

SEPTEMBER 24TH, 2008 – BOARD OF PHARMACY OFFICE – BISMARCK, NORTH DAKOTA

A G E N D A

Wednesday - September 24, 2008

Board of Pharmacy Office – Conference Room 1906 East Broadway – Bismarck, ND 58501

9:45 AM Call to Order – President Gary W. Dewhirst, R.Ph.

Review and approve Agenda

AGENDA TAB

10:00 AM – Proposed Rule Change Hearing

TAB 1

61-02-07.1-12 Technicians checking Technicians and

61-04-04-01 (21) Expedited Partner Therapy.

Request for Re-instatement – William H. Koslofsky,, R.Ph. #3453 [cancelled for non-payment]

Kyle M. Schwandt, PharmD Intern #1074

FILE

Remodeling / Relocation of CVS #8614 – North Bismarck

Gateway Health Mart North

New Pharmacy Permit Request – MedCenter One Bismarck

TAB 2

Aurora Hospital Pharmacy – Grand Forks

Heritage Pharmacy Gateway-Terry Kristensen, R.Ph.

[Three Affiliated Tribes] = TAT Twin Buttes Telepharmacy – Halliday, ND

TAT Mandaree Telepharmacy – Mandaree, ND

TAT Parshall Telepharmacy – Parshall, ND

TAT White Shield Telepharmacy – White Shield, ND

2:00 PM FUNDING REQUESTS:

“Dining with Diabetes Program”

TAB 3

Adding Economic Impact & Small Business Consulting Services to the ND Institute for

Pharmaceutical Care

TAB 4

Technician Medical Reconciliation Pilot Training Packet –

Curtis Trowbridge, R.Ph. Innovis Health

TAB 5

Review Disciplinary Case: Ryan P. Sannes, R.Ph. #4917

Robert A Sieg – P-1

Report on Hospital Telepharmacy Project – Gayle Ziegler, R.Ph.

Collaborative Agreement–Anne Ottney, PharmD–Dr. Napoleon Espejo

[Family Healthcare Center – Fargo]

61-02-01-03 Pharmaceutical compounding standards;

[Texas]

TAB 6

Exam Schedule (1) Kelley M Pugh – Graduated West Virginia

FILE

1:15 - 1:30 PM Roll Call and Orientation of Candidates

1:30 - 2:30 PM Laboratory Section

2:30 - 3:00 PM Errors and Omissions 1

3:00 - 3:30 PM Oral Examination

President Gary W. Dewhirst, R.Ph. called the Board Meeting to order at 9:50 AM in the conference room of the office of the State Board of Pharmacy located at 1906 East Broadway in Bismarck, ND.

Present were: Board Members, Rick L. Detwiller, R.Ph. – Gary W. Dewhirst, R.Ph. – Laurel Haroldson, R.Ph. – Gayle D. Ziegler, R.Ph. - Executive Director Howard C. Anderson, Jr, R.Ph. and Compliance Officer Gerald R. Johnson, R.Ph.,

Also present were: Pharmacist Curtis A. Larson, CVS Pharmacy Regional Manager; Thomas Simmer, R.Ph. and Attorney Bob Rogalski of MedCenter One Pharmacy; Donna Bieri, PharmD, R.Ph. and Lovetta Veach of the Three Affiliated Tribes; Michael Riepl, R.Ph. Gateway Health Mart Pharmacies & Co-Chair of the Pharm-Assist Committee; Kyle Schwandt, PharmD; Patricia Hill, RN of the ND State Board of Nursing; Kirby Krueger, Julie Goplin, Sandy Fetzer and Charlene Reiswig of the ND Department of Health and Dennis DelaBarre, R.Ph. of St Alexius Hospital Pharmacy.

The Agenda was reviewed.

It was moved by Pharmacist Thom and seconded by Pharmacist Haroldson to approve the Agenda with the addition of an item – An Update of the Hospital Telepharmacy Project. All Board Members voted aye the motion carried.

At 10:00 Am President Dewhirst convened the Hearing on Proposed Rule Additions by announcing: I am Gary W. Dewhirst, President of the Board of Pharmacy and I will be acting as hearing officer for this public hearing.

It is now 10:00 AM on Wednesday September 24, 2008 in the conference room of the Board of Pharmacy Office at 1906 East Broadway in Bismarck, North Dakota.

This public hearing has been called for the purpose of allowing all interested individuals an opportunity to submit information concerning: Consideration of Rules to implement;

61-02-07.1-12 Technicians-Checking-Technicians (new)

61-04-01-01 - Expedited Partner Therapy (new)

Information gathered at this hearing will be used by the Boards of Pharmacy, Medical Examiners and Nursing for their deliberation and final decision.

The Executive Director of the Board of Pharmacy is taking minutes of this meeting, so please identify yourself for the record before you speak. The hearing is being recorded.

Everyone present will be given an opportunity to speak. If you have a prepared statement, a written copy of your statement is appreciated and will be helpful.

At this point, I open the hearing for comments.

Hearing Comments/ Record:

61-02-07.1-12 – Technicians Checking Technicians

Activities allowed by law to be performed within a licensed pharmacy by a registered pharmacy technician in the preparation of a prescription or order for dispensing or administration, may be performed by one registered pharmacy technician and verified by another registered pharmacy technician working in the same licensed pharmacy, under the following conditions:

1. The licensed pharmacy where the work is being conducted has policies and procedures specifically describing the scope of the activities to be verified through this practice.
 - a. Training for the specific activity is reflected in a written policy.

- b. A record of the individuals trained is maintained in the pharmacy for two years.
2. The pharmacy has a continuous quality improvement system in place to periodically verify the accuracy of the final product, including:
 - a. Recording any quality related events leading up to the final dispensing or administration of the drug prepared, and
 - b. Recording any errors which actually reach the patient as a result of these activities.
 - c. Specific limits of acceptable quality related event levels before reassessment is required.
3. Any error must trigger pharmacist review of the process. This review and subsequent recommendations must be documented.
4. The pharmacy has a system in place to review all quality related events and errors recorded and takes corrective action based on the information to reduce quality related events and eliminate errors reaching the patient.
5. As always, the pharmacist-in-charge and the permit holder are jointly responsible for the final product dispensed or released for administration from the pharmacy.

Pharmacist Dennis DelaBarre of St Alexius Medical Center Pharmacy asked that an additional subsection be inserted to this rule under #2. as: d. Consideration must be made for high risk medications on the Institute for Safe Medication Practices (ISMP) list and specific monitoring, review and quality assurance parameters must be instituted if any of these products are included in the Pharmacy’s Technician-Checking-Technicians Program.

Expedited Partner Therapy

Board of Nursing NDAC 54-05-03.1-10(8)

Board of Medical Examiners

Board of Pharmacy NDAC 61-04-04-01(21)

Notwithstanding any other provision, a practitioner who diagnoses a sexually transmitted disease, such as Chlamydia, Gonorrhea, or any other sexually transmitted infection in an individual patient may prescribe, or dispense, and a pharmacist may dispense, prescription antibiotic drugs to that patient’s sexual partner or partners, without there having been an examination of that patient’s sexual partner or partners.

Kirby Kruger, epidemiologist at the ND Department of Health spoke in favor of the Expedited Partner Therapy Rule as did Patricia Hill, RN of the ND State Board of Nursing – no changes were suggested.

Thank you all for coming. The Boards will use all of the information gathered at this hearing, in making their decision. The record will be held open for written comment through October 24th, 2008. At this point, I will close the hearing on: Consideration of Rules to implement;

61-02-07.1-12 Technicians-Checking-Technicians (new)

61-04-01-01 - Expedited Partner Therapy (new)

A registration sheet is being circulated; I ask that everyone present please sign this sheet before they leave.

The hearing was recorded on tape and will be kept for at least 60 days after the hearing date, should questions arise.

Resuming the Agenda, the Re-instatement Application for William H. Koslofsky Pharmacist #3453 was reviewed. Pharmacist Koslofsky had let his license lapse due to non-payment.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Zielger to approve the re-instatement of North Dakota Pharmacist #3453 William H. Koslofsky. All Board Members voted aye – the motion carried.

Kyle Schwandt was present to ask for the re-instatement of his Intern License #1074, so that he might begin working in a pharmacy with the goal of full re-instatement of his Intern License, completion of any requirements that the Board asks and eventually sitting for the Licensure Examination and ultimately gaining licensure in North Dakota as a Pharmacist.

It was moved by Pharmacist Haroldson and seconded by Pharmacist Thom to re-instate intern license# 1074 of Kyle M. Schwandt, PharmD under the following restrictions and conditions.

- ***Dr. Schwandt will need to be in full compliance with his Pharm-Assist Contract before re-instatement can occur. This includes compliance with the requirement to attend 90 meetings in 90 days and to come current with this requirement before he can be re-instated. He has one-month from today to reach full compliance or this motion will not take effect. Dr. Schwandt will make a monthly written report to Executive Director Anderson and to the Pharm-Assist Committee indicating his full compliance with his contract.***
- ***Dr. Schwandt will find his own Intern position, he will share his disciplinary order and Pharm-Assist Contract with the potential Pharmacist-in-Charge and preceptor at his place of employment.***
- ***Dr Schwandt will find an internship position where he will have NO direct access to prescription drugs.***
- ***Dr. Schwandt will file internship affidavits on a monthly basis with the Board of Pharmacy indicating the hours he has worked and a summary of the type of work he was involved in during that month.***
- ***Dr Schwandt understands that his intern license will be immediately revoked if at any time he falls out of compliance with his Pharm-Assist Contract.***
- ***These conditions and restrictions will remain in effect until such time as Dr Schwandt appears before the Board for their modification.***

All Board Members voted aye – the motion carried.

Board Members reviewed plans for the expansion and relocation of CVS #8614 from Gateway Mall to a new free standing building at State Street and Calgary Ave in North Bismarck. Pharmacist Curtis Larson was present representing CVS and explained the floor plans to the Board Members. At the Board's questions, Pharmacist Larson pointed out that he was encouraging CVS to utilize the private consultation room, required by North Dakota Building Standards, to make the best utilization of the new Doctor of Pharmacy candidates CVS is hiring to provide medication therapy management services to Medicare Part-D patients, as well as participate in the North Dakota Public Employees Retirement Systems [NDPERS] diabetes medication therapy management program. Immunization administration is also on his plans as they get pharmacists trained and authorized to provide that service. Pharmacist Larson indicated that the actual move would probably occur in late December 2008 or early January 2009.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Thom to approve the expansion and relocation of CVS #8614 from Gateway Mall to a new free standing building at State Street and Calgary Ave in North Bismarck, North Dakota Pharmacy Permit #109. All Board Members voted aye – the motion carried.

Floor plans for an expansion to Gateway Health Mart Pharmacy were reviewed with the Board by compounding Pharmacist Michael Riepl. Pharmacist Riepl explained to the expansions within the supermarket location, for the pharmacy to grow in size and have a specific compounding area, including a powder room for pharmacy compounding.

It was moved by Pharmacist Haroldson and seconded by Pharmacist Ziegler to approve the expansion and remodeling of North Dakota Pharmacy Permit #91 issued to Gateway Health Mart Pharmacy located at 3101 N 11th Street Suite 2 in Bismarck. All Board Members voted aye – the motion carried.

Board Members reviewed the Pharmacy Permit Application for Medcenter One Pharmacy for a Class K Telepharmacy to be located in their walk-in clinic at 3318 N 14th Street in Bismarck. Discussion amongst Board Members and a letter from Board Attorney David A. Lindell, centered around the inappropriateness of a Class K Telepharmacy for a location within one of our larger cities. A copy of Attorney Lindell's letter is attached. Pharmacist Thomas Simmer explained the case for Medcenter One. Pharmacist Simmer was accompanied by Medcenter One Attorney Bob Rogalski. Pharmacist Simmer indicated that Medcenter One felt it was important that they have a pharmacy within their walk-in clinic to serve their patients at the clinic in an integrated fashion by a pharmacy owned by Medcenter One.

It was moved by Pharmacist Thom and seconded by Pharmacist Haroldson to deny the Pharmacy Permit Application for Medcenter One Pharmacy for a Class K Telepharmacy in their walk-in clinic at 3318 N 14th Street in Bismarck. President Dewhirst called for a roll call vote:

Rick L. Detwiller, R.Ph. – abstained Gary W. Dewhirst, R.Ph. – aye

Laurel Haroldson, R.Ph. –aye Bonnie J. Thom, R.Ph. – aye Gayle D. Ziegler, R.Ph. –aye

The motion carried and the Pharmacy Permit was denied.

It was moved by Pharmacist Haroldson and seconded by Pharmacist Detwiller to modify the Agenda to take up the review of 61-02-01-03 on Pharmaceutical Compounding Standards and the Three Affiliated Tribes [TAT] Telepharmacy project to accommodate those that are here to speak on these issues. All Board Members voted aye – the motion carried.

Since Pharmacist Michael Riepl was present and had been asked to provide comments and input on the discussion of 61-02-01-03 on Pharmaceutical Compounding Standards, President Dewhirst took up this Agenda item at this time.

Pharmacist Riepl does non-sterile, USP 795, compounding in his practice. Pharmacist Riepl explained that he sends in products for quality assurance testing on a regular basis, particularly if those products are from high risk ingredients or done with difficult compounding techniques. He pointed out that Pharmacy Compounding Accreditation Board [PCAB] Standards are great, but they are beyond what most pharmacies needed or could afford. He felt that excellent patient protection standards could be put in place, requiring standard operating procedures and quality testing when

indicated by the particular compounding procedure being done. Log books are important to record what is accomplished, as well as keep track of the ingredients, the ingredient lot numbers and the assigned beyond use dates for the prescriptions prepared. The Board will be following up with some suggested rules as soon as Executive Director Anderson gets them written. The Board Members thanked Pharmacist Riepl for his contributions and suggestions.

Some very basic and rough-draft plans of a proposed pharmacy in Aurora Hospital in Grand Forks were submitted by Pharmacist Dennis Johnson. Executive Anderson will write to Pharmacist Johnson to indicate that designs for a pharmacy in this Hospital must be submitted with specificity. After a careful review of what specific types of pharmacy services are anticipated to be provided by the hospital pharmacy. All Board Members generally agreed that the initial allocated space of 219 square feet would hardly be adequate for a drug storage room, let alone a sterile products pharmacy with any kind of dispensing capabilities.

General floor plans for a potential pharmacy were reviewed for a location in Gateway Mall, where Pharmacist Terry Kristensen is currently negotiating for the space. It is anticipated that an Application for Pharmacy Permit will be received sometime in the near future.

Donna Feldman Bieri, PharmD, R.Ph. and Lovette Veach were present to discuss the Three Affiliated Tribes [TAT] Telepharmacy project. Floor plans and Applications for Pharmacy Permits were reviewed for Telepharmacy sites to be located at Halliday – Mandaree – Parshall and White Shield, North Dakota.

Board Members stressed to Dr. Bieri that the Telepharmacies would have to employ Registered Pharmacy Technicians with a minimum of one-year experience in place before any prescriptions could be prepared at those telepharmacy sites. The central pharmacy site will be Twin Buttes in Halliday and it is anticipated that the Three Affiliated Tribes [TAT] Minni-Tohe Health Center Pharmacy in New Town will be added to the loop to provide coverage for the four Telepharmacy sites. Dr. Bieri will be submitting a subclass K Telepharmacy Permit Application for Minni-Tohe Health Center Pharmacy in New Town in the near future.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Haroldson to approve the floor plans and Applications for Pharmacy Permits for TAT Twin Buttes Telepharmacy in Halliday; TAT Mandaree Telepharmacy in Mandaree; TAT Parshall Telepharmacy in Parshall and TAT White Shield Telepharmacy in White Shield. All Board Members voted aye – the motion carried.

Pharmacist Zeigler gave a review of the progress of the Hospital Telepharmacy Project. She represented the Board at the advisory committee meeting, which has been established by the Catholic Health Initiatives to provide feed back to the project. Pharmacist Zeigler indicated that it had been initially anticipated that Jamestown Hospital and Lisbon Hospital would be the first two pharmacies to begin operations with the central site in Fargo. McVile may be added soon after, as they are currently operating without local hospital pharmacist services.

At 1:15 PM Kelly M. Pugh, PharmD graduate from West Virginia arrived for the North Dakota portion of Examination for Licensure as a Pharmacist. The Board Members met with Dr. Pugh and oriented her on the examination protocols and she began her examination in the Executive Director's Office at 1:30 PM.

At 1:45 PM Pharmacist Curtis Trowbridge, R.Ph. Pharmacist-In-Charge of Innovis Health Center Pharmacy arrived to review the pilot project that he has designed for Innovis to utilize their Interns and Pharmacy Technicians in the Medication Reconciliation process. For purposes of the historical record we will include copies of the Innovis Pilot project with these minutes.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Thom to approve the concept of RPh – Tech Medication Reconciliation as outlined in this pilot project at Innovis Health Center Pharmacy and to look forward to semi-annual program reports from Pharmacist Trowbridge. All Board Members voted aye – the motion carried.

At 2:05 Pharmacist Dewhirst reviewed the “Dining with Diabetes Program” and funding request which had been forwarded to us by the North Dakota Pharmacists Association as an opportunity to share with them, on a fifty-fifty basis, funding of this program, which is being conducted by the NDSU Extension Service. This Program provides team training of local healthcare providers to educate residents with diabetes, pre-diabetes and their family members.

It was moved by Pharmacist Ziegler that the Board fund half, \$1,500 for the “Dinning with Diabetes Program” and that a request be forwarded that a Pharmacist be added as a member of the team for the program. This motion was seconded by Pharmacist Detwiller. On a vote by roll call:

Rick L. Detwiller, R.Ph. – aye Gary W. Dewhirst, R.Ph. – aye Laurel Haroldson, R.Ph. – aye Bonnie J. Thom, R.Ph. – aye Gayle D. Ziegler, R.Ph. – aye

The motion carried.

A funding request pertaining to the “Adding Economic Impact and Small Business Consulting Services to the North Dakota Institute for Pharmaceutical Care” from Dan Friesner, Ph.D., Department of Pharmacy Practice at NDSU College of Pharmacy was reviewed.

It was moved by Pharmacist Haroldson and seconded by Pharmacist Ziegler to fund the request. During the discussion, Pharmacist Detwiller indicated that he would feel more comfortable funding a request relative to quality assurance in North Dakota Pharmacies, particularly our telepharmacies and our hospital pharmacy project. Other Board Members seemed to concur. On a vote by roll call:

Rick L. Detwiller, R.Ph. – no Gary W. Dewhirst, R.Ph. – no Laurel Haroldson, R.Ph. – no Bonnie J. Thom, R.Ph. – no Gayle D. Ziegler, R.Ph. – no

The motion failed.

The disciplinary case of Ryan P. Sannes, R.Ph. #4917 was reviewed. Recent reports from Pharm-Assist Committee Member Agnes Harrington indicate that though Ryan does currently have a sponsor for his Pharm-Assist Committee Program, he has had some other trouble with full compliance with his contract with them. Since the Board has set a meeting for October 30, 2008, the Board will set a hearing if necessary or a meeting if appropriate; and as advised by Attorney David Lindell, to meet with Pharmacist Sannes to determine the continuation, modification, or further dispensation.

At the October 30th meeting we could also make the exam available to Elvis Osagie a Nigerian graduate who is seeking licensure in North Dakota.

The Board reviewed the arrest report and court ordered evaluation of Robert A. Sieg, P-1 PharmD Student. They agreed that at this point, Intern Sieg exercised poor judgment on a couple of instances in the past. Executive Director Anderson will ask Intern Sieg to meet with Agnes Harrington to review his reports and to encourage him to use better judgment in the future.

A Collaborative Agreement between Anne Ottney, PharmD and Dr. Napoleon Espejo of the Family Healthcare Center in Fargo was reviewed. This Collaborative Agreement has been developed with some new protocols for modifying prescriptions and authorizing refills as the Family Practice Center Pharmacy in Fargo. Although different from many of the other Collaborative Agreements we have seen recently, this Collaborative Agreement is with the scope of practice of Dr. Ottney and should well serve the patients of the Family Practice Pharmacy and Healthcare Center in Fargo.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Haroldson to approve the Collaborative Agreement between Anne Ottney, PharmD and Dr. Napoleon Espejo. All Board Members present voted aye – the motion carried. Pharmacist Thom was working with the exam candidate at this time.

At this time Kathy Zahn, Program Assistant for the Prescription Drug Monitoring Program [PDMP] addressed the Board to report the recent award of a \$400,000 enhancement grant for the PDMP. She discussed the original budget submitted with the original grant application, including its training implications for Physicians, Pharmacists and Law Enforcement around the state. She also discussed plans to work toward a regional PDMP, between North Dakota, Minnesota, Montana and South Dakota, to share data on an ongoing basis. Additionally, we have just received a summary of a proposal from Dr LeMire of Bureau of Education Services and Applied Research [BESAR] of University of North Dakota to help with the analysis of the data to determine the success of the PDMP and its accomplishments over its first couple of years of operation. Discussions were held with the University of Mary, North Dakota State University and the University of North Dakota when the grant was submitted. Dr. LeMire of UND had indicated they would be willing to work with us. Once the grant notification was received, we asked them to submit their proposal. Ms. Zahn answered questions about the PDMP offering direct access to Pharmacists and Physicians by assigning a password to grant access to look up their own profiles as needed. It is planned that this will kickoff about the 1st of October with an addition of about 20 pharmacists and physicians per week granted direct access.

President Dewhirst called for any further business, none forth coming, the meeting adjourned.

President
Gary W. Dewhirst, R.Ph.

Member
Rick L. Detwiller, R.Ph

Member
Laurel A. Haroldson, R.Ph.

Member
Bonnie J. Thom, R.Ph.

Member
Gayle D. Ziegler, R.Ph.

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