

March 15, 2012

Radisson Hotel – Bismarck, ND

A G E N D A
THURSDAY – MARCH 15th 2012

Radisson Hotel - VanGogh/Remington Room – 701-255-6000
605 E Broadway Ave - Bismarck ND 58501

10: 00 AM Call to Order – President Bonnie Thom, R.Ph.

Agenda

10:00 AM - Administrative Hearing:

Easy Clinic Lab and Rx Shop – Pharmacy Permit #395

Tab 1

Review Board Minutes of **JANUARY 9- 11, 2012**

Minute Tab

Remodeling: Pembina County Memorial Hospital Pharmacy – Cavalier
Thrifty White Drug #9 – Grand Forks
White Drug #17 - Minot

New Pharmacy: Rockview Pharmacy – Parshall
Village West Pharmacy in Hornbachers-Jennifer Kuschel, Pharm D.
Altru Specialty Center [Doctor's]

11:00 AM – New Pharmacy: Hot Shots Nuclear Medicine, LLC - Nathan Fleck, PharmD

Discussion and possible reconsideration relative to the granting of a **Tab 2**
Sub-class K permit to a closed door nursing home pharmacy, Foss Drug, LTC.

Collaborative Agreements:

Renewal: Altru Healthy System Anticoagulation Clinic Pharmacists and Physicians

New: 6 additional Physicians and Altru Healthy System Pharmacists

Lunch Break – reservations in the hotel restaurant

1:30 PM - Ms. Kelli Sem Review of Public Safety Considerations relative to the Americans with Disabilities Act and potential for licensure as an intern and future pharmacist.

Consideration of stipulation signed by licensee: Beth Remington – ND #3804
Review Executive Director Anderson's Stipulation and Settlement Agreement

Tab 3

2:30 PM Donna J. Wagner, Tech#294 – Request for Reinstatement

Mark Hardy, Pharm D-Six month employment review and consideration of Salary Adjustment
Addition of Dr. Hardy to signature on BNC Board Bank Account

3:00 PM Items tabled from last meeting:

Discussion of hospitals continuing to provide the drugs and pharmaceuticals, including IV medications, to hospices patients once the hospice operation has been spun off into a separate, but wholly owned organization.

Discussion on changing our procedure to share proposed stipulated settlements with the complainant before approval by the board. Should we invite them to the meeting, after the pharmacist or pharmacy has signed the stipulation, to participate in the discussion before a vote on approval?

Use of Outdated Pharmaceuticals in Emergency situations **Tab 4**

Controlled Substance Registration legislation **Tab 5**

Discussion on First Dose Review Rule **Tab 6**

Possible 2013 Legislation – Oral Transmission or an Rx – Eyecare **Tab 7**

- **Added**
Board Reports
Executive Director’s Report

Expense Vouchers

Adjournment

The meeting was called to order by President Bonnie Thom at 10:00 AM in the Renoir/Russell Room – having been relocated from the VanGogh/ Remington Room of the Radisson Hotel located at 605 E Broadway in Bismarck, ND. Present at this meeting were Board Members: Rick L. Detwiler, R.Ph. - Gary W. Dewhirst, R.Ph. - Fran Gronberg, Public Member - Diane M. Halvorson, R.Ph.Tech. - Laurel Haroldson, R.Ph. – Bonnie J Thom, R.Ph. – Gayle D. Ziegler, R.Ph.

Also Present: Executive Director Howard C Anderson, Jr, R.Ph. - Assistant Executive Director Mark J. Hardy, PharmD. , R.Ph., Board Attorney David A. Lindell, JD., Nathan Fleck, PharmD, Craig Christianson, CEO of Sheyenne Care Center; Doreen Saylor, R.Ph. and Pharmacy Technician Josie Olson ; Teresa Crooks, R.Ph. and Pharmacy Technician Amanda Chase

10:00 AM was the time scheduled for an administrative hearing for Easy Clinic Lab and Rx Shop, ND Out-of-State Pharmacy Permit #395. However all parties to the hearing have negotiated stipulated settlements with Dr. Mark Hardy and Attorney David Lindell.

The pharmacist of Towne Pharmacy and Hellertown Pharmacy asked that consideration of their stipulated settlements be deferred until 10:00 AM on May 17,th 2012 meeting so they may attend and discuss it with the Board.

Dr. Hardy presented the stipulated settlement with Easy Clinic Lab and Rx Shop, ND Out-of-State Pharmacy Permit #395.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Ziegler to approve the stipulated agreement as signed by Shawn Errol Moki Tavares, representing Easy Clinic Lab and Rx Shop. All Board Members voted aye – the motion carried.

Attorney Lindell will prepare the Order and serve it upon Easy Clinic Lab and Rx Shop.

The Agenda for the meeting was reviewed and ***it was moved by Pharmacist Dewhirst and seconded by Pharmacist Haroldson to approve the Agenda with the addition of Board Reports and the Executive Director's Report at the end of the Agenda. All Board Members voted aye – the motion carried.***

It was moved by Pharmacist Ziegler and seconded by Technician Halvorson to approve the minutes of January 9-11, 2012 as printed. All Board Members voted aye – the motion carried.

It was moved by Pharmacist Detwiller and seconded by Public Member Gronberg to approve the remodeling plans submitted by Pembina County Memorial Hospital Pharmacy located in Cavalier, ND. All Board Members voted aye – the motion carried.

Justin L Heiser, PharmD and Timothy Weippert, R.Ph. arrived at the meeting to participate in the discussion on the remodeling of Thrifty White Drug #9 in Grand Forks and White Drug #17 in Minot and other issues. President Thom asked Dr. Heiser to explain the remodeling plans that were submitted.

It was moved by Pharmacist Ziegler and seconded by Technician Halvorson to approve the remodeling plans submitted for Thrifty White Drug #9 located at 2475 32nd Ave S Suite #1 in Grand Forks, ND. Pharmacist Dewhirst disclosed that he is employed with Thrifty White and intends to vote. All Board Members voted aye – the motion carried.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Haroldson to approve the remodeling plans submitted for Thrifty White Drug #17 located at 1015 S Broadway Suite #3 in Minot, ND. Pharmacist Dewhirst disclosed that he is employed with Thrifty White and intends to vote. All Board Members voted aye – the motion carried.

Executive Director Anderson asked Dr. Heiser to be sure to furnish complete plans for the entire permitted space of each pharmacy for the Board files.

It was moved by Pharmacist Detwiller and seconded by Public Member Gronberg to approve the floor plans submitted by Mark Malzer, R.Ph. for Rockview Pharmacy, a new pharmacy planned for Parshall, ND. The plans submitted by Pharmacist Malzer are approvable for a Class K – Telepharmacy Pharmacy Permit that will be connected to Turtle Lake Rexall Drug. All Board Members voted aye – the motion carried.

Jennifer Kuschel, PharmD appeared at the Board of Pharmacy meeting to discuss her plans for a new pharmacy, Village West Pharmacy to be located in the Hornbachers grocery store. Dr. Kuschel presented her floor plans and explained them to the Board.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Haroldson to approve the submitted floor plans for the planned Village West Pharmacy in Hornbachers to be located at 4101 13th Ave South in Fargo, ND. A Pharmacy Permit will be granted subject to the receipt of the required lease, Application for Pharmacy Permit, appropriate fee and Stock Affidavit and that Executive Director Anderson finds all in compliance with the laws and rules of the Board of Pharmacy. All Board Members voted aye – the motion carried.

Doctor's Pharmacy in Grand Forks, ND was acquired by Altru, an Application for Pharmacy Permit under the new name of Altru Specialty Center was submitted. The floor plans had been approved at a previous meeting when it was still Doctor's Pharmacy.

It was moved by Pharmacist Detwiller and seconded by Public Member Gronberg to approve the Application for a Class B Hospital Pharmacy Permit with a subclass K Telepharmacy for Altru Specialty Center located at 4550 South Washington Street in Grand Forks, ND. All Board Members voted aye – the motion carried.

At 11:00 AM President Thom invited Nathan Fleck, PharmD to explain his plans for a new pharmacy, Hot Shots Nuclear Medicine, LLC in Bismarck, ND. Executive Director Anderson was working with Hot Shots Nuclear Medicine's attorneys out of Iowa to draft an agreement that provided the LLC with an acceptable operating and management agreement for the pharmacy.

It was moved by Public Member Gronberg and seconded by Pharmacist Dewhirst to approve the Application for a Class E Nuclear Pharmacy Permit, the floor plans, lease, operating and member control agreement for Hot Shots Nuclear Medicine, LLC, located at 2124 East Thayer Ave in Bismarck, ND. This approval will be subject to the pending rule Article 61-05 – Radiopharmaceutical Services, which was recently drafted and is moving through the formal hearings and adoption process. All Board Members voted aye – the motion carried.

President Thom introduced the topic based on the questions we received from Doreen Saylor, R.Ph., owner of Central Avenue Pharmacy of Valley City, ND; Justin L Heiser, PharmD and Timothy Weippert, R.Ph. of Thrifty White Drug, relative to the subclass K Telepharmacy Permit granted to Foss Drug LTC in Valley City.

President Thom invited Craig Christianson, CEO of the Sheyenne Care Center in Valley City to give some background to the Board Members about the genesis of this new pharmacy application. Mr. Christianson indicated that he had requested services from all of the pharmacies and met with all of the pharmacies in Valley City, and that since the opening of Foss LTC pharmacy in his facility, they have been getting great service and seemed to be providing great care to the residents of his facility. He stated that he was a strong believer of

freedom of choice and was attempting to provide that to all of the residents of his facility. He asked the Board not to place any restrictions or hardships on Foss Drug LTC as he felt they were providing a much needed patient care in his facility.

Pharmacist Sayler discussed with the Board Members what seems to be a departure from the requirement in the Telepharmacy Rules, which is that a Telepharmacy serve areas where there was no pharmacy, or that pharmacy services closed. She indicated that this just does not seem to fit within that requirement. She stated that much of this original controversy came about when Compliance Officer Judy Swisher pointed out to them some of their prescriptions did not have all of the tenants required on a prescription when being received for patients residing in a nursing home. Since these prescriptions were not valid, she was asking the nursing home's staff for a valid prescription before she could deliver the medication. She felt that this attempt to comply with the Law created some controversy and difficulty to the staff and providers.

Board Member Dewhirst provided some history of the development of the Telepharmacy Rules. Pharmacist Dewhirst pointed out that the rules have gone through various iterations and variations over time and were created from the bottom up based on needs, which have changed as variations and better ways to serve the public became clear.

Pharmacist Crooks pointed out that she was currently working full time at the Foss Drug LTC pharmacy and was hoping that the telepharmacy services could be used when someone had a medical leave, a medical emergency or needed to take a day off. When that occurs, another pharmacist at Foss Drug could cover the pharmacy technician's preparations of the product at the long-term-care facility during these specific periods of time. She pointed out that it was never their intentions to operate without a pharmacist except in an emergency or a unique situation as described.

Pharmacist Dewhirst read from and discussed the letter that had been sent to the residents of the long-term-care facility early in the process, pointing out an "emergency charge" for patients of other pharmacies. Pharmacist Crooks pointed out that this was an attempt to make it clear that they did not want to serve as the "emergency" provider for all the other provider pharmacies within the community. The issue of the emergency charge has been resolved and that this charge could not be charged to the resident, it would have to be born either by the home itself or through a contract arrangement between pharmacies.

Pharmacist Weippert pointed out that the telepharmacy rule certainly seems different than applied in this case. He reported that Thrifty White actively participates in Telepharmacy on both sides of the North Dakota and Minnesota border and understands the necessity of changes over time, as the practice evolves.

Dr. Heiser said that in his experience in working in a long-term-care pharmacy, it helped him believe that having a pharmacist on site was the best option, whenever possible.

Board Member Detwiller pointed out this was a closed door pharmacy, that the operation was for the benefit of the long-term-care patients and that by their Pharmacy Permit they were not allowed to fill prescriptions for ambulatory patients at this pharmacy.

There was some discussion that the subclass K telepharmacy would be restricted to the pharmacist working 40 hours per week and the telepharmacy would be used only in an emergency, medical or otherwise; and no staff prescriptions would be filled through the closed door pharmacy.

Public Member Gronberg reinforced Pharmacist Detwiller's thoughts and Pharmacist Haroldson expressed that she felt the pharmacy should be moved to a closed door only pharmacy without the subclass K – telepharmacy.

Pharmacist Saylor pointed out in response to questions on service to long-term-care patients, she indicated that sometimes her pharmacy delivers to the nursing home before they have received the physician's order, when the order was communicated directly to the pharmacy.

It was moved by Pharmacist Ziegler and seconded by Pharmacist Detwiller to reiterate that Foss Drug LTC pharmacy would be required to have a pharmacist on duty for 40 hours per week, Monday through Friday, and there would be no out-patient or ambulatory prescriptions filled, including employee prescriptions and that the subclass K would remain in place. Six Board Members voted aye – one Board Member voted nay – the motion carried.

Pharmacist Haroldson requested that the Board of Pharmacy clarify the Telepharmacy Rules for situations such as this, in the future.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Ziegler to approve the renewal of the Collaborative Agreement between the Altru Healthy System Anticoagulation Clinic Pharmacists and Physicians, including the six additional physicians. All Board Members voted aye – the motion carried.

The Board broke for lunch at 12:30 to meet in the hotel restaurant.

Erin Navarro, PharmD, an Altru Pharmacist; NDPhA Executive Vice President Michael Schwab and Jordan Wolf, PharmD Student joined the meeting.

At 1:30 PM Ms. Kelli Sem, accompanied by her parents, Claude and Pati Sem, were present to enquire about her long term prospects for getting into pharmacy school, receiving an intern license and eventually becoming licensed as a pharmacist in North Dakota. Ms. Sem is a wheelchair bound individual, with some muscle control problems affecting her speech. Kelli spoke with the Board of Pharmacy at length. She explained that she was a senior in high school interested in the health care field, and interested in whether the Board of Pharmacy would be willing to grant accommodations for her extending to help with the physical tasks necessary in laboratory classes, compounding, opening prescription vials and other physical tasks. The Board Members asked many questions of Ms. Sem and she in turn of the Board Members.

The unanimous consensus of the Board of Pharmacy is that Ms. Kelli Sem could be granted an intern license and would be able to receive reasonable accommodations for her physical disabilities to complete the College of Pharmacy PharmD Program, pass the licensure examinations and receive a North Dakota Pharmacist License. The Board Members looked at

this as an opportunity to encourage the College of Pharmacy's concept pharmacy laboratory to integrate the work of technician's into the concept pharmacy lab, as the Board felt that North Dakota Registered Pharmacy Technicians or those students in an ASHP Accredited Program could perform the duties necessary to assist Ms. Kelli Sem as a pharmacy student, much like they would do in a pharmacy once she was licensed as a pharmacist. Board Members pointed out that there are many roles in pharmacy encompassing mostly cognitive tasks, which would pose no barrier to Ms. Sem. Reasonable accommodations might also allow her to perform most pharmacy duties, with the help of Registered Pharmacy Technicians.

It was moved by Pharmacist Detwiller and seconded by Technician Halvorson to approve the Stipulated Settlement signed by Beth Remington – ND Pharmacist #3804. All Board Members voted aye – the motion carried.

It was moved by Pharmacist Ziegler and seconded by Technician Halvorson to accept the Application for Reinstatement of Donna J. Wagner, ND Technician #294, which was cancelled for nonpayment in 2007, and to grant her a Technician-In-Training Registration for a period of three months, to allow her time to obtain the PTCB Certification. All Board Members voted aye – the motion carried.

At this time the Board Members interviewed Dr. Mark Hardy about his first six months of employment with the Board of Pharmacy and give consideration to his continued employment and a promised salary increase, should his evaluation prove acceptable.

It was moved by Pharmacist Dewhirst and seconded by Public Member Gronberg to grant the \$5,000 per year salary increase to Assistant Executive Director Mark Hardy, PharmD. On a vote by Roll Call: Pharmacist Detwiller – Aye Pharmacist Dewhirst – Aye Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

A resolution was introduced by Pharmacist Detwiller and seconded by Technician Halvorson to authorize Dr. Mark Hardy, Assistant Executive Director to be a signatory on all financial accounts of the Board of Pharmacy, in addition to Executive Director Anderson. Either Executive Director Howard Anderson or Assistant Executive Director Mark Hardy, PharmD will be able to sign financial instruments for the North Dakota State Board of Pharmacy. Only one signature will be required on checks. On a vote by Roll Call: Pharmacist Detwiller – Aye Pharmacist Dewhirst – Aye Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

President Thom announced that it was time to discuss the tabled topics from the last meeting, relative to hospitals continuing to provide the drugs and pharmaceuticals, including IV medications, to hospices patients once the hospice operation has been spun off into a separate, but wholly owned organization. This topic had been tabled to allow the Board of Pharmacy to solicit feedback from our pharmacists.

Margaret Nelson, RN, EdD of Catholic Health Initiatives Hospice Organization was present to discuss the issue with the Board. Assistant Executive Director Hardy distributed a packet of email communications providing comments that we had received in response to a questionnaire sent out by the Board of Pharmacy. The issue was discussed at some length by all parties present.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Ziegler that on a continuum of care basis, a hospital may provide hospice medications for which hospice is responsible for covering as part of the service they provide, to an affiliated hospice, which is either part of the hospital or is a wholly owned division of the corporate parent. All Board Members voted aye – the motion carried.

Executive Director Anderson asked the Board Members to consider a variation in our complaint resolution process. When an actual formal complaint is brought by the Board of Pharmacy as a result of a complaint received from a member of the public, and a hearing is scheduled, but a signed Stipulated Settlement is reached before that hearing, we offer the complainant an opportunity to discuss the stipulation with the Board, before we make the decision on that Stipulated Settlement. The Board Members felt that this was a reasonable accommodation and by consensus our complaint resolution process will be changed.

The issue of outdated pharmaceuticals in hospitals, pharmacies and emergency situations was discussed. No action on a formal guidance was taken by the Board.

Assistant Executive Director Hardy presented an early draft of Controlled Substance Registration legislation. The recent Board of Pharmacy Newsletter contained an article about this potential legislation and Dr. Hardy reported that he had received feedback from Pharmacists Steve McAtee and Mark Malzer, both feeling that this was an unfunded mandate.

Dr Hardy discussed the proposed rule 61-07-01-14 Pharmacist First Dose Review. Dr Hardy also reported having received feedback on this, a hospital pharmacist felt that this might be more restrictive than necessary and that these issues would be carried forward to the rule hearing scheduled at the NDPhA Convention on April 14, 2012 in Minot, ND.

Executive Director Anderson presented a draft of legislation prepared at the request of the Trinity Ophthalmologists and Optometrists group relative to Certified Ophthalmic Assistants, Certified Ophthalmic Medical Technicians, and Ophthalmic Surgical Assistants being added to the list of approved professionals in North Dakota Century Code 43-15-31.3, allowing them to transmit prescriptions to a pharmacy via a telephone or fax. The group has been asked to obtain the support of the Optometric Association, the Ophthalmologists and their respective regulatory Boards before the Board of Pharmacy would be willing to move forward with introducing this legislation on their behalf.

Board Member Dewhirst reported that he had been contacted by Pharmacist Mark Biel indicating that he could not find his original Certificate for the Immunization Course and wondered why the Board of Pharmacy had not kept it for him. Executive Director Anderson explained that we were accepting the Continuing Education credit document from NDSU in a few other such cases. The Pharmacy Program now has the capabilities to be able to scan such

documents and attach them to the individual’s records, so they are available upon renewal in the future, as it seems more than one pharmacist could not keep tract of their own training record.

President Thom asked Michael Schwab, ND Pharmacist Association Executive Vice President if he had any items that he wished to discuss with the Board. Mr. Schwab indicated that he had recently attended the American Pharmacists Association Annual Meeting, where there was some concern about unfunded mandates and although community pharmacy accreditation might be a good avenue for some Boards of Pharmacy, it would undoubtedly cost the pharmacies money. He also expressed concern that community pharmacy accreditation does not take the same approach that CMS did, where a single community pharmacy paid the full fee and chain pharmacies were allowed to enter the program with a fee for one pharmacy accreditation visit and a simple sampling of the chains other pharmacies, with a much smaller fee.

APhA is working hard to get pharmacists recognized as providers of professional services under Medicare requirements.

Multi-state licensure of pharmacists is on the radar screen, partly due to the increasing use of telepharmacy across state lines, and the increasing number of states that are requiring the licensure of the pharmacist-in-charge or at least a staff pharmacist at mail order pharmacies.

President Thom thanked NDPhA Executive Vice President Schwab for his input on these issues, as well as his willingness to contribute to the discussion with Ms. Kelli Sem. Mr. Schwab’s previous tenure as the Executive of The Arc gives him special credentials in this area.

Board Member expense vouchers were distributed, completed and collected.

The meeting adjourned.

Bonnie J. Thom, R.Ph.
President

Gary W. Dewhirst, R.Ph.
Senior Member

Member
Laurel A. Haroldson, R.Ph.

Member
Rick L. Detwiller, R.Ph

Member
Gayle D. Ziegler, R.Ph.

Member
Diane M. Halvorson, RPhTech

Member
Fran Gronberg

Executive Director
Howard C. Anderson, Jr, R.Ph.