BOARD OF PHARMACY
State of North Dakota

Jack Dalrymple, Governor

OFFICE OF THE EXECUTIVE DIRECTOR
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E-mail= ndboph@btinet.net
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William J Grosz, ScD., R.Ph.
Wahpeton, Treasurer

Thursday – June 9th, 2011
Administrative Rules Committee
Roughrider Room – State Capitol Building

Chairman Koppelman, members of the Administrative Rules Committee, thank you for the Opportunity to discuss the following rule changes with you.

I will answer your questions as a group, then when we go through the rules page by page I will point out the differences between one and the other.

1. There is only one of these rules which was impacted by a legislative change, through the passage of Senate Bill 2122. I will address that more specifically later when we get to that rule.

2. That same bill has language which refers to the Drug Enforcement Agency's rule making on electronic signature for controlled substances prescription, and you will see where that is addressed in the rule as well.

3. I have included in the packets the Public Hearing Notice, as well as the hearing record and a copy of the minutes where these rules were considered and adopted by the Board of Pharmacy. As is the general policy of this Board of Pharmacy, we usually go through a fairly extensive process with the profession and interested parties, before developing a rule to the extent that we have a public hearing. This is with the intent to iron out most of the issues in advance. Sometimes this works and sometimes not. In the case of the rule relating to identification required for controlled substances, when I first presented the three page draft of this rule a year and a half ago, our current Board President made a comment such as – "when I see a rule like this, I want to throw up." Therefore, we made significant changes before we had that rule in the form that was acceptable to the Board and some of the commenters who mentioned that there might be some onerous costs related to too much recordkeeping and for example, keeping copies of every identification record for each patient. We typically bring the suggested rule topics to the Pharmacist Convention and various meeting throughout the year, to give people as many opportunities to comment as we can. As you know publication in each county newspaper draws attention usually only to those who hire a clipping service to forward those publication to them.

4. At the rule hearing, there were no significant comments on any of these rules, as previously mentioned they had been well vetted with the interested parties. There was an exception with the compounding rules for sterile and non-sterile products, which we have been working on for about three years. We thought we had a rule which could go forward to a hearing and we did publish a regulatory analysis and included that rule in the regular rule hearing. However, the Board decided

that there were still some issues that needed to be resolved and we have been working with a subcommittee since to resolve them before having another final adoption consideration for that rule. We just had another meeting in May, where I believe we did iron out those things, but I have not yet finalized the draft. We will present this draft to the Pharmacists Association later this week.

5. The approximate cost of giving notice and holding hearings on these rules is $2,214.45

6. Let's walk through the rules one page at a time and I will explain what has happened.

On your page 18, 4. – c. you will see we have modified the language from home health care, which was an old term when this was originally adopted, which included those pharmacies serving mostly injectable products for people in home health care. We have now changed the language to sterile compounding pharmacy as the Unites States Pharmacopeia has developed a USP Compounding Standards called 797 and most states are adopting rules to try and capture the essence of those standards.

On page 20 you will see Chapter 61-02-01-17. Identification. The need for this arose on some of our inspections in recent years. We have always required our Interns to wear a badge which identifies them. With pharmacy technicians, interns and pharmacists all in the pharmacy at the same time, we felt that it was time to ask all pharmacy employees to wear a badge so that the customer or patient could easily identify with whom they were speaking. Thus, if they had personal questions they could ask them without having to ask the person before them – are you a pharmacists? or are you technician? Or are you an intern? Most pharmacies were doing a very good job of this on their own, but others need the formal rule to adopt the practice.

On page 21 - 61-02-06-02 Requirements for storage and retrieval of prescription information. Subsection 2. When this was adopted originally in 1983 computers, like old TVs, used cathod ray tubes to display thing on the screen. Hardly any computers use cathod ray tubes any more, so we made the change to computer screens to pretend we are as up to date as possible.

On page 25 - 61-04-03.1-01 Identification Required for Controlled Substances. This is the one I referred to earlier. It has been determined that in order to cut down on the propensity for individuals to obtain refill prescriptions for persons other than themselves or for people who are attempting to divert or obtain controlled substances fraudulently, this identification requirement became necessary. There are always obvious people that come into a pharmacy that you want to ask for identification, as you suspect they just might not be clearly above board. However, to avoid discrimination the rule makes it clear that identification is required for everyone the pharmacy staff does not know, and therefore eliminates the discrimination issue and makes it easy for the staff personnel to ask for the identification and record who is getting who's prescription, in case the patient themselves call or come back later asking for that same prescription and someone else has already picked it up.

On your page 26 – 61-04-05-03. Computer transmission of prescriptions. We have the modification in the rule to attempt to accommodate the electronic prescribing of controlled substances. You will see that under 2, the electronic transmission of schedule II controlled substances had not been allowed. The Drug Enforcement Administration has now adopted a rule effective June 2010 that allows this practice, however the details of how this is to be implemented is still being worked out by the industry. Thus the language you see here, rather than incorporating the federal register rule, which I believe is 57 pages long. The section originally in Senate Bill #2122 said "brand necessary"

and when it was amended while still in session, we guessed at what the center for Medicaid and Medicare Services was going to require for Medicaid and Medicare prescriptions, our best guess at the time was that they were going to require "brand medically necessary" so that is what was included in the bill and this rule. This will mean that as people redo their prescription blanks they will need to add that one word to the legend which appears below the signature line on each prescription blank.

Lastly, Chapter 61-11-01 Fees. You will see that we have increased the Wholesale License fee by $ 50. Some of you may remember that when we adopted the Prescription Drug Monitoring Program in 2005 we implemented with a grant from the Bureau of Justice Assistance and at that time knew eventually we would need to raise some funding to support that program and considered a State Controlled Substance Registration, which of course is still on the table.

However, since the manufacturers and wholesalers who license with us, are the ones who make, market and sell these products, it seemed logical to the Board of Pharmacy that we attempt to raise some additional revenue, about $40,000 in this case, which will not support the entire Prescription Drug Monitoring Program, but will slow down the decline in the Board of Pharmacy's resources somewhat. At the original $150 we were at or near the lowest in the country, with some states charging as much as $1,000 for a manufacturer/wholesaler license. Should we continue to rely on this license to fund our Prescription Drug Monitoring Program, it will probably need to be increased again. It is notable that we did not receive any comments from the industry organizations representing these groups, except to ask what the implementation date of the higher fee would be. Our renewal cycle has passed for this year, as licenses needed to be renewed by June 1st, 2011. Therefore, this new fee will apply to new licenses obtained after the effective date of these rules.

You will see under 12 – on the fees, where we have not instituted a new fee, but we were charging a $25 verification fee, which we thought should be put in the rule. Many states have required written verification, although we have a verification section on our website which pulls the most current information from our database, some state require written verification with the state seal from the Board of Pharmacy applied. We have been charging $25 for those written verifications. If the online verification is adequate there is no charge for that service.

7. As I indicated, a regulatory analysis was prepared for the modification anticipated in the sterile products rule as that was anticipated to cost more than $50,000 across the state of North Dakota. However, that rule is not part of the final adoption before you today.

8. A regulatory analysis or economic impact statement on small entities was not required and was not issued.

9. No constitutional takings assessment was prepared as this did not apply.

10. None of these rules were adopted as emergency rules.

Again, thank you.

Howard C. Anderson, Jr, R.Ph.

STATE OF NORTH DAKOTA
OFFICE OF ATTORNEY GENERAL
STATE CAPITOL
600 E BOULEVARD AVE DEPT 125
BISMARCK, ND 58505-0040
(701) 328-2210 FAX (701) 328-2226
www.ag.nd.gov

Wayne Stenehjem
ATTORNEY GENERAL

OPINION

March 25, 2011

Mr. Howard C. Anderson, Jr.
Executive Director
North Dakota Board of Pharmacy
1906 E Broadway Ave
Bismarck, ND 58501-4700

Dear Mr. Anderson:

The Office of Attorney General has examined the proposed amendments to N.D.A.C. title 61 concerning the practice of pharmacy, along with the notice of the proposed rules, the publication of that notice, and the filing of that notice with the Legislative Council. This office has also determined that 1) a written record of the agency's consideration of any comments to the proposed rules was made, 2) a regulatory analysis was not issued or requested, 3) a takings assessment was not prepared, 4) a small entity regulatory analysis and an economic impact statement were not prepared because the agency is exempt from the requirement to prepare them, and 5) the proposed rules are within the agency's statutory authority.

These administrative rules are in compliance with N.D.C.C. ch. 28-32 and are hereby approved as to their legality. Upon final adoption, these rules may be filed with the Legislative Council.

Sincerely,

Wayne Stenehjem
Attorney General

eee/vkk
cc: John Walstad, Legislative Council

Full Notice

NOTICE OF INTENT TO [ADOPT, AMEND, OR REPEAL] ADMINISTRATIVE RULES

TAKE NOTICE that the North Dakota State Board of Pharmacy will hold a public hearing to address proposed N.D. Admin. Code Article 61; Chapter 61-02 amended sections 61-02-01-01 Permit required; 61-02-01-03 Pharmaceutical Compounding Standards; 61-02-06-02 Requirements for storage and retrieval of prescription information; new section 61-04-03.1- Identification Required for Controlled Substances plus tramadol and carisoprodol; 61-04-05-03 Computer transmission of prescriptions and 61-11 Fees. The Hearings will be held at 2:00 PM on Tuesday, January 11, 2011, at Candlewood Suites – 1831 NDSU Research Park Drive in Fargo ND 58102.

The purpose of these proposed rules in 61-02-01-01 is to change Class C from home health care to "Sterile Compounding" pharmacy; 61-02-01-03 are to set standards for both non-sterile and sterile compounding [United States Pharmacopeia guidelines have been in place since June 2008]. These rules, once adopted, will give specificity to those individuals and entities in North Dakota wishing to compound pharmaceuticals, both non-sterile and sterile. These rules will give North Dakota entities a basis for coming into compliance with professional standards and a timeline for doing so. 61-02-06-02 Requirements for storage and retrieval of prescription information updates the language and 61-04-03.1 requires an ID when picking up a prescription for a controlled substance and 61-11 Fees adds written North Dakota License Verifications and raises the fee for Wholesale Licenses. The additional funds will help to support the Prescription Drug Repository Program, the prescription take back program and the Prescription Drug Monitoring Program.

The proposed compounding rules may have an impact on the regulated community in excess of $50,000. The regulatory analysis can be obtained at the location bellow.

The proposed rules may be reviewed at the office of the ND State Board of Pharmacy – 1906 E Broadway – Bismarck ND 58501 or Board website www.nodakpharmacy.com. A Copy of the proposed rules and/or a regulatory analysis may be requested by writing P O Box 1354 Bismarck ND 58502-1354; emailing ndboph2@btinet.net or calling 701-328-9535. Written or oral comments on the proposed rules sent to the above address or email address and received by January 28, 2011 will be fully considered.

If you plan to attend the public hearing and will need special facilities or assistance relating to a disability, please contact the ND State Board of Pharmacy at the above telephone number or address at least two weeks (14 days) prior to the public hearing.

Dated this 9th day of December 2010.

Howard C. Anderson, Jr, RPh.
Executive Director

Abbreviated notice

NOTICE OF INTENT TO [ADOPT, AMEND, OR REPEAL] ADMINISTRATIVE RULES RELATING TO THE PRACTICE OF PHARMACY, INCLUDING PHARMACEUTICAL COMPOUNDING STANDARDS

TAKE NOTICE that the North Dakota State Board of Pharmacy will hold a public hearing to address proposed N.D. Admin. Code Article 61; Chapter 61-02 amended sections 61-02-01-01 Permit required; 61-02-01-03 Pharmaceutical Compounding Standards; 61-02-06-02 Requirements for storage and retrieval of prescription information; Chapter 61-04 new section 61-04-03.1- Identification Required for Controlled Substances plus tramadol and carisoprodol; and amend 61-04-05-03-Computer transmission of prescriptions and amend 61-11 Fees. The Hearings will be held at 2:00 PM on Tuesday, January 11, 2011, at Candlewood Suites – 1831 NDSU Research Park Drive in Fargo ND 58102.

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If you plan to attend the public hearing and will need special facilities or assistance relating to a disability, please contact the ND State Board of Pharmacy at the above telephone number or address at least two weeks (14 days) prior to the public hearing.

Dated this 9th day of December 2010.

Howard C. Anderson, Jr, RPh.
Executive Director

North Dakota Newspaper Association
1435 Interstate Loop
Bismarck, ND 58503-0567
Ph (701) 223-6397 • Fax (701) 223-8185

JAN 07 2011

INVOICE

Order 28765-10123NN0 Invoice # 141370

January 6, 2011

Attn: EILEEN HEIDRICH
ND STATE BOARD OF PHARMACY
PO BOX 1354
BISMARCK, ND 58502-1354

Voice: 701.328.9535 Fax: 701.328.9536

Advertiser: ND State Board of Pharmacy

P.O.#:

Amount Due $2,214.45

Amount Paid

Please detach and return this portion with your payment

No charge for the Valley City Times Record publication; it ran in the wrong format.

When placing an administrative rule notice, please fax or email your request. Regular mail is not always reliable when a deadline must be met. Thank you.

ND State Board of Pharmacy Invoice # 28765-10123NN0-141370

Ad Size	*Rate Type*	*Rate*	*Total*	*Discount*	*(%)*	*Caption*	*Page*	*Run Date*
			COUNTY					
Ashley Tribune (Ashley ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/15/10
Beach Golden Valley News (Beach ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/16/10
Bismarck Tribune (Bismarck ND)								
7.00	SPR1	11.14	77.98	0.00		Practice of Pharmacy		12/17/10
Bottineau Courant (Bottineau ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/21/10
Bowbells Burke County Tribune (Bowbells ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/15/10
Bowman County Pioneer (Bowman ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/17/10
Cando Towner Co Record Herald (Cando ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/18/10
Carrington Foster Co Independ (Carrington ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/20/10
Carson Press (Elgin ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/15/10
Cavalier Chronicle (Cavalier ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/15/10
Center Republican (Hazen ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/16/10
Cooperstown Griggs County Courier (Cooperstown ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/17/10
Crosby The Journal (Crosby ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/15/10

ND State Board of Pharmacy Invoice # 28765-10123NN0-141370

Ad Size	Rate Type	Rate	Total	Discount	(%)	Caption	Page	Run Date
			COUNTY					
Devils Lake Daily Journal (Devils Lake ND)								
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Dickinson Press (Dickinson ND)								
7.00	SPR1	7.57	52.99	0.00		Practice of Pharmacy		12/15/10
Elgin Grant County News (Elgin ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/15/10
Ellendale Dickey Co Leader (Ellendale ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/16/10
Fargo, The Forum (Fargo ND)								
7.00	SPR1	11.14	77.98	0.00		Practice of Pharmacy		12/20/10
Finley Steele County Press (Finley ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/17/10
Garrison McLean Co Independ (Garrison ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/16/10
Grafton * Walsh County Record (Grafton ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/15/10
Grand Forks Herald (Grand Forks ND)								
7.00	SPR1	11.14	77.98	0.00		Practice of Pharmacy		12/18/10
Harvey The Herald-Press (Harvey ND)								
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Hazen Star (Hazen ND)								
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Hettinger Adams Co Record (Hettinger ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/17/10
Jamestown Sun (Jamestown ND)								
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Killdeer Dunn County Herald (Killdeer ND)								
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Lakota American (Lakota ND)								
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LaMoure Chronicle (LaMoure ND)								
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Langdon Cavalier Co Republican (Langdon ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/20/10
Linton Emmons County Record (Linton ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/16/10
Lisbon Ransom County Gazette (Lisbon ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/20/10
Mandan News (Bismarck ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/17/10
Mayville * Traill County Tribune (Mayville ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/18/10
McClusky Gazette (McClusky ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/16/10
Medora Billings Co Pioneer (Beach ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/16/10
Milnor Sargent County Teller (Milnor ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/17/10
Minnewaukan Benson Co Farmers Press (Minnewaukan ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/15/10

Ad Size	Rate Type	Rate	Total	Discount	(%)	Caption	Page	Run Date
			COUNTY					
Minot Daily News (Minot ND)								
7.00	SPR1	11.14	77.98	0.00		Practice of Pharmacy		12/17/10
Mohall Renville County Farmer (Mohall ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/15/10
Napoleon Homestead (Napoleon ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/15/10
New England The Herald (New England ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/17/10
New Rockford Transcript (New Rockford ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/20/10
Rolla Turtle Mountain Star (Rolla ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/20/10
Rugby Pierce County Tribune (Rugby ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/18/10
Stanley Mountrail Co Promoter (Stanley ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/15/10
Steele Ozone & Kidder Co. Press (Steele ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/15/10
Towner Mouse River Journal (Towner ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/15/10
Valley City Times-Record (Valley City ND)								
7.00	Special	0.00	0.00	0.00		Practice of Pharmacy		12/17/10
Wahpeton Daily News (Wahpeton ND)								
7.00	SPR1	7.57	52.99	0.00		Practice of Pharmacy		12/15/10
Watford City McKenzie Co Farmer (Watford City ND)								
7.00	SPR1	5.57	38.99	0.00		Practice of Pharmacy		12/15/10
Williston Herald (Williston ND)								
7.00	SPR1	7.57	52.99	0.00		Practice of Pharmacy		12/17/10

Gross Advertising	2,214.45	Total Misc	0.00	Amount Paid	0.00
Agency Discount		Tax	0.00	Adjustments	0.00
Other Discount	0.00	Total Billed	2,214.45	Payment Date	
Service Charge	0.00	Unbilled	0.00	Balance Due	2,214.45

Your payment is due upon receipt. Thank you in advance for your prompt payment!

NDNA
NORTH DAKOTA NEWSPAPER ASSOCIATION

Affidavit of Publication

Colleen Park, being duly sworn, states as follows:

1. I am the designated agent, under the provisions and for the purposes of, Section 31-04-06, NDCC, for the newspapers listed on the attached exhibits.

2. The newspapers listed on the exhibits published the advertisement of: **ND State Board of Pharmacy – Practice of Pharmacy including Pharmaceutical Compounding Standards; 1** time(s) as required by law or ordinance.

3. All of the listed newspapers are legal newspapers in the State of North Dakota and, under the provisions of Section 46-05-01, NDCC, are qualified to publish any public notice or any matter required by law or ordinance to be printed or published in a newspaper in North Dakota.

Signed: Colleen Park

State of NORTH DAKOTA

County of BURLEIGH

Subscribed and sworn to before me this 5th day of JAN ; 20 11.

Linda J. Judd

LINDA J. JUDD
Notary Public
State of North Dakota
My Commission Expires July 9, 2014

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

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

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

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

RULE HEARING FORMAT

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

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

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

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

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

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

Everyone present will be given an opportunity to speak. If you have a prepared statement, a written copy of your statement is appreciated and will be helpful.

At this point, I open the meeting for comments.

CHAPTER 61-02-01 PHARMACY PERMITS

Section 61-02-01-01 Permit Required

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

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

4. Classes of pharmacy permits are as follows:
   a. Class A - Permit to conduct an outpatient pharmacy. These permits are issued to a pharmacy dispensing drugs or devices to the general public pursuant to a valid prescription.

   b. Class B - Permit to conduct a hospital pharmacy. These permits are issued to a pharmacy dispensing drugs or devices to persons who are patients in a hospital, patients who are being discharged, or patients in emergency situations, pursuant to a valid prescription. These permits shall be issued to facilities licensed under North Dakota Century Code chapter 23-16 and shall be issued in the name of the facility.

   Class C - Permit to conduct a ~~home health care~~ sterile compounding pharmacy. These permits are issued to a pharmacy dispensing sterile injectable drug products and devices to the general public who are not patients within a facility with a class B pharmacy permit pursuant to a valid prescription.

   d. Class D - Permit to conduct a long-term care pharmacy. These permits are issued to a pharmacy dispensing drugs and devices to residents of facilities licensed under North Dakota Century Code chapters 23-09.3 and 23-16 pursuant to a valid prescription which are not physically accessed by the general public.

   e. Class E - Permit to conduct a nuclear pharmacy. These permits are issued to a pharmacy dispensing or providing diagnostic or therapeutic radioactive drugs or devices for administration to an ultimate user.

   f. Class F - Permit to conduct a mail-order pharmacy. These permits are issued to a pharmacy dispensing drugs and devices to the general public exclusively through the

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

g. Class G - Permit to conduct an out-of-state pharmacy. These permits are issued to any pharmacy operating outside the state of North Dakota which ships, mails, or delivers in any manner a dispensed prescription drug or legend device into North Dakota, which shall obtain and hold a pharmacy permit issued by the North Dakota state board of pharmacy and that part of the pharmacy operation dispensing the prescription for a North Dakota resident shall abide by state laws and rules of the board.

h. Class H - Permit to conduct a governmental agency pharmacy. This permit is issued to a pharmacy operated by the state of North Dakota, dispensing drugs and devices only to patients within correctional facilities or rehabilitation facilities, or for the purpose of teaching at institutions of higher learning, pursuant to a valid prescription.

i. Class I - Permit to conduct a research pharmacy. This permit is issued to a pharmacy in which scientific research is conducted under protocols established by an institutional review board meeting federal drug administration guidelines. Pharmaceuticals on hand are incident to the research being conducted. Security and storage for pharmaceuticals must meet United States Pharmacopeia and board of pharmacy requirements. A specific application for a pharmacy permit must be made delineating the specific physical facility to be utilized.

j. Class J - Permit to conduct an office practice pharmacy. Any licensed pharmacist may practice in an office pharmacy setting where prescriptions are not routinely dispensed. If legend drugs or devices are maintained, a permit must be obtained by making application to the board of pharmacy delineating specific practice intentions and assuring the board that security and storage requirements are met for any legend drugs or pharmaceuticals on hand.

k. Class K - Permit to conduct telepharmacy. A pharmacy staffed by a registered pharmacy technician with access to its main pharmacy and registered pharmacists by computer link, videolink, and audiolink while open.

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

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

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

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

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

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

2. An electronic system must provide on line retrieval via ~~catho ray tube~~ computer screen or hard-copy printout of original prescription order information for those prescription orders which are currently authorized for refilling. If more refills are authorized, it must be noted on the ~~catho ray tube~~ computer screen or on the hard copy of prescription or a new prescription must be produced.

3. Must produce a hard-copy daily summary of controlled substance transactions. Monthly summaries must be produced and filed with the biennial inventory.

4. Be capable of recording and carrying in the record all dates of refills of any prescription and the initials of the pharmacist.

5. Be capable of producing a patient profile indicating all drugs being taken and the date of refills of these prescriptions, as required by North Dakota Century Code section43-15-31.1.

6. Be capable of reconstructing information, by daily backups in the event of a computer malfunction or accident resulting in destruction of the data base.

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

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ARTICLE 61-04 PROFESSIONAL PRACTICE

Chapter

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

Chapter 61-04-03.1 IDENTIFICATION REQUIRED FOR CONTROLLED SUBSTANCES

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

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

All verbal comment made on this rule expressed support.

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

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

Option 1:

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

Option 2 :

2. Transmission of schedule II controlled substance prescriptions via computer, electronic prescriptions, is ~~not~~ allowed, when it is done in compliance with 21 CFR part 1311 subpart C Electronic Prescriptions.

3. The required legend must appear on the practitioner's prescription screen. The practitioner must take a specific overt action to include the "brand necessary" language with the electronic transmission as set forth in subsections 3 and 4 of North Dakota Century Code section 19-02.1-14.1. For example, the practitioner or the practitioner's agent must type out "brand necessary" letter by letter.

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

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ARTICLE 61-11 FEES

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

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

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

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CLOSING

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

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

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

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

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

Written comments, additions or corrections will be inserted here.

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

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

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

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

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

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

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

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

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

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

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

It was moved by Pharmacist Haroldson and seconded by Pharmacist Ziegler to approve the relocation plans for Hankinson Drug from 309 Main Street to 323 Main Ave South in Hankinson, ND. All Board Members voted aye – the motion carried.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Haroldson to approve the Application for a subclass K to their Class B Hospital Pharmacy Permit for First Care Health Center Pharmacy in Park River, ND. Pharmacist Laurie Larson is their pharmacist-in-charge and the hospital will be doing telepharmacy with the Altru Health Systems in Grand Forks over a Vidyo System. Pharmacist Jeff Zak has looked at this system and has approved it's functionality. All Board Members voted aye – the motion carried.

Board Members reviewed the letter from the Attorney General offering his opinion that the "rules were within the scope of the Board of Pharmacy and acceptable."

It was moved by Pharmacist Ziegler and seconded by Pharmacist Dewhirst that we approve NDAC 61-02-01-01 Permit required; 61-02-06-02 Requirements for storage and retrieval of prescription information; 61-04-03.1 Identification Required for Controlled Substances plus tramadol and carisoprodol and 61-11 Fees as printed. All Board Members present voted aye – the motion carried.

It was moved by Pharmacist Ziegler and seconded by Pharmacist Dewhirst that NDAC 61-04-05-03 Computer transmission of prescriptions be approved with the 2nd alternative and that the term "medically" be added in concurrence with Senate Bill #2122 which says ""brand medically necessary" - and is working it's way through the legislative session. All Board Members present voted aye – the motion carried.

No actions were taken on 61-02-01-03 Pharmaceutical Compounding Standards as that hearing is being continued and will be re-advertised for our May meeting. Pharmacist Ziegler pointed out that she had volunteered to work with a group of sterile products and compounding pharmacists to get some input and make some changes in that rule; based on comments we have received.

Consideration of a temporary Pharmacist License for Adam L. Hergenhahn was discussed. Pharmacist Hergenhahn was granted an Intern License so he could begin working with the coverage pharmacist at Triumph Hospital Central Dakotas Pharmacy in Mandan for the next few weeks. Pharmacist Hergenhahn was originally licensed in Alaska. He let that license go and must re-instate it to reciprocate off that original license to North Dakota. With indications that the Triumph Hospital Central Dakotas Pharmacy had coverage and that Pharmacist Hergenhahn was working quickly to get his Alaska License re-instated and taking his MPJE test for the reciprocity to North Dakota, the exigency for a temporary license did not seem to be present. Therefore, the Board demurred and continued their policy of not granting temporary licenses except those pharmacists serving our state in an emergency.