SEPTEMBER 9, 2010 CONFERENCE ROOM - BOARD OF PHARMACY OFFICE BISMARCK, ND

A G E N D A
THURSDAY – September 9th 2010
ND STATE BOARD OF PHARMACY OFFICE
1906 E BROADWAY AVE – BISMARCK, ND 58501

10:00 AM Call to Order – President Rick Detwiller, R.Ph. **AGENDA**

DISCIPLINARY HEARINGS:

10:00 AM Sarah Huwe, ND Pharmacy Technician #828

10:15 AM Melissa Gedde, ND Pharmacy Technician #602

10:30 AM Jody Doe, R.Ph. – ND #4525
Barbara Buzalsky, ND Pharmacy Technician #1182
New England Drug – ND Pharmacy Permit #590

11:00 AM Kevin Oberlander, R.Ph. – ND #3934
Dakota Pharmacy – ND Pharmacy Permit #5
Dakota Precision Rx ND Pharmacy Permit #428

SIGN ORIGINAL Pharmacist & Technician Certificates

1:30 PM PetMeds Express – Out-of-State Pharmacy Permit #279

2:30 PM CVS #8628 [South] ND Pharmacy Permit #107

3:00 PM Lambert Vet Supply

4:00 PM Review Case: Mark Pajala – ND Pharmacist #3988

Request for Class K for Supervision of oncology product preparation – **TAB 1**
& Critical Access Hospitals -Altru Health System – Jeff Zak, R.Ph. By Phone

Reciprocity Candidate: Germon E. Hill, R.Ph. - Prior convictions **TAB 2**

Intern License Request: Mr. Allen G. Kniep - Prior convictions **TAB 3**
Phone 12:30 to 1:30 or after 4:50 at 218-428-8666

Collaborative Agreement – Rob Nelson, PharmD, Sanford Medical Center
In my file Folder

Floor plans for:
New location of Minne-Tohe Health Center Pharmacy - New Town
Expansion of Southtown Econodrug – Wahpeton
New location of Hankinson Drug

Discussion: Initiated Measure related to Pharmacy Ownership
Pharmacy Call Centers – Lindsay Setliff, JD
Shipping Vaccines Directly to an Employer; Pocock

Update: Drug Destruction/Take-A-Way Program-Mike Schwab
Health Care Environmental Services (HESI)
Pharmacy Week promotion of Repository and Take Back Programs

Review Drafts for Rule changes: **TAB 4**
Positive Identification for Controlled Substances
Compounding
Intern Requirements and Staff Identification

4:00 PM Review Legislative Proposals: **TAB 5**

1) Veterinary Legend Drug Dispensers for food producing and Nancy Kopp; Drs.; Boyce, Clement and Vollmer-non-traditional livestock.

2) Controlled Substances Scheduling

3) Proposed Lowering of Immunization age from 18 down to 11

Review Guidance Documents

1) Central Fill **TAB 6**

Budget Change Requests
Mike Schwab-See Above
Funding for IHS programming from Enhancement Grant
Employment Agreement for Executive Director

The meeting to order at 9:55 AM by Senior Member Gary Dewhirst in the Conference Room of the Board of Pharmacy Office located at 1906 East Broadway in Bismarck, North Dakota, in the absence of President Rick Detwiller.

Present are: Pharmacist Gary W. Dewhirst; Pharmacist Gayle D. Ziegler; Pharmacist Laurel A. Haroldson; Pharmacist Bonnie J. Thom; Executive Director Howard C. Anderson, Jr, R.Ph. In addition were: Board Attorney David A. Lindell; Administrative Law Judge Alan Hoberg, Pharmacy Technician Sara Huwe and her parents Mr. and Mrs. Huwe.

Absent: Pharmacist Rick L Detwiller – who would be joining the meeting later.

Pharmacist Dewhirst turned the meeting over to the Honorable Alan Hoberg for the conduct of the Administrative Hearing scheduled at 10:00 AM for Pharmacy Technician Sara Huwe. The transcript of this hearing was recorded and will be kept for sixty-days should any of the parties to the hearing wish to receive a copy of the transcript. The Honorable Alan Hoberg closed the hearing for **Sara Huwe ND Pharmacy Technician** #828 at 10:35 AM

It was moved by Pharmacist Ziegler that an order be written for the indefinite suspension of ND Pharmacy Technician Registration #828 issued to Sara Huwe. That Ms Huwe seek and sign a contract with the Pharm-Assist Committee requiring any necessary treatment and ongoing substance monitoring, that Ms. Huwe pay the costs of the investigation and prosecution, that she keep up her continuing education during the period of her suspension, that she report quarterly to Executive Director Anderson and that she keep any Board of Pharmacy licensed or permitted employers informed of this order. On vote by roll call: Pharmacist Dewhirst – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Pharmacist Ziegler – Aye Nays none – the motion carried. *[copy of stipulated agreement follows:]* **BEFORE THE NORTH DAKOTA STATE BOARD OF PHARMACY**

IN THE MATTER OF THE CERTIFICATE OF REGISTRATION OF SARAH M. HUWE, R.PH. TECH, AS A REGISTERED PHARMACY TECHNICIAN NO. 828 IN THE STATE OF NORTH DAKOTA,	FINDINGS OF FACTS, CONCLUSIONS OF LAW AND ORDER

RESPONDENT. Administrative No. 2010-9-28-00206

On July 21, 2010, the Complaint and Statement of Charges ("Complaint") and Order of Temporary Suspension was filed with the North Dakota State Board of Pharmacy ("Board") by David A. Lindell, Special Assistant Attorney General, Counsel for the Board, and Howard C. Anderson, Jr., R.Ph., Executive Director of the Board and Chairman of the Board's Investigating Committee, requesting certain administrative action against the certificate of registration (Certificate No. 828) of Sarah M. Huwe ("Huwe") as a Registered Pharmacy Technician in the State of North Dakota. The Complaint states as grounds for administrative action violations of Sections 19-03.1-23(7) and 43-15-10(1)(h) & (i) of the North Dakota Century Code and Section 61-04-04-01(1) of the North Dakota Administrative Code as more specifically set forth in Paragraph IV of the Complaint, subsections a and b.

On July 21, 2010, the Board also issued a Notice of Hearing scheduling a September 9, 2010, hearing on the Complaint. The hearing was held as scheduled in the offices of the Board at 1906 East Broadway Avenue, Bismarck, North Dakota. Mr. Lindell represented the Board at the

hearing. He called two witness to testify. The Respondent Huwe was present at the hearing. Huwe was not represented at the hearing by counsel, but was accompanied by her parents. She stated that she did not wish to have an attorney represent her and she represented herself, but did not testify. She asked questions of the Board's witnesses. The Board offered two exhibits as evidence, all of which were admitted. Huwe did not offer any exhibits. Both Mr. Lindell and Huwe gave oral closing arguments.

NOW, THEREFORE, the North Dakota State Board of Pharmacy makes the following:

FINDINGS OF FACTS

1. Respondent is a Registered Pharmacy Technician in North Dakota and was issued Permit No. 828 for certification to practice as a Pharmacy Technician in the State of North Dakota.

2. That Executive Director, Howard C. Anderson, Jr., R.Ph., received an e-mail from Justin Heiser, Pharmacy District Manager of Thrifty Drug Stores, Inc., informing Mr. Anderson that Thrifty White had terminated the employment of Huwe, who was employed at the Thrifty White Store #17 in Minot, North Dakota. See Exhibit 1. Upon discussions with officers and managers of Thrifty White and other investigation by the Investigating Committee, the Complaint and Statement of Charges as well as the Order for Temporary Suspension was issued.

3. Thrifty White #17 Pharmacist-in-Charge, Bryce Bergeron, testified that personnel of the pharmacy discovered missing narcotics and Schedule II narcotics from the routine inventory counts performed in the pharmacy. Internal investigation narrowed the perpetrator to be Huwe. Based upon finding bottles of Schedule II drugs in her work area when no such prescriptions were filled and dispensed during the times she was scheduled to work and from taking inventory of the schedule II drugs of the pharmacy which were short during the times of which she was working for Thrifty White.

Pharmacist-in-Charge Bergeron confronted Huwe regarding the missing drugs. During the confrontation, Huwe did produce some of the narcotics from her purse. An inventory of the pharmacy supply of Oxycotin revealed a shortage of pills in the same amount that was in the possession of Huwe. Huwe's employment with Thrifty White was immediately terminated and Minot Law Enforcement was notified.

4. Pharmacist-in-Charger Bergeron, when asked of the amount of drugs that were taken from the pharmacy by Huwe, stated that the value of the stolen drugs amounted to $5,585.00. See Exhibit 2 DEA Form 106, Report of Theft or Loss of Controlled Substances. Pharmacist-in-Charge Bergeron stated that he did not think that most of the drugs stolen were personally ingested by Huwe.

5. Huwe apologized to the Pharmacist-in-Charge Bergeron and the Board and stated that she was uncomfortable saying much more due to the current criminal case against her.

From the foregoing FINDINGS OF FACTS and in conformity therewith, the Board makes the following:

CONCLUSIONS OF LAW

1. Respondent, Sarah M. Huwe, is a Registered Pharmacy Technician in the State of North Dakota, certified by the Board and was issued Certificate No. 828, to certify registration to practice as a Pharmacy Technician in the State of North Dakota.

2. Investigation by the Board's Investigating Committee and other investigation as well as testimony heard during the hearing, shows that Respondent, Sarah M. Huwe, violated provisions of law and is subject to disciplinary administrative action by the Board because of her actions of diverting narcotics as follows:

   a. The unlawful, willful possession of controlled substances that were not obtained directly from or pursuant to a valid prescription or order of a practitioner while acting in the course of the practitioner's professional practice. Section 19-03-01.23(7) NDCC.

b. Engaged in unprofessional conduct as defined by Section 61-04-04-01 of the ND Admin. Code for purposes of Section 43-15-10(1) NDCC by violating or attempting to violate directly and indirectly through actions of another assisting or abetting the violation of or conspiring to violate any provision or term of NDCC Chapter 43-15, the Prescription Drug Marketing Act, the Robinson Patman Act, or the applicable federal and state laws and rules governing pharmacies or pharmacists in violation of Section 43-15-1(h)(i) NDCC and Section 61-04-04-01(1) ND Admin. Code.

3. The Board has the authority in regard to the violations of law and grounds for disciplinary action stated in the above Conclusion of Law to place on probation, reprimand, or fine any pharmacy technician or to suspend, revoke, restrict or cancel the registration of any pharmacy technician. Section 43-15-10(1) NDCC.

4. The Board has the authority to direct a technician found not in compliance or in violation of one or more of the grounds set forth in Section 43-15-10(1) to pay the Board a sum not to exceed the reasonable and actual costs of the investigating and prosecution of the case. Section 43-15-45 NDCC.

From the foregoing FINDINGS OF FACTS and CONCLUSIONS OF LAW, the Board now makes and files herein its ORDER

The greater weight of the evidence shows that Respondent, Sarah M. Huwe, violated the provisions of law and engaged in activities and conduct that are grounds for administrative disciplinary action under the provisions of law stated in Conclusion of Law #2. Because of the violations and grounds, it is hereby ORDERED:

1. Respondent's registration to practice as a pharmacy technician is hereby suspended.

2. Respondent may make a request to the Board for reinstatement of her Pharmacy Technician Registration subject to the completion of the following terms:

a. Respondent shall enter into a contract with the Pharm-Assist Committee and follow the recommendations and directions they provide, and continue and complete any other treatment she currently is receiving. Respondent shall keep the Board informed of her progress at all times and sign a release to authorize any reports of her treatment, including psychiatric treatment, be forwarded directly to the Board's Executive Director.

b. Respondent shall violate no federal, state or local drug laws, regulations or rules.

c. Respondent shall reimburse the Board the cost of the investigation and prosecution incurred by the Board in the amount of $1,165.00.

Dated this _27th__ day of September, 2010.

North Dakota State Board of Pharmacy

By: Rick L. Detwiller, R.Ph., President
(701) 328-9535

Attest: Howard C. Anderson, Jr., R.Ph., Secretary
1906 East Broadway Avenue
PO Box 1354
Bismarck, ND 58502-1354

Melissa Gedde, ND Pharmacy Technician #602; the case was explained by Executive Director Anderson. Her registration was initially suspended, as it was feared that the errors she made at the pharmacy she worked may have indicated a diversion of prescription drugs, or the possible dilution of some liquid preparations. It was later determined by her employer, that though errors had occurred, these probably did not indicate any diversion or adulteration on her part. Therefore the Board of Pharmacy issued an order reinstating her registration completely. See Addendum A at the end of the minutes.

Jody Doe, R.Ph. ND Pharmacist #4525 and **Barbara Buzalsky, ND Pharmacy Technician #1182** representing themselves and North Dakota Pharmacy Permit #590 issued to **New England Drug** appeared before the Board, signed the Stipulated Agreement that had been sent to them and answered questions from the Board Members about the incident relating to the complaint.

It was moved by Pharmacist Haroldson and seconded by Pharmacist Ziegler to accept the signed Stipulated Agreement from Jody Doe, R.Ph. ND Pharmacist #4525 *and* ***Barbara Buzalsky, ND Pharmacy Technician #1182*** *and* ***New England Drug, North Dakota Pharmacy Permit #590. All Board Members present voted aye – motion carried.*** *[Copy of Stipulated Agreement follows:]*

BEFORE THE NORTH DAKOTA STATE BOARD OF PHARMACY

IN THE MATTER OF THE CERTIFICATE OF)
REGISTRATION OF JODY DOE, R.Ph, AS A)
LICENSED PHARMACIST No. 4525) **FINDINGS OF FACTS,**
ENTITLED TO PRACTICE PHARMACY IN) **CONCLUSIONS OF LAW**
THE STATE OF NORTH DAKOTA) **AND**
ORDER

RESPONDENT.

IN THE MATTER OF CERTIFICATE OF)
REGISTRATION OF BARBARA BUZALSKY)
AS A REGISTERED PHARMACY TECHNICIAN)
No. 1182 ENTITLED TO PRACTICE IN)
THE STATE OF NORTH DAKOTA)

RESPONDENT.

THE REGISTRATION OF NEW)
ENGLAND DRUG)
LICENSED TO OPERATE A)
PHARAMCY PERMIT No. 590)
IN THE STATE OF NORTH DAKOTA)

RESPONDENT. Administrative No. 2010-04-27-00188

On July 21, 2010, a Complaint and Statement of Charges ("Complaint") was filed with the North Dakota State Board of Pharmacy ("Board") by David A. Lindell, Special Assistant Attorney General, Counsel for the Board, and Howard C. Anderson, Jr. R. Ph., Executive Director of the Board and Chairman and member of the Board's Investigating Committee, requesting certain administrative action against the certificate and registration ("Certificate No. 4525") of Jody Doe, R. Ph. ("Doe") as a licensed pharmacist in the State of North Dakota, and the registration ("Permit No. 1182) of Barbara Buzalsky ("Buzalsky") as a licensed pharmacy technician in the State of North Dakota, and the registration ("Permit No. 590) of New England Drug, Inc., a holder of a permit entitled to operate a pharmacy in the State of North Dakota.

The Complaint sites as grounds for administrative action, a violation of Sections 19-02.1-15.1(2), 43-25-01, 43-15-43(4), and 43-15-10(1)(i) of the North Dakota Century Code and Sections 61-04-04-06-03(11) and 61-04-04-01(1) of the North Dakota Administrative Code, more specifically set forth in Paragraph VI of the Complaint, Subsections a-d.

The Respondents were served the Complaint and Statement of Charges, and a Notice of Hearing by certified mail, which was received by the Respondents on July 22, 2010. A Stipulation, Settlement Agreement and Recommendation of Discipline was stipulated and agreed to by Respondents and Howard C. Anderson, Jr., R. Ph., the Executive Director of the Board regarding the sentence and discipline for the Respondents. The Respondents, Jody Doe and Barbara Buzalsky met with the Board at a Board Meeting held on September 9, 2010.

NOW, THEREFORE, upon agreement of Respondent and the Executive Director of the Board, the North Dakota State Board of Pharmacy makes the following:

FINDINGS OF FACTS

1. Respondent, JODY DOE, R.Ph., is a licensed pharmacist in North Dakota, and was issued Certificate No. 4525 to certify licensure to practice pharmacy in the State of North Dakota, and who is Pharmacist-in-Charge and majority owner of NEW ENGLAND DRUG, INC., whose last known address is PO Box 238, Kildeer, North Dakota 58640-0238.

2. Respondent, BARBARA BUZALSKY, is a registered pharmacy technician in North Dakota, holding Certificate No. 1182, whose last known address is PO Box 368, New England, North Dakota 58647-0368, and who is employed by and works at New England Drug, Inc. in New England, North Dakota.

3. Respondent, NEW ENGLAND DRUG, Inc. is a registered holder of a permit to operate a community (retail) drug store in the State of North Dakota, and was issued Pharmacy Permit No. 590, and whose registered address is PO Box 238, Kildeer, North Dakota 58640-0238.

4. Board Executive Director, Howard C. Anderson, Jr., R. Ph., received from NDBCI agent Nicholas Gates, prescriptions written by Dr. Michael L. Cassidy, MD, which were prescribed for his patient (BI) and were filled at New England Drug, Inc. The drugs prescribed were Oxycodone and Hydrocodone/APAP10-325 and Hydrocodone BT/Ibuprofen. Executive Director Anderson reviewed the prescriptions which showed that on many of the prescriptions the date of the prescriptions and when they were filled were altered and prescriptions were filled prior to the date written. Other prescriptions may not have contained a physician's signature as required and had been refilled prior to when the quantity of the prior prescription had run out, which would allow the patient to receive the drugs in excess of the prescriber's intentions and incorrectly entered into the pharmacy's computer system. The Respondent's admitted to these actions, but informed that the prescribing physician had been contacted regarding the earlier refills and the Respondent Buzalsky was informed to provide the prescription refill, although such verification was not indicated on any of the prescriptions. Respondents admitted that they should have showed any verifications on the prescription or in the pharmacy's computer system and should not have changed or altered any of the prescriptions so that the refills would be allowed in the pharmacy's computer system.

From the foregoing FINDINGS OF FACTS and in conformity therewith, the Board makes the following

CONCLUSIONS OF LAW

1. Respondent, Jody Doe, R. Ph. as a licensed pharmacist in North Dakota, and was issued certificate No. 4525 to certify licensure to practice pharmacy in the State of North Dakota, and is the pharmacist in charge and the majority owner of New England Drug, Inc., a registered holder of a permit to operate a community/retail pharmacy or drug store in the State of North Dakota, which was issued Permit No. 590.

2. Respondent, Barbara Buzalsky is a registered pharmacy technician in North Dakota, holding Certificate No. 1182 to certify registration to practice as a pharmacy technician in the State of North Dakota.

3. Investigation by the Board's investigating committee and Respondents admissions show that the Respondents have violated provisions of law and is subject to disciplinary administrative action by the Board because of their actions as follows:

a. Delivered, distributed or dispensed a controlled substance or specific drug without a valid prescription as defined by NDCC Sections 43-15-01(26) in violation of Section 19-02.1-15.1(2).

b. Dispensed controlled substances with a prescription that did not contain the signature of the prescriber in violation of Section 43-25-01 NDCC and Section 61-04-06-03(11) ND Admin. Code.

c. Dispensed a greater or less quantity of an article than that prescribed or ordered in violation of Section 43-15-43(4) NDCC.

d. Engaged in unprofessional conduct by making or filing a report or record which a pharmacist or pharmacy knows to be false and violating provision or term of the North Dakota Century Code Chapter 43-15 or of the applicable Federal and State Laws and Rules governing pharmacies or pharmacists in violation of Section 43-15-10(1)(i) NDCC, and Section 61-04-04-01(1) ND Admin Code.

4. The Board has the authority in regards to the violations of law and grounds for disciplinary action stated in the above Conclusions of Law, to place on probation, reprimand, or fine any licensed pharmacist or pharmacy or suspend, revoke, restrict or cancel the license of any licensed pharmacist. Section 43-15-10(1) NDCC.

5. The Board has the authority to direct a pharmacist found not in compliance with the drug laws and rules of the State of North Dakota, to pay to the Board the sum not to exceed the reasonable actual costs of their investigation or prosecution of the case. Section 43-15-45 NDCC.

From the foregoing FINDINGS OF FACTS AND CONCLUSIONS OF LAW, the Board now makes and filed herein its

ORDER

The greater weight of the evidence shows and the Respondents admit in their Stipulation and directly to the Board that they violated the provisions of law and engaged in activities and conduct that are grounds for administrative disciplinary action under the provisions of law stated in the Conclusions of Law No. 2. Because of the violations and grounds, it is hereby

ORDERED:

1. That Respondent JODY DOE's pharmacist license shall be suspended for a period of 30 days, with said suspension stayed for a period of three (3) years in which Respondent's pharmacist license shall be placed on probation during that time.

2. That Respondent BARBARA BUZALSKY's pharmacy technician registration shall be suspended for a period of 30 days, with said suspension stayed for a period of three (3) years in which Respondent's technician registration shall be placed on probation during that time.

3. That Respondent NEW ENGLAND DRUG's pharmacy permit shall be suspended for a period of 30 days, with said suspension stayed for a period of three (3) years in which Respondent's pharmacy permit shall be placed on probation during that time.

4. That Respondent JODY DOE pay to the Board a fine in the amount of $500.00. Payment shall be made by November 1, 2010.

5. That Respondent NEW ENGLAND DRUG, INC. pay to the Board a fine in the amount of $500.00. Payment shall be made by November 1, 2010.

6. That the Respondents' stay of suspension shall be subject to the following terms and conditions:

a. Respondents shall violate no local, state or federal drug laws, regulations or rules.

b. No prescriptions will be filled without a valid signature from the prescriber. That accurate days supply calculations will be used in the computer record on all prescriptions and that these prescriptions will not be refilled earlier than would be indicated by the prescriber's

intention for the care of the patient. Reasonable variances will be expected to be sure the patient has their medication on weekends or when the prescriptions are being mailed.

c. Respondents shall reimburse the Board the costs of the investigation and prosecution incurred by the Board in the amount of $1,006.15. Payment shall be made by November 1, 2010.

Dated this _27th_ day of September, 2010.

North Dakota State Board of Pharmacy
By: Rick L. Detwiller, R. Ph., President
701-328-9535

Attest: Howard C. Anderson, Jr., R.Ph., Secretary
1906 East Broadway Avenue – P O Box 1354
Bismarck, ND 58502-1354

Kevin Oberlander, R.Ph. ND Pharmacist #3934 representing both Dakota Pharmacy – ND Pharmacy Permit #5 and **Dakota Precision Rx ND Pharmacy Permit #428** was present to discuss the details of this complaint. Pharmacist Oberlander has signed a Stipulated Agreement provided by Executive Director Anderson and Attorney Lindell.

It was moved by Pharmacist Ziegler and seconded by Pharmacist Haroldson to accepted the Stipulated Agreement as signed by Pharmacist Kevin Oberlander for himself, Dakota Pharmacy and Dakota Precision Rx. This will not be considered a Final Action until the one year time period is up.. All Board Members present voted aye – motion carried.

President Rick Detwiller arrived at the meeting in time to join in the quick lunch that was brought in from the outside and assumed Chairmanship of the Board Meeting.

President Detwiller resumed the Board Meeting at 12:50 PM and Board Members signed Original Certificates for Pharmacists and Pharmacy Technicians to be used in the future, for licensure and registration.

Michael Schwab, Executive Director of the North Dakota Pharmacists Association arrived at the meeting and suggested that the ND Pharmacists Association and the Board of Pharmacy partner together to publicize the "Drug Destruction and Take-A-way Program" – the "Prescription Drug Repository Program" and to publicize to the citizens of North Dakota the "Patients Bill of Rights" which has been adopted as a rule by the Board of Pharmacy. The Pharmacist Association will develop the brochures, public service announcements or paid advertisements for radio and print media. We will use the previously prepared television piece for the Repository Program. The Pharmacist Association agreed to arrange for the advertizing times and placement, and all materials are to be approved by the Executive Director of the Board of Pharmacy.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Thom to provide up to $28,700.00 for these three projects as described by Association Executive Director Schwab. The focus of the project will be about the patient and will begin approximately September 24th, 2010 along with the Drug Enforcement Administration [DEA] Take Back Day. On a vote by Roll Call: Pharmacist Detwiller – Aye Pharmacist Dewhirst – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

Mr. Schwab presented the concept of developing a Pain Management Course for pharmacists, as they had some overtures from Workforce Safety & Insurance that a coordinated program was

needed within the State. He suggested combining this course with the general medication therapy management training. Board Members suggested that the pain management training also be made available to nurse practitioners, physician assistants, and physicians within North Dakota as well.

It was moved by Pharmacist Thom and seconded by Pharmacist Dewhirst to allocate up to$45,000 of enhancement grant funds to a Medication Therapy Management and specific Pain Management Program for pharmacists and practitioners. On a vote by Roll Call: Pharmacist Detwiller – Aye Pharmacist Dewhirst – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

At 1:30 PM the complaint that had been issued to **PetMeds Express** – North Dakota Out-of-State Pharmacy Permit #279 was reviewed by the Board. Attorney Lindell had elicited a Stipulated Settlement with PetMeds Express in which they will change the format of their fax to Veterinarians eliminating the default of one refill on their faxed prescription requests. A letter was received from the attorney of PetMeds Express indicating this and Dr. Rick Odegard, the original complainant, told Attorney Lindell that he had already received the new fax request form which has been brought into compliance with our request.

It was moved by Pharmacist Haroldson and seconded by Pharmacist Ziegler to accept the PetMeds Express – ND Out-of-State Pharmacy Permit #279 Stipulated Agreement settlement. All Board Members voted aye – the motion carried. See Addendum B at the end of the minutes.

Pharmacist Curt Larson, CVS Pharmacy District Manager arrived at the meeting.

The Board of Pharmacy discussed the complaint issued to CVS #8628 [525 South 3rd Street Bismarck ND 58504] ND Pharmacy Permit #107, which centered around filling a prescription and refilling said prescription more often than the prescriber had requested, when she had clearly marked "no early refills" on the face of the prescription. A Stipulated Agreement Settlement signed by Susan DelMonico, R.Ph., JD, Director of Regulatory Compliance of CVS was presented. Pharmacist Curt Larson explained the controls that had been put into place at CVS pharmacies to prevent similar incidents from happening in the future.

It was moved by Pharmacist Thom and seconded by Pharmacist Dewhirst to approve the signed Stipulated Settlement with CVS #8628 [525 South 3rd Street Bismarck ND 58504***] ND Pharmacy Permit #10. All Board Members voted aye – the motion carried.*** See Addendum C at the end of the minutes.

The time arrived for the Hearing set for Lambert Vet Supply. Attorney Lindell reported that a Stipulated Agreement had been sent to Lambert and that he and Executive Director Anderson had agreed with Lambert's attorney to defer the conduct of the hearing until our January 2011 Board Meeting as there was not enough time for them to obtain a North Dakota Licensed Attorney to represent them at this meeting. The hearing for Lambert Vet Supply will be deferred to the January 2011 Meeting.

Mark Pajala, North Dakota Pharmacist #3988 and his wife, Linda joined the meeting. President Detwiller asked if it was alright to proceed with the discussion of Mark's case, since it was 3:40 PM. All were in agreement.

Pharmacist Pajala presented his request to the Board, saying he would like the Order issued to him to be modified to allow him to work alone in a pharmacy, as he was having difficulty obtaining employment with the current restriction that he could only work with another pharmacist present in the pharmacy. Because a year has passed since his original Order with the Board, he has received excellent reports from the Pharm-Assist Committee, his treatment program and counselors; he has kept good compliance with his reporting to Executive Director Anderson and having all of his drug screens clear, the Board viewed his request favorably.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Thom to grant the variation to the original Order of Pharmacist Mark Pajala and allow his work full time and alone in a pharmacy. All the other elements of his Original Order will remain in place. All Board Members voted aye – the motion carried.

At 4:15 PM President Detwiller welcomed veterinarians Dr. Boyce, who is the Executive Secretary of the Veterinary Medical Examiners Board, Drs. Clement, Martin and Dr Vollmer, a member of the Board of Animal Health, as well as Veterinary Medical Association Executive Nancy Kopp to the meeting. They have come to discuss the issue of Veterinary Legend Drug dispensers for food producing and non-traditional livestock. A suggested rule change by the Board of Veterinary Medical Examiners was presented by Dr. John R. Boyce. The rule would allow their veterinarians to dispense medication under a second veterinarian's prescription in emergencies or times when the second veterinarian was out of stock. The veterinarian would need to obtain confirmation of the prior veterinarian/client relationship before dispensing the medication. A draft of the rule is follows:

87-04-01-02(4) A veterinarian may dispense limited quantities of a prescription drug, other than a controlled substance, prescribed by another veterinarian, including a veterinarian licensed in another state, if the prescribing veterinarian does not have an adequate supply of the drug in inventory, or if failure to dispense the drug could interrupt a therapeutic regimen or cause the animal to suffer. The dispensing veterinarian must verify with the prescribing veterinarian, who has established the veterinarian-client-patient relationship, that the drug is appropriate and necessary for the animal, and must comply with the record keeping and labeling requirements of this chapter.

A draft prepared by legal intern, Justin Stubstad, PharmD, for legislation to make legal what is occurring in our farm supply stores, relative to the selling of veterinarian drugs directly to owners of food producing and non-traditional livestock, was discussed. The veterinarians asked that they be given time to present this draft to all the veterinarians around the state before the decision be made to introduce it as a proposed piece of legislation. The Board of Pharmacy indicated that we would hold a conference call sometime around the end of October or early November to determine what legislation would be prefiled for the 2011 Legislative Session.

All present seemed in agreement that the draft was well done by Dr. Stubstad, and that he should be commended.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Thom to proceed with the rule making process for the proposed rule on Positive Identification for Controlled Substances. All Board Members voted aye – the motion carried. A copy of the rule follows:

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.

It was moved by Pharmacist Ziegler and seconded by Pharmacist Dewhirst proceed with the rule making process for the 795 and 797 Compounding Requirements. All Board Members voted aye – the motion carried. A copy of the Rule follows:

61-02-01-03. Pharmaceutical compounding standards. The minimum standards and technical equipment to be considered as adequate shall include:

1. **Definitions.**

a. "Active Chemical or Ingredient" refers to chemicals, substances, or other components of articles intended for use in the diagnostics, cure, mitigation, treatment, or prevention of diseases.

b. "Aseptic Processing" is the method of preparing pharmaceutical and medical products that involves the separate sterilization of the product and of the package, the transfer of the product into the container and closure of the container under ISO Class 5 or superior conditions and using procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during the process.

c. "Beyond Use Date" refers to the date placed on a prescription label that is intended to indicate to the patient or caregiver a time beyond which the contents of the prescription are not recommended to be used. The beyond-use date is determined from the date or time compounding of the preparation is completed.

d. "Component" is any ingredient used in the compounding of a drug product, including any that are used in its preparation, but may not appear on the labeling of such a product .

e. "Compounding" is the preparation, mixing, assembling, packaging, and labeling of a drug or device in accordance to a licensed practitioner's prescription or medication order. Compounding includes:

i. Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

ii. Reconstitution or manipulation of commercial products that may require the addition of one (1) or more ingredients as a result of a licensed practitioner's prescription drug order.

iii. Preparation of drugs or devices for the purposes of, or as an incident to, research, teaching, or chemical analysis.

iv. Categories of compounding.

1. Category 1 – Non-sterile Simple.

a. Simplex – Mixing of two (2) or more commercial products.

b. Complex – Compounding with the bulk drug substances or when calculations are required.

2. Category 2 – Sterile Compounds.

a. Immediate Use (containing no more than three (3) sterile, commercially supplied non-hazardous drugs with administration starting within one (1) hour of the beginning of preparation and completed within twelve (12) hours.

b. Low Risk – Risk Level I

c. Medium Risk – Risk Level II

d. High Risk – Risk Level III

3. Category 3 – Radiopharmaceuticals.

4. Category 4 – Veterinary pharmaceuticals.

f. "Compounded Sterile Preparation" (CSP)will include all of the following:

i. Preparations prepared according to the manufacturer's labeled instructions and other manipulations when manufacturing sterile products that expose the original contents to potential contamination.

ii. Preparations containing non-sterile ingredients or employing non-sterile components or devices that must be sterilized before administration.

iii. Biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that possess either of the above two characteristics, and which include, but are not limited to, baths and soaks for live organs and tissues, implants, inhalations, injections, powders for injection, irrigations, metered sprays, and ophthalmic preparations.

g. "Compounder or Compounding Personnel" is the pharmacist or other licensed health care professional responsible for preparing the compounded preparations.

h. "Compounding supervisor" is a person who supervises and is responsible for the compounding and dispensing of a non-sterile or sterile preparation.

i. "Critical Site" is a location that includes any component or fluid pathway surfaces (such as injection ports) or openings (such as opened ampules or needle hubs) exposed and at risk of direct contact with air, moisture, or touch contamination.

j. "Direct and Contiguous Compounding Area" refers to the specific area where a compound is prepared.

k. "Disinfection" is the process by which the total number of microorganisms is reduced to a safe level or eliminated by applying an agent to inanimate objects that destroys disease-causing pathogens or other harmful microorganisms but may not kill bacterial and fungal spores.

l. "Immediate-Use" is defined as a compound prepared with no more than three (3) sterile, commercially supplied non-hazardous drugs; using commercial, sterile devices; the compounding process is a continuous process not to exceed one (1) hour and administration begins not later than one (1) hour following the start of the preparation of the compound and to be completed within twelve (12) hours, not including any chemotherapy or other hazardous drug preparations.

m. "ISO Class" is the description of an atmospheric environment characterized by the number of particles within a diameter per cubic foot of air.

    i. "ISO Class 5" atmospheric environment contains less than 100 particles, 0.5 microns or larger in diameter per cubic foot of air.

n. "Media Fill Test" refers to tests used to validate aseptic techniques of compounding personnel and of processes that ensure the personnel and processes used are able to produce sterile products without microbial contamination; testing uses a microbiological growth medium to substitute for the actual drug product to simulate admixture compounding in determining the quality of a person's technique.

o. "NDC Number "is the National Drug Code given to each drug separately and specifically approved by the Food and Drug Administration for identification and reporting.

p. "Preparation" is a drug dosage form, dietary supplement, or a finished device; it contains one (1) or more substances formulated for use on or for the patient or consumer.

q. "Primary Engineering Control" or PEC refers to a device or room that provides an ISO Class 5 or superior environment during the compounding process; including, but not be limited to, laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).

r. "Product "is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA; accompanied by full prescribing information.

s. "Repackaging" is the transfer of an excipient from one container to another.

t. "Risk levels" of CSPs determine the level assigned that represent the probability that it will be contaminated with microbial organisms, spores, endotoxins, foreign chemicals, or other physical matter.

u. "Stability" is defined as the extent to which a preparation retains, with specified limits, and throughout its period of storage and use, the same properties and characteristics it possessed at the time of compounding.

v. "Seventy Percent (70%) Isopropyl Alcohol" or IPA is a sterile microbial used to clean surfaces used in sterile preparations.

w. "US Pharmacopeia" or USP is the book of official compendia of standards for the United States.

2. **General Compounding.**

a. Responsibility of the Compounder.

i. Personnel engaging in compounding must be proficient, capable, and qualified to perform assigned duties in the compounding area while expanding his or her knowledge of compounding through seminars or appropriate literature

ii. Compounding personnel must be familiar with USP Standards and North Dakota regulations including but not limited to:

1. Certifying all prescription orders.

2. Approving or rejecting all components, drug product containers, closures, in-process materials, and labeling ensuring preparations and ingredients are of acceptable strength, quality, and purity, with appropriate packaging.

3. Preparing and reviewing all compounding records to assure that errors have not occurred in the compounding process and the finished product has expected qualities as well as implement procedures to prevent cross-contamination.

4. Assuring the proper maintenance, cleanliness, sanitization and use of all equipment used in prescription compounding practice including the direct and contiguous compounding area allowing for the compounding environment to be suitable for its intended purpose.

a. Established procedures must be performed at the beginning of each shift, using approved residue-free sanitizers and non-shedding equipment.

5. Assuring that the drug product and components of drug products are not on the list of federally recognized drug products that have been withdrawn or removed from the market for public health reasons.

iii. Policies and procedures must be established concerning washing and donning the appropriate clothing specific to the type of process performed to protect the personnel from chemical exposures and prevent drug contamination.

b. **Training.** All compounding supervisors and all personnel involved in compounding must be well trained and must participate in current, relevant training programs. All training activities will be covered by standard operating procedures and must be properly documented. Steps in the training procedure include:

i. Be familiar with *Pharmaceutical Compounding – Non-Sterile Compounding* (USP 795), *Pharmaceutical Compounding – Sterile Compounding* (USP 797), and *Pharmaceutical Calculations in Prescription Compounding* (USP 1160).

ii. Be familiar with all procedures relating to compounding specific to your facility, equipment, personnel, compounding process, evaluation, packaging, storage, and dispensing.

iii. Compounding supervisors must be responsible to follow the instructions below to show that personnel are appropriately trained:

1. Demonstrate compounding procedures to compounding personnel.

2. Guide personnel through the compound process with assistance.

3. Observe personnel performing a compound without assistance but under supervision.

4. Review the compound, correct mistakes and answer questions concerning compounding and associated processes.

5. Confirm verbal and functional knowledge of the personnel concerning compounding.

6. Have personnel perform a compounding procedure without supervision, yet checking off the final preparation.

7. If properly compounded and when satisfied, sign the documentation records confirming appropriate training.

8. Continually monitor the work of the personnel including calculations.

iv. Compounding supervisors are ultimately responsible for the finished product.

c. Procedures and Documentation. Procedures must be developed for the facility, equipment, personnel, preparation, packaging and storage of the compounded preparation to ensure accountability, accuracy, quality, safety, and uniformity in compounding. This allows for a compounder, whenever necessary, to systematically trace, evaluate, and replicate the steps included throughout the preparation process of a compounded preparation.

d. **Drug Compounding Facilities** must include all of the following:

i. Compounding facilities and equipment are clean, accurate, of appropriate size and construction and properly inspected and the compounding environment is properly maintained, isolated and inspected.

1. Personnel must have a written plan and schedule while maintaining records of cleaning and disinfecting.

ii. Aseptic processes must be conducted in an area separate from the area used for non-sterile preparations.

iii. Areas designated for compounding including space for storage must have adequate space, designed and well-lighted to prevent mix-ups, errors or adventitious cross-contamination.

iv. Heating, ventilation, and air conditioning systems are controlled to avoid decomposition of chemicals.

v. A supply of potable water is available for washing with adequate washing facilities that are easily accessible including, but not limited to, hot and cold water, soap or detergent, and an air dryer or single use towels.

1. Plumbing system should be free of defects that could contribute to contamination of the compounded product.

vi. All areas maintained in a clean and sanitary condition; trash, sewage and other refuse should be disposed of in a safe and timely manner.

vii. Bulk drugs, chemicals, or materials must be properly labeled and stored in an area that is clean, dry, at appropriate temperature (i.e., controlled room, refrigerator, or freezer), and protected from contamination .

e. Drug Compounding Equipment.

i. Equipment and utensils must be of appropriate design and capacity and properly stored to avoid contamination while located in a place appropriate for facility operations for its use, maintenance, and cleaning.

ii. All equipment must be constructed so that surfaces that contact components, in-process materials, or finished preparations are not reactive, additive, or adsorptive to avoid altering the preparation.

iii. Equipment, apparatus, and devices used to compound a preparation must be calibrated, maintained, and monitored for proper function; records must be kept for the lifetime of the equipment.

f. **Packaging, Drug Preparation Containers, Storage, and Beyond-Use Dating.**

i. Containers and container closures.

1. Must meet USP requirements found under *Containers – Glass* (USP 660), *Containers – Plastic* (USP 661), and *Containers – Performance Testing* (USP 671).

2. Those intended for compounding of sterile and non-sterile preparations must be handled, sterilized (if appropriate), and stored according to *Pharmaceutical Compounding – Sterile Preparations* (USP 797) and *Pharmaceutical Compounding – Non-Sterile Preparations* (USP 795).

3. Must be stored off the floor, handled and stored to prevent contamination, and rotated to use the oldest stock first.

4. Must be stored in a way to facilitate inspection and cleaning

5. Must be constructed in such a way that surfaces are not reactive, additive, or absorptive.

6. The containers and closures shall be of suitable material so as not to alter the quality, strength, or purity of the compounded drug.

ii. Storage area.

1. Compounded preparations must be stored strictly in accordance with the conditions stated on the label of ingredient products and finished preparations.

2. Monitoring of appropriate temperatures must occur daily for controlled storage areas and temperatures recorded in the Temperature Log.

a. Controlled room temperature areas, 20°C to 25°C with mean kinetic temperature 25°C.

b. Controlled cold temperature, 2° C to 8°C with mean kinetic temperature 8°.

c. Controlled freezing temperature, -25° C to -10° C.

iii. Beyond-Use dates.

1. The compounder must establish an appropriate beyond-use date determined by drug-specific chemical and physical stability parameters of the components in

conjunction with the manufacturer's product label, appropriate literature and USP Standards.

2. Compounders establish a beyond-use date considering the nature of the drug, degradation mechanism, purposed container, expected storage conditions, and intended duration of therapy.

3. Beyond-use dating is assigned conservatively to all compounded preparations excluding immediate-use preparations.

   a. For non-aqueous liquids and solid formulations where the manufactured drug product is the source of active ingredient, the beyond-use date is no later than twenty-five percent (25%) of the time remaining until the product's expiration date or six (6) months, whichever earlier.

   b. For water-containing, liquid formulations prepared from ingredients in solid form, the beyond-use date is no later than fourteen (14) days when stored at cold temperatures between two and eight degrees Celsius (2°C to 8°C).

   c. For all other formulations the beyond-use date is no later than the intended duration of therapy or thirty (30) days, whichever is earlier unless supporting valid scientific stability information can be applied.

4. Solid or liquid forms of drugs without manipulation that are transferred from one container to another is defined as repackaging and not compounding; the beyond use date is not to exceed the manufacturer's date or one (1) year use date, whichever is less.

   g. Compounding Controls.

      i. Compounder must ensure that the written procedures for compounding are available electronically or in hard copy and assure the finished products have the correct identity, strength, quality, and purity.

      ii. Procedures must be established that give a description of the following:

         1. Components and their amounts.

         2. Order of component additives.

         3. Compounding process.

         4. Drug product.

         5. Required equipment and utensils including container and closure system.

      iii. The compounder will accurately weigh, measure, and subdivide all components as appropriate.

         1. Compounder will check and re-check each procedure at each point of the process to ensure that each weight or measure is correct.

         2. If a component is transferred from the original container to another, the new container must be identified with the component name, weight or measure, the lot or control number, the expiration or beyond-use date, and the transfer date.

      iv. The compounder must write procedures that describe the tests or examinations that prove uniformity and integrity of the compounded preparations

v. Control procedures must be established to monitor the output and validate the performance of compounding personnel that affect variability of final preparations such as:

1. Capsule weight variation.

2. Adequacy of mixing to assure uniformity and homogeneity.

3. Clarity, completeness, or pH of solutions.

vi. The compounder must establish an appropriate beyond-use date for each compounded preparation.

vii. Facilities engaging in compounding must have a specifically designated and adequate space for orderly compounding of non-sterile and sterile preparations, including the placement and storage of equipment and materials.

h. **Labeling.**

i. The compounder's preparation label will contain all information required by North Dakota state law and accepted standards of practice found under *Chapter 61-04-06 Prescription Label Requirements*.

ii. The compounder will label any excess compounded products so as to refer to the formula used.

iii. Preparations compounded in anticipation of a prescription prior to receiving a valid prescription should be made in a regularly used amount based on the history of prescriptions filled, they should be labeled with:

1. Complete list of ingredients or preparation time and reference or established chemical name or generic name.

2. Dosage form.

3. Strength.

4. Preparation date and time.

5. Inactive ingredients.

6. Batch or lot number.

7. Assigned beyond-use date.

8. Storage conditions

iv. The compounder must examine the preparation for correct labeling after completion.

i. Records and Reports.

i. Records must be maintained including, but not limited to, a hard copy of the prescription with formulation and compounding records.

ii. Adequate records of controlled substances used in compounds.

iii. All records must be kept for 5 years according to North Dakota state law and be available for inspection.

1. **Formulation Record** provides a consistent source document for preparing the preparation and must list:

   a. Name, strength, and dosage form of the preparation compounded.

   b. All ingredients and their quantities.

   c. Equipment needed to prepare the preparation, when appropriate.

   d. Mixing instructions including order of mixing, mixing temperatures, and other valid instructions such as duration of mixing.

   e. Assigned beyond-use date.

   f. Container used in dispensing.

   g. Storage requirements.

   h. Any quality control procedures.

2. **Compounding Record** documents the actual ingredients in the preparation and the person responsible for the compounding activity and includes:

   a. Name and strength of the compounded preparation.

   b. The formulation record reference.

   c. Sources and lot numbers of the ingredients.

   d. Total number of dosage units compounded.

   e. Name of compounding personnel who prepared the preparation.

   f. The date of preparation.

   g. The assigned internal identification number or prescription number.

   h. Assigned beyond-use date.

   i. Results of all quality control procedures.

3. **Temperature Log** records the daily monitoring of temperatures in the storage area specifically for the controlled room temperature, refrigerator, freezer or incubator

   j. **It is acceptable** to compound drug products to be used by practitioners in their office for administration to patients. These products cannot be dispensed or sold to others. Sales to other pharmacies, clinics, or hospitals are manufacturing and are not allowed.

3. Non-Sterile Compounding. Compounders are to use the following steps to minimize error and maximize the prescriber's intent, specifics can be found in *Pharmaceutical Compounding – Non-Sterile Compounding* (USP 795):

   a. Judge the suitability of the prescription of the preparation in terms of safety and intended use.

b. Perform necessary calculations to establish the amounts of ingredients needed

c. Identify equipment and utensils needed.

d. Don the proper attire and properly wash hands and arms.

e. Clean the compounding area and needed equipment .

f. Only one (1) prescription can be compounded at a time in the specified compounding area.

g. Assess weight variation, adequacy of mixing, clarity, odor, color consistency, and pH as appropriate of the completed preparation.

h. Annotate the compounding and formulation records.

i. Label the prescription containers appropriately.

j. Sign and date the prescription or compounding record affirming that all procedures were carried out to ensure uniformity, identity, strength, quantity, and purity.

k. Thoroughly clean the facility and all equipment immediately when finished.

4. **Compounding Process for Compounded Sterile Preparations.** Compounders are to use the following steps to minimize error and maximize the prescriber's intent, specifics can be found in *Pharmaceutical Compounding-Sterile Compounds* (USP 797):

a. Judge the suitability of the prescription of compounded sterile preparation in terms of safety and intended use.

b. Perform necessary calculations to establish the amounts of ingredients needed.

c. Identify equipment and utensils needed for the preparation of the compounded sterile preparation.

d. Sterile compounding areas and critical areas must be structurally isolated from other areas designated to avoid unnecessary traffic and airflow disturbances, separate from non-sterile compounding areas, and restricted to qualified compounding personnel.

e. Policies and procedures must be established for personnel cleaning and garbing for protection and avoidance of contamination including, but not limited to:

i. Remove all jewelry from hands and arms.

ii. Wash hands and arms.

iii. Abstain from gum chewing, candy or food items in or near the compounding area.

f. Clean and sanitize the compounding area and needed equipment.

i. At the beginning of each day and after spills, the surface of the compounding area should be cleaned with purified water to remove water soluble residues, then immediately with seventy percent (70%) isopropyl alcohol, or another antimicrobial agent, using non-linting wipe.

ii. All rubber stops of vials and bottles and the neck of ampules must be sanitized with seventy percent (70%) isopropyl alcohol prior to introduction of a needle or spike for the removal of a product.

iii. After procedures are completed, used syringes, bottle, vials, and other supplies must be removed.

g. Only one (1) prescription can be compounded at a time in the specified compounding area.

h. Assess weight variation, adequacy of mixing, clarity, odor, color consistency, and pH as appropriate of the completed compounded sterile preparation.

i. If preparing in anticipation of future orders, annotate the compounding and formulation records.

j. Label the prescription containers appropriately.

k. Sign and date the prescription or compounding record affirming that all procedures were carried out to ensure uniformity, identity, strength, quantity, purity, and sterility

5. RISK LEVELS OF COMPOUNDED STERILE PREPARATIONS

Risk levels are assigned according to the corresponding probability of contaminating a preparation with microbial organisms, spores, and endotoxins, or chemical and physical contamination such as foreign chemicals and physical matter.

a. Low risk preparations are compounded sterile preparations under the following conditions:

i. Compounded with aseptic manipulations entirely with ISO Class 5 or superior air quality using only sterile ingredients, products, components, and devices.

ii. The compounding involves only transfer, measuring, and mixing using not more than three (3) commercially manufactured packages of sterile products and not more than two (2) entries into any one sterile container.

iii. Manipulations must be limited to aseptically opening ampules, penetrating disinfected stoppers with sterile needles and syringes, and transferring sterile liquids into sterile administration devices or containers for storage.

iv. In the absence of passing a sterility test, the storage periods cannot exceed forty-eight (48) hours at controlled room temperature, for not more than fourteen (14) days at a refrigerated temperature, or forty-five (45) days in solid frozen state, between -25^{0}C and -10^{0}C, unless supported by manufacturer or medical literature.

v. Examples of Low Risk compounded sterile preparations include:

1. Single volume transfers of sterile dosage forms from ampules, bottles, bags, and vials with sterile needles.

2. Simple aseptic measuring and transferring with not more than three (3) packages of manufactured sterile products including and infusion or diluents solutions. The solution content of ampules must be passed through a sterile filter to remove any particles.

vi. Low Risk Quality Assurance programs must include routine disinfection, air quality testing, visual confirmation that compounding personnel are properly gowned and garbed, review of all orders and packages of ingredients, and visual inspection of the compounded sterile preparation to ensure the absence of particulate matter or leakage, and thoroughness of labeling in addition to annual Media Fill Tests by each of the compounding personnel specific for Low-Risk Preparation.

b. Medium Risk Preparations are compounded sterile preparations prepared aseptically under Low-Risk Level conditions and one (1) or more the following conditions exist:

i. Multiple small doses of sterile products are combined or pooled to prepare the sterile preparation that will be administered either to multiple patients or to one (1) patient on multiple occasions.

ii. The compounding process includes complex aseptic manipulations other than the single volume transfer.

iii. The compounding process requires unusually long duration such as that required to complete dissolution.

iv. In the absence of passing a sterility test, the storage periods cannot exceed thirty (30) hours at controlled room temperature, for not more than nine (9) days at refrigerated temperature unless and for forty-five (45) days in solid frozen state, between -25^{0}C and -10^{0}C, unless supported by manufacturer or medical literature.

v. Examples of Medium Risk compounded sterile preparations include:

1. Total parenteral nutrient fluids using manual or automated devices.

2. Filling reservoirs of injection and infusion devises with more than three (3) sterile drug products.

3. Transfer volumes from multiple ampules or vials into one (1) or more final sterile containers.

vi. Medium Risk Quality Assurance includes all elements of Low Risk compounded sterile preparations in addition to annual Media Fill Tests by each of the compounding personnel specific for Medium Risk preparations.

c. High Risk Preparations are compounded sterile preparations are either contaminated or at a high risk to become contaminated.

i. When the following criteria take place, the preparations will be considered High Risk:

1. If non-sterile ingredients are incorporated or a non-sterile is employed before terminal sterilization.

2. If there has been exposure to air quality inferior to ISO Class 5 for more than one (1) hour by the sterile contents, sterile surfaces of devices and containers, or a lack of effective antimicrobial preservatives.

3. If personnel are improperly garbed and gloved.

4. If non-sterile water-containing preparations are stored for more than six (6) hours before being sterilized.

5. If the storage periods have exceeded twenty-four (24) hours at controlled room temperature; three (3) days at refrigerated temperature or forty-five (45) days in solid frozen state, between -25^{0}C and -10^{0}C, unless supported by manufacturer or medical literature.

ii. All non-sterile measuring, mixing, and purifying devices must be rinsed thoroughly with sterile pyrogen free water, then thoroughly drained or dried immediately before use for High Risk compounding.

iii. All High Risk solutions subjected to terminal sterilization are pre-filtered by passing through a filter not larger than 1.2 microns. Sterilization of High Risk Level solutions by filtration should be performed with a sterile 0.2 micron normal pore size filter entirely within and ISO Class 5 or superior air quality environment.

iv. An example of High Risk compounded sterile preparations is dissolving non-sterile bulk drug and nutrient powders to make solutions that will be terminally sterilized.

v. High Risk Quality Assurance includes all elements of Low-Risk compounded sterile preparations in addition to bi-annual Media Fill Tests by each of the compounding personnel specific for High Risk preparations.

6. Facilities for Sterile Compounding

a. The facilities that engage in Low and Medium Risk preparations must meet the standards including but not limited to:

i. Limits access and activities to qualified personnel, materials, and processes that are directly related to productions of sterile compounded products.

ii. Structurally isolated from other areas including other non-sterile compounding areas.

iii. Designed to avoid unnecessary traffic and airflow disturbances.

iv. Of sufficient size to accommodate at least one primary engineering control device.

v. Able to provide storage and preparation of drugs, supplies, and finished products under appropriate temperature, light, moisture, sanitation, ventilation, and security conditions.

1. Ventilation must maintain appropriate ISO Class designations of each separate working area and avoid disruption and cross-room currents.

2. Walls, floors, and ceilings, along with fixtures , counters, shelves, and cabinets must be resistant to damage that could occur from routine disinfection with cleaning agents.

3. Procedures and policies must be established for personnel in the sterile compounding area regarding proper hand washing, proper donning of appropriate attire, and restrictions on items and practices within the compounding area.

b. The facilities that engage in High-Risk preparations must meet the standards including but not limited to:

i. All of the facilities listed for Low and Medium-Risk preparations.

ii. Buffer areas must have the following standards; but not limited to:

1. Maintain ISO Class 7 or superior air quality during compounding activity.

2. Be physically divided or have designated boundaries that separate it from the anteroom with appropriate ventilation that assures contamination from the anteroom does not enter the buffer area through utilization of filtered Unidirectional Flow and principles of air displacement.

3. Must not have unsealed windows or doors that connect to the outdoors, or be located adjacent to a construction site, warehouse, or food preparation area.

4. Must not contain sinks or drains and shall be void of all materials, equipment, and fixtures that are not directly involved in the current processing of compounded sterile preparations.

5. The construction, arrangement, and ventilation must not allow conditions that could adversely affect compounding, such as aberrant heating, cooling, door-drafts, and personnel traffic air currents.

6. Policies and procedures must be established for cleaning and sanitizing.

a. Cleaning and sanitizing must occur in the buffer area first, then move to the anteroom and other areas.

b. All cleaning and sanitizing must not occur simultaneously with aseptic operations.

c. Storage shelving cleaned and sanitized weekly.

d. Floors must be mopped daily. Trash must be collected and removed daily.

iii. Anteroom must have the following standards, but not limited to:

1. Located adjacent to the buffer area and maintained at ISO Class 8 or superior air quality during compounding activity.

2. Must be established with the purpose of unpacking and disinfecting supplies for storage and areas to support hand and arm washing and donning of appropriate attire.

a. Hands free sinks and closed system soap dispenser must be used for hand and arm washing.

3. Procedures must be established for cleaning and sanitizing.

a. Must occur secondary to cleaning and sanitizing.

b. All cleaning and sanitizing must not occur simultaneously with aseptic operations.

c. Counters and easily cleanable work areas must be cleaned daily.

d. Supplies and equipment must be removed and wiped with a sanitizing agent weekly.

e. Floors must be mopped daily.

f. Storage shelving must be emptied and cleaned and sanitized monthly.

c. Storage areas for Sterile Preparations

i. When ingredients and finished preparations are exposed to temperatures warmer than the warmest labeled limit, but not exceeding forty degrees Celsius (40^0C) for more than four (4) hours, they must be discarded.

7. Equipment Specific for Sterile Compounding

a. Primary Engineering Controls (i.e. Laminar Airflow Workbenches, Biological Safety Cabinets, Compounding Aseptic Isolators, and Compounding Aseptic Containment Isolators) must be used to prepare all sterile preparations except those compounded for immediate-use and must be capable of maintaining ISO Class 5 or superior air quality during normal compounding activity.

i. Must be placed in the buffer area, if required, where HEPA filters are employed and the air quality is maintained at ISO Class 7 or superior.

ii. Must be maintained as continuously powered on, if turned off; however, allow the blowers to run continuously for at least 30 minutes before using.

b. Environmental Monitoring

i. Barrier certification for proper functioning and ISO Class 5 air flow requirements must be tested every 6 months and after relocation of the primary engineering control.

ii. Maintain the air quality of the buffer area and anteroom, if required, at ISO Class 7 and ISO Class 8, respectively must be tested every 6 months and after any renovation of the compounding area

ii. Where High Risk sterile preparations are being compounded air sampling via sterile nutrient agar plates or suitable electric air samplers must be performed monthly at locations judged by compounding personnel to be the most prone to contamination during compounding activities.

1. Instructions and verification of air sampling devices must be located with the equipment.

2. Passive exposure processes of sterile nutrient agar settling plates can be found in USP Standards

8. **Immediate-Use Preparations.** Immediate-use preparations must not be medium-risk level or high-risk level compounded sterile preparations. Immediate-use Preparations must be designed for immediate administration and are exempt from the requirements described for Low-Risk Level compounded sterile preparations only when all the following criteria are met:

a. The compounding process involves simple transfer of no more than three (3) commercially manufactured packages of sterile non-hazardous products from the manufacturer's original containers and no more than two (2) entries into any one (1) container.

b. Unless required for the preparation, the compounding procedure is a continuous process to exceed one (1) hour.

c. During preparation and prior to administration, aseptic technique must be followed. At no point are critical sites and ingredients of the compounded sterile preparation directly exposed to contact contamination. If not immediately administered, the finished compounded sterile preparation is under continuous supervisions to minimize the potential for contact with non-sterile surfaces, introduction of particulate matter, or biological fluids, mix-ups with other products, and direct contact of outside surfaces.

    i. Administration begins no later than one (1) hour following the start of the preparation.

        1. Must be immediately and completely administered by the person who prepared it, or immediate and complete administration is witnessed by the preparer.

        2. If administration has not begun within one (1) hour following the start of preparing the compounded sterile preparation, must be promptly, properly, and safely discarded; not be stored for later use.

It was moved by Pharmacist Haroldson and seconded by Pharmacist Dewhirst to proceed with the modified internship rule requirements and the staff identification requirements as proposed. All Board Members voted aye – the motion carried. A copy of the rule follows:

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

After review of the suggested Interim Health Committee Legislation on allowing Pharmacists to provide immunizations to youths down to 11 years old, and specifically down to 5 years old for flu vaccinations.

It was moved by Pharmacist Thom and seconded by Pharmacist Haroldson to support the concept of Pharmacists participating in vaccinating these younger individuals, to increase the immunization rates within North Dakota. All Board Members voted aye – the motion carried.

Controlled Substance scheduling was reviewed and legislation will be drafted to comply. Executive Director Anderson is scheduled to go before the Interim Rules Committee on September 14th, 2010 with the rules passed by the Board of Pharmacy this summer, and at that time the decision will be made as to where or not they will be included in the proposed legislative draft.

A guidance document on central fill was reviewed. ***It was moved by Pharmacist Dewhirst and seconded by Pharmacist Haroldson to approve this guidance document as prepared by the Board summer PharmD Intern Amy Crawford. All Board Members voted aye – the motion carried.*** See Addendum D at the end of the minutes

Executive Director Anderson discussed a proposal and opportunity to help the Indian Health Services [IHS] program their pharmacy management system to allow reporting with the ASAP 4.1 Standard to Prescription Drug Monitoring Programs [PDMP]. It is envisioned that this would

be available to all IHS facilities, wishing to report to PDMPs. There if adequate funding in our enhancement grant and preliminary work has been done with the Bureau of Justice assistant grant administrators and it looks like such a request would be approved.

It was moved by Pharmacist Thom and seconded by Pharmacist Ziegler to approve the modification in the enhancement grant and the funding for the programming for the Indian Health Services to report to our Prescription Drug Monitoring Program, as well as others. On a vote by Roll Call: Pharmacist Detwiller – Aye Pharmacist Dewhirst – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

An employment agreement for Executive Director Anderson was moved by Pharmacist Thom and seconded by Pharmacist Haroldson. On a vote by Roll Call: Pharmacist Detwiller – Aye Pharmacist Dewhirst – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Pharmacist Ziegler – Aye Nays none – the motion carried. See Addendum E at the end of the minutes

It was moved by Pharmacist Dewhirst to approve the addition of the Class K – Telepharmacy to North Dakota Pharmacy Permit #180 issued to Altru Health System Pharmacy, to allow them work with other hospitals who request their help in Telepharmacy services. All Board Members voted Aye – the motion carried.

Relative to the discussion of supervision of oncology product preparation at remote sites, it was determined that a Class K – Telepharmacy should not be necessary, as pharmacists would be providing this service as professional pharmacists.

It was moved by Pharmacist Thom and seconded by Pharmacist Ziegler to allow the reciprocity process for Pharmacists Germon E. Hill to proceed, as his prior convictions did not appear to bar his licensure in North Dakota. All Board Members voted Aye – the motion carried.

It was moved by Pharmacist Ziegler and seconded by Pharmacist Thom to communicate to Mr. Allen G. Kniep that his prior convictions would not bar him from becoming licensed as an intern in North Dakota. At the time of his actual internship application, his record will need to be clear since the prior convictions. He will need to disclose all activities relative to prior convictions at that time and have a clean record subsequent to his previous actions. All Board Members voted Aye – the motion carried.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Haroldson to approve the change in the Collaborative Agreement for Meritcare Hospital now known as Sanford Medical Center, as presented by Rob Nelson, PharmD. All Board Members voted Aye – the motion carried.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Thom to approve the floor plans for the new location submitted by Minne-Tohe Health Center Pharmacy, current located at 9281 Highway 23 in New Town. All Board Members voted Aye – the motion carried.

It was moved by Pharmacist Ziegler and seconded by Pharmacist Dewhirst to approve the expansion plans submitted by Southtown Econodrug located at 387 S 11th Street in Wahpeton. All Board Members voted Aye – the motion carried.

It was moved by Pharmacist Thom and seconded by Pharmacist Ziegler to approve the floor plans for the new location submitted by Hankinson Drug, now located at 309 S Main in Hankinson, with the caveat that the skylights or roof windows appeared to afford some security concerns, and due consideration should be taken during construction. All Board Members voted Aye – the motion carried.

It was suggested by Board Members that the new Intern Affidavits be reviewed to be sure that current language was used on the affidavits to match the College's current program.

There was discussion about a rule change specific to controlled substances transfers, where we indicate that the word "*Void*" must be written on hardcopy of the prescription, was a concern since most records are now being kept electronically and people do not often look up the original hardcopy when transferring a prescription.

The meeting adjourned at 6:50 PM.

Rick L. Detwiller, R.Ph
President

Gary W. Dewhirst, R.Ph.
Member

Member
Laurel A. Haroldson, R.Ph.

Member
Bonnie J. Thom, R.Ph.

Member
Gayle D. Ziegler, R.Ph.

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