

A G E N D A
NORTH DAKOTA STATE BOARD OF PHARMACY
MAY 17-18-19-20, 2010

MONDAY-MAY 17, 2010- CANDLEWOOD SUITES 1831 NDSU Research Park Drive - Fargo ND 58102
(1-701-235-8200)

5:00 PM - Call to Order – President Gayle Ziegler

A. BUSINESS SESSION

Seat new members – if appointed – administer Oath of Office

Review and Approval of Agenda AGENDA TAB

Make final preparations for tomorrows exams Candidate TAB

Review Candidate Files

Review Intern Portfolios

Review & Approval of Minutes of the MINUTE TAB

January 5-6-7, 2010; February 25th, 2010 and April 24th, 2010

Appoint two Pharmacists to review all paid expenses.

Sign Certificates – RPh & Technicians

Election of President for the July 1, 2010 to July 1, 2011 Board Year

Year to date financial reports-2010-2011 Budget BUDGET TAB

Application for Re-instatement:

Darren G Mack, RPh. – ND #4663 [cancelled for non-payment]

Possible Exam Dates: [4 candidates]

Meritcare dba Mills Avenue Pharmacy FILE

Article 61-11 Fees – adjustments – non substantive TAB 1 Article 61-13
– Controlled Substances – consideration of final adoption

7:32 PM District V – Uniform Internship Registration TAB 2

Veterinary Prescriptions and who can fill them - TAB 3
Legend Devices and sale directly to consumers

*** Move things out of Room for Breakfast

TUESDAY-MAY 18, 2010 COLLEGE OF PHARMACY- NDSU Sudro Hall - Room 21

8:00 - 8:30 AM Roll Call and Orientation of Candidates

8:30 - 9:30 AM Laboratory Section 1

8:45 - 9:15 PM Errors and Omissions Section 1

9:45- 10:15 PM Errors and Omissions Section 2

9:45 -10:45 PM Laboratory Section 2

11:00-12:00 PM Laboratory Section 3

1:00- 2:00 PM Laboratory Section 4

2:15- 3:15 PM Laboratory Section 5

3:30- 4:30 PM Laboratory Section 6

Review Intern Portfolios

6:30 Dinner & Preparations for Oral Exam - to be held in the Willow Room–Radisson Hotel–
201 N 5th Street Fargo [232-7363]

Pharma Trust Presentation – Matt Sneller, PharmD, VP of Pharmacy Affairs
Dean Charles Peterson, PharmD, R.Ph., Provost Craig Schnell, Mike Schwab Executive VP
NDPhA, Brad Morrison, R.Ph. NDPhA President, Brian Ament, R.Ph. President NDSHP; William
J. Grosz, R.Ph.

WEDNESDAY - MAY 19, 2010

7:00 AM Board Breakfast – ND Pharmacy Advancement Meeting – TAB 4
CALL 1-800–423-1988 – Under the NAME HOWARD Conference # 1455766
CANDLEWOOD SUITES Board Room 1831 NDSU Research Park Drive

Fargo, ND 58502

ORAL EXAMINATION SCHEDULE

9:00 -	AM	SECTION 1	FOLLOW THIS SEQUENCE FOR EACH SECTION:	
9:20 -	AM	SECTION 2		
9:40 -	AM	SECTION 3		
10:00 -	AM	BREAK		To Room _____
10:20-	AM	SECTION 4		
10:40-	AM	SECTION 5		To Room _____
11:00-	AM	SECTION 6		To Room _____
1:20 -	PM	SECTION 7		
1:40 -	PM	SECTION 8		
2:00 -	PM	SECTION 9		
2:20 -	PM	SECTION 10		
2:40 -	PM	SECTION 11		
3:00 -	PM	SECTION 12		

Final Scoring of Exams

6:30 Dinner with Attorney Lindell, Inspectors Swisher and Johnson
Investigating committee meetings

THURSDAY – May 20, 2010-

7:30 AM CALL TO ORDER - President Gayle Ziegler, R.Ph.
8:00 AM Aadnes, Brandy - ND Pharmacy Technician #587
8:30 AM Graig S Wells – Pharmacy Technician-In-Training
9:00 AM Carl Nilles – ND Pharmacist #2806
Nilles Drug – ND Permit #153
10:00 AM Michelle L. Courtney – Pharmacy Tech #718
10:30 AM Patrick W. Slifka – ND Pharmacist #4130
10:30 AM Richard D. White – Pharmacy Tech #336
Bryan Miller, PharmD – ND Pharmacist #5186 [DUI Evaluation]

11:00 AM RULE HEARING:

Chapter 61-02-01-03 – Pharmaceutical Compounding Standards
Chapter 61-02-07.1-13 – Pharmacy Technician Reinstatement

TAB 5

Chapter 61-13-02 - Identification Required for Controlled Substances

Review open Cases

Ryan Sannes-Progress Report

Mark Pajala

Review Administrative Settlements/Investigative Committee Actions

Consider Approval of the actions of the Executive Director

Approval of all paid expenses.

Review Future Meeting Dates

Other business

ADJOURNMENT

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President Ziegler called the Meeting to Order at 5:00 PM on Monday May 17th, 2010 in the Board Room of the Candlewood Suites in Fargo, ND.

Present were: Pharmacist Rick L. Detwiller; Pharmacist Gary W. Dewhirst; Pharmacist Laurel A. Haroldson; Pharmacist Bonnie J. Thom; Pharmacist Gayle D. Ziegler ; Executive Director Howard C. Anderson, Jr, R.Ph.; Legal Intern Dr. Justin Stubstad and CVS Pharmacies District Manager Curtis Larson, R.Ph.

Since neither the public member nor the Pharmacy Technician member have been appointed to the State Board of Pharmacy by Governor John Hoeven, it was not necessary to seat them as new members.

It was moved by Pharmacist Thom and seconded by Pharmacist Haroldson to approve the Agenda as printed. All Board Members voted aye – the motion carried.

Board members commenced final preparations for tomorrow’s exams with review of the Candidate files and the discussion of the review of the online intern portfolios. Board Member Bonnie Thom, R.Ph. reported that she had completed most of her online portfolio reviews and that she felt the process seemed to go fairly well. We will hear more comments once all of the portfolios have been reviewed, estimated to be by the end of Wednesday.

It was moved by Pharmacist Haroldson and seconded by Pharmacist Thom to approve the minutes of the January 5-6-7, 2010 Board Meeting, the February 25th, 2010 Board Meeting and the April 24th, 2010 Board Meeting, as printed. All Board Members voted aye – the motion carried.

President Ziegler appointed all four Board Members, save herself, to review the paid invoices to date.

Board Members then signed Original Certificates for both the future Pharmacists and registered Pharmacy Technicians.

President Ziegler announced that nominations were open for President of the Board of Pharmacy

for the July 1, 2010 to June 30th, 2011 Board Year.

It was moved by Pharmacist Haroldson and seconded by Pharmacist Thom that Pharmacist Rick Detwiller be nominated and that a unanimous ballot be cast for Pharmacist Detwiller. All Board Members voted aye – the motion carried.

President Detwiller was congratulated on his election by all.

Year to date financial reports were reviewed, along with 2010-2011 proposed Budget. Executive Director Anderson pointed out that we are in the transition from the old Quickbooks accounting system to the new Greatplains Accounting System, which is integrated with our licensing data base. Executive Director Anderson reported the financials were as accurate as he could get them at this point, and that the budget should prove to be pretty close to the final numbers. He suggested the appointment of an Audit Committee to keep on top of the financials and the Budget.

President Ziegler appointed Pharmacists Detwiller and Dewhirst to serve as the Audit Committee Executive Director Anderson had requested.

It was moved by Pharmacist Thom and seconded by Pharmacist Haroldson to approve the 2010-2011 proposed Budget as presented, with the understanding that it would be reviewed again at the next meeting. All Board Members voted aye – the motion carried.

It was moved by Pharmacist Haroldson and seconded by Pharmacist Thom to approve the Reinstatement of Darren G. Mack, R.Ph. North Dakota Pharmacist License #4663; which had been cancelled for non-payment. All Board Members voted aye – the motion carried.

Possible summer Exam dates were discussed. We presently have four candidates who either missed the deadline for the current examinations or were graduating from other Colleges of Pharmacy and could not be here at this time. We also have the possibility of two other candidates who have expressed interest in future examination and licensure in North Dakota, but have not as yet filed the proper paperwork.

President Ziegler established, by consensus, Wednesday June 23rd, 2010 as the date for the next Board of Pharmacy Meeting and the Exam Date for those candidates eligible at that time.

The request by MeritCare Hospital Pharmacy to use a “doing-business-as” name for the out-patient location of their Hospital Pharmacy Permit #315 was discussed. The pharmacy is located within MeritCare, at the same address and the request for the dba name is to facilitate understanding of patients about where in the hospital to go for these services, as well as for delivery of medications which are destined for the out-patient pharmacy.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Haroldson to approve the use of the Meritcare dba Mills Ave Pharmacy designation for the out-patient portion of the MeritCare Hospital Pharmacy. All Board Members voted aye – the motion carried.

Executive Director Anderson presented the proposed modifications in Article 61-11 – Fees to come into compliance with the changes made by the 2009 Legislature, as we had previously overlooked the statement of the \$200 fee when the current Active Pharmacist Fee is now \$100. Also, a typographical

error was noticed in the designation of the Northland Association of Pharmacy Technicians, this was corrected at the same time as the fee adjustment. And in #11 we just expanded the explanation of the fee for a Pharmacy Technician-In-Training to per year and the two years allowed to complete the program. Copy as follows:

Section 61-11-01-01 Fees. The following fees must be paid to the board of Pharmacy:

1.	North Dakota Examination	\$	100.00
2.	Original or Duplicate Certificate		25.00
3.	Reciprocal Licensure		150.00
4.	Internship Licensure –		
	a. NDSU Professional Student		100.00
	(\$90 is paid to the NDSU College of Pharmacy for student programs)		
	b. Internship Licensure – Pre-pharmacy students		10.00
5.	Manufacturer-Distributor-Warehouse-Reverse Distributor		
	Wholesale Drug License		150.00
	Penalty for Late Renewal		50.00
6.	Pharmacy or Drug Store Permit		175.00
	Permitting in additional Classes	0.00	
	Penalty for Late Renewal		50.00
7.	Annual Renewal for Pharmacist In-State <u>Active</u>	200.00 <u>100.00</u>	
	(One-half is forwarded to the North Dakota Pharmacists association)		
	Penalty for late Renewal		25.00
8.	Annual Renewal for Pharmacist In-State (Inactive Status)		75.00
	Penalty for late Renewal		25.00
9.	Annual Renewal for Pharmacist Out-Of-State		35.00
	Penalty for late Renewal		25.00
10.	Annual Registration for Pharmacy Technician		35.00
	(\$17.50 is forwarded to the <u>Northland national</u> Association of Pharmacy Technicians [NAPT])		
	Penalty for late Renewal		10.00
11.	Pharmacy Technician-In-Training [<u>per year</u>]		10.00
	(two years <u>allowed to complete a program</u>)		

History: Effective January 1, 2006; amended May 2010

General Authority: NDCC 43-15-10

Law Implemented: NDCC 43-15-10, 43-15-18, 43-15-20, 43-15-25,
43-15-27, 43-15-38, 43-15.1-04, 43-15.1-05

It was moved by Pharmacist Thom and seconded by Pharmacist Haroldson to approve this as a non-substantive rules change, which will be forwarded directly to the Legislative Council for publication. All Board Members voted aye – the motion carried.

Article 61-13 Controlled Substances was discussed. Board Members reviewed the minutes of the Emergency Scheduling Meeting held on February 25, 2010 with it's summary of comments along with the April 24th, 2010 Rule Hearing. All comments received have been in favor of adopting the rule. There was one comment at the April 24th meeting, expressing concern that scheduling may prevent research into the medical uses of these substances. It was explained at that time to the individual expressing the concern that scheduling did not impede research into the medical uses of these substances, but did require the researcher to request authorization from the Board of Pharmacy to do the research, furnish the research protocols and have institutional review Board before getting authorization from the Board of Pharmacy to do research with these substances.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Detwiller to approve Article 61-13 Controlled Substances as presented at the Rule Hearing, contingent upon approval from the Attorney General's Office. 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.

The efforts by District V, led by Lloyd Jessen of Iowa, to establish a uniform Internship Registration was discussed. We will include the topic on the Agenda for our dinner meeting with NDSU College of Pharmacy Dean Charles Peterson and Provost Craig Schnell Tuesday May 18th, 2010.

Mr. Robert Jameson of Stockmen's Supply of West Fargo and Dr. James C. Clement, DVM, a part owner of Stockmen's Supply West in Mandan, arrived at the meeting to discuss the question of Veterinary Prescriptions and who can fill them. This issue first came up after Dr. John Boyce, Director of the Veterinary Board and Executive Director Anderson wrote an article for the Veterinarian's Newsletter which was published in January 2010. This article spelled out the law, relative to veterinarians dispensing prescription medication and pointing out that dispensing by unlicensed individuals or facilities was not legal. The following is a copy of the Article:

Veterinary Prescription Drugs, Dispensing, and Compounding

John R. Boyce, DVM, PhD
Executive Secretary
ND Board of Veterinary Medical Examiners

Howard C. Anderson, Jr. R.Ph.
Executive Director
ND Board of Pharmacy

Veterinary prescription drugs are to be used or prescribed only within the context of a valid veterinarian-client-patient relationship (VCPR) (87-04-01). The definition of the VCPR in the North Dakota veterinary medical practice act (43-29-01.1) was taken directly from the US Code of Federal Regulations, and includes three provisions: A veterinarian has assumed the responsibility for making medical judgments regarding the health of an animal and the need for medical treatment, and the client, who is the owner or other caretaker, has agreed to follow the instructions of the veterinarian.

There is sufficient knowledge of the animal by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal.

The practicing veterinarian is readily available for follow-up in the case of adverse reactions or failure of the regimen of therapy. This relationship exists only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal by virtue of an examination of the animal and by medically appropriate and timely visits to the premises where the animal is kept.

The use, prescription, or sale of any veterinary prescription drug, or the prescription or an extra-label use of any over-the-counter drug in the absence of a valid VCPR constitutes grounds for discipline (43-29-14).

According to the board rules, in order for a veterinarian to exercise properly the rights granted by the veterinary license, a VCPR must exist (87-05-02-02).

Veterinarians may prescribe drugs for their patients, and they may fill their own prescriptions and

dispense drugs to their own clients. Prescriptions may also be filled by licensed pharmacists. Veterinarians may not fill prescriptions written by other veterinarians.

Pharmacies must be licensed to do business in North Dakota in order to fill prescriptions for clients living in North Dakota. Mail-order or internet pharmacies are subject to the same provisions. The National Association of Boards of Pharmacy maintains an accreditation process for internet pharmacies called the Veterinary-Verified Internet Pharmacy Sites (Vet-VIPPS™), and clients seeking to fill prescriptions on the internet should be directed to a Vet-VIPPS-accredited pharmacy (see www.nabp.net).

Veterinarians may compound drugs for use on specific animals owned by their own clients, as long as there is a valid VCPR, and there is no approved animal drug available for use. In such cases, the veterinarian must diagnose the condition requiring treatment, must establish an appropriate withdrawal time, and must ensure the identity of the treated animal(s) to avoid illegal drug residues. Pharmacies may also compound drugs for use by a veterinarian. Those compounded drugs should not be sold to other pharmacies or veterinarians, or directly to animal owners. The US Food and Drug Administration is concerned when veterinarians and pharmacies engage in compounding that is intended to circumvent the drug approval process and provide for the mass marketing of products that have been produced with little or no quality control or manufacturing standards.

The rules of the Board of Veterinary Medical Examiners require veterinarians to maintain adequate treatment records for at least three years, to show that the drugs were supplied to clients with whom a valid VCPR existed. The rules also contain specific provisions regarding drug records, prescriptions, and prescription labels (87-04-01-02 and 87-04-01-03).

Veterinarians who have questions about these topics should consult the applicable practice act and rules, which are available on the board web sites (www.ndbvme.org and www.nodakpharmacy.com) or the veterinary or pharmacy board offices.

As a practical matter, businesses such as Stockmen's Supply currently sell medications, which are veterinary legend drugs, directly to consumers. Mr Jameson described their process for the Board of Pharmacy. He indicated that they contact the veterinarian who services the animal for the client and get a prescription from that veterinarian. The prescription is then reduced to writing and filed in the files of Stockmen's Supply. Stockmen's Supply West works in a very similar manner. Dr. Clement has done some research and discovered that some state's have provisions to allow veterinarians both to dispense refills of prescriptions for other veterinarians and some state's have licensing provisions for Veterinary Drug Retail Outlets. Dr. Clement named several states and Board of Pharmacy Members promised to research that information with those respective state's at the upcoming National Association of Board's of Pharmacy meeting next week.

Mr. Jameson, Dr. Clement and the Board of Pharmacy agreed to continue discussing this issue and to come up with a solution to service the animal production industry in a cost effective manner consistent with North Dakota Laws & Rules.

The issue of legend devices and medical gasses as well as their sale directly to consumers was discussed. It was the consensus of the Board, that we would develop legislation specific to licensing legend drug manufacturers and those who could sell directly to the public, as well as clearing up the definitions in the Wholesale Licensing Law to more clearly describe the multiple variations of

business practices that we have found over the last few years implementing NDCC 43-15.3 Wholesale Drug Pedigree.

President Ziegler recessed the meeting until 7:30 Wednesday morning May 18th, 2010 at NDSU College of Pharmacy to begin the examination process with the Laboratory Sections and Errors and Omissions being administered to 43 candidates.

At 6:30 PM the Board met in the Willow Room of the Radisson Hotel for a planned dinner meeting with Matt Sneller, PharmD; Dean Charles Peterson, PharmD, R.Ph., Provost Craig Schnell, Mike Schwab Executive VP NDPhA, Brad Morrison, R.Ph. NDPhA President, Brian Ament, R.Ph. President NDSHP and William J. Grosz, R.Ph. Mike Schwab Executive VP NDPhA and Brad Morrison, R.Ph. NDPhA President sent their regrets that they would not be able to attend.

After introductions, Matt Sneller, PharmD representing Pharma Trust was asked to explain his telepharmacy automatic dispensing device system. Board Members generally agreed that this was a good telepharmacy video and audio connection with the patient and that the automatic dispensing device could generally be relied on to accurately produce and label the medication for dispensing by the pharmacist via the video and audio telepharmacy connections. Discussion followed about who would be allowed to fill the machine. Dr. Sneller indicated that the pre-labeled cassettes contained bar-code scanning technology and placement within the machine could be in any of the available slots and the machine would recognize the bar-coded medication that it was directed by the central pharmacist to dispense. Questions were asked about where the machine could be placed with confidentiality and HIPPA considerations in mind. Dr. Sneller indicated that they had confidentiality panels which could be placed around the machine to create a more confidential environment. Questions were raised about whether such a device could be used at a telepharmacy within a city where other pharmacies existed. Locations within hospital emergency rooms seemed a logical location when serviced by the hospital pharmacist or a contract entity. Clinics outside of the hospital could be used as a physician dispensing moieties.

Dean Charles Peterson presented a comprehensive report on the College of Pharmacy's statics and activities, as well as a time-line for the anticipated ACPE Accreditation visit in the spring of 2012. Both of these are attached as addendums to these minutes. Dean Peterson discussed the Masters of Public Health Program. He stated that June 10th, 2010 was their approval target date, with a January 1, 2011 goal to start the first class.

The Dean then discussed the Center for Excellence in Research and Development. He also discussed the concept pharmacy and the utilization within the College. He pointed out that ACPE had now approved Introductory Pharmacy Experience [IPPE] to be done by simulation. He felt this would give them an opportunity to utilize the tools we already have in place to provide this required experience to our students.

Dr. Craig Snell, Provost, indicated that despite the challenges NDSU has had relative to the recruiting of a new President, the eight colleges within the University and the library were ready to go and "are just waiting for fuel for the rocket". He pointed out that funding is always a problem. With the increase of 3,800 students in two-years and no significant increase in dollars for new faculty, this presented a constant challenge for the university.

International students will continue to be a focus at the university, and Dr. Snell pointed out that tuition wavers will be kept to a minimum. He spoke about the relationship between the University of

North Dakota and North Dakota State University, saying that presently they have a good relationship. Dr. Chapman began the relationship and it is continued by Dr. Hanson and he anticipated the relationship would remain good into the future.

Brian Ament, PharmD, President of the North Dakota Society of Health Systems Pharmacists brought up the American Medical Association's [AMA] Scope of Practice for Pharmacists document, which had recently been released. It was pointed out that the American Society of Health Systems Pharmacists [ASHP] has made a very good response to the AMA and that Association Executives and others were looking into additional responses.

Dean Peterson suggested that the ND Pharmacists should approach the Medical Association about a pilot project, on collaborative agreements.

President Ziegler recessed the working dinner meeting until Wednesday May 19th, 2010.

Wednesday – May 19th, 2010 the Oral Examination was administered to 43 candidates for licensure, and the final scoring of the exams was completed.

At 6:30 PM the Board met for a working dinner with Board Attorney David Lindell and Compliance Officer Judith Swisher.

On Thursday May 20, 2010, with the concurrence of all those who had come to participate in the Rule Hearing scheduled for 11 AM, the Rule Hearing will be continued until the completion of the Disciplinary Hearings of those called before the Board of Pharmacy.

Board Disciplinary Hearings Held Thursday May 20, 2010

The meeting was called to order at 7:30 AM by President Gayle Ziegler, R.Ph. Present were: Pharmacist Rick L. Detwiller – Pharmacist Gary W. Dewhirst – Pharmacist Laurel Haroldson – Pharmacist Bonnie J. Thom – Pharmacist Gayle Ziegler - Executive Director Howard C. Anderson, Jr, R.Ph. - Justin C. Stubstad, PharmD – Compliance Officer Judith Swisher, R.Ph. and Board Attorney David A. Lindell, JD.

Brandy Aadnes, Registered Pharmacy Technician #587 was invited in to discuss her situation with the Board of Pharmacy. Technician Aadnes discussed an incident where she had been arrested for Unauthorized Possession of Xanax, which she had received from her Aunt. This was found in her blood stream subsequent to a car accident, which occurred in November 2008.

It was moved by Pharmacist Haroldson to write a letter to Ms. Brandy Aadnes indicating that we have reviewed her case, accepted her explanation for her failure to disclose the above incident on a previous Application for Registration as a Pharmacy Technician and determined that no further action is necessary at this time. The motion was seconded by Pharmacist Detwiller – all Board Members voted aye – the motion carried.

Craig Scott Wells Applicant for Registered Technician-In-Training. At 8:30 AM Mr. Craig S. Wells appeared before the Board of Pharmacy as requested. Mr Wells has applied for a Technician-In-Training Registration to complete his Clinical Rotations through the Minnesota State Community and Technical College out of Wadena, Minnesota. Mr. Wells has disclosed a prior conviction for unauthorized credit card use, for which he spent some time in the Federal Correctional Facility, was ordered to make restitution and now seeks his Technician-In-Training Registration. Mr. Wells is currently a Licensed

Practical Nurse in Minnesota and is an EMT. He is also registered as a Technician Interning in Minnesota. Mr. Wells brought his record of restitution from the Clerk of Court, which indicated that he has paid between \$200 and \$75 per month based on his income.

It was moved by Pharmacist Thom to allow Mr. Craig Scott Wells to obtain a Pharmacy Technician-In-Training Registration, good through January 31, 2011, which will allow him to complete his clinical program, get his diploma and apply for registration. We will require a full background check for Mr. Wells upon Application for Registration as a Pharmacy Technician in North Dakota and will also monitor Mr. Well's restitution payments between now and the time he applies for registration. The motion was seconded by Pharmacist Dewhirst – all Board Members voted aye – the motion carried.

At 9:00 AM President Ziegler announced that it was the appointed time for the hearing of Carl Nilles, North Dakota Pharmacist License #2806 and Nilles Drug North Dakota Pharmacy Permit No 153. President Ziegler turned the conduct of the hearing over to the Honorable Allen Hoberg, who conducted the hearing.

The hearing was recorded and Board Attorney David Lindell, JD has possession of the Exhibits presented at the hearing.

At 10:55 AM the Honorable Allen Hoberg closed the hearing of Carl Nilles, North Dakota Pharmacist License #2806 and Nilles Drug North Dakota Pharmacy Permit No 153.

President Ziegler announced that since we were running behind schedule deliberations on the Nilles Hearings and determination of Findings of Facts, Conclusions of Law and any necessary Order would be deferred until later in the day.

At 11:00 AM the Honorable Allen Hoberg began the hearing for Richard D. White – ND Registered Pharmacy Technician #336. Mr. White had signed a Stipulated Agreement prior to the conduct of this Hearing, which, if accepted, will be made a part of this record. Mr. White explained the situation surrounding the forging of prescriptions and his self-admission into a treatment facility in Crookston, Minnesota and his subsequent follow-up in treatment.

The Honorable Allen Hoberg closed the hearing for Richard D. White – ND Registered Pharmacy Technician #336 at 11:15 AM.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Thom to accept the Stipulated Agreement signed by Registered Pharmacy Technician Richard D. White. On a vote by roll call: Pharmacist Detwiller – Aye Pharmacist Dewhirst – Aye Pharmacist Thom – Aye Pharmacist Ziegler – Aye Nays none – the motion carried. Pharmacist Haroldson did not participate in the hearing or the voting, as she had declared that she served on the Investigating Committee concerning this case.

At 11:25 AM the Honorable Allen Hoberg began the hearing on the case of Patrick W. Slifka, ND Pharmacist No 4130. This hearing centered on actions taken by the Iowa Board of Pharmacy against Pharmacist Slifka, who was not present at the hearing and was not represented by counsel.

The Honorable Allen Hoberg closed the hearing on Patrick W. Slifka, ND Pharmacist License No 4130 at 11:40 AM.

It was moved by Pharmacist Thom and seconded by Pharmacist Haroldson to formulate the Findings of Facts, Conclusions of Law and an Order mirroring the actions of the Iowa Board and suspend the license of Patrick W. Slifka, until such time as he obtains re-instatement of his license in Iowa. At that time he may apply for re-instatement of his North Dakota Pharmacist No. 4130. On a vote by Roll Call: Pharmacist Detwiller – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Pharmacist Ziegler – Aye Nays none – the motion carried. Pharmacist Dewhirst did not participate in the discussion or the vote as he served on the Investigating Committee concerning this case.

Michelle L. Courtney, Registered Pharmacy Technician #718 was present and invited to meet with the Board of Pharmacy. Even though a Hearing Notice was served upon her, the Board Members agreed to conduct this informal process with Technician Courtney.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Haroldson that the records show that Michelle L. Courtney, Registered Pharmacy Technician #718 appeared before the Board of Pharmacy and the Board of Pharmacy accepted her explanation as to why she did not disclose suspension of her MN Technician Registration. The information and record of this appearance will be maintained in her file for any future reference, but that no further action will be taken at this time. All Board Members voted aye – the motion carried.

At 12:15 PM President Ziegler called for the deliberations on Carl Nilles, North Dakota Pharmacist License #2806 and Nilles Drug North Dakota Pharmacy Permit No 153 cases. Present were: Pharmacist Rick L. Detwiller – Pharmacist Gary W. Dewhirst – Pharmacist Laurel Haroldson – Pharmacist Bonnie J. Thom – Pharmacist Gayle Ziegler - Executive Director Howard C. Anderson, Jr, R.Ph. - Justin C. Stubstad, PharmD - Compliance Officer Judith Swisher, R.Ph. and Board Attorney David A. Lindell, JD. Along with Pharmacist Carl Nilles and his Attorneys Leo Ryan and Kara Helgeson.

Pharmacist Thom did not participate in this discussion or vote as she declared that she had served on the Investigating Committee concerning this case.

Pharmacist Dewhirst read aloud the Complaint allegations for the Board. President Ziegler pointed out that there was no documentation on the prescriptions about how the prescriptions were received. She said that if it was not documented, it was not done.

Pharmacist Dewhirst indicated that we need the hard copy and the documentation. The health and welfare of the public is the Board's responsibility and it is clear that something happened here that was not appropriate.

Pharmacist Detwiller recalled that Compliance Officer Swisher testified that she had called Pharmacist Nilles and that he responded in general terms, that his standard of practice was that he makes a new prescription based on talking to his patient.

Pharmacist Haroldson indicated that there was no record from a prescriber giving refill authorization.

Pharmacist Dewhirst indicated that we need to make a decision.

Pharmacist Detwiller stated that there were indications of wrong doing apparent in the testimony.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Dewhirst that the ND Board of Pharmacy find that there were violations of law and that there were prescriptions refilled without authorization of the prescriber. Additionally, the Board finds that there were no notations on the prescriptions orders of refill authorization. It is clear that copies can be regenerated from the computer. Pharmacist Nilles stated to Compliance Officer Swisher that he bases new prescriptions off of conversations with his patients. That JV was not a patient of the prescriber whose name appeared on the prescription.

Pharmacist Dewhirst pointed out that some current prescriptions say Yes in a box created for telephone and others do not, the older ones that do not are silent, meaning No.

Pharmacist Detwiller stated that a basic tenet of pharmacy practice is to record who called in a prescription.

President Ziegler pointed out that we cannot write a rule for everything in professional practice. If you are going to have a new prescription from a different prescriber, you need some indication of how you received that prescription.

Pharmacist Detwiller pointed out that you cannot separate the law, the rule and the standards of practice for a profession.

On a vote by Roll Call: Pharmacist Detwiller – Aye Pharmacist Dewhirst – Aye Pharmacist Haroldson – Aye - Pharmacist Ziegler – Aye Nays none – the motion carried. As Pharmacist Thom declared earlier, she did not participate in the deliberation or vote as she had served on the Investigating Committee concerning this case.

It was moved by Pharmacist Detwiller that an Order be prepared for Pharmacist Nilles, stating that his Pharmacist License #2806 be suspended for one month, with that suspension stayed for two years, during which time he will be on probation. The Board of Pharmacy will conduct quarterly inspections on site, of Nilles Drug during the two years of his probation, for which Pharmacist Nilles must pay the costs. Pharmacist Nilles must also pay the costs of the Investigation and prosecution of this case. There must be no violations of laws or rules during this time of probation. The motion was seconded by Pharmacist Haroldson. On a vote by Roll Call: Pharmacist Detwiller – Aye Pharmacist Dewhirst – Aye Pharmacist Haroldson – Aye - Pharmacist Ziegler – Aye Nays none – the motion carried. Again Pharmacist Thom did not participate in the deliberation or vote as she had served on the Investigating Committee concerning this case.

At 1:30 PM Bryan D. Miller, PharmD, ND Pharmacist License #5186 met with the Board of Pharmacy to discuss his recent arrest. In review of Bryan D. Miller's file it was noted that on May 20, 2004 he met with the Board of Pharmacy to ask if his conviction for Felony Theft from a previous employer would be a bar to licensure when he completed the PharmD Program. At that time the Board Members admonished him that he would have to be very careful until such time as he became licensed as a pharmacist; that he did not engage in any illegal or unprofessional activities. In July 2004 Bryan D. Miller was suspended from NDSU. He was eligible to reapply one year later and was readmitted to the PharmD Program and his intern

license was reinstated at that time. In January 2008 Bryan D. Miller was arrested for a DUI, which was later reduced by the court. During his meeting with the Board at their January 2008 meeting, Bryan was asked to meet regularly with Agnes Harrington of the Pharm-Assist Committee. The Board also stressed that Intern Miller could not have another incident occur prior to graduation and passing of the Board Exams, as he only had three rotations left to complete at that time. On February 25, 2010 Bryan D. Miller appeared in Ramsey County Northeast Judicial District Court and pled guilty to Reckless Driving, a Class B Misdemeanor. Upon the subsequent intervention and evaluation done on behalf of the Pharm-Assist Committee Pharmacist Bryan D. Miller was judged not to be chemically dependent and was asked to appear before the Board of Pharmacy on May 20, 2010.

After meeting and discussing this case with the Board, Pharmacist Detwiller pointed out that Bryan D. Miller's repeated incidents were trying his patience. Pharmacist Ziegler asked Bryan to consider the example he must be presenting to the students he might be proctoring as they come through the Hospital Pharmacy where he is employed.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Ziegler to write a letter to Bryan D. Miller, PharmD, ND Pharmacist License #5186 summarizing his history and pointing out the concerns of the Board of Pharmacy. All Board Members voted aye – the motion carried.

Mark Pajala, R.Ph., ND Pharmacist License #3988 and his wife, Linda met with the Board of Pharmacy to review his case. Pharmacist Pajala asked that the frequency of his random urine tests be reduced and that he be allowed to work full time, should he be able to find full time employment.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Dewhirst to allow the recommendation of the random urine screenings to be reduced to two times per month or if needed for Pharmacist Mark Pajala, ND Pharmacist License #3988 and to allow him to work full time, once confirmation of the appropriateness of this is received from his Psychiatrist. All Board Members voted aye – the motion carried. [Confirmation was received from Naveed Haider, MD, Psychiatry by fax from Pharmacist Pajala on May 21st 2010 that he feels Mark is capable of returning to the work force.]

At 2:00 PM President Ziegler commenced the Rule Hearing protocols for:

Chapter 61-02-01-03 – Pharmaceutical Compounding Standards

Chapter 61-02-07.1-13 – Pharmacy Technician Reinstatement

Chapter 61-13-02 - Identification Required for Controlled Substances

Present for the Rule Hearings were: Pharmacist Rick L. Detwiller; Pharmacist Gary W. Dewhirst; Pharmacist Laurel A. Haroldson; Pharmacist Bonnie J. Thom; Pharmacist Gayle D. Ziegler; Executive Director Howard C. Anderson, Jr, R.Ph.; Legal Intern Dr. Justin Stubstad; CVS Pharmacies District Manager Curtis Larson, R.Ph.; Board Attorney David Lindell; Compliance Officer Judith Swisher; Joel Aukes, PharmD, Pharmacist-In-Charge of Triumph Hospital Pharmacy in Fargo.

Dr. Aukes discussed whether or not it was necessary to place an ISO Class 5 barrier isolator or glove-box in a second ISO Class 5 area, or to have a buffer zone when one is included with the device.

Comments from Architect Karl Kilgore, who is working on several hospitals within North Dakota, mirrored the comments of Pharmacist Aukes. He felt that the barrier isolator or glove-box could be

placed in a corner of the pharmacy, or other low traffic location, and would serve very well as the qualifying primary engineering controls.

There were some questions about whether or not adding water to an antibiotic was considered compounding. It was expressed by Pharmacist Michael Riepl that some confusion might exist with the current definition of "compounding". It was also indicated that new data and definitions of "expiration dates" should be included.

Dr. Aukes expressed that there were no positive tests that gloving and gowning when doing immediate use preparations or when mixing preparations for immediate administration added any benefit to the process, while clearly adding to the expenses.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Thom that considering the significant number of comments on Chapter 61-02-01-03 – Pharmaceutical Compounding Standards as presented that we rework this rule and republish the revision for a rule hearing at a later date. All Board Members voted aye – the motion carried.

President Ziegler then opened the discussion on proposed rule Chapter 61-02-07.1-13 – Pharmacy Technician Reinstatement. There were no oral comments and there were no written comments received on this rule, to date.

President Ziegler next opened the discussion on proposed rule Chapter 61-13-02 - Identification Required for Controlled Substances. There were no oral comments presented on this rule. Pharmacist Curtis Larson, CVS Pharmacies District Manager presented a letter from his company's Director of Government Affairs, Michael Ayotte, R.Ph. These comments will be considered by the Board before final adoption of this rule.

At 2:35 PM President Ziegler closed the hearing on the rules. The record will be held open until June 18th, 2010 for any written comments received on these rules, to be taken into consideration prior to final adoption.

It was moved by Pharmacist Haroldson and seconded by Pharmacist Ziegler to approve the purchase of a new sign for the Board office, obtained by Eileen Heidrich, in the amount of \$240.00. On vote by roll call Pharmacist Detwiller – Aye Pharmacist Dewhirst – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Haroldson to approve all the legal actions taken by Executive Director Anderson since this motion was last made. All Board Members voted aye – the motion carried.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Thom to approve the revised floor plans for the remodeling of Paul Bilden Pharmacy located at 10 North Main Street in Northwood, ND. The revised plans have the addition of a counseling room clearly designated. It was noted that security is currently not in place for the Pharmacy to be locked-off when the pharmacist is not present, it will be assumed that the pharmacy will not be operated without a pharmacist present until such time as the necessary security provisions are in fact establish. All Board Members voted aye – motion carried.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Thom to approve all the paid invoices through May 19th, 2010. 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.

President Ziegler left the meeting as she had a flight to catch to the NABP Annual Meeting, we will be attending.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Thom to approve the contract extension for Health Information Designs, as contractor for the Prescription Drug Monitoring Program [PDMP]. On a vote by Roll Call: Pharmacist Detwiller – Aye Pharmacist Dewhirst – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Nays none – the motion carried. [Pharmacist Ziegler was absent for this vote]

Discussion followed on a complaint that was forwarded to the Board of Pharmacy Office by Dr. Sena Kihitir of MedCenter One Pain Clinic in Bismarck. Dr Kihitir expressed concern that pharmacies were filling or refilling prescriptions for her patients sooner than what should have been, as indicated by the days supply on the original prescription. Sometimes this amounted to a patient receiving refills on what should have been a 10 day supply of medication, every 7 days. Over a period of three or four refills this results in a significant increase in the number of doses the patient takes and these early refills are not being requested through the doctor's office. The Board Members agreed that a 30% early refill, on a ten day supply, was difficult to catch in the computer, but indicated that they all agreed the pharmacies should pay more attention to participating in the intended care of these patients with the physician and that the Board would write an advisory to our Pharmacies pointing out this concern.

The plans for the West River Regional Medical Center Pharmacy in Hettinger were reviewed, with consideration of a previous motion, relative to the compliance with the new 797 rules.

It was moved by Pharmacist Detwiller to approve the plans for the West River Regional Medical Center Pharmacy in Hettinger, as the 797 rules were not yet finalized and once they are actually finalized, the West River Regional Medical Center Pharmacy in Hettinger would be grandfathered under these rules, should slight variations exist in the final rule relative to compliance of the barrier isolators or glove-boxes, as the primary engineering controls, intended to be installed in the West River Regional Medical Center Pharmacy in Hettinger. The motion was seconded by Pharmacist Dewhirst. All Board Members present voted aye – the motion carried.

No further business remained and the meeting was adjourned.

Gayle D. Ziegler, R.Ph.
President

Gary W. Dewhirst, R.Ph.
Member

Member
Laurel A. Haroldson, R.Ph.

Member
Bonnie J. Thom, R.Ph.

Member
Rick L. Detwiller, R.Ph

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