement, to which he voiced his approval.

Board Member Shane Wendel, PharmD disclosed that he knows the Spiese Family very well and intends to vote unless there were any objections – none were forthcoming.

It was moved by Pharmacist Dewhirst and seconded by Public Member Gronberg to approve the Stipulated Agreement for Pharmacist Michael Spiese, RPh4393 and Oakes Drug, North Dakota Pharmacy Permit Phar217 as presented. On a vote by roll call: Pharmacist Ziegler – Aye Technician Halvorson – Aye Pharmacist Schmidt – Aye Public Member Gronberg – Aye Pharmacist Wendel – Aye Pharmacist Dewhirst – Aye Pharmacist Irsfeld – Aye Nays none – the motion carried.

Pharmacist Robert Treitline and his wife Cheryl, owners of ND Pharmacy Inc in Dickinson, ND joined the meeting to address the relocation plans submitted for ND Pharmacy Permit Phar35 in Dickinson. The new location is within a supermarket located at 1761 3rd Ave West. The move was facilitated because the supermarket they are currently location within closed.

President Irsfeld stated he intended to recuse himself and abstain from the vote as he and his pharmacy are in direct competition in Dickinson, ND.

It was moved by Pharmacist Schmidt and seconded by Technician Member Halvorson to approve the lease and relocation plans as submitted for ND Pharmacy Permit Phar35 issued to ND Pharmacy Inc currently located at 446 18th Street West to the new location of 1761 3rd Ave West in Dickinson, ND - On a vote by roll call: Pharmacist Ziegler – Aye Technician Halvorson – Aye Pharmacist Schmidt – Aye Public Member Gronberg – Aye Pharmacist Wendel – Aye Pharmacist Dewhirst – Aye Pharmacist Irsfeld – abstained from voting Nays none – the motion carried.

President Irsfeld then opened the Hearing for Pharmacist Scott J Maves, RPh4259. Pharmacist Maves was properly notified of the hearing, however was not present at the meeting and was not represented at the meeting. For the record the hearing proceedings were recorded by Executive Director Hardy.

Board Attorney David Lindell called one witness, Executive Director Hardy, to answer questions relating to the disciplinary actions taken by the Minnesota State Board of Pharmacy, which necessitated the complaint filed against Mr Scott Maves North Dakota Pharmacist License RPh4259 and the hearing. Executive Director Hardy answered other questions from Board Attorney Lindell about the violations listed in the complaint.

It was moved by Pharmacist Schmidt and seconded by Pharmacist Dewhirst to Revoke the pharmacist license of Mr Scott Maves ND Pharmacist License RPh4259. Mr. Maves has the ability to come before the Board if and when the MN Board of Pharmacy were to reinstate his MN Pharmacist License. On a vote by roll call: Pharmacist Ziegler – Aye Technician Halvorson – Aye Pharmacist Schmidt – Aye Public Member Gronberg – Aye Pharmacist Wendel – Aye Pharmacist Dewhirst – Aye Pharmacist Irsfeld – Aye Nays none – the motion carried.

Board Members reviewed the floor plans submitted for the remodeling of the 1st Care Health Center Phar202 in Park River. After review, Technician Member Halvorson asked the Board to encourage the pharmacy to adopt a policy specifying who has access to the pharmacy area. It was noted in the request that this was a temporary location, to facilitate a reconstruction of a larger hospital pharmacy area, which will have the capacity to do 797 and USP 800 compounding activities.

It was moved by Technician Member Halvorson and seconded by Public Member Gronberg to approve the temporary relocation plans for the 1st Care Health Center Pharmacy Phar202 in Park River. On a vote by roll call: Pharmacist Ziegler – Aye Technician Halvorson – Aye Pharmacist Schmidt – Aye Public Member Gronberg – Aye Pharmacist Wendel – Aye Pharmacist Dewhirst – Aye Pharmacist Irsfeld – Aye Nays none – the motion carried.

It was moved by Pharmacist Dewhirst and seconded by Technician Member Halvorson to approve the remodeling floor plans of Roger Maris Cancer Center Pharmacy, which is an extension of the Sanford Broadway Pharmacy Phar309 in Fargo. On a vote by roll call: Technician Halvorson – Aye Pharmacist Schmidt – Aye Public Member Gronberg – Aye Pharmacist Wendel – Aye Pharmacist Dewhirst – Aye Pharmacist Irsfeld – Aye Pharmacist Ziegler recused herself as she is employed with Sanford and abstained from voting Nays none – the motion carried.

It was moved by Pharmacist Dewhirst and seconded by Technician Member Halvorson to approve the Anticoagulation Collaborative Agreement between Jesse Rue, PharmD of Carrington Medical Center and Dr Rick Geier – Bradley Hoff, PA - Mary Hoff, PA – Jacqui Nelson, PA and Dr Michael Page. On a vote by roll call: Pharmacist Ziegler – Aye Technician Halvorson – Aye Pharmacist Schmidt – Aye Public Member Gronberg – Aye Pharmacist Wendel – Aye Pharmacist Dewhirst – Aye Pharmacist Irsfeld – Aye Nays none – the motion carried.

It was moved by Technician Member Halvorson and seconded by Pharmacist Ziegler to approve the Point-of-Care Collaborative Agreement between staff pharmacists of The Medicine Shoppe in Dickinson, ND: Brandi Ollerman – Ronald Davison and Lisa Brennan and Robert Bathurst, MD On a vote by roll call: Pharmacist Ziegler – Aye Technician Halvorson – Aye Pharmacist Schmidt – Aye Public Member Gronberg – Aye Pharmacist Wendel – Aye Pharmacist Dewhirst – Aye Pharmacist Irsfeld – Aye Nays none – the motion carried.

It was moved by Pharmacist Ziegler and seconded by Pharmacist Wendel to approve the Point-of-Care Collaborative Agreement between staff pharmacists of The Medicine Shoppe in Jamestown, ND: Matthew Perkins – John Fugleberg – Karen Sinner - Lori Graves and Robert Bathurst, MD On a vote by roll call: Pharmacist Ziegler – Aye Technician Halvorson – Aye Pharmacist Schmidt – Aye Public Member Gronberg – Aye Pharmacist Wendel – Aye Pharmacist Dewhirst – Aye Pharmacist Irsfeld – Aye Nays none – the motion carried.

It was moved by Pharmacist Wendel and seconded by Public Member Gronberg to approve the Point-of-Care Collaborative Agreement between staff pharmacists of The Medicine Shoppe North in Fargo, ND: LaNell Hagen – Karl Krenz - Kyle Hilleren and Robert Bathurst, MD On a vote by roll call: Pharmacist Ziegler – Aye Technician Halvorson – Aye Pharmacist Schmidt – Aye Public Member Gronberg – Aye Pharmacist Wendel – Aye Pharmacist Dewhirst – Aye Pharmacist Irsfeld – Aye Nays none – the motion carried.

It was moved by Public Member Gronberg and seconded by Technician Member Halvorson to approve the Point-of-Care Collaborative Agreement between staff pharmacists of The Medicine Shoppe South in Fargo, ND: LaNell Hagen – Karl Krenz - Kyle Hilleren and Robert Bathurst, MD On a vote by roll call: Pharmacist Ziegler – Aye Technician Halvorson – Aye Pharmacist Schmidt – Aye Public Member Gronberg – Aye Pharmacist Wendel – Aye Pharmacist Dewhirst – Aye Pharmacist Irsfeld – Aye Nays none – the motion carried.

Executive Director Hardy provided an update on the status of PCMA –vs- Tufte lawsuit. It was noted that there was no need to go into Executive Session, unless the Members of the Board had questions that were related to strategy of the lawsuit. Board Members agreed with the stance that the Board should provide legal assistance to the state in defending statutes passed and enacted by the ND State Legislature in the regulation of the profession of pharmacy. Executive Director Hardy indicated that the state was still waiting for the judge to issue a decision on the temporary injunction of the laws specific to the applicability to claims that are ERISA or Medicare Part D plans. Once the judge makes that decision then discussion on the next steps will begin. Board Attorney Lindell indicated the need to get special counsel to help defend the Board and state was necessary as he and the other attorneys working for the Attorney General's Office do not have the specific knowledge of the matter at hand in the case.

It was moved by Public Member Gronberg and seconded by Pharmacist Dewhirst to affirm the decision to hire the law firm Katten Muchin Rosenman,LLP to represent the Board of Pharmacy and work with the Attorney General's Office in the PCMA –vs- Tufte lawsuit due to the required expertise necessary in the matters to which the lawsuit is structured. On a vote by roll call: Pharmacist Ziegler – Aye Technician Halvorson – Aye Pharmacist Schmidt – Aye Public Member Gronberg – Aye Pharmacist Wendel – Aye Pharmacist Dewhirst – Aye Pharmacist Irsfeld – Aye Nays none – the motion carried.

The Board Members reviewed a request for sponsorship of Continuing Education for Pharmacists on Dementia Care submitted by Dr. Marketa Marvanova, Associate Professor at NDSU. The Board Members had a vibrant discussion on the manner in which the education would be provided to pharmacists across the state, as well as their concern that NDSU would not be the provider and therefore part of the cost would go to CEI to make the Continuing Education ACPE accredited. Ultimately the Board Members concluded that it was an educational need and an opportunity for pharmacists to learn from the NDSU School of Pharmacy's expertise which is crucial for our profession.

It was moved by Pharmacist Wendel and seconded by Public Member Gronberg to approve the \$3,784.59 in funding for the Continuing Education for Pharmacists on Dementia Care submitted by Marketa Marvanova, Associate Professor at NDSU. On a vote by roll call: Pharmacist Ziegler – Aye Public Member Gronberg – Aye Pharmacist Wendel – Aye Pharmacist Dewhirst – Aye Pharmacist Irsfeld – Aye Technician Halvorson- Nay and Pharmacist Schmidt – Nay - the motion carried.

At noon the Board Members broke for lunch and preparations for the afternoon examinations.

At 1:00 PM the two Candidates for examination : Ronald Davison , Jr, PharmD – Drew T Pentland PharmD arrived and met with the Board Members to begin the examination process.

At about 1:30 Compliance Officer Dennis DelaBarre, Pharmacist Michael Reipl, Pharmacist Kevin Oberlander and Registered Pharmacy Technician Darcy Triplett arrived at the Board Meeting to participate in the discussion of USP 800 with the Board.

An open discussion ensued relative to USP 800 and the impact on the various models of practice. It was noted that it actually impacts all aspects of the practice of pharmacy in all healthcare settings where hazardous drugs are handled.

Pharmacist Oberlander reported that there was a discussion in the state of Texas about the concern with the research behind the changes in USP 800 and a potential need for USP to address those concerns at a future meeting.

President Irsfeld discussed the importance of protecting our employees and the public from hazardous drugs and there certainly is room for improvement in these processes that USP 800 would create. He went on to indicate that he felt a task force may be a good approach for the Board and the regulatory community to work together to determine what path going forward would be appropriate to protect our healthcare professionals and patients. Everyone present agreed that a task force would be a positive step. Pharmacist Irsfeld agreed to chair that task force. There was gratitude expressed by all in attendance for the open dialogue on this issue.

Pharmacist Wendel gave an update in statistics on a medication reconciliation process that Jesse Rue, PharmD, Pharmacist-in-Charge at CHI Carrington Health Center Pharmacy and his staff pharmacists are participating. He indicated that there were many positive results and the Board Members encouraged him to publish the results of this medication reconciliation process.

Compliance Officers Detwiller and DelaBarre gave the Board an overview of what they are experiencing during their current Pharmacy Inspections, including recommendations for potential improvements.

Pharmacist Detwiller indicated that he was still observing consultation issues in pharmacies across the state and found improvements that could be made in the refrigeration of medications and the monitoring of temperatures. Board Members thanked the Compliance Officers for their observations and suggestions and agreed that it was important for the Board to develop strategies for pharmacies when deficiencies are detected so they can be rectified in a quick and efficient manner. Given the Changes in Patient Consultation Standards going into effect October 1st this is a timely undertaking.

Compliance Officer DelaBarre gave an overview of the hospital pharmacy inspections he has conducted , indicating that the Board should explore a requirement for automated dispensing cabinets , which would be a true positive step in patient care, especially in those facilities where access to a pharmacist may be limited within the facility. He indicated that the cabinets have come down in price and that there is a fair amount of grant money available to make this transition financially minimal to the hospitals.

The examination were completed and the candidates scores tabulated, with both Ronald Davison , Jr, PharmD – Drew T Pentland PharmD receiving passing scores.

Executive Director Hardy reported on the overdose and opioid abuse discussions he attended at a state level, including a call for action from the Governor's Office to address and work towards solutions. He indicated that to date we have nearly 100 pharmacies signed up to participate in the disposal program and the PDMP utilization has increased at a high rate over the past couple years.

Executive Director Hardy reported on the transferring / forwarding of controlled substances prescriptions. Indicating that just this morning he got a response from DEA on the definition of "forwarding" saying it looked like the DEA was seeking an electronic forwarding process for transferring electronically prescribed controlled substances prescriptions and that he will be communicate with the pharmacies on that fact to ensure compliance is occurring.

Board Members asked several questions and noted that to their knowledge there is not currently a system that has these capabilities and would likely have to be designed.

As requested by Teri Udem, RPh, Director, Advanced Pharmacy Practice Experience/Pharmacy Practices at NDSU the Board Members reviewed the portfolio requirements and prepared to give her feedback. The Board Members felt that the current requirements that are outlined in her email request would be sufficient for their purposes of reviewing the student portfolios. This would review the specific requirements of primary examples of best work. However, the scoring may need to be adjusted to account for the new setup. Board Members also felt that as long as they met the accreditation requirement, it would be a sufficient amount of information to review the portfolios.

Executive Director Hardy presented an email received from Michael Schwab, Executive Vice President of the ND Pharmacists Association requesting a cooperative effort in providing education for Pharmacists Month, specifically on opioids and the issues involved with them.

It was moved by Public Member Gronberg and seconded by Pharmacist Ziegler to approve a financial contribution of \$1,500 to the ND Pharmacists Association to assist in providing education for Pharmacists Month, specifically on opioids and the issues involved with them. On a vote by roll call: Pharmacist Ziegler – Aye Technician Halvorson – Aye Pharmacist Schmidt – Aye Public Member Gronberg – Aye Pharmacist Wendel – Aye Pharmacist Dewhirst – Aye Pharmacist Irsfeld – Aye Nays none – the motion carried.

Executive Director Hardy reviewed the financial report with the Board Members.

It was moved by Pharmacist Schmidt and seconded by Pharmacist Ziegler to approve the financial report as presented by Executive Director Hardy. On a vote by roll call: Pharmacist Ziegler – Aye Technician Halvorson – Aye Pharmacist Schmidt – Aye Public Member Gronberg – Aye Pharmacist Wendel – Aye Pharmacist Dewhirst – Aye Pharmacist Irsfeld – Aye Nays none – the motion carried.

President Irsfeld called for any further business – none forthcoming - the meeting adjourned at 4:45 PM.

President
Steven P Irsfeld, RPh.

Gary W. Dewhirst, RPh.
Senior Member

Member
Diane M. Halvorson, RPhTech

Member
Gayle D. Ziegler, RPh.

Public Member
Fran Gronberg

Member
Shane R. Wendel, PharmD

Member
Tanya L Schmidt, PharmD

Executive Director
Mark J. Hardy, PharmD