

November 17, 2016 Conference Room -Board Office – Bismarck, ND

AGENDA November 17, 2016

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

10:00 AM – Call to Order – Shane R Wendel, PharmD, President **AGENDA**

Recite Mission Statement

Review and sign September 15, 2016 Board Minutes **MINUTES**

Sign original Pharmacist and Technician Certificates

10:45 AM Jayme Wolf – RPh5459 **TAB 1**

11:00 AM **Stipulated Agreements:** **TAB 2**

Terrance R Kristensen – ND RPh3893

Essentia Specialty Pharmacy – No Permit

Collaborative Agreement: Brody Maack, PharmD @ Family Healthcare in Fargo
Matthew Song, PharmD @ Craven Hagen Clinic - Williston

Compounding Rule: Attorney General’s opinion **TAB 3**

2017 Legislative Items **TAB 4**

Scheduling / rescheduling of drugs to the DEA equivalent
Gabapentin as a reportable PDMP medication

Request for CE Credit: Bio-Identical Hormone Replacement – Shawnel Berry, RPh
Nutri-Dyn – Great Plains Conference review materials and feedback if presented

Discussion item: Procedures for Controlled Substances Administration, **TAB 5**
Reconciliation and Disposal in Basic Care and Assisted Living Facilities
Measure 5 – “Medical” Marijuana – Report

Noon Lunch Break

Technician to Pharmacist Ratio – NDAC 61-02-07.1-04 **TAB 6**
and Report from NAPT meeting

THURSDAY – November 17, 2016 Exam Schedule - [2] Candidates
Hanan Alameddin and Driss Gaieb

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

2016-2017 Financial Report **Budget Tab**

President Shane Wendel, PharmD called the meeting to order on Thursday September 15, 2016 at 10:00 AM in the Conference Room of the Board of Pharmacy Office, 1906 East Broadway in Bismarck, ND.

Present in addition to President Wendel were: Public Member Fran Gronberg -Gary W. Dewhirst, R.Ph. - Tanya L. Schmidt, PharmD - Diane M. Halvorson, RPhTech, - Steven P. Irsfeld, R.Ph. - Gayle D Ziegler, R.Ph. -Executive Director Mark J Hardy, PharmD and Howard C Anderson, Jr, R.Ph. Senior Compliance Officer

Also present: Katti Kramer, PharmD, Tara Dammer, PharmD and Megan Trout, PharmD accompanied Board Member Tanya Schmidt; Duane Kram, RPh - Kathy Zahn of the PDMP and Rod St Aubyn representing the Pharmaceutical Care Management Association

President Wendel 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.*

It was moved by Pharmacist Gary Dewhirst and seconded by Public Member Fran Gronberg to approve the printed agenda with the addition of a Medical Marijuana report and an adjustment of the time for Dr. Wolf to when she arrives at the meeting. All board members present voted aye, nays none. The motion carried.

It was moved by Pharmacist Gayle Ziegler and seconded by Pharmacist Steve Irsfeld to approve the minutes of September 15, 2016 as printed. All board members present voted aye, nays none. The motion carried.

Board members signed original certificates for future use.

It was moved by Pharmacist Gayle Ziegler and seconded by Pharmacist Tanya Schmidt to approve the collaborative agreement submitted by Brody Maack between the pharmacists and practitioners at the Family Health Care Center in Fargo. On vote by roll call Technician Halvorson, Pharmacist Ziegler, Public Member Gronberg, Pharmacist Dewhirst, Pharmacist Schmidt, Pharmacist Irsfeld and Pharmacist Wendel voted aye. Nays none. The motion carried.

It was moved by Pharmacist Tanya Schmidt and seconded by Public Member Fran Gronberg to approve the collaborative agreement submitted by Matthew Song and the practitioners at Craven Hagen Clinic in Williston. On vote by roll call Technician Halvorson, Pharmacist Ziegler, Public Member Gronberg, Pharmacist Dewhirst, Pharmacist Schmidt, Pharmacist Irsfeld and Pharmacist Wendel voted aye. Nays none. The motion carried.

A letter from the Attorney General approving the adoption process for the Compounding Rule was reviewed by the board. It points out that the United States Pharmacopeia reference to sections 797 and 795 will be those in existence on the date the rule becomes effective. The next step would be to submit them to Legislative Council with the soonest effective date to be April 1, 2016.

Dr. Hardy reviewed the suggested legislative changes to the Controlled Substance Act to schedule those substances scheduled by the Drug Enforcement Agency since the last legislative session. He pointed out that a new section on fentanyl analogs and isomers has been created with an effort to include any new analogs under the chemical class to keep ahead of the chemists. The currently

scheduled fentanyl derivatives are being moved to the new grouping with the known ones listed as examples. Shane Wendel asked why the examples are listed if the new grouping includes all current and future chemicals, Dr. Hardy responded that it makes it easier for prosecutors if the known ones are listed as it is then not necessary to get a chemist as an expert witness at the trials to testify they are really part of that group when a new drug surfaces.

It was moved by Public Member Fran Gronberg and seconded by Pharmacist Steve Irsfeld to move ahead with the introduction of the controlled substances legislation and ask for an emergency clause on the bill. On vote by roll call Technician Halvorson, Pharmacist Ziegler, Public Member Gronberg, Pharmacist Dewhirst, Pharmacist Schmidt, Pharmacist Irsfeld and Pharmacist Wendel voted aye. Nays none. The motion carried.

Kathy Zahn, PDMP administrator reported that the advisory committee wants to include gabapentin as a reportable PDMP medication much like we did with carisoprodol and tramadol, which were later scheduled because of the abuse we were seeing with them.

It was moved by Pharmacist Tanya Schmidt and seconded by Technician Diane Halvorson to move forward with a bill to add gabapentin to the reportable drugs to the PDMP. On vote by roll call Technician Halvorson, Pharmacist Ziegler, Public Member Gronberg, Pharmacist Dewhirst, Pharmacist Schmidt, Pharmacist Irsfeld and Pharmacist Wendel voted aye. Nays none. The motion carried.

At 10:45 AM Jayme Wolf - ND 5459 appeared before the Board to report her progress and request her reinstatement. Agnes Harrington of the PharmAssist Committee joined the discussion by phone. Dr. Wolf reported that the summer off has been good for her. She has been taking care of her children so no day care expenses and her husband's job has allowed him to be home much of the time in the evenings. Now that the children are all in school Dr. Wolf would like to return to work part time. Reports from Dr. Hoff, the psychologist from ShareHouse, are very positive and state no evidence of ongoing addiction. Agnes Harrington supports the return to work by Dr. Wolf and talks with or meets with her weekly.

It was moved by Pharmacist Gary Dewhirst and seconded by Pharmacist Steve Irsfeld to reinstate Dr. Wolf's pharmacy license and revise her stipulation to allow her to work. She is to report to Dr. Hardy when she finds employment and return to the Board meeting in January to report and discuss her progress. Dr Wolf is to comply with the conditions recommended by Dr. Hoff including; Random observed UAs coordinated through Nancy Austin at ShareHouse and monthly individual therapy appointments for the next three months. If symptoms remain stable she can then move to scheduling appointments on an "as needed" basis and begin family/marital therapy sessions through The Village in Fargo.

It was moved by Pharmacist Gayle Ziegler and seconded by Public Member Fran Gronberg to amend the motion to allow Dr. Wolf to return to work in a non-dispensing role where she has no access to controlled substances. On vote by roll call Technician Halvorson, Pharmacist Ziegler, Public Member Gronberg, Pharmacist Dewhirst, Pharmacist Irsfeld and Pharmacist Wendel voted aye. Pharmacist Schmidt voted Nay. The amendment carried.

President Wendel called for the vote on the motion as amended. On vote by roll call Technician Halvorson, Pharmacist Ziegler, Public Member Gronberg, Pharmacist Dewhirst, Pharmacist Irsfeld and Pharmacist Wendel voted aye. Pharmacist Schmidt voted Nay. The amended motion carried.

It was moved by Pharmacist Tanya Schmidt and seconded by Public Member Fran Gronberg to grant 25 hours of continuing education credit to Shawnel Berry, RPh. for completion of the program Bio-Identical Hormone Replacement. On vote by roll call Technician Halvorson, Pharmacist Ziegler, Public Member Gronberg, Pharmacist Schmidt, Pharmacist Irsfeld and Pharmacist Wendel voted aye. Pharmacist Dewhirst voted nay stating that he opposed granting CE for any program not accredited by ACPE. The motion carried.

It was moved by Public Member Fran Gronberg and seconded by Technician Diane Halvorson to grant seven [7] hours of continuing education credit to pharmacists and technicians who complete the program Nutri-Dyn at the Great Plains Conference and request credit in writing. Seven of the ten hours are approved as three of the hours were promotion of commercial products. On vote by roll call Technician Halvorson, Pharmacist Ziegler, Public Member Gronberg, Pharmacist Schmidt and Pharmacist Wendel voted aye. Pharmacist Dewhirst voted nay stating that he opposed granting CE for any program not accredited by ACPE. Pharmacist Steve Irsfeld abstained. The motion carried.

At 12:30 the board broke for lunch and at 1 PM welcomed Hanan Alameddin and Driss Gaieb, candidates for the licensure exam. Board members oriented the candidates and set them to work in separate offices. The meeting continued while board members with exam assignments worked with the candidates.

Dr. Hardy presented three alternatives for consideration to modify the technician to pharmacist ratio. Diane Halvorson presented results of the Technician Fall meeting consideration of the topic.

Tanya Schmidt reported results of her research saying that 18 states have no set ratio and leave the issue to the Pharmacist in Charge. Diane Halvorson pointed that Technicians-in-training are included in the ratio.

All agreed that our technicians with the ASHP program required, as well as the PTCB exam are very well trained and competent in their role.

Some wondered if the pharmacists are able to resist pressure to increase workload presented by more technicians. Diane stated that some technicians at the fall conference felt the pharmacist was barely able to devote enough time to checking and counseling with three technicians pushing completed prescriptions to them.

Shane Wendel stated he was uncomfortable with a wide open ratio and might feel comfortable going to 4-1 in a retail setting.

There was a suggestion of going to three different work site descriptions; retail, hospital and closed door. Tanya Schmidt suggested we write a fourth option for consideration including no ratio in closed door operations.

President Wendel directed Dr. Hardy to prepare a fourth option and placed the issue on the January Agenda for further consideration along with scheduling a visit to tour the Thrifty White closed door facility.

At 3:15 PM the board considered the proposed stipulations negotiated by Dr. Hardy and Attorney Lindell. There were questions and discussions about the amount of the fines proposed.

It was moved by Technician Diane Halvorson and seconded by Pharmacist Gayle Ziegler to approve the Signed Stipulation for Terrence R. Kristensen-ND License RPh3893. On vote by roll call Technician Halvorson, Pharmacist Ziegler, Public Member Gronberg, Pharmacist Schmidt, Pharmacist Irsfeld and Pharmacist Wendel voted aye. Pharmacist Gary Dewhirst recused himself as he served on the investigating committee for this case. Nays none. The motion carried.

It was moved by Pharmacist Gayle Ziegler and seconded by Pharmacist Steve Irsfeld to approve the stipulation for Essentia Specialty Pharmacy. On vote by roll call Technician Halvorson, Pharmacist Ziegler, Public Member Gronberg, Pharmacist Schmidt, Pharmacist Irsfeld and Pharmacist Wendel voted aye. Pharmacist Gary Dewhirst recused himself as he served on the investigating committee for this case. Nays none. The motion carried.

Dr. Hardy explained Procedures for Controlled Substances Administration, Reconciliation and Disposal in Basic Care and Assisted Living Facilities being developed by the Department of Health for their licensed facilities. Board members felt the best approach would be to change the rule to allow the appropriately trained medication aides to count controlled substances to assure safeguards to prevent diversion. Also the double locking is intended to be in place while no administration staff is present and only one lock is necessary when they are present in the room where the drugs are stored. Destruction of a used fentanyl patch should occur immediately after removal by flushing and be witnessed by two staff members. Dr. Hardy will continue to work with the Department, the Board of Nursing and the Long Term Care Association on this issue.

Dr. Hardy reported that the Department of Health is meeting daily to work out the details of the initiated medical marijuana measure. Pharmacies will not be able to participate in the process, as the plant and chemicals will continue to be schedule I products except where FDA approved products are specifically assigned to other schedules.

Dr. Hardy reviewed the financial reports.

It was moved by Public Member Fran Gronberg and seconded by Technician Diane Halvorson to approve financial reports as presented. On vote by roll call Technician Halvorson, Pharmacist Ziegler, Public Member Gronberg, Pharmacist Schmidt, Pharmacist Dewhirst, Pharmacist Irsfeld and Pharmacist Wendel aye. Nays none. The motion carried.

President Wendel adjourned the meeting at 4:30 PM.

President
Shane R. Wendel, PharmD.

Gary W. Dewhirst, R.Ph.
Senior Member

Member
Diane M. Halvorson, RPhTech.

Member
Gayle D. Ziegler, R.Ph.

Public Member
Fran Gronberg

Member
Steven P Irsfeld, R.Ph.

Member
Tanya L Schmidt, PharmD

Executive Director
Mark J. Hardy, PharmD