

A G E N D A JULY 26th, 2006 (Thursday)

ND State Board of Pharmacy -1906 E Broadway Ave – Bismarck ND 58501

9:45 AM Call to Order: President Laurel Haroldson, R.Ph.

Review & Approval of Agenda

AGENDA TAB

Review of ALL Paid Invoices through June 30, 2007

Budget Review

Budget Tab

PharmAssist Web Site support

PDMP positions – Manager / Assistant

Review & Approval of Minutes of the May 14-17, 2007

MINUTE TAB

10:00 AM Review written plan for remedial action for Jessica Havelka

TAB 1

10:15 AM Carla Hiller – expired Tech-In-Training after extension File

10:30 AM Brandon Sis – PharmD Student

Bid for Software updates – Albertson Consulting

TAB 2

NDSU Proposal for Quality Assurance coordinator

TAB 3

Requests for exemption to Daily Reporting for Rx Drug Monitoring Program

TAB 4

Request for Continuing Education Credit: Shawnel Berry, R.Ph.

TAB 5

Gateway Pharmacists

NDPhA for CE at Business Session of Conventions

NDSU Suggestion for transition to Electronic Portfolios (Laptops for Board Meeting Use) **TAB 6**

District V August 7- 9 2008, Ramada Plaza Suites, Fargo. (Promo For Deadwood meeting)

Final Adoption :

(HB 1054) 61-02-01-15 Pharmacy Closings and Reporting Requirements (new)

61-02-01-16 Transfer of Controlled Substances when selling a business (new)

61-03-01-02 Approved Schools (correction)

61-03-02-04 Definitions. (new) Automated Dispensing System

61-04-04-01 Definition of Unprofessional Conduct (new) reporting

Review Forms: Drug Repository Program and Registration Forms

TAB 7

Request – Theresa M. Satlak – Active Status (after illness non-practice)

Randy Wald – NDSU 1983 but never licensed as RPh

Remodeling: Beach Telepharmacy (new location)

Clinical Supplies Management (new location)

Review Candidates Files (4)

CANDIDATE TAB

Anderson, Aaron NV Grad

Heiser, Justin

Horriat, Massoud – Canada

Kabbara, Wissam – Lebanon Grad

12:00 Noon L U N C H B R E A K – Inspectors Grosz & Johnson

Exam Schedule

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

1:30 - 3:00 PM Laboratory Section 1

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

3:30 - 4:00 PM Oral Examination

1:30 Compliance Officer Meeting

4:30 PM Adjournment

JULY 26, 2007

BOARD OF PHARMACY OFFICE

President Laurel Haroldson called the meeting to order in the conference room of the Board of Pharmacy Office, located at 1906 E Broadway in Bismarck at 9:45 AM.

Present were: Laurel Haroldson, R.Ph. – Gary Dewhirst, R.Ph. – Bonnie J. Thom, R.Ph.
Executive Director Howard C. Anderson, Jr, RPh. and David A. Lindell, JD,
Special Assistant Attorney General

Also present were: Intern Kyle Schwandt who was doing a rotation at the office; Executive Vice President of the ND Pharmacist Association Michael Schwab and Compliance Officer William J. Grosz, R.Ph.

Absent were: Dewey Schlittenhard who is recuperating from back surgery and Rick Detwiller, R.Ph. who is on vacation, they had notified the office that they would not attend

President Haroldson asked for review of the Agenda. **It was moved and seconded that the Agenda be approved as presented – motion carried.**

The Balance Sheet and Budget vs Actual Comparison for the past year were reviewed by the Board Members in anticipation of suggested modifications to this years budget that will be made later in the meeting.

PharmD Intern Kyle Schwandt reported on his work with the Pharm-Assist Committee to develop their website pages to be located either on the Board of Pharmacy website or the Pharmacists Association website. He reported that the Pharm-Assist Committee was still deciding where the pages would be located.

It was moved by Pharmacist Thom and seconded by Pharmacist Dewhirst to cover the costs of the Pharm-Assist Committee web-pages, wherever located. On a vote by roll call: Gary W. Dewhirst, R.Ph. – Yea Laurel Haroldson, R.Ph- Yea Bonnie J. Thom, R.Ph.- Yea Nays- none Motion carried.

It was reported by Executive Director Anderson that we have finally received notification from the US Department of Justice that the Prescription Drug Monitoring Program funds are available to North Dakota. The Board Members reviewed the position description for the PDMP Manager and Program Assistant. **It was moved by Pharmacist Dewhirst and seconded by Pharmacist Thom that the Board of Pharmacy include and expend the \$372,315 dollars through the Board of Pharmacy's budget and seek reimbursement from the Federal Grant, based on the stipulations outlined in the Grant Application. On a vote by roll call: Gary W. Dewhirst, R.Ph. – Yea Laurel Haroldson, R.Ph- Yea Bonnie J. Thom, R.Ph.- Yea Nays- none The motion carried.**

It was moved by Pharmacist Thom and seconded by Pharmacist Dewhirst to approve the minutes of the May 14-17, 2007 Board Meeting as printed. The motion carried.

Since PharmD Student Brandon Sis had arrived at the meeting, President Haroldson agreed to hear from him at this time. Mr Sis was at the Board Meeting to explain his situation to the Board. Intern Sis explained that he had taken pictures with his cell phone of a test and test Key in his renal class and sent them by email to some of his classmates. He indicated that though he felt that this was a tool for student to learn, a teacher felt that this was wrong and

had asked the students to turn in their tests before leaving the class. Intern Sis explained that the students who had received the email and not reported them to the College, received some disciplinary action and will not be eligible for scholarships through the College this next year. He himself had been terminated from the College of Pharmacy PharmD Program, effective May 15, 2007. Executive Director Anderson explained that an Intern is someone who is enrolled in Pre-Pharmacy or enrolled in a PharmD Program, or in special circumstances approved by the Board.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Thom to suspended Intern License #1714 issued to Brandon Sis until such time as he was accepted back into the PharmD Program at the College of Pharmacy. This suspension will become effective August 19th, 2007 and continue until Brandon Sis furnishes evidence that he has been accepted into a College of Pharmacy Program. All Board Members present voted aye. The motion carried.

Ms. Carla Hiller arrived to meet with the Board. Ms. Hiller has an expired Technician-In-Training Registration after having been granted a previous extension. Ms Hiller asked the Board to give her yet another extension to complete the Technician-In-Training program. Ms. Hiller indicated that another six-month extension would allow her to complete the module program.

It was moved by Pharmacist Thom and seconded by Pharmacist Dewhirst to grant the six-month extension to Ms. Carla Hiller, contingent upon her being accepted in the Technician Program at the ND State College of Science, gaining employment in a pharmacy and upon approval of her pharmacist preceptor. The motion carried.

Executive Director Anderson presented a written proposal for remedial action from Jessica Havelka. Ms Havelka is a May 2004 graduate of the PharmD Program at NDSU, and must re-educate herself in order to successfully complete the NAPLEX Examination by January 15th, 2009. **It was moved by Pharmacist Thom and seconded by Pharmacist Dewhirst to approve the remedial action program and grant Ms. Havelka a window of opportunity through January 15th, 2009 to successfully complete the NAPLEX Examination and licensure process. The motion carried.**

The Board Members then reviewed a proposal by Albertson's Consulting to update the Board of Pharmacy's data base and website. Along with this proposal the maintenance will continue at \$190.00 per month, which will include 2 gigabytes of memory in the online document repository. This will include the ability to scan in existing documents and store them linked to licensees. **It was moved by Pharmacist Thom and seconded by Pharmacist Dewhirst to approve the proposal for \$33,474.00 from Albertson's Consulting and add it into the 2007-2008 budget. On vote by roll call: Gary W. Dewhirst, R.Ph. – Yea Laurel Haroldson, R.Ph- Yea Bonnie J. Thom, R.Ph.- Yea Nays- none The motion carried.**

A proposal by NDSU for a Quality Assurance Coordinator was reviewed. The cost of utilizing Ann Rathke for this position would be \$15,785.00 from July 1, 2007 to June 30, 2008 payable to NDSU College of Pharmacy for Ann Rathke to continue to be employed. It is possible, that should adequate earmarked funds come through to expand the North Dakota

Telepharmacy project during the coming year, Anne Rathke's time might not be available to the Board of Pharmacy. **It was moved by Pharmacist Dewhirst and seconded by Pharmacist Thom to accept the proposal by Dean Charles Peterson for the utilization of Ann Rathke's time at a cost of \$15785 for Quality Assurance Monitoring. On vote by roll call: Gary W. Dewhirst, R.Ph. – Yea Laurel Haroldson, R.Ph- Yea Bonnie J. Thom, R.Ph.- Yea Nays- none The motion carried.**

A report was given by Executive Director Anderson on requests for exemptions to daily reporting for the Prescription Drug Monitoring Program. These decisions will be made by Executive Director Anderson on a case-by-case basis, based on the importance to the PDMP and the efforts of the individual dispensing pharmacies to comply.

A request from Shawnel Berry, RPh. for Continuing Education Credit for a course on "Psychopharmacology Practical Mental Health Strategies" was reviewed. **It was moved by Pharmacist Dewhirst and seconded by Pharmacist Thom to grant Pharmacist Shawnel Berry 5 hours Continuing Education for this program. The motion carried.**

Pharmacist Patrick Brunelle of Gateway Health Mart Pharmacy North in Bismarck requested Continuing Education Credit for a Zostavax presentation on vaccines. After review of this request, **It was moved by Pharmacist Thom and seconded by Pharmacist Dewhirst to grant Pharmacist Brunelle and Pharmacist Michael Riepl 2 hours CE credit relating to immunization renewal for the Zostavax presentation they reviewed and developed for nursing home personnel. Other personnel that only reviewed their presentation will receive 1 hour CE upon application for credit to the Board Office. The motion carried.**

The Board then reviewed a written request made by North Dakota Pharmacist's Association President, Pharmacist Jerome Wahl and discussed with Michael Schwab, Executive Vice President of the ND Pharmacist Association, the possibility of offering Continuing Pharmaceutical Education Credit for attending their Association Convention's business sessions to encourage attendance. After review and discussion, **It was moved by Pharmacist Thom and seconded by Pharmacist Dewhirst to grant up to 3 hours of Law CE, IF continuing education topics can be integrated into the business sessions at the NDPhA Annual Convention. If possible, ACPE credit should be sought for these sessions. All members present voted aye – motion carried.**

A suggestion from NDSU College of Pharmacy for a transition to electronic portfolios was discussed. The comments by Executive Director Anderson, relative to this issue were reviewed and with no objections, will become the policy of the Board.

It was reported by Executive Director Anderson that he has signed a contract on behalf of District V NABP/AACP with the Ramada Plaza Suites in Fargo, as North Dakota will be hosting the August 7-9, 2008 District Meeting. We have asked for a promotional video to present at the August 2007 District Meeting that will be held in Deadwood, South Dakota and will develop details of the program as time goes on.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Thom for final adoption of the following rules:

Article 61-02 – Pharmacies

Section 61-02-01-15 Closing a Pharmacy. Follow these procedures to close a North Dakota licensed pharmacy.:

1. Notify the State Board of Pharmacy 30 days in advance of the closing date.
2. Notify your customers 15 days in advance of the closing date and where their records will be maintained.
3. Notify the Drug Enforcement Administration (DEA) 14 days in advance of the closing date.
4. At the closing date:
 - a. Take an Inventory of your controlled substances and maintain it for two years.
 - b. Return the North Dakota Pharmacy Permit to the board.
 - c. Cover all signage indicating "Drug Store or Pharmacy" until removed in a timely manner.
 - d. Send the DEA Certificate of Registration and any unused official order forms (DEA form-222) to the nearest DEA Registration field office. The pharmacist should write or stamp the word "VOID" across the face of each official order form, before returning them to DEA.
 - e. Notify the board of pharmacy and DEA as to where the controlled substances inventory and records will be kept and how the controlled substances were transferred or destroyed. Records involving controlled substances must be kept available for two years for inspection and copying. This requirement applies, even though the business has been discontinued.

Section 61-02-01-16. Transfer of controlled substances when selling a business.

1. Notify the board of pharmacy and the nearest DEA Registration field office at least 14 days before the date of the proposed transfer, and provide the following information:
 - a. The name, address, and registration number of the pharmacy discontinuing business.
 - b. The name, address, and registration number of the pharmacy acquiring the business.
 - c. The date on which the controlled substances will be transferred.

Chapter 61-03-01 – Licensure of Pharmacists

61-03-01-02. Approved schools. The board of pharmacy designates as approved schools all colleges of pharmacy which are members of the American association of colleges of pharmacy or maintain standards equivalent to those required for membership in that association, and have been accredited by the ~~American-~~ Accreditation council of pharmaceutical- for pharmacy education.

Chapter 61-03-02-Consulting Pharmacist, Regulations for Long-Term-Care Facilities (Skilled, Intermediate, and Basic Care)

Section 61-03-02-04. Definitions. Distribution and control.

1. General. The consulting pharmacist shall establish written procedures for the safe and efficient distribution of pharmaceutical products; which shall be on hand for inspections.
2. Responsibility of consulting pharmacist. The consulting pharmacist shall be responsible for the safe and efficient distribution of, control of, and accountability of medications by developing procedures subject to the approval of the pharmaceutical services committee of the long-term care facility, to include:
 - a. Establishment of specifications for the storage, distribution, and procurement of medications and biologicals.
 - b. Participation in those aspects of the long-term care patient evaluation program which relate to drug utilization and effectiveness.
 - c. Providing information on a twenty-four-hour basis for assistance in emergency situations.
 - d. Assuring all medication shall be stored in a locked area or locked cart.
 - e. Review, evaluate, and make recommendations monthly regarding drug utilization to the pharmaceutical services committee.
 - f. Minimum standards that all provider pharmacists must meet to include the following:
 - (1) Expected delivery times for new orders and reorders.
 - (2) Procedures to ensure accountability during delivery.
 - (3) Methods to document receipt of medications by the facility.
 - (4) Procedure to obtain emergency medications and for the provider pharmacist to receive orders.
 - (5) Procedures used by the facility to reorder medications and for the provider pharmacist to receive reorders.
 - (6) Expected scope of services and medications to be provided by the provider pharmacist. If the provider pharmacist cannot provide the complete scope of services and medications, the provider pharmacist shall designate alternative sources.
 - g. Procedures that allow for use of or repackaging of medications received which are not in the packaging system used by the facility.
 - h. Policy that is included as a part of the patient admissions packet that describes the responsibility of the patient or provider pharmacist to compensate a secondary pharmacist for medications or packaging services that the provider pharmacist chosen by the patient is either unwilling or unable to provide.
3. Responsibility of provider pharmacist. All provider pharmacists shall meet the minimum standards established by the consulting pharmacist.
4. Discontinued drugs.
 - a. The consulting pharmacist shall develop and implement policies and procedures to ensure that all discontinued or outdated drugs or containers with

- worn, illegible or missing labels are destroyed or disposed of so as to render them unusable. Controlled drugs shall be destroyed by the consulting pharmacist subject to guidelines and approval of the state board of pharmacy.
- b. Controlled drugs shall be destroyed at the specific institution. Noncontrolled drugs may be destroyed at the institution or returned to the provider pharmacy, for possible credit or destruction. A log must be made when the drugs are discontinued. If drugs are destroyed at the institution, two professionals must sign the destruction log.
5. Practitioner's orders. A pharmacist shall review the medication order, or a copy thereof.
- a. Authorization. Any licensed practitioner authorized by law to prescribe drugs within the scope of the practitioner's license may prescribe for the practitioner's patient in a long-term facility.
- b. Abbreviations. Orders employing abbreviations or chemical symbols will be only those which are customarily used in the practice of medicine and pharmacy or those on a list of approved abbreviations developed by the pharmaceutical services committee of the facility.
- c. Requirements. Orders for drugs for use by patients of the facility shall, at a minimum, contain patient name, drug name and strength, directions for use, date of order, and name of prescriber. On the facility reorder form, include all of the above except for directions.
- d. Emergency medication order. In cases where an emergency medication order is written when pharmacy services are unavailable, the medication order shall be reviewed by the pharmacist as soon as reasonably possible.
- e. Verification. Verification of the accuracy of any medication dispensed and of any transcriptions made of that order shall be done by handwritten initials of the pharmacist so certifying.
- f. Duration. The prescribed medications should be for a specific time.
6. An Automated Dispensing System (ADS) is authorized for use in a long-term-care facilities to store controlled bulk drugs.
- a. Drugs in the ADS are not considered dispensed until taken out by authorized personnel at the long-term-care facility, once released by the pharmacy pursuant to a prescription.
- b. Only single doses are removed from the ADS at one time.
- c. The pharmacy must have a separate drug enforcement administration number for the ADS at each location.
- d. All records of dispensing shall be kept at the central pharmacy.
- e. The ADS shall permit access to only one controlled substance at each authorized entry.
- f. Only retail pharmacies are authorized.
- g. Pharmacies cannot share ADS at a long-term-care facility.
- h. North Dakota controlled substance registration is required.

7. ~~6.~~ Controlled drug accountability. The consulting pharmacist shall establish and implement effective procedures and assure that adequate records be maintained regarding use and accountability of controlled substances which meet federal and state laws and regulations, and which shall at least specify the following:
- a. Name of drug.
 - b. Dose.
 - c. Prescriber.
 - d. Patient.
 - e. Date and time of administration.
 - f. Person administering the drug.
8. ~~7.~~ Recall. The consulting pharmacist shall develop and implement a recall procedure that can readily be activated to assure the medical staff of the facility, the provider pharmacy, and the consulting pharmacist that all drugs included in the recall, located within the facility, are returned to the provider pharmacy for proper disposition.
9. ~~8.~~ Records and reports. The consulting pharmacist shall supervise the maintenance of such records and reports as are required to ensure patient health, safety, and welfare and, at a minimum, the following:
- a. Pharmacy patient profiles and medication administration records.
 - b. Reports of suspected adverse drug reactions.
 - c. Inspections of drug storage areas.
 - d. Controlled drug and accountability reports, including board of pharmacy destroyed medication forms for controlled and noncontrolled medications.
 - e. Such other and further records and reports as may be required by law and this chapter.
10. ~~9.~~ Labeling.
- a. All stock drugs intended for use within the facility shall be in appropriate containers and adequately labeled as to identify at a minimum: brand name or generic name and manufacturer, and strength. An internal code which centrally references manufacturer and lot number can be utilized.
 - b. Whenever any drugs are added to parenteral solutions, whether within or outside the direct and personal supervision of a pharmacist, such admixtures shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, date and time of addition, expiration date, administration time and infusion rate when applicable, and name or initials of person so adding. This excludes any single dose medication prepared and totally administered immediately.

History: Effective August 1, 1983; amended effective October 1, 1999; December 1, 2003.

General Authority: NDCC 28-32-02, 43-15-10(12), 43-15-10(14)

Law Implemented: NDCC 28-32-02, 43-15-10(12), 43-15-10(14)

Chapter 61-04-04- Unprofessional Conduct

Section 61-04-04-01. Definition of Unprofessional Conduct

19. Failure to report to the Prescription Drug Monitoring Program as required by North Dakota Century Code 19-03.5.

20. The failure to comply with the reporting requirement of North Dakota Century Code Section 43-15-42.3, including:
- a. Actions that affect your practice privileges in a facility.
 - b. Actions that result in the loss of your employment or membership in a professional organization due to alleged incompetence; negligence; unethical or unprofessional conduct; or physical, mental, or chemical impairment.
 - c. Actions based on a professional liability claim against you, such as an adverse judgment or settlement, a refusal to issue or renew coverage, or a cancellation of coverage.
 - d. Actions resulting in the loss of your authorization to practice by any state or jurisdiction.
 - e. Conviction of any misdemeanor or felony in this or any other state, territory or jurisdiction.

The only comments, orally or written received were the corrections in 61-04-04-01 Definition of Unprofessional Conduct Reporting subsection 19 from NDCC 50-05-27 to 19-03.5 and the Correction in the numbering of the statute from House Bill 1054 correcting 43-15-44.2 to 43-15-42.3 as specified in the bill. There were no comments received at the hearing and no comments received during the open comment period. The rules are being adopted. The motion carried.

PharmD Student Kyle Schwandt reviewed the Drug Repository Program Registration Forms and Participant Information Forms that he and Administrative Assistant Eileen Heidrich have developed for use in the Program.

It was moved by Pharmacist Thom and seconded by Pharmacist Dewhirst to expend the \$22,000.00 from the Board's funds for the development and maintenance of the Drug Repository Program's website and to seek reimbursement through the Grant at the State Health Department for the \$22,000 expenditure. On vote by roll call: Gary W. Dewhirst, R.Ph. – Yea Laurel Haroldson, R.Ph- Yea Bonnie J. Thom, R.Ph.- Yea Nays- none The motion carried.

ND Pharmacist #3826 Theresa M. Satlak has completed the requirements of internship, continuing education and payment of fees has requested Active status of her License. **It was moved by Pharmacist Thom and seconded by Pharmacist Dewhirst to grant Pharmacist Satlak Active Status. All Board Members present voted aye – motion carried.**

The request and situation of Mr. Randy Wald, a 1983 NDSU graduate was reviewed and discussed. Mr. Wald, having graduated in 1983, never obtained a pharmacist license in any state. **It was moved by Pharmacist Dewhirst and seconded by Pharmacist Thom that Mr. Randy Wald be required to obtain 1,500 hours of current Internship, successfully complete the NAPLEX and MPJE Examinations, as well as the North Dakota Board of Pharmacy Examination protocols to be considered for licensure as a Pharmacist in North Dakota. All Board Members present voted aye – motion carried.**

Remodeling

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Thom to approve the submitted floor plans for the relocation of the Beach Telepharmacy to 181 Central Ave in Beach. All Board Members present voted aye – motion carried.

It was moved by Pharmacist Thom and seconded by Pharmacist Dewhirst to approve the submitted floor plans for the relocation of Clinical Supplies Management to 342 42nd Street SW in Fargo. These floor plans and relocation will include both ND Pharmacy Permit #470 and Wholesale License #76. All Board Members present voted aye – motion carried.

The Board Members adjourned for a working lunch and will reconvene to administer the North Dakota Examination Protocols.

The Board met back in the Board of Pharmacy Office to administer the North Dakota Examination Protocols to three candidates:

Aaron Anderson; Justin Heiser and Wissam Kabbara

All three candidates successfully completed the North Dakota Examination Protocols.

The meeting adjourned at 5:00 PM.

President
Laurel A. Haroldson, R.Ph.

Member
Gary W. Dewhirst, R.Ph.

Member
Dewey Schlittenhard, R.Ph.

Member
Rick L. Detwiller, R.Ph.

Member
Bonnie J. Thom, R.Ph.

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