

AGENDA July 14, 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 May 23-26, 2016 Board Minutes **MINUTES**

Sign original Pharmacist and Technician Certificates

10:30 AM Consider changing the Technician to Pharmacist ratio **Tab 1**
61-02-07.1-04 Ratio of Pharmacists to Pharmacy Technicians

11:00 AM Rule Changes from April 30th, 2016- Hearing – NDPhA Convention **Tab 2**

61-02-01-03 Compounding Standards
61-02-07.1-05 Tasks Technicians *MAY* perform
61-04-12 Patient consultation requirements
61-08-01-10 [Out-of-State] Counseling Services

Tamra Weal – Tech Educational Requirement exemption request **Tab 3**

Remodeling – Name Change

Thrifty White Pharmacy #068 [was White Drug #68] - Fargo
Thrifty White Pharmacy #065 [was White Drug #65] – new location in Grafton

12: 00 Lunch Break

2015-2016 Final Financial Report **Budget Tab**
2016-2017 Financials to Date

THURSDAY - July 14, 2016 Exam Schedule - **Candidates**

~~Hanan Alameddin – Foreign Grad [Nov]~~ Emily Rogers, PharmD - SDSU
Megan G Trout, PharmD U of MO grad Robert A Yeshe, U of MI
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 Shane Wendel, PharmD called the meeting to order on Thursday July 14, 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: Gary W. Dewhirst, R.Ph., Diane M. Halvorson, RPhTech, Public Member Fran Gronberg - Tanya L. Schmidt, PharmD. - Gayle D Ziegler, R.Ph. –Executive Director Mark J Hardy, PharmD; Board Attorney David Lindell, JD; and Howard C Anderson, Jr, R.Ph. Senior Compliance Officer - with Steven P. Irsfeld, R.Ph., being delayed but arriving about noon.

Also present were Rod St Aubyn and Patrick Ward J.D. representing the Pharmaceutical Care Management Association; John Long R.Ph., MBA. with CVS Caremark; Patrick Ward represented Express Scripts; Abigail Stoddard and Jack McDonald J.D. representing Prime Therapeutics.

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 Public Member Fran Gronberg and seconded by Technician Diane Halvorson to approve the minutes of May 23-26, 2016 as printed. All board members present voted aye. Nays none. The motion carried.

It was moved by Technician Member Diane Halvorson and seconded by Pharmacist Tanya Schmidt to approve the agenda with the addition of the remodeling and name changes for White Drug #68 in Fargo and White Drug #65 in Grafton. All board members present voted aye. Nays none. The motion carried.

Since it was only 10:05 President Wendel moved down the agenda, with no objections, to take up the issue of Education requirements for Tamra Weal. Ms Weal sent a request for consideration of an Application for Registration as a ND Pharmacy Technician, in lieu of proof an ASHP degree. Board member reviewed the material she submitted and came to the consensus that proof she completed an ASHP program cannot be ascertained.

It was moved by Public Member Fran Gronberg and seconded by Technician Member Diane Halvorson to stick with the requirement for Ms. Weal to obtain certification of completion from an ASHP accredited program prior to registration as a North Dakota technician. All board members present voted aye. Nays none. The motion carried.

President Wendel asked Pharmacist Tanya Schmidt to explain the request from Thrifty White. She explained that the name changes were intended to make names of pharmacies consistent across the chain and to make the numbering consistent for the growing chain of pharmacies; Grafton is moving into a new location and the pharmacy at Bethany in Fargo is moving to a remodeled space within the same address.

It was moved by Technician Member Diane Halvorson and seconded by Pharmacist Gayle Ziegler to approve the remodeling plans and name change for White Drug #68 at 4255 30th Ave South in Fargo, to Thrifty White Pharmacy #068. Pharmacist Tanya Schmidt disclosed that she works at this pharmacy and would abstain from voting. Pharmacist Gary Dewhirst disclosed that he is a former employee of Thrifty White at

another location, but would vote. All board members present, except Pharmacist Tanya Schmidt, voted aye. Nays none. The motion carried.

It was moved by Pharmacist Gayle Ziegler and seconded by Public Member Fran Gronberg to approve the plans for relocation from 544 Hill Ave in Grafton to 737 12th Street West in Grafton and name change for White Drug #65 to Thrifty White Pharmacy #065. Pharmacist Tanya Schmidt and Pharmacist Gary Dewhirst disclosed they are current or former employees of Thrifty White, but would vote. All board members present voted aye. Nays none. The motion carried.

It being 10:30 AM President Wendel moved to the discussion of consideration of changing the technician ratio. Pharmacist Tanya Schmidt stated she felt our pharmacists are good at technician utilization and we should let them decide how many technicians are appropriate as each site is different, as to their work flow and specific tasks performed by pharmacists and technicians. Pharmacist John Long of CVS said they have success in all states, some of which have more stringent ratios than North Dakota and some which have no set ratio. Some states do include interns and techs in training in the ratio, while North Dakota does not include interns, even though they may take more time, when on rotation with a college. Technician Member Diane Halvorson asked that we wait until the new counseling rule is in place before assessing the ratio. She also suggested we run the suggested change by the Fall Conference of NAPT and perhaps the 2017 Pharmacy Convention before making a final decision. Pharmacist Gayle Ziegler suggested we add the NDSHP meeting to the list.

It was moved by Technician Member Diane Halvorson and seconded by Pharmacist Gary Dewhirst to consider the change at the three suggested venues, NAPT, NDPhA and NDSHP. All board members present voted aye. Nays none. The motion carried.

Executive Director Hardy will prepare a couple of drafts for consideration, to reflect potential changes.

At 11:00 AM, Mike Schwab, Executive Director of the ND Pharmacists Association [NDPhA] arrived at the meeting via phone for the discussion of the rule changes.

Executive Director Hardy explained the suggested consideration of comments, which are attached, relative to the Compounding Standards particularly those changes we will make in response to the comments by Veterinarians. Board member Pharmacist Steve Irsfeld and Executive Director Hardy plan to meet with the ND Veterinary Medical Association in August. One of the discussion points will be whether to extend the time for which a veterinary may dispense a compounded product from the drafted three days. All Board Members agreed to hold off on adoption until a later time which may include consideration of proposed 797 changes in their recent revision.

Discussion moved to 61-04-12 Patient consultation requirements.

Executive Director Hardy pointed out that a few typo corrections would be made and the language changed to patient or their agent, as recommended by Attorney Lindell, throughout the draft before inclusion with these minutes.

Pharmacist Gayle Ziegler said the “six months” language in 61-04-12 subsection (2) really should be considered a new prescription, if a new document is created by the pharmacy. On the other hand, a prescription being refilled is good for one year, if authorized by the prescriber.

Technician Diane Halvorson stated changes in the patient's clinical state might occur and thus a new prescription created should be treated as new for consultation purposes.

John Long R.Ph., MBA. with CVS Caremark and Abigail Stoddard representing Prime Therapeutics both said that a new prescription, whether created from a previous prescription, or received as just prescribed, invokes their new prescription procedure and consultation would be done the same under each situation. Pharmacist Tanya Schmidt said that in-state and out-of-state prescriptions should be treated the same, as far as the patient is concerned.

It was moved by Pharmacist Gayle Ziegler and seconded by Pharmacist Tanya Schmidt to remove the last sentence under 61-04-12 (2). For the purpose of this section a refilled prescription includes any drug that the patient has utilized in the past 6 months. All board members present voted aye. Nays none. The motion carried.

Pharmacist Steve Irsfeld arrived at the meeting at noon. He apologized for being late, saying he had made plans to be here on time, but something intervened.

The discussion moved to 61-04-12 subsection (3).

Rod St Aubyn representing the Pharmaceutical Care Management Association asked what was considered "incentivized"? Is it a varied copay, a varied co-insurance and of course the patient can always use the pharmacy of their choice, but sometimes must pay the whole cost of the prescription. John Long, Abigail Stoddard and Pat Ward all had similar concerns.

Executive Director Hardy pointed out that the complaints which come to the Board are from patients who must use a particular pharmacy, or pay a much higher price, and sometimes receive prescriptions they did not order and cannot have the pharmacy accept returns and give them credit.

John Long proposed that this problem is really a benefit question and not a consultation question. Pat Ward, Rod St Aubyn and Abigail Stoddard all agreed. Ms. Stoddard suggested that the patient needs to ask their employer to change their benefit through their insurance company.

It was moved by Pharmacist Tanya Schmidt and seconded by Public Member Fran Gronberg to remove subsection (3) of 61-04-12. Six board members voted aye, one nay, the motion carried.

Discussion moved to subsections (5) and (6) of 61-04-12.

John Long with CVS Caremark said their success rate on calls to patients is about 20% and Pharmacist Tanya Schmidt said Thrifty White's is close to this as well. Pharmacist Steve Irsfeld pointed out that he has a different perspective on that success rate and that talking to one out of five patients is well worth the call.

At 12:30 the Board broke for lunch and planned to return to the discussion once the candidates for the exam have started their work. Three candidates were started on their exams.

The board reconvened at 1:30 PM to continue the discussion

Discussion centered on the requirement to make an attempt to contact the patent or their agent via a telephone call.

Pharmacist Tanya Schmidt stated that a well-educated patient is very important to proper utilization of medications.

Pharmacist John Long reiterated the low yield of about 20% on an outbound phone call attempt and wondered if an text or e mail would suffice, along with an invitation to call the pharmacist if there are questions.

Pharmacist Gayle Ziegler said she felt the patient should expect the pharmacist to make the attempt to talk to them.

Pharmacist Tanya Schmidt stated that we cannot rely on the prescriber to have provided all of the storage, side effects or interactions consultation the patient might expect.

Public Member Fran Gronberg said she felt it was important to make every attempt to get the patient the service they need.

Pharmacist Shane Wendel feels that contact with the patient is impactful. He feels that even one out of 100 patients getting the in-depth counseling they need is worthwhile in care and dollars saved.

Pharmacist Tanya Schmidt questioned how compliance with the attempt to contact would be monitored on compliance. Executive Director Hardy answered that complaints would shed light on the pharmacies activities, and call logs could also be monitored. Most mail order pharmacy operations keep very good records of their contacts with patients.

Discussion moved to 61-04-12(7).

John Long R.Ph. asked, “What is the patient care aspect the Board is trying to accomplish with this section and what does “*assure*” mean.

Pharmacist Steve Irsfeld and Pharmacist Gayle Ziegler responded that we should have been doing this all along. Pharmacist Shane Wendel stated that rules are made for that small percentage of us who do not comply with expected standards of practice.

Dr. Hardy reiterated that we all seemed to understand the goal of this section and asked John Long, Abigail Stoddard and Pat Ward to get language to us which would be satisfactory to them.

Pharmacist Schmidt asked about the attempt to reach the patient - does it have to be by phone or can it be other contact methods? Board Members were in consensus that the intention of “*contact*” is a phone call. But, those in attendance felt a message [via text or email] may be sufficient. Board Members thought further discussion was needed on this issue at the next meeting to assure clarify on provision in subsection (6) in 61-04-12.

All those in attendance thanked the Board for listening to their concerns. Those from out-of-state were complimentary of the openness of the meeting and willingness to allow an open dialogue.

Dr. Mark Hardy reviewed the financials for the Board. He indicated that most categories of licensee numbers were up and expenses are as expected or below accounting for the good condition of our financials.

It was moved by Pharmacist Gary Dewhirst and seconded by Technician Member Diane Halvorson to approve \$30,000 in seed money to help NDSCS get their cohort group up and running at BSC. On vote by roll call: Pharmacist Dewhirst – Aye Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Irsfeld – Aye Pharmacist Schmidt – Aye Pharmacist Wendel – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

It was moved by Pharmacist Tanya Schmidt and seconded by Pharmacist Steve Irsfeld to approve the financials as presented. On vote by roll call: Pharmacist Dewhirst – Aye Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Irsfeld – Aye

**Pharmacist Schmidt – Aye Pharmacist Wendel – Aye Pharmacist Ziegler – Aye
Nays none – the motion carried.**

Dr. Hardy discussed a communication from GW Pharmaceuticals on a recent FDA approved clinical trial for a medication for seizures containing cannabinoids [Epidiolex]. It was consensus that the board liked the FDA approved clinical trial approach for approval of new therapies better than the current initiated measure for medicinal marijuana.

Executive Director Hardy paid the Board Member meeting expense vouchers.

President Wendel called for any further business, none was forthcoming.

It was moved by Pharmacist Gary Dewhirst and seconded by Pharmacist Tanya Schmidt to adjourn. All board members voted aye and the meeting was adjourned.

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