

**A G E N D A**  
**NORTH DAKOTA STATE BOARD OF PHARMACY**  
**JANUARY 10, 11, 12, 2011**

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**MONDAY - JANUARY 10, 2011** - CANDLEWOOD SUITES

1831 NDSU Research Park Drive - Fargo ND 58102 (1 -701-235-8200)

**5:00 PM**      CALL TO ORDER – President Rick L. Detwiller, R.Ph.

**5:05 PM**      Request for Legislative Support - Cheryl Rising, FNP -President NDNPA    **TAB 2**

FIRST BUSINESS SESSION

1.     Review and approval of agenda   **AGENDA TAB**
2.     Review and approval of Minutes of June 23, 2010 &  
   September 9, 2010   **MINUTE TAB**
3.     Assign members to review all paid invoices
4.     Grant Lifetime Licenses and Sign certificates = 14                         **TAB 1**  
           Sign RPh Original Licenses  
           Sign RPhTech Original Licenses
5.     Class addition Request: White Drug #68 in Fargo
6.     Re-instatement Request:     Kurt Drawz, R.Ph. #3620  
   Sandra Giefer, R.Ph. #3976  
   Jon C Haugan, R.Ph. #4034  
   Grant A Torfin, R.Ph. #3569
7.     Cost over-run for Programming: David Scott, NDSU    [Resolved paid in full]
8.     Proposed Rule Changes:   **TAB 3**  
  
           61-02-01-01    Permit required  
  
           61-02-01-03    Pharmaceutical Compounding Standards  
                                   Regulatory Analysis  
                                   Small Entity Economic Impact Statement  
                                   Small Entity Regulatory Analysis  
                                   Comments & Questions like Ketoprofen in a transdermal base OTC  
  
           61-02-06-02    Requirements for storage and retrieval of prescription  
   information  
           61-04-03.1    Identification Required for Controlled Substances plus tramadol  
   and carisoprodol  
           61-04-05-03    Computer transmission of prescriptions

The Pharmacy Audit Integrity Act – preview **TAB 3**

Year to date Financial Report - Budget comparisons **BUDGET TAB**  
**Auditor's Report** - Hand Out

9. ASHP Guidelines on Remote Medication Order Processing **TAB 4**  
Robert Biberdorf, R.Ph. Comments and questions

10. 2011 LEGISLATION: **TAB 5**

HB 1040 Long-Term-Care Moratorium

HB 1041 Nurses Aide Registry

HB 1084 Health Department Records

SB 2035 Pharmacists Administration of Immunizations

1<sup>st</sup> Heard January 5<sup>th</sup> 10:30 AM by Human Services

SB 2080 Veterinary Rx Drugs - ours

SB 2088 Veterinary Prescription Drugs - Board of Vet Med's

SB 2119 Rescheduling of Controlled Substances - ours

SB 2122 "Brand Necessary" Language - ours

SB 2151 Access to PDMP by License Addiction Counselors

11. Renew Collaborative Agreement for Pharmacist Anne Ottney &  
Dr Napoleon Espejo of Family Health Center in Fargo

12. Shipping prescription medical devices to home health agencies **TAB 6**

**5:30 PM** Application for Reciprocity – Heriberto Martinez [withdrawn]

**6:30 PM – Dinner– Lone Star Steakhouse – 4328 13<sup>th</sup> Ave SW – Alamo Room**

Technician Advisory Committee: 701-282-6642

President: Kristina Foster [kristinafoster3@yahoo.com](mailto:kristinafoster3@yahoo.com)

Vice-President: Donna Kisse [gdkisse@hotmail.com](mailto:gdkisse@hotmail.com)

Past-President: Angela Buchanan [abuchanan@csmondemand.com](mailto:abuchanan@csmondemand.com)

Ken Strandberg and Barbra Lacher – NDSCS

Discussion Items:

Proposed Rule to require certification

Veterinarian Dispensing Technician training module

Discussion by NAPT Officers of items of interest to NAPT

NDSCS plans for the future and current statistical data

**TUESDAY - JANUARY 11, 2011**

7:30 AM Working Breakfast –

9:00 AM Edgeley Prescription Shop – Sub Class K - Telepharmacy

9:30 AM New Pharmacy Permit – Curtis McGarvey, R.Ph. [Waterford]

- 10:00 AM Suzanne Dietrich, PharmD – Hospice of the Red River Valley  
Discussion of nursing home policy and procedures related to Controlled Substances and Hospice
- 11:00 AM HIE, REACH, etc – Sheldon Wolf

EXAM SCHEDULE - No Candidates as of today

**RULE HEARING**

- 2:00 PM** 61-02-01-01 Permit required;  
61-02-01-03 Pharmaceutical Compounding Standards; new section  
61-02-06-02 Requirements for storage and retrieval of prescription information  
61-04-03.1 Identification Required for Controlled Substances plus tramadol and carisoprodol  
61-04-05-03 Computer transmission of prescriptions  
61-11 Fees [written license verifications]
- 3:30 PM** ND Addition Treatment Provider’s Coalition concerning access to the PDMP by Licensed Addiction Councilors - Kurt A. Snyder **TAB 7**
- 4:30 PM** Tour Hospital Telepharmacy – Shelley Doherty-Johnsen, R.Ph.

**6:30 PM Dinner**– Radisson Hotel - 201 N 5<sup>th</sup> Street – Willow Room (1 –701-232-7363)  
NDSU President Dean Bresciani [invited but out of town]; Dean Charles Peterson, Provost Craig Schnell, Mike Schwab Executive VP NDPhA, Brad Morrison, R.Ph. NDPhA President, Brian Ament, R.Ph. President NDSHP; Dr. Jayme Steig, NDPSC Clinical Coordinator; Dennis Johnson, R.Ph.- NDPSC President or David J. Olig, R.Ph., Vice-President; David A. Lindell, Board Attorney

Discussion Items:

Provost Schnell relative to the research opportunities underway and how the College of Pharmacy fares relative to the other departments within the university.  
Dean Peterson will present an update on the College of Pharmacy’s performance and plans, as well as reviewing the ACPE Accreditation Visit, for which the self study either is or soon will be, underway.  
Mike Schwab and Brad Morrison will discuss item important to the Pharmacists Association  
Brian Ament will present items important to the North Dakota Society of Health Systems Pharmacists  
We will all have the opportunity to discuss proposed legislation of mutual interest.

**8:00 PM Investigating Committee Work**

- Review and Approval of paid invoices
- Board Member Reports
- Executive Director’s Report
- Approval of all legal action of the Executive Director

Preparations for May , 2011 Exams - New Books

**WEDNESDAY - January 12, 2011**

8:00 AM Breakfast

New Business

**Hearings:**

**9:00 AM** - Ryan Sannes - ND #4917

**10:00 AM** - Lambert Vet Supply

**11:00 AM** Charles Oien, PharmD  
Sherri Rafteseth, R.Ph.Tech

**11:15 AM Review Active Cases:**

**Noon** -  
Vouchers - Adjourn

The meeting was called to order by President Rick Detwiller at 5:04 PM on Monday January 10<sup>th</sup>, 2011 in the Board Meeting Room of the Candlewood Suites in Fargo, North Dakota.

Present at the meeting were: Pharmacist Rick L. Detwiller; Pharmacist Gary W Dewhirst; Pharmacist Laurel Haroldson; Pharmacist Bonnie J Thom; Pharmacist Gayle D Ziegler and Executive Director Howard C Anderson, Jr, R.Ph.

Present on the telephone was Cheryl Rising, Family Nurse Practitioner and President of the North Dakota Nurse Practitioners Association to present and explain legislation introduced to “eliminate the requirement that a nurse practitioner must have a collaborative prescribing agreement with a licensed physician in order to prescribe legend drugs.”

***It was moved by Pharmacist Ziegler and seconded by Pharmacist Haroldson to approve the Agenda as printed with the understanding that should visitors arrive at the meeting to discuss a specific Agenda item or topic, we will leave the option open to discuss those items or topics when the visitors are present. All Board Members voted aye – the motion carried.***

***It was moved by Pharmacist Dewhirst and seconded by Pharmacist Haroldson to approve the Board Minutes of June 23, 2010 and September 9<sup>th</sup>, 2010 after correcting the typographical error on Page 6 of the June 23<sup>rd</sup> minutes where the first letters of some of the words has been omitted.***

At 9:30 PM Mark Plencner, R.Ph. arrived at the meeting to discuss some of the issues relating to USP 797 and Rule 61-02-01-03 on Compounding Standards for which a hearing has been scheduled for Tuesday January 11<sup>th</sup>, 2011 at 2:00 PM. Pharmacist Plencner’s particular concern was that it did not appear that hazardous substances were address in this version of the rule. He felt that this issue needed to be addressed in the rule. He also discussed the use of sterile Isopropyl alcohol, as apposed to the current language of just Isopropyl alcohol as a sterilant. He pointed out that in some cases Isopropyl alcohol can harbor spores and therefore he felt the language should be changed to include the word sterile. The Board Members discussed at length with Pharmacist Plencner the difficulties of individuals obtaining chemotherapy such as 5-Flurouracil in local clinics or hospitals without having to travel. Pharmacist Plencner and some of the Board Members pointed out that for the safety of personnel not familiar with the administration of these hazardous drugs; more stringent requirements are probably indicated.

The Board Members met the Technician Advisory Committee at the Lone Star Steakhouse for a working dinner. Present at the dinner with the Board was: NAPT President Kristina Foster; Vice-President: Donna Kisse; Past-President: Angela Buchanan; Ken Strandberg and Barbra Lacher of NDSCS and Drs Charley Stoltenow and Dwyer of the Veterinary Medical Association. Executive Director Anderson asked everyone to introduce themselves and the discussion of movement to ASHP only education standards and the requirement for a Registered Technician to obtain and maintain Certification was underway. It was agreed that those obtaining registration after January 1, 1995 would have three years to obtain Certification. Those obtaining registration prior to January 1, 1995 would be grandfathered.

NAPT President Kristina Foster pointed out that they had plans to alter the by-laws at the Pharmacists Association Convention to allow the Board to fill unexpired terms, which were open on their Executive Committee. She indicated that they would be having some traveling Continuing Education that would be hosted at various locations around the state. Discussion

centered around the appointment of a Registered Technician to the Board of Pharmacy and all were encouraged to submit Applications to the Governors Office, or to check on their Applications if they had already submitted one.

Barbara Lacher reported that they were changing the procedure for proctoring exams for PATSIM students to require someone other than their Pharmacist Preceptors be asked to proctor the exams. Arrangements have been made for adequate proctors in most communities. She is willing to work with those who do not have a place to go for a proctored exam. Barb pointed out that the current procedures would allow for a little more research on their examinations with the computerized capture of the examination scores. She also pointed out that they currently have between 19 and 21 online students, five of whom are in the military service. There are 90 students in the module program and 29 on campus.

Discussion followed on the proposed Veterinary Technician dispensing training module and Drs Stoltenow and Dwyer offered the assistance of the NDSU Veterinary Technician Program in structuring the technician training module.

President Detwiller assigned Board Members Gary Dewhirst, R.Ph, Laurel Haroldson, R.Ph., Bonnie Thom, R.Ph. and Gayle Ziegler, R.Ph. to review all the paid invoices.

*It was moved by Pharmacist Thom and seconded by Pharmacist Haroldson to grant Lifetime Certificates to the following North Dakota Pharmacists:*

- |  |  |
|--|--|
| 2502 David A Anderson, R.Ph.<br>950 SE Arrow Creek Lane<br>Gresham OR 97080      | 2518 Jerome E Staska, R.Ph.<br>1848 Horseback Trail<br>Vienna VA 22182-1817      |
| 2508 Charles E Haeffner, R.Ph.<br>218 Evergreen Street<br>Anaconda MT 59711-1718 | 2520 Donald J Tucker, R.Ph.<br>16013 N Lakeforest Drive<br>Sun City AZ 8531-1449 |
| 2525 John N Fleck, R.Ph.<br>1208 NW 7th Ave<br>Rochester MN 55901                | 2530 Blayne V Myhre, R.Ph.<br>2803 Hemlock Street<br>Longview WA 98632-2048      |
| 2534 Kathleen P Harter, R.Ph.<br>20506 Kalmeadow Court<br>Lakeville MN 55044     | 2535 Riley H Rogers, R.Ph.<br>1314 Chautauqua Blvd<br>Valley City ND 58072       |
| 2536 Karen L Shannon, R.Ph.<br>2447 Harris<br>Richland WA 99352-1635             |  |

**Originally issued on November 10, 1960**

- |  |   |
|--|---|
| 2539 John J Lee, R.Ph.<br>P O Box 36<br>Roslyn SD 57261-0036 | 2541 ElRoy Herbel, R.Ph.<br>405 2 <sup>nd</sup> Ave NE<br>Elgin ND 58533-7017 |
|--|---|

2547 Lloyd Schnaidt, R.Ph.  
676 21st St W  
Dickinson ND 58601-2709

2548 Richard W Shannon, R.Ph.  
2447 Harris  
Richland WA 99352-1635

***All Board Members voted aye – the motion carried.***

The Board Members signed Original Certificates for Pharmacists and Technicians to be used by the office until the next meeting of the Board.

***It was moved by Pharmacist Thom and seconded by Pharmacist Haroldson to grant a Subclass A to Pharmacy Permit #702 issued to White Drug #68 located at 4255 30th Ave S in Fargo, North Dakota, which currently holds just a Class D - Long Term Care Pharmacy Permit. Pharmacist Dewhirst disclosed that he is employed by Thrifty White who is the current owner of this pharmacy. All Board Members voted aye – the motion carried.***

***It was moved by Pharmacist Ziegler and seconded by Pharmacist Thom to grant the application for Re-Instatement of Kurt Drawz, ND Pharmacist License #3620, which had been canceled for non-payment. All Board Members voted aye – the motion carried.***

***It was moved by Pharmacist Dewhirst and seconded by Pharmacist Ziegler to grant the application for Re-Instatement of Sandra Giefer, ND Pharmacist License #3976, which had been canceled for non-payment. All Board Members voted aye – the motion carried.***

***It was moved by Pharmacist Dewhirst and seconded by Pharmacist Haroldson to grant the application for Re-Instatement of Jon C Haugan, ND Pharmacist License #4034, which had been canceled for non-payment. All Board Members voted aye – the motion carried.***

***It was moved by Pharmacist Thom and seconded by Pharmacist Ziegler to grant the application for Re-Instatement of Grant A Torfin, ND Pharmacist License #3569, which had been canceled for non-payment. All Board Members voted aye – the motion carried.***

The Board Members reviewed the proposed rule changes in anticipation of the Rule Hearing scheduled for tomorrow.

The preliminary draft of the Pharmacy Audit Integrity Act being considered by the North Dakota Pharmacists was also previewed.

The year-to-date financial reports and budget versus actual were reviewed by the Board Members. The auditor's draft preliminary report was distributed to the Members so they may review it over the next two days.

The meeting recessed for the evening at 11:30 PM.

On Tuesday January 11, 2011 at 8:00 AM President Detwiller called the meeting to order.

Discussion followed about the American Society of Health System Pharmacists [ASHP] guidelines on remote medication order processing. It was the general opinion of the Board Members that the North Dakota Telepharmacy Project met or exceeded the expectations in ASHP's guidelines.

Pharmacist Ziegler spoke for Robert Biberdorf, Pharmacist-In-Charge of Sanford Pharmacy Medical Center Fargo. She indicated that Pharmacist Biberdorf had questions relative to pharmacists being able to provide telepharmacy from their homes. The position of the ND Board of Pharmacy has been - *“with the proper computer, audio and video hookups available, pharmacists could work from their homes to provide on-call telepharmacy services.”*

***It was moved by Pharmacist Thom and seconded by Pharmacist Haroldson to support Senate Bill #2035 Pharmacists Administration of Immunizations, as amended to require use of the North Dakota Immunization Tracking System. All Board Members voted aye – the motion carried.***

***It was moved by Pharmacist Ziegler and seconded by Pharmacist Thom to approve and support Senate Bill #2080 Veterinary Prescription Drugs and to accept the responsibilities under the bill. All Board Members voted aye – the motion carried.***

***It was moved by Pharmacist Haroldson and seconded by Pharmacist Dewhirst to support Senate Bill #2119 Rescheduling of Controlled Substances and Bill #2122 “Brand Necessary” Language as they pertain to electronic prescribing. All Board Members voted aye – the motion carried.***

Senate Bill #2151 Access to PDMP by Licensed Addiction Counselors was discussed. President Detwiller postponed action on this Bill until after we have heard from the addiction counselors, who were expected about 3:30 PM.

***It was moved by Pharmacist Thom and seconded by Pharmacist Ziegler to approve the renewal of the Collaborative Agreement between Pharmacist Anne Ottney and Dr. Napoleon Espejo of Family health Center in Fargo, ND.***

After review of the information relative to shipping prescription medical devices to home health agencies, it was the consensus to continue the licensing policy that prescription drugs or medical devices could not be shipped to home health agencies.

At 9:00 AM Pharmacist Lane Nelson and Pharmacist John Beringer were present to discuss with the Board the impending purchase of The Prescription Shop in Edgeley by Pharmacist Nelson from Pharmacist Beringer

***It was moved by Pharmacist Dewhirst and seconded by Pharmacist Thom to approve a Class A Out-Patient Pharmacy Permit for the current space occupied by The Prescription Shop, with a Subclass K – Telepharmacy Permit – subject to the installation of a counseling booth; the audio and video equipment, a contract between LaMoure Drug Store, Inc. for telepharmacy central site services and a completed lease. The pharmacy will then go by the name of Edgeley Pharm Store to be located at 509 Main Street in Edgeley, North Dakota. All Board Members voted aye – the motion carried.***

After review and some discussion, President Detwiller postponed any action on the New Pharmacy Permit Application made by Pharmacist Curtis McGarvey to be located in the Waterford in Bismarck, until Pharmacist McGarvey could be contact by telephone and consulted for clarifications.



Suzanne Dietrich, PharmD arrived at the meeting along with the Medical Director and the Nursing Director of the Hospice of the Red River Valley. Discussion followed about the details surrounding electronic prescribing, as well as prescribing for patients in hospice and the use of standing orders for initiation or renewal of medications.

Pharmacist Dietrich reported that in 2010 she had dispensed \$48,000 of medications at cost to the clients of Hospice of the Red River Valley and that she has sent out another \$32,000 worth of medications to other pharmacies.

At 10:30 AM Pharmacist Curt Larson, District Manager of CVS arrived at the meeting.

At 11:00 AM the Board Members welcomed Sheldon Wolf of the State Health Information Technology Office. He presented information about the current status of Health Information Exchange work in North Dakota, grants that are available and legislation in the form of House Bill #1021 and Senate Bill 2037, which have been introduced to authorize the activities of the office over the next two years.

### **RULE HEARING FORMAT**

I am Rick Detwiller President of the Board of Pharmacy and I will be acting as Hearing Officer for this hearing.

It is now 2:00 PM on Tuesday January 11, 2011 in the Board Meeting Room of the Candlewood Suites in Fargo, North Dakota.

This public meeting has been called for the purpose of allowing all interested individuals an opportunity to submit information concerning the proposed N.D. Admin. Code Article 61; Chapter 61-02 amended sections

- 61-02-01-01 Permit required;
- 61-02-01-03 Pharmaceutical Compounding Standards;
- 61-02-06-02 Requirements for storage and retrieval of prescription information;
- Chapter 61-04 new section
- 61-04-03.1- Identification Required for Controlled Substances plus tramadol and carisoprodol; and amend
- 61-04-05-03 Computer transmission of prescriptions and amend
- 61-11 Fees.

Information gathered at this meeting will be used by the Board of Pharmacy for it's deliberation and final decision.

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

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 meeting for comments.

### **CHAPTER 61-02-01 PHARMACY PERMITS**

Section 61-02-01-01 Permit Required

61-02-01-02	Application for Permit
61-02-01-03	Pharmaceutical Compounding Standards
61-02-01-04	Permit Not Transferable
61-02-01-05	Change of Ownership
61-02-01-06	Affidavit of Ownership
61-02-01-07	Renewal of Permits
61-02-01-08	Change of Location
61-02-01-09	Permit for Heirs at Law of Pharmacist
61-02-01-10	Pharmacist-in-Charge -Requirement - Definitions - Duties
61-02-01-11	Pharmacist-in-Charge - Termination of Service
61-02-01-12	Posting of Permit
61-02-01-13	Pharmacist on Duty
61-02-01-14	Limitation on Rent
<u>61-02-01-15</u>	<u>Closing a Pharmacy</u>
<u>61-02-01-16</u>	<u>Transfer of controlled substances when selling a business.</u>
<u>61-02-01-17</u>	<u>Identification</u>

**61-02-01-01. Permit required.** No person, partnership, association, or corporation shall conduct a pharmacy in North Dakota without first obtaining a permit to do so from the board. A fee, set by the board but not to exceed that prescribed by statute, shall be charged for each permit.

4. Classes of pharmacy permits are as follows:
  - a. Class A - Permit to conduct an outpatient pharmacy. These permits are issued to a pharmacy dispensing drugs or devices to the general public pursuant to a valid prescription.
  - b. Class B - Permit to conduct a hospital pharmacy. These permits are issued to a pharmacy dispensing drugs or devices to persons who are patients in a hospital, patients who are being discharged, or patients in emergency situations, pursuant to a valid prescription. These permits shall be issued to facilities licensed under North Dakota Century Code chapter 23-16 and shall be issued in the name of the facility.
  - Class C - Permit to conduct a ~~home health care~~ sterile compounding pharmacy. These permits are issued to a pharmacy dispensing sterile injectable drug products and devices to the general public who are not patients within a facility with a class B pharmacy permit pursuant to a valid prescription.
  - d. Class D - Permit to conduct a long-term care pharmacy. These permits are issued to a pharmacy dispensing drugs and devices to residents of facilities licensed under North Dakota Century Code chapters 23-09.3 and 23-16 pursuant to a valid prescription which are not physically accessed by the general public.
  - e. Class E - Permit to conduct a nuclear pharmacy. These permits are issued to a pharmacy dispensing or providing diagnostic or therapeutic radioactive drugs or devices for administration to an ultimate user.
  - f. Class F - Permit to conduct a mail-order pharmacy. These permits are issued to a pharmacy dispensing drugs and devices to the general public exclusively through the

United States postal service or other parcel delivery service pursuant to a valid prescription but which are not physically accessed by the general public.

- g. Class G - Permit to conduct an out-of-state pharmacy. These permits are issued to any pharmacy operating outside the state of North Dakota which ships, mails, or delivers in any manner a dispensed prescription drug or legend device into North Dakota, which shall obtain and hold a pharmacy permit issued by the North Dakota state board of pharmacy and that part of the pharmacy operation dispensing the prescription for a North Dakota resident shall abide by state laws and rules of the board.
- h. Class H - Permit to conduct a governmental agency pharmacy. This permit is issued to a pharmacy operated by the state of North Dakota, dispensing drugs and devices only to patients within correctional facilities or rehabilitation facilities, or for the purpose of teaching at institutions of higher learning, pursuant to a valid prescription.
- i. Class I - Permit to conduct a research pharmacy. This permit is issued to a pharmacy in which scientific research is conducted under protocols established by an institutional review board meeting federal drug administration guidelines. Pharmaceuticals on hand are incident to the research being conducted. Security and storage for pharmaceuticals must meet United States Pharmacopeia and board of pharmacy requirements. A specific application for a pharmacy permit must be made delineating the specific physical facility to be utilized.
- j. Class J - Permit to conduct an office practice pharmacy. Any licensed pharmacist may practice in an office pharmacy setting where prescriptions are not routinely dispensed. If legend drugs or devices are maintained, a permit must be obtained by making application to the board of pharmacy delineating specific practice intentions and assuring the board that security and storage requirements are met for any legend drugs or pharmaceuticals on hand.
- k. Class K - Permit to conduct telepharmacy. A pharmacy staffed by a registered pharmacy technician with access to its main pharmacy and registered pharmacists by computer link, videolink, and audiolink while open.

*There were no public comments, or written comments submitted on this rule as published.*

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**61-02-01-17. Identification.** All pharmacy employees shall wear a name badge while in the pharmacy, which clearly identifies the person’s title.

*There were no public comments, or written comments submitted on this rule as published.*

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**61-02-06-02. Requirements for storage and retrieval of prescription information.**  
 Electronic data processing equipment or media, when used to store or process prescription information, shall meet the following requirements:

- 1. Must guarantee the confidentiality of the information contained in the data base, must require that the transmission of electronic prescriptions from prescriber to pharmacist

not be compromised by interventions, control, or manipulation of said prescriptions by any other party.

- 2. An electronic system must provide on line retrieval via ~~eatho-ray tube~~ computer screen or hard-copy printout of original prescription order information for those prescription orders which are currently authorized for refilling. If more refills are authorized, it must be noted on the ~~eatho-ray tube~~ computer screen or on the hard copy of prescription or a new prescription must be produced.
- 3. Must produce a hard-copy daily summary of controlled substance transactions. Monthly summaries must be produced and filed with the biennial inventory.
- 4. Be capable of recording and carrying in the record all dates of refills of any prescription and the initials of the pharmacist.
- 5. Be capable of producing a patient profile indicating all drugs being taken and the date of refills of these prescriptions, as required by North Dakota Century Code section 43-15-31.1.
- 6. Be capable of reconstructing information, by daily backups in the event of a computer malfunction or accident resulting in destruction of the data base.

***There were no public comments, or written comments submitted on this rule as published.***

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**ARTICLE 61-04 PROFESSIONAL PRACTICE**

Chapter

- 61-04-01 Return of Drugs and Devices Prohibited
- 61-04-02 Physician Exemption
- 61-04-03 Destruction of Controlled Substances
- 61-04-03.1 Identification Required for Controlled Substances
- 61-04-04 Unprofessional Conduct
- 61-04-05 Electronic Transmission of Prescriptions
- 61-04-05.1 Prescription Transfer Requirements
- 61-04-06 Prescription Label Requirements
- 61-04-07 Pharmacy Patient’s Bill of Rights
- 61-04-08 Limited Prescriptive Practices
- 61-04-09 Warning Notice
- 61-04-10 CLIA Waived Laboratory Tests
- 61-04-11 Administration of Medications and Immunizations

**Chapter 61-04-03.1 IDENTIFICATION REQUIRED FOR CONTROLLED SUBSTANCES**

61-04-03.1 Identification Required for Controlled Substances. Pharmacists, Pharmacy Intern, Pharmacy Technicians, and clerical personnel are required to obtain positive identification if they are unsure of the identify of the person picking up a prescription for any controlled substance, tramadol, or carisoprodol. Positive identification means a document issued by a governmental agency which:

- a. Contains a description of the person or a photograph of the person, or both; and
- b. Includes, but is not limited to, a passport, military identification card, or driver’s license.

***All verbal comment made on this rule expressed support.***

**61-04-05-03. Computer transmission of prescriptions.** In addition to the requirements in section 61-04-05-02, a prescription order may be transmitted from an authorized prescribing practitioner to a pharmacy under the following provisions:

- 1. Schedule II, III, IV, and V controlled substances prescriptions received via computer require an electronic signature by the authorized prescriber, as defined in North Dakota Century Code section 9-16-01, for the prescription to serve as the original copy.

Option 1:

- 2. Transmission of schedule II controlled substance prescriptions via computer is ~~not~~ allowed when the prescribing system and the pharmacy system are in compliance with Drug Enforcement Agency requirements for e prescribing.

Option 2 :

- 2. Transmission of schedule II controlled substance prescriptions via computer, electronic prescriptions, is ~~not~~ allowed, when it is done in compliance with 21 CFR part 1311 subpart C Electronic Prescriptions.
- 3. The required legend must appear on the practitioner’s prescription screen. The practitioner must take a specific overt action to include the "brand necessary" language with the electronic transmission as set forth in subsections 3 and 4 of North Dakota Century Code section 19-02.1-14.1. For example, the practitioner or the practitioner’s agent must type out "brand necessary" letter by letter.

***Discussion distilled to a consensus that Option 1 of the presented alternatives was the one for the final draft. Only Board Members commented on this rule, with Pharmacist Curt Larson concurring.***

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**ARTICLE 61-11 FEES**

North Dakota Examination	\$ 100.00
Original or Duplicate Certificate	25.00
Reciprocal Licensure	150.00
Internship Licensure – NDSU Professional Student	100.00
{\$90 is paid to the NDSU College of Pharmacy for student programs}	
Internship Licensure – Pre-pharmacy students	10.00
Manufacturer/ Distributor/Warehouse/Reverse Distributor	
Wholesale Drug License	<del>150.00</del> <u>200.00</u>
Penalty for Late Renewal	50.00
Pharmacy or Drug Store Permit	175.00
Permitting in additional Classes	- 0 -

Penalty for Late Renewal	50.00
Annual Renewal for Pharmacist IN-STATE	100.00
Penalty for late Renewal	25.00
Annual Renewal for Pharmacist IN-STATE (Inactive Status)	75.00
Penalty for late Renewal	25.00
Annual Renewal for Pharmacist OUT-OF-STATE	35.00
Penalty for late Renewal	25.00
Annual Registration for Pharmacy Technician	35.00
{\$17.50 is forwarded to the Northland Association of Pharmacy Technicians}	
Penalty for late Renewal	10.00
Pharmacy Technician-In-Training (2 years allowed)      per year	10.00
<u>License Verifications</u> <u>[self-addressed return envelope]</u>	<u>\$ 25.00</u>

*There were no comments made or submitted in writing concerning this rule.*

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**CLOSING**

Thank you all for participating. The Board of Pharmacy will use all of the information gathered at this meeting, in making their decision.

At this point, I will close the discussion on N.D. Admin. Code Article 61; Chapter 61-02 amended sections 61-02-01-01 Permit required; 61-02-01-03 Pharmaceutical Compounding Standards; 61-02-06-02 Requirements for storage and retrieval of prescription information; Chapter 61-04 new section 61-04-03.1- Identification Required for Controlled Substances plus tramadol and carisoprodol; and amend 61-04-05-03- Computer transmission of prescriptions and amend 61-11 Fees.

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

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**61-02-01-03 Pharmaceutical Compounding Standards – there were so many comments on this rule that it is being addressed at the end. A conference call was arranged at the request of several potential commenters’. Pharmacists: Brian Ament; Thomas Simmer; Keith Horner; Dennis DelaBarre; Rick Boehm were all present via the conference call, with Joel Aukes, Shelley Doherty-Johnsen and Curt Larson present with the Board at the Hearing.**

President Detwiller asked Pharmacist Ament to go through his comments and the others to listen and add any additional items that he did not cover.

Written comments, additions or corrections will be inserted here.

In summary, commenters felt that this rule needed to be made clearer, relative to the separation of sterile and non-sterile compounding requirements. They suggested a short section at the begin for general compounding standards, then clearly delineate what items are required for non-sterile compounding and what items are required for sterile compounding, would make the rule much more clear. Several commenters also indicated that they felt that the USP 797 language of sterile ISO propel alcohol should be used through out.

Several felt that the specific requirements on recording lot numbers for product use should be used only in the sterile compounding section when batches or multiple IVs were being prepared for future use.

Pharmacist Rick Boehm pointed out that there should be additional cleaning requirements for walls and ceiling, as well as the sterile preparation area and the mopping of the floors.

Several commenters pointed out that USP did allow exceptions for "proprietary bag and vial systems" and that this language should also be included in the rule.

Some commenters felt that we should just adopt the 795 and 797 standards, while Pharmacist Joel Aukes pointed out that this was not in the best interest of North Dakota and the facilities that we have here. Pharmacist Boehm pointed out that a glove-box ought to be clearly delineated as okay for most uses.

[The hearing record is on tape should questions arise about specific instances.]

At 3:30 PM Kristy Anderson, President of the ND Addiction Counselors Association and Kurt A. Snyder, Licensed Addiction Counselor and chair of the providers joined the Board meeting to discuss Senate Bill #2151, which would allow access to the Prescription Drug Monitoring Program [PDMP] data via a log-in and password, to licensed addiction counselors working within a licensed program.

Mr. Snyder pointed out that the Board of Addiction Counselors requires a four-year degree, with 1400 hours of work experience prior to passing a written exam. He also indicated that he did not feel that any delegates should be approved for licensed addition counselors and that a tailored training module should be used to be sure that they pass it, and understand the parameters before they are issued a log-in and password for access.

***It was moved by Pharmacist Haroldson to support Senate Bill #2151. The motion was seconded by Pharmacist Thom - All Board Members voted aye - the motion carried.***

At 4:30 PM the Board Members met at the hospital telepharmacy central site for a tour, along with Ann Rathke ; Dean Charles Peterson and Shelley Doherty-Johnsen, Pharmacist-In-Charge of the central telepharmacy site.

Pharmacist Doherty-Johnsen asked her staff to demonstrate to the Board how the system works and how they are able to accommodate hospitals with varying medical records systems and in some cases no electronic medical records system. Board members were impressed with how the computer, audio and video technology worked to serve the patients of these hospitals. The central hospital telepharmacy site is now open 24 seven with 14 hospitals currently participating and one more to be added soon. The hospital telepharmacy central site serves hospitals in both Minnesota

and North Dakota, and is developing plans to expand into other states.

Board Members discussed the long-term goal of the hospital telepharmacy project, which is to put the tools in place to allow pharmacist first dose review for every practitioners order in these hospitals. Pharmacist Doherty-Johnsen pointed out that Altru Hospital is considering working with some hospitals in the northeast corner of North Dakota and the northwest corner of Minnesota. Also, Averia is considering serving some hospitals in the southern portion of North Dakota.

Board Members met at the Radisson Hotel for a working dinner at 6:30 PM with: NDSU Provost Craig Schnell; Dean Charles Peterson, NDPhA Executive Vice-President Michael Schwab; David J. Olig, R.Ph., Representing the Pharmacy Services Corporation [NDPSC]; Pharmacist Curt Larson of CVS Pharmacies

Dr. Craig Schnell, who has spent sixteen years as Academic Vice-President and Provost at NDSU, thanked the Board of Pharmacy for their collaborative work with the University over his years of service. Dr. Schnell explained that he would be moving into the College of Pharmacy, as a professor and that a search committee has been appointed by President Bresciani to select his replacement as Provost. Dr. Schnell congratulated the College of Pharmacy for being in the top 5 in funded research at the University.

Dr. Schnell did point out that with the budget short falls and with the financial situation at NDSU, there was some pressure to use program fees to cover the shortfall in the budget. Dr. Schnell also pointed out that NDSU was up 124 students from the prior year.

Dr. Schnell performed several accreditation visits during the year for the Accreditation Council on Pharmacy Education, and expressed some concern that pharmacy schools were being opened more quickly than future needs may require. We will need to look into the future to resolve that question long term.

Dean Charles Peterson reported on the approvals for the masters of public health program, in cooperation with the University of North Dakota, which is ready to kick off in the fall 2012. He spoke about the Center of Excellence in Vaccine Research and that the College would now be granting a Vaccinology minor, in conjunction with that new program. He spoke about the medication therapy management program in pain management, which was again being developed in collaboration with the North Dakota Pharmacists Association and the Board of Pharmacy in keeping with the A-B-Cs of pharmacy in North Dakota.

Dean Peterson reported that we were looking forward to the April 2012 ACPE Accreditation visit and pointed out that we now have 1,781 students in the professional and pre-professional program at NDSU College of Pharmacy, Nursing and Allied Sciences.

Pharmacist Olig of NDPSC who is managing the contracts for medication therapy management with the North Dakota Public Employees Retirement System and will be rolling out the pain management program with Workforce Safety and Insurance in a month.

Michael Schwab of NDPhA spoke about the pain management program and how the details would be managed. He thanked the Board of Pharmacy for working with the Association and College in developing the program and providing it's accessibility pharmacists around the state.



The program is being developed as a live and webinar program, so that it will be available beyond the Mid-Winter Institute.

Pharmacist Curt Larson of CVS Pharmacies congratulated the College of Pharmacy on the development of the Medication Therapy Management Programs in Diabetes and Pain Management. Pharmacist Larson pointed out that he likes to see Association – Board – College together at the same table discussing common problems and working for the good of the patients and the people in North Dakota.

After dinner the Board returned to the Board meeting room at the Candlewood, where Board Members worked individually on cases relative to the Investigating Committee's work.

The meeting recessed again at 11:30 PM with the plan to meet for a working breakfast at 8:00 AM to resume Board business before the scheduled hearings.

At 8:00 AM on Wednesday January 12<sup>th</sup>, 2011 Board Members contact Curtis McGarvey, R.Ph. by telephone to get specificity on the new Pharmacy Permit Application he submitted.

***It was moved by Pharmacist Thom and seconded by Pharmacist Haroldson to grant a North Dakota Pharmacy Class D Long-term-Care Pharmacy Permit, with a Subclass Class A - Out-Patient to Professional Pharmacy West located within the Waterford at 1000 West Century Ave in Bismarck, North Dakota, contingent upon Executive Director Anderson receiving a signed lease, a more detailed floor plan and grant a space variance, considering the primary use of the pharmacy will be serving the Long-Term-Care and assisted living residents of this facility. All Board Members voted aye – the motion carried.***

9:00 AM – Ryan Sannes – ND Pharmacist License #4917 was present to visit with the Board and to deliver his signed Stipulated Agreement. He signed this agreement before Executive Director Anderson and Board Attorney David Lindell. Also present for this meeting was Chad Nelson, owner and Pharmacist-In-Charge of Medical Pharmacy and Mary Leier, a Registered Pharmacy Technician who worked at Medical Pharmacy with Ryan Sannes, when he was also employed in the pharmacy.

Ryan described his current recovery process, working with Share House, completing a five month in-patient treatment in September 2009 and now working outside the profession of pharmacy in Wahpeton. He is keeping up his weekly meetings with his sponsor and keeping in contact with his counselor, Dr. Virdee.

Ryan Sannes volunteered some information to the Board, because he felt it might be instructive and helpful for others in the same situation, and for others might be working with professionals who are becoming impaired. Ryan pointed out that he began by abusing the trust of the nursing staff at long-term-care facilities where medications were being destroyed, by taking some of the medications. This evolved into taking more and more medications from pharmacies where he worked. He did this usually by pocketed a bottle and going to the bathroom to take medications. Ryan stressed that questioning of any specific behavior which appeared was in the best interest of the pharmacy and the potentially impaired professional. He strongly supported the in-patient treatment as the only viable solution to a problem, such as his. Ryan believes that he is on the road to recovery and looks forward to the opportunity to re-instate his pharmacist license one day.

***It was moved by Pharmacist Dewhirst and seconded by Pharmacist Ziegler to approve the signed Stipulated Agreement with Ryan Sannes. President Detwiller asked for a roll call vote: Pharmacist Detwiller –No Pharmacist Dewhirst – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Pharmacist Ziegler – Aye the motion carried and the Stipulated Agreement was accepted.***

Board Attorney David Lindell reviewed the case of Lambert Vet Supply and the signed Stipulated Agreement that he had negotiated with them.

***It was moved by Pharmacist Haroldson and seconded by Pharmacist Thom to approve the signed Stipulated Agreement. All Board Members voted aye – the motion carried.***

Pharmacist Charles Oien and Sherrie Rafteseth, RPhTech were present to discuss their case with the Board.

***It was moved by Pharmacist Dewhirst and seconded by Pharmacist Haroldson to approve the signed Stipulated Agreement with Pharmacies Oien and Pharmacy Technician Rafteseth. All Board Members voted aye – the motion carried.***

At 11:15 AM President Detwiller returned to the Agenda and any unfinished business. He called for Board Member Reports.

Board Members asked that the issue of whether we should accept Pharmacy Technician Certification Board [PTCB] and or accept ExCPht Certification for our Pharmacy Technician be placed on the May 2011 Agenda.

Board Members discussed the poster session at NABP and it was agreed that we would continue to sponsor three sets of students and a preceptor to go to the NABP Meeting. This money will come out of our current travel budget, as had previously been done.

Pharmacist Ziegler asked about the talyst machine which was located in the Rosewood long-term-term-care facility and Board Members reiterated their position that any stocking of a talyst machine should be done by a pharmacist or a pharmacy technician and that the location of that machine in a facility would need to have a Pharmacy Permit.

Executive Director Anderson reviewed several items with the Board Members, which had come to the Board Office since our last meeting.

***It was moved by Pharmacist Ziegler and seconded by Pharmacist Thom to approve all legal actions of Executive Director Anderson since the last such motion. All Board Members voted aye – the motion carried.***

Board Members reviewed the Pharmacotherapy Books for the May examinations and decided that these manuals would work fine for the May 2011 exams. Some Board Members took books with them to prepare for the examination.

***It was moved by Pharmacist Thom and seconded by Pharmacist Dewhirst to approval all of the paid invoices since the last actions was taken, with the exception of: which require further clarification. All Board Members voted aye – the motion carried.***

*It was moved by Pharmacist Dewhirst and seconded by Pharmacist Ziegler to approval the preliminary draft Audit Report that was handed out on Monday evening. All Board Members voted aye – the motion carried.*

*It was moved by Pharmacist Dewhirst and seconded by Pharmacist Haroldson to affirm the Board of Pharmacy’s policy that we will only accept American Society of Health Systems Pharmacists [ASHP]Accredited programs as minimum qualifications for Registration as a Pharmacy Technician in North Dakota. We will discontinue accepting those didactic portions of online programs for new technician-in-training registrants. Those currently in previously approved will be allowed to continue to completion, but only those in ASHP accredited programs will be accepted from this time forward. All Board Members voted aye – the motion carried.*

Board members continued discussions. Pharmacist Detwiller pointed out his concern over the lack of consulting, which seems to be occurring in our pharmacies. He asked that Executive Director Anderson prepare an Article for *The NoDak Pharmacist* pointing out that it is part of the professional obligation of every pharmacist to comply with North Dakota Laws and Rules and to consult every patient, or make a specific, conscious decision that they did not need the information or recognize that the patient has refused the consultation.

*After review of information from WellFount it was moved by Pharmacist Haroldson and seconded by Pharmacist Thom that a Pharmacy Permit for a location of a talyst machine would need to be obtained, if inventory not labeled with patient specific labeling was contained in the machine or the room where the machine was located. The only exception would be a small emergency box where this would be allowed under our current rule. A technician or pharmacist must be employed or contracted by the pharmacy to refill and service the machine. All Board Members voted aye – the motion carried.*

President Detwiller called for any further business, none forthcoming. The meeting adjourned.

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Rick L. Detwiller, R.Ph  
President

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Gary W. Dewhirst, R.Ph.  
Member

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Member  
Laurel A. Haroldson, R.Ph.

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Member  
Bonnie J. Thom, R.Ph.

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Member  
Gayle D. Ziegler, R.Ph.

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