

A G E N D A THURSDAY – MARCH 21st 2013

ND STATE BOARD OF PHARMACY OFFICE - 1906 E BROADWAY AVE – BISMARCK, ND 58501

10: 00 AM Call to Order – President Laurel Haroldson, R.Ph.

Agenda

Review Board Minutes of JANUARY 7-9, 2013 & January 28, 2013

Minute Tab

Consideration of Comments on Class L Pharmacy Permit Rule

Tab 1

Sponsorship 6 – 3rd year students to present posters at NABP Annual meeting

Consideration of CE Credit: RPh5242 – Nicolas Kadrmas, PharmD

11:00 AM Request for Telepharmacy Permits for:

Badlands Human Services Center – Dickinson

North Central Human Service Center – Minot

Northwestern Human Service Center - Williston

Filling of medication boxes by Nurses and Medication Assistants- Joan Slusser

TAB 2

11:30 AM Derek Gaffney – Intern

Consideration for Reciprocity: Sue Z. Aksay, R.Ph. – Disciplinary Action

Request for Re-instatement: Kristin Striha ND Tech 684 [cancelled for non-payment]

Collaborative Agreements: Altru Anticoagulation Clinic - additions

Presentation Medical Center - Rolla

Lunch Break

1:30 PM Health Policy Consortium – Discussion of Ownership law

TAB 3

2:30 PM - New Pharmacy – Skripts Pharmacy – Costco in Fargo

Floor plans remodel Sakakawea Medical Center Pharmacy - Hazen

Mike Chase, R.Ph. – Dennis DelaBarre, R.Ph.

Remodeling/Relocation: The Medicine Shoppe - Minot

Floor Plans: New Pharmacy - Williston

Legislative Updates

Discussion of Medicare Part B services in ND – Jenna Wahlstrom, PharmD Student

TAB 4

Board Reports

Executive Director's Report [Howard's Hours]

TAB 5

Expense Vouchers

Adjournment

President Haroldson called the meeting to order at 10:02 AM on Thursday March 21, 2013 in the conference room of the Board of Pharmacy Office, located at 1906 East Broadway in Bismarck, ND.

Present were: Gary W. Dewhirst, R.Ph. - Diane M. Halvorson, R.Ph.Tech. - Laurel Haroldson, R.Ph. – Bonnie J Thom, R.Ph. – Shane Wendel, R.Ph. - Gayle D Ziegler, R.Ph. – Board Attorney David A. Lindell, Assistant Executive Director Mark J Hardy, PharmD. and Jenna Wahlstrom, PharmD Student doing a rotation with the Board and Allan J DeMuth, R.Ph. doing a residency with Sanford Health.

Absent were: Public Member Fran Gronberg and Executive Director Howard C. Anderson, Jr, R.Ph. as both are still active in the legislative session.

Also present were: Tanya Schmidt, PharmD and Julie A. Boyer, PharmD Student; Steven Kawulok, R.Ph.; Joan Slusser, R.Ph.

It was moved by Pharmacist Thom and seconded by Technician Halvorson to approve the Agenda with the additions of remodeling plans for the Roger Maris Cancer Center at Sanford in Fargo and a discussion item on the May 2013 Examinations. All members present voted aye – the motion carried.

It was moved by Pharmacist Thom and seconded by Pharmacist Ziegler to approve the Board Minutes of January 7-9, 2013 as printed. All members present voted aye – the motion carried.

It was moved by Technician Halvorson and seconded by Pharmacist Dewhirst to approve the Board Minutes of the January 28, 2013 conference call as printed. All members present voted aye – the motion carried.

Pharmacist Dewhirst announced that he plans to run for the Executive Committee representing District V during the May 18-21, 2013 Annual NABP meeting to be held in St Louis, MO. The Board Members were all supportive and congratulated Pharmacist Dewhirst for putting his name forward for this important position.

The comments regarding the Class L Pharmacy Permit rule, relative to dispensing devices in long-term-care facilities, was reviewed. Assistant Executive Director Hardy indicated that there had been no comments received, after the Board Meeting, so only the comments reviewed during the hearing needed to be considered. He briefly reviewed the comments and responses received at the January Board Meeting about approval, and discussed how other states viewed these devices.

Pharmacist Tanya Schmidt asked the Board – “if a pharmacist must be present within a licensed pharmacy to release prescription orders at the dispensing device located in a long-term-care setting?”

The Board Members did not feel that it was necessary for a pharmacist to be present within a pharmacy, but could review medication orders remotely via a secure computer connection.

The Board also discussed how it will handle the permit requests and requirements for approval.

Assistant Executive Director Hardy noted that before a device is allowed to be operational in a long-term-care setting, the Board of Pharmacy would be able to inspect the actual device, the safeguards and security procedures, to ensure that all requirements were in place prior to approving a pharmacy permit.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Wendel to approve the final adoption of 61-02-01-01, 4(I) Class L Pharmacy Permit and submit them to the Attorney General's Office for review. All members present voted aye – the motion carried.

It was moved by Pharmacist Ziegler and seconded by Technician Halvorson to approve the 15 hours Continuing Education requested by Nicolas D. Kadrmas, PharmD, ND RPh5242, contingent upon him receiving a successful completion certification relative to his coursework. All members present voted aye – the motion carried.

Mr. Derek Gaffney joined the meeting to request the re-instatement of his intern license.

Assistant Executive Director Hardy briefed the Board on Mr. Gaffney's progress since the last Board Meeting, including the intervention with Pharm-Assist Members Larry E. Nelson and Agnes Harrington and the report from Mr. Gaffney's medical practitioner.

Mr. Gaffney gave his account on his progress since last meeting with the Board, including a new job with a farm machinery dealer and his interaction with Pharmacist Nelson. He maintains that he has learned from the incidents and felt that the Board's actions were appropriate. He felt that his new employment gave him a fresh perspective on some of the issues that led to his suspension from the PharmD Program at NDSU College of Pharmacy. He felt he has improved his communication skills and that he felt it has been good to have contact with the Pharm-Assist Committee Member Nelson, regarding his issues with alcohol.

Board Members questioned Mr. Gaffney and asked if he felt he was ready to resume his rotations. The Board expressed that their interaction with Mr. Gaffney has been improved since their initial meeting with him.

It was moved by Technician Halvorson and seconded by Pharmacist Thom to reinstate ND Intern License 477 issued to Derek L. Gaffney, provided that he continue meeting with the Pharm-Assist Committee Member Larry Nelson and comply with requests set by Pharmacist Nelson; and Intern Gaffney must meet with the Board of Pharmacy during the May 2013 Meeting. All members present voted aye – the motion carried.

Pharmacist Brendan Joyce, Director of Pharmacy Services for ND Medicaid joined the meeting.

At 11:00 AM Pharmacist Joan Slusser was present to discuss the request for Telepharmacy Permits for Badlands Human Services Center in Dickinson; North Central Human Service Center in Minot and Northwestern Human Service Center in Williston.

Pharmacist Slusser reported that over 500 orders during the last quarter were checked for the three currently Telepharmacy permitted Human Service locations. She indicated an approximate 7% detection rate in the Quality Related Events of the prescriptions that were checked. The events were related to labeling, child resistant packaging issues and filling mistakes. She informed the Board that a pharmacy technician was hired for the Bismarck site and there are plans to hire one for the Grand Forks location. She indicated that there are growing pains in getting the nurses through the educational program to become pharmacy technicians and a resistance to becoming cross trained as technicians. However, the department agrees that this would be in the best interest of the patients being serviced by Human Services Centers, to maintain the highest level of care.

It was moved by Pharmacist Thom and seconded by Pharmacist Dewhirst to approve a Class K Telepharmacy Permit to the Badlands Human Services Center – 300 13th Ave West, Suite 1 in Dickinson. All members present voted aye – the motion carried.

It was moved by Technician Halvorson and seconded by Pharmacist Wendel to approve a Class K Telepharmacy Permit to the North Central Human Services Center – 1015 South Broadway Suite 18 in Minot. All members present voted aye – the motion carried.

It was moved by Pharmacist Ziegler and seconded by Pharmacist Dewhirst to approve a Class K Telepharmacy Permit to the Northwest Human Services Center – 316 2nd Ave West, in Williston. All members present voted aye – the motion carried.

Dr. Andy McLean, Medical Director of the Human Service centers joined the meeting by telephone to discuss, along with Pharmacist Slusser, nurses filling of medication boxes in the Human Service Centers.

Assistant Executive Director Hardy briefed the Board on the meetings with the ND Department of Health and the Board of Nursing regarding the role of nurses and medication assistants in filling medication boxes for patients outside of the home setting. He point out that this activity, especially when it relates to the Human Service Centers, done in the context of a pharmacy, should be under the supervision of a pharmacist. Pharmacist Slusser reported that nurses were currently filling medication boxes and had been doing so for a long time. She indicated that up to 800 medication boxes are filled weekly in all the Human Service Centers and that it would be difficult to deal with the large volume within the context of the telepharmacy setting.

Board Members reviewed the letter sent from Pharmacist Slusser expressing concern over the difficulty in checking these filled medication boxes over the telepharmacy.

Dr. McLean indicated that it was important to maintain the service to these patients as this is crucial service for this patient population. The Board Members agreed that this is a significant service, and felt it was important to ensure that there was proper safety and supervision of these duties and in the pharmacy.

Assistant Executive Director Hardy suggested using the Tech-check-Tech process currently in our statutes to help ensure an enhanced level of safety is provided to patients in the preparation of the medication boxes.

Pharmacist Slusser expressed the desire to slowly roll out a process such as this, but would agree that a Tech-check-Tech process would be a potential solution. She indicated that they could possibly try a pilot project in one of the Human Service Centers. The Board felt that this could be an important step and that the detection of quality related events should be monitored to safeguard that they are truly being caught. Board Members gave accounts from their own practices on their use of a double check process to identify quality related events.

The Board also discussed the desire to include on the boxes, a medication list, as to what is in the boxes and that the name of the patient for which the medication is intended is on the boxes.

Pharmacist Steven Kawulok was present to request a Class A Pharmacy permit for a new pharmacy within the Costco store in West Fargo, ND. Pharmacist Kawulok expressed excitement to opening this pharmacy and relocating to the Fargo area. He explained that he would be the sole owner of the pharmacy and would be leasing space within the store from Costco. This will be a new venture and business model for Costco as there is only one other such pharmacy that is currently located in Lincoln, NE. Pharmacist Kawulok explained the floor plans submitted with his proposal, that included photos and detailed work space arrangements. When Board Members questioned him, he reported that Costco will not have a financial interest in the pharmacy operation.

It was moved by Pharmacist Dewhirst and seconded by Technician Halvorson to approve the floor plans as presented for Skripts Pharmacy to be located at 750 23rd Ave East in West Fargo, ND a new pharmacy within the Costco. This Pharmacy has 1110 square feet and 250 square feet of common area within the store. All members present voted aye – the motion carried.

At 12:20 PM the meeting recessed for lunch that was delivered from Jimmy John's.

The meeting resumed at 1:05 PM.

It was moved by Pharmacist Thom and seconded by Pharmacist Ziegler to allow the Application for Reciprocity of Sue Z. Aksay to go forward, it was noted that the disciplinary action taken by Oregon against her pharmacist license appeared to be a medication error and not a deliberate action. All members present voted aye – the motion carried.

It was moved by Technician Halvorson and seconded by Pharmacist Wendel to

grant the reinstatement of Kristin Striha ND Technician Registration #684, which had been cancelled for non-payment of her renewal. All members present voted aye – the motion carried.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Thom to approve the additions of Marissa Clarin, PharmD and Dr. Keith Swanson and Dr. Jon Berg to the Altru Anticoagulation Clinic Collaborative Agreement. All members present voted aye – the motion carried.

It was moved by Technician Halvorson and seconded by Pharmacist Ziegler to approve the modifications of removing Dr. Penny Wilkie and Pharmacist Douglas Demontigney and replacing them with Dr. Roy Cordy and Pharmacists Zachary Marty and Laurie Thompson, along with language changes in the Collaborative Agreement of Presentation Medical Center in Rolla. All members present voted aye – the motion carried.

It was moved by Pharmacist Ziegler and seconded by Pharmacist Dewhirst to approve the floor plans submitted for the relocation of The Medicine Shoppe, ND Pharmacy Permit #158 currently located at 209 11st Ave SW to 1118 South Broadway in Minot, ND. The issuance of the permit is contingent upon the address of the new location being submitted to the Board of Pharmacy office. All members present voted aye – the motion carried.

At 1:30 PM the Board began the discussion on the proposal by the Health Policy Consortium, which had been extended from the January Board Meeting. Present with the Board Members for the discussion was Scott Hulst, RPhTech; Allan DeMuth, R.Ph.; Steven Kawulok, R.Ph.; Michael Schwab, Executive Vice President of NDPhA and Tucker Kreft, PharmD Student on rotation with the ND Pharmacist Association; Dennis DelaBarre, R.Ph. and Keith Horner, R.Ph. from St Alexius Medical Center; Thomas Simmer, R.Ph. - John Vastag – Dennis Millirons from Sanford Health and Dave Olman from Altru Health System.

President Haroldson welcomed all to the discussion and requested that they introduce themselves so all would know who was speaking.

Assistant Executive Director Hardy briefed the Board on the previous discussion at the January 2013 meeting and distributed a guidance handout that was created after looking at the legislative and legal implications of the proposal received from the Health Policy Consortium and the issue of the Medicare provider based billing and its implications for retail pharmacy services. Assistant Executive Director Hardy indicated that the proposal to grant an exemption to the ownership law to hospitals or integrated health system locations did not appear to fit with the legal and legislative history of NDCC 43-15-35. In regards to the Medicare provider based billing, it was interpreted to not apply to pharmacy permits and would not conform to provisions in North Dakota's rules and laws.

Dennis Millirons felt the Board's interpretation was not correct and provided clarification as to how his interpretation of the Medicare provider based billing entity and how it would relate to providing pharmacy services.

The Board asked about the exemption as it related to providing retail pharmacy services, if it would be for only Medicare patients and how the billing would relate to retail pharmacy prescriptions. The consortium would like the opportunity to service all patients regardless of the 3rd party payor. The billing for the retail prescriptions are not included within the provider based billing to Medicare and would still be considered a separate billing transaction.

The consortium felt that this exemption would lead to a better continuum of care and provide an improved reconciliation of medication process for patient care.

Board Attorney David Lindell indicated that considering these patients as hospital patients at an address different from the actual hospital pharmacy permit, is not consistent with what the provision of the North Dakota law set forward and does not comply with the legal rulings on this matter.

Pharmacist Dewhirst indicated that he believed this to be a deviation from our law and expressed that the Board would have to defend that deviation. He felt that granting an exemption from the state law for this Medicare provision would not be defensible. This appears to be a legislative matter and not something the Board can just change. Attorney Lindell agreed that this would not be a variation that the Executive Branch, under which the Board of Pharmacy falls, would be able to create and is a legislative function of the government.

Pharmacist Ziegler inquired as to the continuum of care for a hospital pharmacy to serve a patient. She questioned whether her hospital pharmacy permit would allow her to fill prescriptions for patients discharged from a setting, within the health system and if that would be something that would fit within the content of the current law.

Attorney Lindell felt the law is clear that a Class B-Hospital Pharmacy Permit allows the pharmacy to dispense out-patient prescriptions only to those that are discharged from the hospital address where the permit is held. The provision of provider based billing is a federal Medicare billing requirement and not a provision to circumvent the provisions in state law.

President Haroldson asked if there were any more comments to be heard on the proposal, none were forthcoming. She thanked everyone for coming.

Pharmacists Keith Horner and Dennis DelaBarre, Nursing Director Marcy Schultz and Technician Michelle Wolf came forward to discuss the remodeling plans for Sakakawea Medical Center Pharmacy in Hazen. Pharmacist DelaBarre indicated that this is a collaborative effort between their consultant pharmacist, Michael Chase and St Alexius Medical Center to augment pharmacy services. This will eventually lead to Telepharmacy services and eventually be their method to comply with the first dose review rule. The hospital is a 25 bed facility. Pharmacist Horner indicated that he would like to use the locations at the hospitals in Hazen, Garrison and Turtle Lake to develop a residency program to train future pharmacists in providing pharmaceutical care in rural hospitals. This location will conduct medium risk compounding.

It was moved by Pharmacist Dewhirst and seconded by Technician Halvorson to approve the remodeling floor plans submitted for Sakakawea Medical Center Pharmacy located at 510 8th Ave NE in Hazen. All members present voted aye – the motion carried.

Assistant Executive Director Hardy presented floor plans received from Pharmacist Gerald Gratz for a proposed new pharmacy in a new clinic planned in Williston, ND. Pharmacist Gratz indicated that these were preliminary plans and that it would not be able to open for at least a year and would keep us posted of any changes, should they occur.

It was moved by Technician Halvorson and seconded by Pharmacist Dewhirst to approve the preliminary floor plans submitted by Pharmacist Gerald Gratz for a proposed pharmacy in the clinic being built in Williston, ND. The plans are approvable contingent upon seeing the lease agreement, full application, and fee. All members present voted aye – the motion carried.

It was moved by Pharmacist Thom and seconded by Technician Halvorson to approve the remodeling plans submitted by Pharmacist Mark Plencner of Roger Maris Cancer Center of Broadway Pharmacy located in Sanford Health at 820 4th Street North in Fargo, ND. All members present voted aye – the motion carried.

Assistant Executive Director Hardy asked PharmD Student Jenna Wahlstrom, who is on a rotation with the Board of Pharmacy, to discuss the recent concerns regarding Medicare Part B services in North Dakota.

PharmD candidate Wahlstrom reported that the Board Office has heard reports of pharmacies dropping Medicare Part B contracts due to reimbursement issues, along with great difficulties with audits. Pharmacies are reporting difficulty in navigating the appeals process and are reportedly taking multiple financial losses due to the inability to determine the necessary information required.

A letter that had been drafted to Noridian was distributed to the Board Members for their review. It would be sent to Noridian Administrative Services and a copy going to our congressional delegation to ensure that everyone is aware of the Board's concerns. The Board Members determined that this is an appropriate step, as they themselves have either experienced similar situations or have heard reports of providers choosing not to provide Medicare Part B services to their patients. They felt it was important to let them know that the Board feels that it was necessary to audit claims to ensure proper standards, but that it was just as important for Noridian to clearly communicate Medicare's standards and to be equally clear in their requirements for these audits.

PharmD candidate Tucker Kreft, on rotation with the ND Pharmacists Association, explained to the Board the reductions in payments for Medicare Part B providers in diabetic testing supplies and the potential impact that will have on pharmacies providing that service.

Mr. Michael Schwab, Executive Vice President of the ND Pharmacists Association gave an overview of the steps the Association has taken in their concern with the Medicare Part B system and the future for pharmacies providing that service to their patients.

The Board Members expressed concern about the access that patients would have to these types of services and what would happen in an emergency situation or if the patient needed medication quickly, especially in our rural areas or in harsh winter weather or turbulent summer conditions. They agreed it was time to send a letter to Noridian expressing our concerns.

Assistant Executive Director Hardy provided folders of each of the legislative bills along with their contexts and the current status of each bill that the Board has been tracking during the current legislative session. Board Members inquired about the different bills and asked questions about the rewrite of Senate Bill 2342 on our Wholesalers and the implications on the Board's finances.

The Board discussed the May 2013 examinations and potential task assignments and the necessity of updating the testing processes.

The Board expressed the importance of alerting all the registered pharmacy technicians and their employers about the significance of obtaining and maintaining PTCB Certification as a requirement for registration in North Dakota. Reminding the technicians that it is essential they maintain the appropriate Continuing Education to preserve their PTCB Certification as required of all pharmacy technicians registration in North Dakota. The Board suggested a reminder be included in the renewal notices.

Mr. Schwab then presented a proposal for the "*About the Patient*" program, which would be a grant program set up through the Department of Human Services or Medicaid to do specific Disease State Management [DSM] interventions for patients with chronic medical conditions.

The disease states targeted that have been talked about at this time were asthma, antipsychotic medications and ADHD medications. The preparation would consist of training one pharmacist and two pharmacy technicians per site. Mr. Schwab indicated they are working through the approval process through Medicaid and anticipate this project to move forward. He indicated that the training that would be required would cost \$8,000 to \$10,000 dollars total. This project is intended to cover about 15,000 individuals currently enrolled in the Medicaid system. He requested the Board of Pharmacy consider designating funds to help with the cost of training of pharmacists and technicians in the settings for the purpose of implementing this DSM project.

The Board Members were very supportive of this proposal and thought it was a good patient care initiative.

It was moved by Pharmacist Thom and seconded by Pharmacist Dewhirst to designate up to \$10,000 to the ND Pharmacists Association for the training of pharmacists and pharmacy technicians for the Disease State Management [DSM] project through the Department of Human Services / Medicaid. The Board Members requested a data report from the project coordinator Wendy Brown, PharmD at our May 2013 Board Meeting relative to the specific use of the designated funds in its entirety. On vote by roll call: Pharmacist Dewhirst – Aye

Technician Halvorson – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Pharmacist Wendell – Aye Pharmacist Ziegler – Aye – the motion carried.

Assistant Executive Director Hardy directed the Board Members to printouts received from Executive Director Howard Anderson relative to the hours he spent working on Board business, 20 in January and 28 hours in February. He responds to Board related issues by email and signs all necessary documents, outside of the context of serving in the legislature.

It was moved by Technician Halvorson and seconded by Pharmacist Wendell to approve payment of the \$2,524.56 for 48 hours to Executive Director Howard C. Anderson, Jr, R.Ph. expended on behalf of Board of Pharmacy issues. On vote by roll call: Pharmacist Dewhirst – Aye Technician Halvorson – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Pharmacist Wendell – Aye Pharmacist Ziegler – Aye the motion carried.

It was moved by Technician Halvorson and seconded by Pharmacist Ziegler to appropriate up to \$200 for the purchase of an all-weather rug for the front entrance floor area of the Board of Pharmacy office, as requested by Eileen Heidrich, Executive Assistant to the Board's two directors. On vote by roll call: Pharmacist Dewhirst – Aye Technician Halvorson – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Pharmacist Wendell – Aye Pharmacist Ziegler – Aye - the motion carried.

Executive Assistant Eileen Heidrich thanks the Board Members for their consideration and looks forward to them seeing the purchase of an NDSU green floor covering greeting them at the front door at the next meeting held at the Board of Pharmacy Office.

Assistant Executive Director Hardy collected the Board Members expense vouchers.

It was moved by Pharmacist Thom and seconded by Pharmacist Dewhirst to adjourn the meeting. All members present voted aye – the motion carried.

Laurel A. Haroldson, R.Ph.
President

Member
Bonnie J. Thom, R.Ph.

Member
Diane M. Halvorson, RPhTech

Assistant Executive Director
Mark J. Hardy, PharmD

Gary W. Dewhirst, R.Ph.
Senior Member

Member
Gayle D. Ziegler, R.Ph.

Member
Shane R. Wendel, R.Ph.

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