



BOARD OF PHARMACY
State of North Dakota

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Gary W. Dewhirst, R.Ph.
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Dewey Schlittenhard, MBA, R.Ph.
Bismarck
Rick L. Detwiller, R.Ph.
Bismarck
Bonnie J Thom, R.Ph.
Granville
William J. Grosz, Sc.D., R.Ph.
Wahpeton, Treasurer

Administrative Rules Committee

2:45 PM - Thursday – September 13, 2007 – Roughrider Room

Thank you for the opportunity to discuss the following rule changes with you today.

Chapter 61-02-01-15 Closing a Pharmacy
Chapter 61-02-01-16 Transfer of controlled substances when selling a business
Chapter 61-03-01 Approved Schools
Chapter 61-03-02 Definitions. Distribution and control.
Chapter 61-04-04-01 Definition of Unprofessional Conduct

1. All but one of these rule changes are a result of statutory changes made by the Legislative Assembly and the one that is not is an update for a name change. The changes in 61-02-01-15 and 61-02-01-16 are rules adopted as the result of changes made by House Bill #1054 in NDCC 43-15-38.1 Closing a Pharmacy. The change in 61-03-02 is to spell out the requirements for the use of an Automatic Dispensing System now defined through the changes in House Bill #1054. The additions to the Unprofessional Conduct rule are the results of the requirement to report to the Prescription Drug Monitoring Program under Senate Bill 2134 and the reporting requirements adopted by House Bill 1054 under 43-15-42.3.
2. The rules for Closing a Pharmacy, the Transfer of Controlled Substances when Selling a Business and the definition for the use of an Automatic Dispensing System are all related to Drug Enforcement Administration Requirements. We have attempted in the rule to facilitate the use of an Automatic Dispensing System in North Dakota by including them in our law and rule and we are reiterating the reporting requirements under the DEA rules to help our pharmacies comply with not only North Dakota rule but with Federal Requirements when closing a pharmacy or transferring controlled substances when selling a pharmacy.
3. Attached is a copy of our hearing notice. The Board held some preliminary meetings on these rules and they were actually thoroughly discussed before the legislation was proposed. Of course, we had them ready for adoption once the legislation became effective. Since they were thoroughly vetted, there were no comments about the substance of the rules as the Board had done all that before the final promulgation.
4. Attached are Hearing Record and pertinent sections of the May Minutes and July Board Meeting Minutes.

5. The cost of giving public notice was \$1,532.50 and the hearing was held in conjunction with a scheduled Board Meeting to keep the costs to a minimum.
6. Let me briefly review each of the rule changes and the rational for the change.

On page 21- Chapter 51-02-01-15 Closing a Pharmacy – was in response to the many telephone calls to the Board Office repeatedly asking questions on this topic. This new rule establishes guidelines and gives them a reference to answer their questions.

On page 22 -Chapter 61-02-01-16 Transfer of controlled substances when selling a business – again was in response to the repeated questions being asked and gives them a reference to answer their questions.

On page 23 - Chapter 61-03-01 Approved Schools is a correction or update to the name change from the American Council of Pharmaceutical Education to the Accreditation Council for Pharmacy Education.

On page 26 - Chapter 61-03-02 Definitions. Distribution and control. Is an addition of the definition of an Automated Dispensing System (ADS) and sets guidelines for their use.

On page 31 - Chapter 61-04-04-01 Definition of Unprofessional Conduct. Is the addition of two definitions that address the reporting to the Prescription Drug Monitoring Program and the reporting of any disciplinary actions to the Board of Pharmacy.

7. There was no regulatory analysis required by NDCC Section 28-32-08 and none was issued.
8. There was no regulatory analysis or economic impact statement on small entities required By NDCC Section 28-32-08.1 and none was issued.
9. There was no constitutional takings relating to any of these rules and thus NDCC 28-32-09 did not require preparation of an assessment.
10. None of these rules were adopted as emergency rules.

Thank You.



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

HCA/eh

Full Notice

NOTICE OF INTENT TO ADOPT OR AMEND ADMINISTRATIVE RULES

TAKE NOTICE that the North Dakota State Board of Pharmacy will hold a public hearing to address proposed new rules and amendments to, the N.D. Admin. Code Title 61 at 10:00 AM on Thursday, May 17th, 2007 in Room 1206 at the Radisson Inn – 201 N 5th Street in Fargo, North Dakota.

The purpose of the proposed new rules, or amendments, these rules will in part, implement changes to NDCC 43-15 and Title 19 Chapter 19-03 as adopted in House Bill 1054 and House Bill 1055. The proposed new rules, and amendments, address NDAC 61-02-01-15 Pharmacy Closings and Reporting Requirements; 61-02-01-16 Transfer of Controlled Substances when Selling a Business; 61-03-01-02 Approved Schools; 61-03-02-04 Definitions – Automated Dispensing Systems; 61-04-04-01 Definition of Unprofessional Conduct Reporting. The proposed rules, and amendments, are not expected to have an impact on the regulated community in excess of \$50,000.

We will also hold a preliminary meeting to begin drafting rules to implement House Bill 1455 on Wholesale Licensing, VAWD Certification and Pedigree Requirements and House Bill 1256 on the Prescription Drug Donation Program.

The proposed rules may be reviewed at the office of ND State Board of Pharmacy – 1906 E Broadway Ave – Bismarck 58501. A copy of the proposed rules and/or a regulatory analysis may be requested by writing the above address or calling 701-328-9535 or email ndboph2@btinet.net. Written comments on the proposed rules sent to the ND Board of Pharmacy - P O Box 1354 – Bismarck ND 58502-1354 or and received by June 1st, 2007, 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 12th day of April 2007.

Howard C. Anderson, Jr, RPh.
Executive Director

HEARING RECORD

May 17, 2007

Fargo Radisson Inn – Room 1206

Page 1

I am Bonnie Thom, President of the Board of Pharmacy and I will be acting as hearing officer for this public hearing.

It is now 10:00 AM on Thursday May 17, 2007 at RADISSON INN (201 5TH St N-Fargo) in Room 1206.

This public hearing has been called for the purpose of allowing all interested individuals an opportunity to submit information concerning:

Consideration of Rules to implement;

(HB 1054)	61-02-01-15	Pharmacy Closings and Reporting Requirements (new)
	61-02-01-16	Transfer of Controlled Substances when selling a business (new)
	61-03-01-02	Approved Schools (correction)
	61-03-02-04	Definitions. Automated Dispensing System (new)
	61-04-04-01	Definition of Unprofessional Conduct reporting (new)

Information gathered at this hearing 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, 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 hearing for comments.

The only comments, orally or written received were the corrections in 61-04-04-01 Definition of Unprofessional Conduct Reporting subsection 19 from NDCC 50-05-27 to 19-03.5 and the Correction in the numbering of the statute from House Bill 1054 correcting 43-15-44.2 to 43-15-42.3 as specified in the bill.

CLOSING

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

The record will be held open for written comment through June 7th, 2007.

At this point, I will close the hearing on:

(HB 1054)	61-02-01-15	Pharmacy Closings and Reporting Requirements (new)
	61-02-01-16	Transfer of Controlled Substances when selling a business (new)
	61-03-01-02	Approved Schools (correction)
	61-03-02-04	Definitions. (new) Automated Dispensing System
	61-04-04-01	Definition of Unprofessional Conduct (new) reporting

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

At 10:00 AM President Thom opened the Hearing on the rules by stating, it is now 10:00 AM on Thursday May 17, 2007 at the Radisson Inn (201 5TH St N-Fargo) in ROOM 1206.

This public hearing has been called for the purpose of allowing all interested individuals an opportunity to submit information concerning:

Consideration of Rules to implement;

(HB 1054) 61-02-01-15 Pharmacy Closings and Reporting Requirements (new)
61-02-01-16 Transfer of Controlled Substances when selling a business

(new)

61-03-01-02 Approved Schools (correction)

61-03-02-04 Definitions. Automated Dispensing System (new)

61-04-04-01 Definition of Unprofessional Conduct Reporting (new)

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

The only comments, orally or written received were the corrections in 61-04-04-01 Definition of Unprofessional Conduct Reporting subsection 19 from NDCC 50-05-27 to 19-03.5 and the Correction in the numbering of the statute from House Bill 1054 correcting 43-15-44.2 to 43-15-42.3 as specified in the bill.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Thom for final adoption of the following rules:

- (HB 1054) 61-02-01-15 Pharmacy Closings and Reporting Requirements (new)
61-02-01-16 Transfer of Controlled Substances when selling a business
(new)
61-03-01-02 Approved Schools (correction)
61-03-02-04 Definitions. Automated Dispensing System (new)
61-04-04-01 Definition of Unprofessional Conduct Reporting (new)

The only comments, orally or written received were the corrections in 61-04-04-01 Definition of Unprofessional Conduct Reporting subsection 19 from NDCC 50-05-27 to 19-03.5 and the Correction in the numbering of the statute from House Bill 1054 correcting 43-15-44.2 to 43-15-42.3 as specified in the bill. There were no comments received at the hearing and no comments received during the open comment period. The rules are being adopted. The motion carried.