

A G E N D A
THURSDAY – NOVEMBER 15th, 2012
ND STATE BOARD OF PHARMACY OFFICE
1906 E BROADWAY AVE – BISMARCK, ND 58501

- 10:00 AM** Call to Order: **AGENDA**
- 10:00 AM Mandy L Jensen – RPh5398 Consideration of Stipulation
- Review minutes of the September 20, 2012 Board Meeting **MINUTES**
- Sign Original Certificates: Pharmacist
Pharmacy Technician
- 11:00 AM** Shelby J Roerick – request for Registration as Tech-In-Training **TAB 1**
- 11:15 AM Discussion of requirements to sell compounded Over-the-Counter medications**
- Financials **BUDGET**
- Medication Cards for distribution to patients from NDPhA **TAB 2**
- CE Request: Curt McGarvey, R.Ph.#4416
Nancy Seim, R.Ph. 3120
- Remodeling:
Grand Forks: Altru Out-Patient Pharmacy – Phar18A – Erin Navarro, PharmD **TAB 3**
- Stipulated Agreements for CE violations:
Benson, Pamela – ND RPh3903
Copa, Alan - ND RPh4462
Kessler, Matthew ND RPh5200
Pfister, Gregory ND RPh4473
- Proposed Rule Hearing:
Chapter 61-02-01-01 Pharmacy Permits [new subsection]
- l) Class L – Permit for a dispensing device in a long-term care facility, retirement care, mental care, or other facility or institution which provides extended health care to residents. The dispensing device must be located in a facility defined in NDCC Chapter 50-10.1, as any assisted living facility, any skilled nursing facility, basic care facility, nursing home as defined in subsection 3 of the NDCC section 43-34-01, or swing bed hospital approved to furnish long-term care services. The device must be under the control of a licensed Pharmacist in the state of North Dakota
- Proposed legislations
- Controlled Substance Registration **TAB 4**
Controlled Substance Scheduling
Wholesale rewrite to include DME and Medical Gases
- 2:00 PM** Consideration of possible methods of scheduling synthetic cannabinoids and bath salts
- 2:10 PM** Class K Pharmacy Permit Request – Devils Lake Human Services – Joan Slusser, R.Ph.

November 15, 2012

Board of Pharmacy Office

Bismarck, ND

President Laurel Haroldson called the meeting to order at 10:00 AM on Thursday November 15, 2012 in the conference room of the Board of Pharmacy Office located at 1906 East Broadway in Bismarck, North Dakota.

Present were: Gary W. Dewhirst, R.Ph. - Fran Gronberg, Public Member - Diane M. Halvorson, R.Ph.Tech. - Laurel Haroldson, R.Ph. - Bonnie J Thom, R.Ph. - Shane Wendel, R.Ph. - Gayle D. Ziegler, R.Ph. - Executive Director Howard C. Anderson, Jr., R.Ph. and Assistant Executive Director Mark J Hardy, PharmD. Also present were: Pharmacy Technician Luke V Fichter and Erick K. Bommersbach a 4th year PharmD Student Intern assigned to Board Member Wendel.

Assistant Executive Director Mark J Hardy, PharmD called Mandy L Jensen, ND RPh5398 so she could discuss the Stipulated Agreement that she signed and returned to the Board of Pharmacy with the Board Members. Pharmacist Jensen explained her case; stating she took controlled substances from the pharmacy where she worked to alleviate back pain and her subsequent termination of employment. Pharmacist Jensen has entered into a contract with the Pharm-Assist Committee but cannot afford the treatment prescribed and could not afford to attend the Board Meeting today.

It was moved by Pharmacist Ziegler and seconded by Technician Halvorson to approve the Stipulated Agreement signed by Pharmacist Mandy Jensen, ND RPh5398 with the additional provision that she attend the January 2012 Board Meeting in Fargo and meet with the Board Members face-to-face. All Board Members voted aye - the motion carried.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Thom to approve the Agenda with the additions of: a report by Bonnie Thom, R.Ph on the NABP Meeting she recently attended; discussion of compounding relative to the New England Compounding Center allegations; consideration of Justin's Law revisions and PDMP law changes and a clarification for Grafton Developmental Center on filling prescriptions for transitioned residents. All Board Members voted aye - the motion carried.

It was moved by Pharmacist Ziegler and seconded by Technician Halvorson to approve the September 20, 2012 Board of Pharmacy meeting minutes as printed. All Board Members voted aye - the motion carried.

The Board Members signed original pharmacist licenses and technician registration certificates for use until their January 2012 meeting.

ND Pharmacy Technician Luke V Fichter Tech1004 was present to discuss his Minor in Possession and Driving well intoxicated charges with the Board of Pharmacy.

It was moved by seconded by Technician Halvorson and seconded by Public Member Gronberg that no further action be taken at this time against Registered Pharmacy Technician Luke V Fichter Tech1004. All Board Members voted aye - the motion carried.

The Board reviewed a request for registration as a ND Pharmacy Technician-In-Training by Shelby J Roerick. Ms Roerick explained the history of allegations against her and assured the Board of Pharmacy that the incidents were in the past and that she had learned many lessons from them and does not intend to repeat them.

It was moved by Pharmacist Ziegler and seconded by Public Member Gronberg to approve the Technician-In-Training Registration of Shelby J Roerick. All Board Members voted aye – the motion carried.

At 11:15 AM Pharmacists Michael Riepl and Kevin Oberlander arrived to discuss the compounding and sale of Over-the-Counter medications and the labeling required for that sale. The discussion also included aspects of sterile compounding and consideration of what might happen relative to the FDA's increased scrutiny of compounding in light of the New England Compounding issue.

Pharmacist Riepl distributed a label that he had prepared for one of the Over-the-Counter products which he has been making and which are in clinical trials with the Mayo Clinic and his pharmacy.

It was moved by Pharmacist Ziegler and seconded by Pharmacist Thom to table the Over-The-Counter compounding issue until the January 2013 Board Meeting and invite non-sterile compounding pharmacists interested in the preparation of Over-the-Counter products to attend that meeting with specific suggestions for how the Board should regulate this activity. All Board Members voted aye – the motion carried.

It was moved by Pharmacist Wendel and seconded by Pharmacist Ziegler to approve the financial report, profit and loss and balance sheet. All Board Members voted aye – the motion carried.

It was moved by Pharmacist Thom and seconded by Technician Halvorson to approve the request from the North Dakota Pharmacists Association for \$1,030 for the purchase of medication record cards for distribution by North Dakota Pharmacies. On a vote by Roll Call: Pharmacist Dewhirst – Aye Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Pharmacist Wendel – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

It was moved by Pharmacist Thom and seconded by Pharmacist Dewhirst to approve 17.5 hours of continuing education for Curtis J. McGarvey, R.Ph.4416 for his attendance at the Transition in Care Conference. All Board Members voted aye – the motion carried.

It was moved by Technician Halvorson and seconded by Pharmacist Ziegler to approve 10.5 hours continuing education for Nancy Seim, R.Ph.3120 for her attendance at the Healthcare Horizons program by Altru Health Systems. All Board Members voted aye – the motion carried.

It was moved by Pharmacist Ziegler and seconded by Technician Halvorson to approve the remodeling plans for Altru Health Systems Out-patient Pharmacy, located within the Altru Health Systems facility and part of their ND Pharmacy Permit 180 in Grand Forks. All Board Members voted aye – the motion carried.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Thom to approve the Stipulated Agreement signed by Pamela Benson, NDRPh3903 for continuing education violations. All Board Members voted aye – the motion carried.

It was moved by Technician Halvorson and seconded by Pharmacist Wendel to approve the Stipulated Agreement signed by Alan Copa, NDRPh4462 for continuing education violations. All Board Members voted aye – the motion carried.

It was moved by Pharmacist Ziegler and seconded by Public Member Gronberg to approve the Stipulated Agreement signed by Matthew Kessler, NDRPh5200 for continuing education violations. All Board Members voted aye – the motion carried.

It was moved by Pharmacist Thom and seconded by Public Member Gronberg to approve the Stipulated Agreement signed by Gregory Pfister, NDRPh4473 for continuing education violations. All Board Members voted aye – the motion carried.

Assistant Executive Director Hardy presented the following proposed rule for consideration:

- 1) Class L – Permit for a dispensing device in a long-term care facility, retirement care, mental care, or other facility or institution which provides extended health care to residents. The dispensing device must be located in a facility defined in NDCC Chapter 50-10.1, as any assisted living facility, any skilled nursing facility, basic care facility, nursing home as defined in subsection 3 of the NDCC section 43-34-01, or swing bed hospital approved to furnish long-term care services. The device must be under the control of a licensed Pharmacist in the state of North Dakota

It was moved by Pharmacist Dewhirst and seconded by Public Member Gronberg to proceed with this rule for a Class L Pharmacy Permit. All Board Members voted aye – the motion carried.

Assistant Executive Director Hardy presented a draft of our Controlled Substances scheduling legislation for review by the Board.

It was moved by Pharmacist Dewhirst and seconded by Public Member Gronberg to proceed with pre-filing the Controlled Substances scheduling legislation. All Board Members voted aye – the motion carried.

Assistant Executive Director Hardy presented a draft of our legislation requiring a Controlled Substances Registration, which is intended to fund the Prescription Drug Monitoring Program into the future.

It was moved by Pharmacist Thom and seconded by Public Member Gronberg to proceed with pre-filing the legislation requiring a Controlled Substances Registration. All Board Members voted aye – the motion carried.

Assistant Executive Director Hardy presented a suggested revision of ND Century Code 19-02 to include the middle-man provisions from the Ryan Haight National Act in Justin's Law in this legislative session.

It was moved by Pharmacist Wendel and seconded by Pharmacist Thom to proceed with pre-filing the legislation for the revision of ND Century Code 19-02.1-15.1 to include the middleman prohibitions. All Board Members voted aye – the motion carried.

Assistant Executive Director Hardy presented a draft of legislation to modifying the Prescription Drug Monitoring legislation to allow the Board to select the American Society of Automation in Pharmacy Standard [ASAP] by rule.

It was moved by Public Member Gronberg and seconded by Pharmacist Wendel to proceed the legislation and rule to modify the Prescription Drug Monitoring legislation to allow the Board to select the American Society of Automation and Pharmacy Standard [ASAP] by rule. All Board Members voted aye – the motion carried.

Executive Director Anderson discussed the rewrite of NDCC 43-15.3 Wholesale Drug Pedigree to include durable medical equipment and medical gases. He reported that this piece of legislation still had a little work left to do, to include some definitions.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Thom to proceed with rewrite of NDCC 43-15.3 Wholesale Drug Pedigree to include durable medical equipment and medical gases and to proceed with pre-filing of this legislation. All Board Members voted aye – the motion carried.

Pharmacist Joan Slusser arrived at the meeting to discuss a Class K Pharmacy Permits for the Devils Lake Human Services Center and West Central Human Services Center in Bismarck.

It was moved by Pharmacist Thom and seconded by Pharmacist Dewhirst to approve the plans for a Class K Telepharmacy Permit for the Lake Region Human Services Center in Devils Lake, contingent upon the receipt of the appropriate fee. All Board Members voted aye – the motion carried.

It was moved by Pharmacist Ziegler and seconded by Technician Halvorson to approve the plans for a Class K Telepharmacy Permit for West Central Human Services Center in Bismarck, contingent upon the receipt of the appropriate fee. All Board Members voted aye – the motion carried.

At 2:00 PM Attorney General Wayne Stenehjem, Charlene Schweitzer, a forensic scientist from the ND State Crime Laboratory and Attorney Edward Erickson of the Attorney General's Office arrived to discuss possible methods of scheduling synthetic cannabinoids and bath salts with the Board of Pharmacy. There were also several BCI agents present to provide background information and field observations if necessary.

President Haroldson asked Attorney General Stenehjem to address the Board relative to his concerns. His remarks are attached to the minutes.

Attorney General Stenehjem stated that he felt that we could not wait even the three or four months that it would take to pass an emergency piece of legislation through the 2013 North Dakota Legislative session starting in January, as young people are at risk now and getting hurt today. Attorney General Stenehjem indicated that since his news conference yesterday, he had received many calls from consumers thanking him for the cease-and-desist order that he had issued for some of the businesses selling these substances.

Charlene Schweitzer reviewed the legislation which she and Assistant Executive Director Hardy developed to try and address all of these substances by category, with the Board of Pharmacy.

The analog statements in the law will capture substitutions on the chemical structures as they are designed by the chemists.

The synthetic hallucinogens which are included in this emergency rule are the ones that caused the death of the two young people in June in Grand Forks.

Ms Schweitzer also addressed the phenylethylamines and the psilocybin compounds as well as some other six specifically listed chemicals that have been identified upon seizure from the Bureau of Criminal Investigation and law enforcement agents.

Pharmacist Ziegler asked if the proposed legislation included all of the known substances and found the answer to be yes.

President Haroldson asked for an explanation of the emergency rule making process. Attorney Edward Erickson summarized the due process procedures for the Board Members. He also addressed issues raised by the case law developed two-years ago subsequent to the emergency scheduling done by the Board of Pharmacy at that time. Attorney Erickson pointed out that the changes that were made in the law should address any problems the Judges had concerning Notice to the Public about the emergency rule making.

It was moved by Pharmacist Dewhirst and seconded by Public Member Gronberg to proceed with the emergency rule making process and to schedule the first meeting for consideration on November 30, 2012. Discussion followed and Pharmacist Dewhirst expressed that he felt that the health and safety of the people of North Dakota was at risk. Pharmacist Thom agreed that we must move ahead with this for the protection of the public.

On a vote by Roll Call: Pharmacist Dewhirst – Aye Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Pharmacist Wendel – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

President Haroldson thanked Attorney General Wayne Stenehjem, his staff and Ms. Charlene Schweitzer for their attendance and contribution to the meeting.

Board Member Bonnie Thom reported that the NABP meeting she attended was a very important and worthwhile interactive session with 41 of the Boards of Pharmacy represented. A lot was learned about what others states were doing. Other items discussed were the future of pharmacy regulations, the registration and training of technicians, where North Dakota is ahead of most others and community pharmacy accreditation. Pharmacist Thom also introduced discussion on Board policy on outdated pharmaceutical products used in an emergency. Executive Director Anderson had written a draft policy back in the spring, which he distributed to the Board Members.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Ziegler to approve the policy on outdated pharmaceutical products for North Dakota. The motion failed.

Executive Director Anderson presented an email communication from Sandra L Offutt, R.Ph. Pharmacist-In-Charge at Grafton Developmental Center. Pharmacist Offutt asked that as the Grafton Developmental Center transitions to providing services to their individuals in a community setting, the pharmacy would like to be an option for these individuals as a choice for

providing pharmacy services. These independent living arrangements would be staffed by the Grafton facility throughout the Grafton Community. They would be administered and staffed by the Developmental Center. Pharmacist Offutt asked if their current pharmacy class would allow them to continue to provide prescriptions to the individuals residing in these ISLAs if they choose them as their pharmacy. Typically these individuals would still be considered residents, just not on the campus of the Developmental Center.

President Haroldson asked that Board staff contact the other pharmacies in the Grafton community for their opinion on this matter and that we consider this issue at the January 2013.

The meeting adjourned.

Laurel A. Haroldson, R.Ph.
President

Gary W. Dewhirst, R.Ph.
Senior Member

Member
Bonnie J. Thom, R.Ph.

Member
Gayle D. Ziegler, R.Ph.

Member
Diane M. Halvorson, RPhTech

Member
Shane R. Wendel, R.Ph.

Member
Fran Gronberg

Assistant Executive Director
Mark J. Hardy, PharmD

Executive Director
Howard C. Anderson, Jr, RPh.