NOVEMBER 16TH, 2006 – RADISSON HOTEL – BISMARCK, ND

President Bonnie Thom called the meeting to order at 12:00 Noon on Thursday November 16th, 2006 in the Renoir Russell Room of the Radisson Hotel – 605 East Broadway Ave in Bismarck, North Dakota.

Present were: Bonnie J. Thom, R.Ph. – Gary W. Dewhirst, R.Ph. – Rick L. Detwiller, R.Ph.- Laurel Haroldson, R.Ph. and Executive Director Howard C. Anderson, Jr, R.Ph. Additionally, Pharmacists David J. Olig – Dennis Johnson – Jerome Wahl and Brian Ament were present for discussions on various items on the Agenda.
Absent: Dewey Schlittenhard, R.Ph. who notified the Board he was unable to attend.

After review of the Agenda, it was moved by Pharmacist Dewhirst and seconded by Pharmacist Detwiller to approve the Agenda, with the addition of consideration of rules on Technician's Reinstatement and the paying of back registration fees and modifications in the statute governing the Prescription Drug Monitoring Program. Also, Pharmacist David Olig asked that consideration of the fee cap increase in NDCC 43-15-25 be moved to the beginning of the Agenda, so that he could head for home (Fargo) in time to make it to his daughter's recital. All Board Members present voted aye and the Agenda was approved as modified.

President Thom invited David Olig to begin the discussion on the proposed increase in the cap for the active pharmacist license fee in NDCC 43-15-25. Pharmacist Olig stated that the Pharmacist Association was in support of the increase in the fee cap. They have also indicated that they have discussed the possibility of getting a larger percentage of the fee, or at least of the fee increase, which is now at 50%. Board members expressed their reservations about changing the percentage of distribution. If the Board were ever in the position of needing added revenue, they did not want to have to increase the license fee by $5 in order to obtain $1 to finance the Board of Pharmacy. Nationally there are some threats, in that Wholesale License fees and perhaps Out-of-State Pharmacy License fees, might eventually gravitate toward a national licensure, cutting out the states. Should this occur, wholesale license fees alone contribute approximately $120,000 per year to the Board of Pharmacy's budget. Where as, the entire $100 for each of the 770+ licensed active pharmacists only contributes $77,000. Dennis Johnson, who is currently the President of the North Dakota Pharmacists Association supported the comments Pharmacist Olig made and indicated that the Association was in support of the increase in the fee cap. Pharmacist Brian Ament stated that he had no objection to the increase in the fee cap, but that any increases in the actual fee should be supported by good financial information provided to all members of the Pharmacists Association. Pharmacist Jerome Wahl, Director of Pharmacy at St Josepeh's Hospital in Dickinson, North Dakota, and the incoming Pharmacists Association President indicated that he felt the support for the legislative increase in the fee cap was strong, in his district.

Resuming the order of the Agenda, the Board Members then signed original certificates for Pharmacists and Technicians.

Board Members then considered the request for Reinstatement of Registration for Pharmacy Technician #393 – Julia Zimmerman. Ms. Zimmerman had let her registration

lapse and was cancelled for non-payment in 2001. Executive Director Anderson had written to Ms. Zimmerman, based on the Board's past policy, that she must pay the back registration fees, late fees and 10 hours of Continuing Education obtained in the past year. Board Members saw no reason to change reinstatement policies. Ms. Zimmerman has already paid the back fees and submitted the CE to reinstate her registration. Pharmacy Technician Registration #393 issued to Julia Zimmerman has been reinstated, no further action was necessary at this time.

A request for a pharmacy permit for Prairie St John's Hospital Pharmacy in Fargo was reviewed. After review of the plans, it was moved by Pharmacist Detwiller and seconded by Pharmacist Haroldson to grant a Class B – Hospital Pharmacy Permit to Prairie St John's, as soon as a Pharmacist-In-Charge is hired and designated. All Board Members present voted aye – the motion carried.

A letter of request from Pharmacist Russel Kruger, asking if Mandan Drug could be converted to a Telepharmacy was reviewed. Mandan Drug began as Clark Drug in 1883 and has operated at 316 West Main Street since the early 1920s. The Board reviewed and discussed of the original purpose of the telepharmacy rule, which was to provide and extend pharmacy services to rural areas and to serve patients who would not otherwise have pharmacy services in their community. Since Mandan does have three other pharmacies, two of which are in very close proximity to Mandan Drug, and could provide pharmacy services to the people of Mandan. I**t was moved by Pharmacist Detwiller and seconded by Pharmacist Haroldson to deny the request of Pharmacist Kruger to allow the conversion of Mandan Drug to a telepharmacy. All four Board Members present voted aye – the motion carried.**

A request for a telepharmacy permit for White Drug #66 in Ashley North Dakota, with Pharmacist-In-Charge Teri Lutz was reviewed. Dallas & Karen Lang have decided to sell Ashley Drug to Thrifty White effective January 23, 2007. It is the intention of Thrifty White that this pharmacy be supervised out of their Fargo central supervision site with Pharmacist Teri Lutz overseeing verification of prescriptions and counseling patients. Thrifty White also indicated their Karlstad telepharmacy site will be transferred to a Moorhead pharmacy by the end of November 2006. The Pharmacist-In-Charge who will do the monthly visits will be determined at a later date.

After review of the plans, Application for Pharmacy Permit and Stock Affidavit for White Drug #66 in Ashley, the Board Members determined that all was in compliance. **It was moved by Pharmacist Detwiller and seconded by Pharmacist Haroldson to grant a Class K – Telepharmacy Permit to White Drug #66 in Ashley, North Dakota, effective January 24, 2007. All four Board Members present voted aye – the motion carried.**

Pharmacist Tim Weippert VP of Pharmacy Operations at Thrifty White Pharmacy sent an email to Executive Director Anderson on Wednesday November 15th at 3:59 PM asking for consideration of a variance from the one year minimum registration requirement for Josie Olson, currently a Technician-In-Training to be employed as the Telepharmacy Technician

at Thrifty White #66 in Ashley. At this time, there was not adequate information to make a decision for a variance for Josie Olson, as she is still registered as a Technician-In-Training. The Board took no action on this item and we will ask Thrifty White to continue to search for a qualified Registered Technician and to revisit this issue during the Board Meeting scheduled for January 8-10, 2007.

A request for Licensure as a Pharmacy Intern by Matthew Troyer was reviewed. Mr. Troyer graduated from high school in May 2006. Ordinarily, this would seem not to meet our requirement of at least one year of college prior to licensure as a pharmacy intern. However, since Mr. Troyer has accumulated 32 hours of college credits through courses he took during high school and since, it was determined that he did meet the requirement of one academic year beyond high school. **It was moved by Pharmacist Haroldson and seconded by Pharmacist Dewhirst that since Mr. Troyer has met the requirement of one academic year of college credit, that he be granted a license as a Pharmacy Intern. All four Board Members present voted aye – the motion carried.**

A request to convert from In-Active Status to Active Status for Pharmacist #3826 Theresa Satlak, R.Ph. was reviewed. Ms. Satlak's license was In-active because she was diagnosed with serious health problems and has not practiced since May 2001. Pharmacist Satlak believes she is now in significant recovery, allowing her to again practice the profession of pharmacy. She anticipates starting at about 10 hours a week. We also have a letter from Pharmacist Dennis Buchholz, proprietor of Lisbon-Sheyenne Pharmacy indicating that he is ready and willing to employ Pharmacist Satlak as an intern. **It was moved by Pharmacist Dewhirst and seconded by Pharmacist Detwiller to grant Theresa Satlak an Intern License, at no additional fee, as she has kept her In-Active Pharmacist License current. She will need to obtain 30 hours continuing education and 300 hours Internship, under the supervision of Pharmacist Buchholz. Once the CE, Internship hours and appropriate fee have been received, we will issue her an Active Status Pharmacist License. All four Board Members present voted aye – the motion carried.**

Since Pharmacist Brian Ament was at the meeting to discuss the request for a variance for Jamestown Hospital Pharmacy, President Bonnie Thom asked him to explain his request to the Board of Pharmacy. Pharmacist Ament explained that he was requesting a variance from the ownership law, to contract with the Veterans Administration Clinic, which is located within their hospital, to provide out-patient prescriptions for patients of that clinic. Pharmacist Ament indicated that Jamestown Hospital Pharmacy was the only one to submit a bid for the clinic and of course obtained the award. The VA then asked if they would provide the prescription services for the VA Patients, where they would provide, usually a two week limited supply, for VA Patients until such time as they could receive their medications through the VA System. Pharmacist Ament also indicated that they would keep a separate inventory for the VA Patients and would expect to fill 10 to 20 prescriptions per week. Upon questioning by the Board Members Pharmacist Ament indicated that no RFP had been done on the prescription services to other Jamestown Pharmacies. Coincidently, Board Attorney David Lindell arrived at the meeting about this time with a letter from John Kapsner, attorney for The North Dakota Healthcare

Association, asking for a list of previous variances granted by the Board of Pharmacy to statutes governing pharmacy ownership. This initiated a discussion about the necessity for maintaining consistency. Also, each variance granted might have to be explained to the next person seeking a variance. **It was moved by Pharmacist Dewhirst to deny the variance request. This motion died for lack of a second. After further discussion and questioning of Pharmacist Ament, it was moved by Pharmacist Detwiller to deny the variance request and to that an RFP be offered to the other four retail pharmacies in the community. Should none of the four retail pharmacies wish to participate with Veteran's Administration in filling these out-patient prescriptions, the Board will revisit this issue at a latter date. The motion was seconded by Pharmacist Dewhirst. On a roll call vote: Bonnie J. Thom, R.Ph.– Yes Gary W. Dewhirst, R.Ph – Yes Rick L. Detwiller, R.Ph.-Yes Laurel Haroldson, R.Ph.- abstained since she is employed by one of the Jamestown Pharmacies.**

A Collaborative Agreement renewal between Melanie Cairns, PharmD and Altru Health Systems physicians was reviewed. I**t was moved by Pharmacist Dewhirst and seconded by Pharmacist Detwiller** to approve the Collaborative Agreement renewal. All Board Members present voted aye – motion carried.

Executive Director Anderson provided some updated information on a request by Pharmacist Randy Skalsky of the Dakota Clinic Pharmacy to consider the InstyMeds Dispensing System as a possibility to upgrade the dispensing of sample and generic medications at the Dakota Clinic in Fargo. Executive Director Anderson explained the meeting he had had with IntyMeds, the situation with the rule in 61, which attempts to restrict the exemptions for physicians from NDCC 43-15. There is some question as to whether this rule would be enforceable by pharmacy on physicians, since the statute declared them exempt. Executive Director Anderson was directed to write a letter explaining the Board's position on InsyMeds Dispensing Systems and provide it to the Board for review.

A Stipulated Settlement for Registered Pharmacy Technician #573 Sara Brackett has not been obtained at this time, so no action was taken at this time. Board Attorney David Lindell is attempting to obtain a Stipulated Settlement from Registered Pharmacy Technician Sara Brackett prior to her hearing, which is scheduled for December 14th, 2006 at 10:00 AM in the Board of Pharmacy Office.

Pharmacist Brendan Joyce stopped by the meeting to ask if the Board of Pharmacy would be willing to accept the Prescription Drug Monitoring Grant. He explained that the Grant was erroneously allocated to the North Dakota Highway Patrol instead of the Department of Medicaid because of the slight difference in the last number on the Federal Grant Designation when the grant was originally sent in. The Grant will need to be de-obligated and then re-obligated. Pharmacist Joyce asked if the Board of Pharmacy would be willing to accept the re-obligation. **It was moved by Pharmacist Dewhirst and seconded by Pharmacist Haroldson to allow the re-obligated grant to be allocated to the**

Board of Pharmacy for the purpose of running the Prescription Drug Monitoring Program, if Medicaid agrees to this approach. All four Board Members present voted aye – the motion carried.

It was moved by Pharmacist Haroldson and seconded by Pharmacist Detwiller to pursue a rule change to make it clear that a Pharmacy Technician re-instating or re-activating their registrations would need to pay any back and late fees unpaid during the lapsed period. All Board Members present voted aye – the motion carried.

Next on the agenda was the consideration and action on law changes and proposals for the 2007 Legislative Assembly. After consideration and review of the suggested changes in the law: (Addendum A – Legislative Bill)

NDCC 43-15-01 – Definitions new subsection (2) Automated Dispensing System (ADS) means – **It was moved by Pharmacist Haroldson and seconded by Pharmacist Detwiller to pursue this legislative change. All Board Members present voted aye – the motion carried.**

NDCC 43-15-05 – Compensation of Board – Disposition of fees. It was moved by Pharmacist Dewhirst and seconded by Pharmacist Haroldson to pursue this legislative change. All Board Members present voted aye – the motion carried.

NDCC 43-15-10 – Powers of the Board It was moved by Pharmacist Detwiller and seconded by Pharmacist Dewhirst to pursue this legislative change. All Board Members present voted aye – the motion carried.

NDCC 43-15-25 Term of License – Renewal – Fee It was moved by Pharmacist Dewhirst and seconded by Pharmacist Haroldson to pursue this legislative change. All Board Members present voted aye – the motion carried.

NDCC 43-15-38.1 Closing a Pharmacy (new section) It was moved by Pharmacist Detwiller and seconded by Pharmacist Dewhirst to pursue this legislative change. All Board Members present voted aye – the motion carried.

NDCC 43-15-42.3 – Reporting Requirements (new section) It was moved by Pharmacist Detwiller and seconded by Pharmacist Dewhirst to pursue this legislative change. All Board Members present voted aye – the motion carried.

NDCC 19-03 – Rescheduling It was moved by Pharmacist Dewhirst and seconded by Pharmacist Haroldson to pursue this legislative change. All Board Members present voted aye – the motion carried.

NDCC 19-03.1-20.1 Report of any theft or Loss It was moved by Pharmacist Dewhirst and seconded by Pharmacist Haroldson to pursue this legislative change. All Board Members present voted aye – the motion carried.

NDCC 19-03.1-22 Prescriptions It was moved by Pharmacist Dewhirst and seconded by Pharmacist Haroldson to pursue this legislative change. All Board Members present voted aye – the motion carried.

Consideration of Rule changes to go out to hearing. (Addendum B – Rules changes in their entirety)

NDAC 61-02-01-15 Closing a Pharmacy (new) **It was moved by Pharmacist Detwiller and seconded by Pharmacist Haroldson to pursue this rule change. All Board Members present voted aye – the motion carried.**

NDAC 61-02-01-16 Transfer of controlled substances when selling a business (new) **It was moved by Pharmacist Dewhirst and seconded by Pharmacist Haroldson to pursue this rule change. All Board Members present voted aye – the motion carried.**

NDAC 61-03-01 – Licensure of Pharmacists (Approved Schools) **It was moved by Pharmacist Detwiller and seconded by Pharmacist Dewhirst to pursue this rule change. All Board Members present voted aye – the motion carried.**

NDAC 61-03-02 Consulting Pharmacist, Regulations for Long-Term-Care Facilities (Skilled, Intermediate, and Basic Care) **It was moved by Pharmacist Detwiller and seconded by Pharmacist Dewhirst to pursue this rule change. All Board Members present voted aye – the motion carried.**

NDAC 61-04-04 – Unprofessional Conduct **It was moved by Pharmacist Haroldson and seconded by Pharmacist Detwiller to pursue this rule change. All Board Members present voted aye – the motion carried.**

Pharmacist Haroldson moved and Pharmacist Dewhirst seconded that the Board of Pharmacy should introduce the Legislation to be included in the Prescription Drug Monitoring Program the liability issues requested by the North Dakota Medical Association and the addition of the drugs tramadole and carisopordol , which were requested by the working group of the Prescription Drug Monitoring Program. It is our attention that, should legislators wish to introduce this legislation, we will take that approach.

Proposals for Focus Groups and a Pharmacy Quality Assurance Residency at NDSU were reviewed. **It was moved by Pharmacist Haroldson and seconded by Pharmacist Dewhirst to allocate funds, and include in the budget $10,000 for Focus Groups along the lines of the attached proposal. On a vote by Roll Call: Bonnie J. Thom, R.Ph.– Yes Gary W. Dewhirst, R.Ph – Yes Rick L. Detwiller, R.Ph.-Yes Laurel Haroldson, R.Ph.-Yes Motion carried.**

It was moved by Pharmacist Detwiller and seconded by Pharmacist Dewhirst to approve the concept outlined in the Pharmacy Quality Assurance Fellowship proposal at NDSU. We will ask Dean Charles Peterson to finalize a proposal for review at our January 2007 meeting. It is anticipated that this will cost in the

neighborhood of $70,000 over a two-year period. The final action will be considered at the January 2007 Board Meeting. All Board Members present voted aye – the motion carried. (Addendum C – Fellowship Proposal in it's entirety)

ADDENDUM A - LEGISLATIVE BILL IN IT'S ENTIRETY

Sixtieth
Legislative Assembly of North Dakota

Bill No. _____

Introduced by

The North Dakota State Board of Pharmacy

A BILL for an Act to amend sections of the North Dakota Century Code, relating to the practice of pharmacy.

SECTION 1. AMENDMENT. Title 43 – Occupations and Professions Chapter 43-15 – Pharmacists; 43-15-05. Compensation of board - Disposition of fees; 43-15-10. Powers of board; 43-15-25. Term of license - Renewal - Fee - Where displayed; and create a new sections 43-15-38.1 Closing a Pharmacy and 43-15-42.3 – Reporting Requirements

43-15-01. Definitions. In this chapter, unless the context or subject matter otherwise requires:

1. "Administration" means the direct application of a drug to the body of a patient.
   a. The term includes:
      (1) The emergency maintenance of a drug delivery device used in home infusion therapy by a qualified home pharmacist when nursing service is not available;
      (2) Immunization and vaccination by injection of an individual who is more than eighteen years of age, upon an order by a physician or nurse practitioner authorized to prescribe such a drug or by written protocol with a physician or nurse practitioner; and
      (3) Provision of drugs by subcutaneous, intradermal, and intramuscular injection to an individual who is more than eighteen years of age upon the order of a physician or nurse practitioner authorized to prescribe such a drug.
   b. The term does not include the regular ongoing delivery of a drug to the patient in a health care setting and other parenteral administration of a drug.

2. Automated Dispensing System (ADS) means a mechanical system that performs operations or activities other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls and monitors all transaction information.

3. ~~2.~~ "Board" means the state board of pharmacy.

4. ~~3.~~ "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:
   a. As the result of a practitioner's prescription drug order or initiative based on the practitioner, patient, and pharmacist relationship in the course of professional practice; or
   b. For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing.

Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

5. ~~4.~~ "Confidential information" means individually identifiable health information maintained by the pharmacist in the patient's records or which is communicated to the patient as part of a patient counseling.

6. ~~5.~~ "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

7. ~~6.~~ "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any

component part or accessory, which is required under federal or North Dakota law to be prescribed by a practitioner and dispensed by a pharmacist.

8. ~~7.~~ "Dispense" or "dispensing" means the preparation and delivery of a prescription drug, pursuant to a lawful order of a practitioner or a nurse licensed under chapter 43-12.1 who is authorized by the practitioner to orally transmit the order that has been reduced to writing in the patient's record, in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

9. ~~8.~~ "Distribute" means the delivery of a drug other than by dispensing or administering.

10. ~~9.~~ "Drug" or "drugs" means:
   a. Articles recognized as drugs in the official United States pharmacopeia, official national formulary, official homeopathic pharmacopeia, other drug compendium, or any supplement to any of them;
   b. Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal;
   c. Articles other than food intended to affect the structure or any function of the body of man or other animals; and
   d. Articles intended for use as a component of any articles specified in subdivision a, b, or c.

11. ~~10.~~ "Drug regimen review" includes the following activities:
   a. Evaluation of the prescription drug orders and patient records for:
   (1) Known allergies;
   (2) Rational therapy-contraindications;
   (3) Reasonable dose and route of administration; and
   (4) Reasonable directions for use.
   b. Evaluation of the prescription drug orders and patient records for duplication of therapy.
   c. Evaluation of the prescription drug orders and patient records for interactions:
   (1) Drug-drug;
   (2) Drug-food;
   (3) Drug-disease; and
   (4) Adverse drug reactions.
   d. Evaluation of the prescription drug orders and patient records for proper utilization, including over-utilization or underutilization, and optimum therapeutic outcomes.

12. ~~11.~~ "Emergency pharmacy practice" means in the event a pharmacist receives a request for a prescription refill and the pharmacist is unable to obtain refill authorization from the prescriber, the pharmacist may dispense a one-time emergency refill of up to a seventy-two hour supply of the prescribed medication, provided that:
    a. The prescription is not for a controlled substance listed in schedule II;
    b. The pharmaceutical is essential to the maintenance of life or to the continuation of therapy;
    c. In the pharmacist's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences or may cause physical or mental discomfort;

    d. The pharmacist properly records the dispensing; and
    e. The dispensing pharmacist notifies the prescriber of the emergency dispensing within a reasonable time after the one-time emergency refill dispensing.
13. ~~12.~~ "Labeling" means the process of preparing and affixing of a label to any drug container exclusive, however, of the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged legend drug or device. Any label shall include all information required by federal and North Dakota law or regulation.
14. ~~13.~~"Manufacture" means the production, preparation, propagation, compounding, conversion, or processing of a device or a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis and includes any packaging or repackaging of the substances or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging, or labeling of a drug:
    a. By a pharmacist or practitioner as an incident to dispensing or administering of a drug in the course of the person's professional practice; or
    b. By a practitioner or by the practitioner's authorization under supervision for the purpose of or as an incident to research, teaching, or chemical analysis and not for sale.
15. ~~14.~~ "Manufacturer" means a person engaged in the manufacture of drugs in facilities located within North Dakota.
16. ~~15.~~"Medicine" means a drug or combination of drugs, used in treating disease in man or other animals.
17. ~~16.~~"Nonprescription drugs" means medicines or drugs which may be sold without a prescription and which are prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of this state and the federal government.
18. ~~17.~~"Original package" means the original carton, case, can, box, vial, bottle, or other receptacle, put up by the manufacturer or wholesaler or distributor, with label attached, making one complete package of the drug article.
19. ~~18.~~"Person" means an individual, corporation, limited liability company, partnership, association, or any other legal entity.

20. ~~19~~."Pharmaceutical care" is the provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process as defined in the rules of the board.
21. ~~20~~."Pharmacist" means a person to whom the board has issued a license to practice the profession of pharmacy whose license has not expired or been suspended.
22. ~~21~~."Pharmacy" or "drugstore" means every store or shop where drugs, medicines, or chemicals are dispensed, displayed for sale, or sold, at retail for medicinal purposes, or where prescriptions are compounded, and which is duly registered by the board.
23. ~~22~~."Pharmacy technician" means a person registered by the board who is employed by a pharmacy to assist licensed pharmacists in the practice of pharmacy by performing specific tasks delegated by and under the immediate personal supervision and control of a licensed pharmacist, as permitted by the board.
24. ~~23~~."Practice of pharmacy" means the interpretation, evaluation, and monitoring of prescription orders and patient drug therapy; the compounding, dispensing, labeling of drugs and devices except labeling by a manufacturer, packer, or distributor of nonprescription drugs and commercially packaged legend drugs and devices; the participation in drug selection, drug monitoring, drug administration, drug regimen review, the provision of these acts or services necessary as a primary health care provider of pharmaceutical care, and drug utilization evaluations; the proper and safe storage of drugs and devices and the maintenance of proper records for this storage; the responsibility for advising, consulting, and educating if necessary or if regulated, patients, public, and other health care providers on the rational, safe, and cost-effective use of drugs including therapeutic values, content, hazards, and appropriate use of drugs and devices; the participation in interpreting and applying pharmacokinetic data and other pertinent laboratory data to design safe and effective drug dosage regimens; if appropriate and if regulated, the participation in drug research either scientific or clinical as investigator or in collaboration with other investigators for the purposes of studying the effects of drugs on animals or human subjects, with other drugs or chemicals, and with drug delivery devices; emergency pharmacy practice; prescriptive practices as limited under this chapter; the performance of laboratory tests to provide pharmaceutical care services which are waived under the Federal Clinical Laboratory Improvement Act of 1988 [Pub. L. 100-578, section 2; 102 Stat. 2903; 42 U.S.C. 263a et seq.], as amended; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of pharmacy.
25. ~~24~~."Practitioner" means an individual licensed, registered, or otherwise authorized by the jurisdiction in which the individual is practicing to prescribe drugs in the course of professional practice.
26. ~~25.~~"Prescription" means any order for drugs or medical supplies, where such order is written or signed or transmitted by word of mouth, telephone, telegram, or other means of communication by a duly licensed physician, optometrist, dentist, veterinarian, or other practitioner, licensed by law to prescribe and administer such drugs or medical supplies intended to be filled, compounded, or dispensed by a pharmacist or any order for drugs or medical supplies transmitted orally by a nurse

licensed under chapter 43-12.1 as written and signed by such a duly licensed physician, optometrist, dentist, veterinarian, or other practitioner.

27. ~~26~~."Prescription drug or legend drug" means a drug which, under federal law is required, prior to being dispensed or delivered, to be labeled with one of the following:
    a. "Caution: Federal law prohibits dispensing without prescription";
    b. "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; or
    c. Rx only; or a drug which is required by any applicable federal or North Dakota law or rule to
    be dispensed on prescription only or is restricted to use by practitioners only.
28. ~~27~~."Radiopharmaceutical service" means, but is not limited to, the compounding, dispensing, labeling, and delivery of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the

    proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards, and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of radiopharmaceuticals.
29. ~~28~~."Wholesaler" means a person with facilities located in this state who buys for resale and distribution to persons other than consumers.

43-15-05. Compensation of board - Disposition of fees. Each member of the board shall receive a per diem of ~~twenty~~ two-hundred dollars for attendance at board meetings, and all actual and necessary expenses incurred in attending such meetings and in performing other official duties. The mileage and travel expense allowed may not exceed the amount provided for in section 54-06-09. All funds collected or received by the board must be deposited and disbursed in accordance with section 54-44-12.

43-15-10. Powers of board. In addition to other powers provided by law, the board shall have the following powers and duties, which shall be exercised in conformity with chapter 28-32 in order to protect the public health, welfare, and safety:

1. To place on probation, reprimand, or fine any pharmacy, pharmacist, or licensed pharmacist; or refuse to issue or renew, or suspend, revoke, restrict, or cancel, the license, permit, or license of any pharmacy, pharmacist, or licensed pharmacy intern, and pharmacy technician ~~pharmacist~~, if any of the following grounds apply and the pharmacy, pharmacist, or licensed pharmacy intern, and pharmacy technician ~~pharmacist~~:
    a. Is addicted to any alcohol or drug habit.
    b. Uses any advertising statements of a character tending to deceive or mislead the public.
    c. Is subject to drug or alcohol dependency or abuse.
    d. Permits or engages in the unauthorized sale of narcotic drugs or controlled substances.
    e. Permits or engages an unauthorized person to practice pharmacy.
    f. Is mentally or physically incompetent to handle pharmaceutical duties.

g. Is guilty of fraud, deception, or misrepresentation in passing the pharmacist examination.
h. Is found by the board in violation of any of the provisions of the laws regulating drugs, pharmacies, and pharmacists, interns, technicians or the rules and regulations established by the board.

i. Is found to have engaged in unprofessional conduct as that term is defined by the rules of the board.
j. Is subject to incapacity of a nature that prevents a pharmacist from engaging in the practice of pharmacy with reasonable skill, competence, and safety to the public.
k. Is found guilty by a court of competent jurisdiction of one or more of the following:
   (1) A felony, as defined by the statutes of North Dakota.
   (2) Any act involving moral turpitude or gross immorality.

   (3) Violations of the pharmacy or the drug laws of North Dakota or rules and regulations pertaining thereto, or of statutes, rules or regulations of any other state, or of the federal government.
l. Commits fraud or intentional misrepresentation in securing the issuance or renewal of a license or pharmacy permit.
m. Sells, dispenses, or compounds any drug while on duty and while under the influence of alcohol or while under the influence of a controlled substance without a practitioner's prescription.
n. Discloses confidential information to any person, except as authorized by law.

2. To prescribe rules and regulations not inconsistent with this chapter governing the cancellation or suspension of a license.
3. To examine and license as pharmacist any applicant found entitled to such license.
4. To prescribe rules and regulations for the guidance of its members, officers, and employees, and to ensure the proper and orderly dispatch of its business.
5. To employ and pay such persons as it may deem necessary to inspect pharmacies in this state, investigate pharmacies for the information of the board, procure evidence in any proceeding pending before the board, or procure evidence in aid of any prosecution or action in any court commenced or about to be commenced by or against the board in relation to any matter in which the board has any duty to perform.
6. To employ and pay counsel to advise the board or to prosecute or defend any action or proceeding commenced by or against the board or pending before it.
7. To grant permits and renewals thereof for the establishment and operation of pharmacies.
8. Only for good cause to cancel, revoke, or suspend permits and renewals thereof for the establishment and operation of pharmacies.
9. To prescribe reasonable and nondiscriminatory rules and regulations in regard to granting, renewing, canceling, revoking, or suspending permits and renewals for establishing and operating pharmacies.
10. Action by the board canceling, revoking, suspending, or refusing to renew a permit to establish or operate a pharmacy shall not be enforced for thirty days after notice

has been given an aggrieved party by the board, nor during the time that an appeal by such aggrieved party is pending and until such appeal is finally determined.

11. To prescribe reasonable rules and regulations relating to the physical design of space occupied by a pharmacy to ensure appropriate control of and safeguards over the contents of such pharmacy.
12. To regulate and control the practice of pharmacy in North Dakota.
13. To adopt, amend, and repeal rules for the regulation of pharmacies and pharmacists, providing radiopharmaceutical services, including special training, education, and experience for pharmacists and physical design of space, safeguards, and equipment for pharmacies.
14. To adopt, amend, and repeal rules determined necessary by the board for the proper administration and enforcement of this chapter, chapter 19-02.1 as that chapter pertains to drugs, subject to approval of the director of the state department of health, and chapter 19-03.1.
15. The board or its authorized representatives may investigate and gather evidence concerning alleged violations of the provisions of chapter 43-15, chapter 19-02.1 that pertains to drugs, chapters 19-03.1, 19-03.2, and 19-04, or of the rules of the board. Board investigative files are confidential and may not be considered public records or open records for purposes of section 44-04-18, until a complaint is filed or a decision made by the board not to file a complaint.
16. In addition to other remedies, the board may apply to the district court in the jurisdiction of an alleged violation, and that court has jurisdiction upon hearing and for cause shown, to grant a temporary or permanent injunction restraining any person from violating any provision of chapter 43-15, chapter 19-02.1 pertaining to drugs, and chapter 19-03.1, whether or not there exists an adequate remedy at law. Whenever a duly authorized representative of the board finds or has probable cause to believe that any drug or device is adulterated, misbranded, mislabeled, or improperly identified, within the meaning of chapter 19-02.1, the representative shall affix to that drug or device a tag or other appropriate marking giving notice that the article is or is suspected of being adulterated, misbranded, mislabeled, or improperly identified, has been detained or embargoed and warning all persons not to remove or dispose of such article by sale or otherwise until provision for removal or disposal is given by the board or its agents or the court. No person may remove or dispose of such embargoed drug or device by sale or otherwise without the permission of the board or its agent, or, after summary proceedings have been instituted, without permission from the court.
17. When a drug or device detained or embargoed has been declared by such representative to be adulterated, misbranded, mislabeled, or improperly identified, the board shall, as soon as practical thereafter, petition the district court in whose jurisdiction the article is detained or embargoed for an order for condemnation of such article. If the judge determines that the drug or device so detained or embargoed is not adulterated, misbranded, mislabeled, or improperly identified, the board shall direct the immediate removal of the tag or other marking. If the court finds the detained or embargoed drug or device is adulterated, misbranded, mislabeled, or improperly identified, such drug or device, after entry of the decree, shall be destroyed at the expense of the owner under the supervision of a board representative and all court costs and fees, storage, and other proper expense shall

be borne by the owner of such drug or device. When the adulteration, misbranding, mislabeling, or improper identification can be corrected by proper labeling or processing of the drug or device, the court, after entry of the decree and after such costs, fees, and expenses have been paid and a good and sufficient bond has been posted, may direct that such drug or device be delivered to the owner for labeling or processing under the supervision of a board representative. Expense of supervision shall be paid by the owner. Bond posted shall be returned to the owner of the drug or device on representation to the court by the board that the drug or device is no longer in violation of the embargo and the expense of supervision has been paid. Nothing in this section shall be construed to require the board to report violations whenever the board believes the public's interest will be adequately served in the circumstances by a suitable written notice or warning.

18. The board shall establish a bill of rights for patients concerning the health care services a patient may expect in regard to pharmaceutical care.
19. To adopt, amend, and repeal rules as may be deemed necessary by the board to register pharmacy technicians pursuant to qualifications established by the board, to charge a pharmacy technician an annual registration fee not to exceed fifty dollars, to specify tasks associated with and included in the practice of pharmacy which may be delegated by a licensed pharmacist to a registered pharmacy technician, to provide for suspension or revocation of a pharmacy technician's registration, and to regulate and control pharmacy technicians. The board may allocate up to fifty percent of the amount of the registration fee to an appropriate pharmacy technician association for its general operating expenses, including pharmacy technician education and development standards.
20. Require the self-reporting by an applicant or a licensee of any information he board determines may indicate possible deficiencies in practice, performance, fitness, or qualifications.

43-15-25. Term of license - Renewal - Fee - Where displayed. The license issued by the board to a pharmacist under the provisions of this chapter, and the registration thereof, shall entitle the holder to act in the capacity therein stated for one year unless duly canceled, suspended, or revoked. Every licensee who desires to retain a license, on or before the first day of March in each year, shall pay to the secretary of the board a renewal fee in an amount to be fixed by the board not to exceed ~~two~~ four hundred dollars. Upon payment of the fee, a renewal license must be issued. The license and renewal must be displayed in a conspicuous place in the pharmacy and drugstore where the holder is employed. After a licensee has held licenses duly issued over a period of fifty consecutive years, the secretary of the board may issue the licensee a lifetime license which will entitle the licensee to act in the capacity of pharmacist thereafter without further payment unless such license is canceled, revoked, or suspended.

43-15-38.1 Closing a Pharmacy. The permit holder and the pharmacist-in-charge are jointly responsible to follow the procedures outlined in the rules for closing a pharmacy.

43-15-42.3 – Reporting Requirements. A pharmacist, pharmacy permit holder, a pharmacy intern, a pharmacy technician, a healthcare institution in the state, a state agency, or law enforcement agency in the state having any actual knowledge that a pharmacist, a pharmacy intern, or a pharmacy technician, may have committed any of the grounds for disciplinary action provided by law or rules adopted by the board shall promptly report that information in writing to the board of pharmacy. A pharmacist,

pharmacy technician or any institution from which the pharmacist or pharmacy technician voluntarily resigns, or voluntarily limits their staff privileges, shall report that licensee's actions to the board of pharmacy, if that action occurs while the licensee is under formal or informal investigation by the institution, or a committee of the institution for any reason related to possible professional incompetence, unprofessional conduct, or mental or physical impairment. Upon receiving a report concerning a licensee or registrant, the boards investigative committee may investigate any evidence that appears to show a licensee or registrant is, or may have committed any of the grounds for disciplinary action provided by law or rules adopted by the board. A person required to report under this section who makes a report in good faith is not subject to criminal prosecution or civil liability for making the report. For purposes of any civil proceeding, the good faith of any person who makes the report to this section is presumed. A report to the impaired pharmacist program (the Pharm-Assist Committee) of the North Dakota pharmacists association, will be considered reporting under this statute. For purposes of this section, a person has actual knowledge if that person acquired the information by personal observation or under circumstances that cause that person to believe there exists a substantial likelihood that the information is correct. An agency or health care institution that violates this section is guilty of a class B misdemeanor. A pharmacist, pharmacy permit holder, a pharmacy intern, or a pharmacy technician who violates this section is subject to administrative action by the North Dakota state board of pharmacy as specified by law or by administrative rule.

ADDENDUM B - Proposed Rule Changes in their entirety

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 50-06-27.
20. The failure to comply with the reporting requirement of North Dakota Century Code Section 43-15-44.2, 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.

Addendum C – Fellowship Proposal in it's entirety

QUALITY ASSURANCE FELLOWSHIP PROPOSAL

This is a proposal for the North Dakota State Board of Pharmacy to fund a fellowship at the NDSU College of Pharmacy, to provide ongoing support for Quality Assurance in North Dakota Pharmacies, for the benefit of the patients of North Dakota.

This individual would work with North Dakota Pharmacists to develop an effective quality assurance program in each community and hospital pharmacy in North Dakota. We already have a good start with the Pharmacist Mutual Quality Assurance Program that our telepharmacies, central pharmacies and control group are using. The North Dakota Pharmacist's Association is also marketing this program.

I have spoken with David Scott, who believes that the program could be modified for collection of data in hospitals as well.

The first goal of this program would be to establish, in every pharmacy, a continuous quality assurance program, including Policies & Procedures and data collection.

The second goal would be to provide some research relative to this project in both hospital and community pharmacies to determine what the quality related events are, in all of our pharmacies.

The third goal would be to utilize the data gathered from these, to allow the Board to devise improvement strategies our pharmacies could use.

This project could be funded by the Board of Pharmacy, through a $35,000 grant for each of two-years.

My recommendation is that we fund the fellowship and that we consider the renewal of that fellowship toward the middle of that second year.

Howard C. Anderson, Jr, R.Ph.

The meeting was adjourned.

President Bonnie J. Thom, R.Ph.	Member Gary W. Dewhirst, R.Ph.
Member Dewey Schlittenhard, R.Ph.	Member Rick L. Detwiller, R.Ph
Member Laurel A. Haroldson, R.Ph.	Executive Director Howard C. Anderson, Jr., R.Ph.