



State of North Dakota
Jack Dalrymple, Governor

OFFICE OF THE EXECUTIVE DIRECTOR

1906 E Broadway Ave
Bismarck ND 58501-4700
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STATE BOARD OF PHARMACY

E-mail= Mhardy@btinet.net www.nodakpharmacy.com

Mark J. Hardy, PharmD, R.Ph.
Executive Director

Administrative Rules Committee
10:30 AM - Monday – March 14th, 2016
Roughrider Room – State Capitol

Chairman Devlin, members of the Administrative Rules Committee, for the record I am Mark J. Hardy, PharmD, Executive Director of the ND State Board of Pharmacy. Thank you for the opportunity to discuss the following rule changes with you.

1. Two of these rules were enacted based on a legislative change. Through the passage of Senate Bill 2104, which allows a pharmacist to obtain prescriptive authority to prescribe and dispense Naloxone Rescue kits to prevent overdose death. Secondly, Senate Bill 2173 on the limited prescriptive practices, through the collaborative agreements between pharmacists and practitioners.
2. There are no rules related to Federal changes in statute or legislation.
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 the 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.
4. At the rule hearing, there were comments received on a few of these rules. The consideration of these comments is included in the packet, along with the detailed written comments that were received. The Board made revisions based on the comments.
5. The cost of public notice and holding the hearings was \$2,199.86 for publication. The cost of the legal opinion is also attached.
6. I will address each of the rules in turn:

61-02-09 Continuous Quality Improvement [page 101] – will require pharmacies to adopt and utilize a tracking system for quality related events, to improve their practices to ensure the highest level of care is administered to their patients. Many third-party insurances require pharmacies to have a continuous quality improvement at their location as part of their contract. The Board of Pharmacy felt it was important that each

pharmacy location maintain continuous improvement of standards for their patients. These tracking systems are confidential, so the filed reports cannot be used punitively against their practice. Examples of quality related events might be a dispensing error, selecting the wrong medication or general practice error that may not have reached the patient level. Tracking these events and making improvements to prevent them, while addressing them with staff is very important for the highest quality of care.

61-03-01-04 Pharmacist License Transfer [page 105] –revises the administrative code language on the license transfer procedures currently in place for those pharmacists licensed in another state. This rule does not change the process, simply clarifies it for a pharmacist transferring their license to North Dakota. The current language created confusion, implying that they may not have to take the law examination before becoming licensed. The examination referenced in the original rule was for a pharmacist just graduating and becoming licensed in North Dakota, which the Board of Pharmacy will administer a practical examination. The practical examination tests compounding, dispensing, counseling and answering oral questions from the Board to effectively determine they are competent to practice and communicate with the public.

61-04-08 Limited Prescriptive Practices [page 106] - revise the administrative code based upon recent legislative changes in the ND Century Code set forth in Senate Bill 2173. These changes are uniform to the changes instituted by SB 2173 relative to Collaborative Agreements between pharmacists and physicians or nurse practitioners to modify or initiate drug therapy. Practitioners and healthcare facilities rely upon pharmacists to use their knowledge to improve patient outcomes. The changes made by you, the legislature have been very positive across the state of North Dakota.

61-04-10 CLIA Waived Laboratory Tests [page 112] - is revised to expand and modify the language to the current practice standards for those tests pharmacists are able to perform. It has been a while since the Board had reviewed the provisions of this rule and modifications were required to bring the language to the current practice standards. Pharmacists are being asked to provide CLIA waived tests, which include blood glucose, blood pressure, cholesterol, as well as rapid influenza, rapid strep and narcotic drug tests, to assist in identifying patient health issues to refer them to the appropriate practitioner if necessary.

61-04-12 Limited Prescriptive Authority for Naloxone [page 116] – creates the administrative code based upon Senate Bill 2104 allowing a process for a pharmacist to obtain prescriptive authority to prescribe and dispense Naloxone Rescue kits to prevent overdose death. This prescriptive authority for pharmacists is one of the tools to help prevent overdose deaths. The Board will develop a protocol and provide pharmacists information on where to obtain the appropriate education and also look to provide notification to the public on how, when and where, which pharmacies Naloxone can be obtained. Naloxone is typically an injected

medication. However, the rescue kits can be stocked with a rapid injection device, similar to an EpiPen or have a nasal inhalation atomizer device.

7. A regulatory analysis was not required, however we did prepare one and it is attached
8. An Economic impact statement on small entities was not required, however we did prepare one and it is attached.
9. We do not anticipate these rules will have a fiscal effect on the Board of Pharmacy.
10. No constitutional takings assessment was prepared as this did not apply.
11. None of these rules were adopted as emergency rules.

Respectfully,
Mark J. Hardy, PharmD
MJH/eh

NOTICE OF INTENT TO ADOPT AND AMEND ADMINISTRATIVE RULES

TAKE NOTICE that the North Dakota State Board of Pharmacy will hold a public hearing to address proposed new N.D Admin. Code 61-02-01-19-Continuous Quality Improvement and 61-04-12 Limited Prescriptive Authority for Naloxone; and proposed amendments to N.D. Admin. Code 61-03-01-04-Licensure Transfer; 61-04-08-Limited Prescriptive Practices; and 61-04-10-CLIA Waived Laboratory Tests at 10:00AM on Thursday, September 17, 2015, in the Board of Pharmacy conference room at 1906 East Broadway, Bismarck, ND.

61-02-01-19 Continuous Quality Improvement – will require pharmacies to adopt and utilize a tracking system for quality related events, to improve their practices to ensure the highest level of care is administered to their patients.

61-04-12 Limited Prescriptive Authority for Naloxone – creates the administrative code based upon Senate Bill 2104 allowing a process for a pharmacist to obtain prescriptive authority to prescribe and dispense Naloxone Rescue kits to prevent overdose death.

61-03-01-04 Pharmacist License Transfer –revises the administrative code language reflecting the license transfer procedures currently in place for those pharmacists licensed in another state.

61-04-08 Limited Prescriptive Practices - revise the administrative code based upon recent legislative changes in the ND Century Code set forth in Senate Bill 2173.

61-04-10 CLIA Waived Laboratory Tests - is revised to expand and modify the language to the current practice standards for those tests pharmacists are able to perform.

The proposed amendments and new sections are not expected to have an impact on the regulated community in excess of \$50,000. A copy of the proposed rules are on our website: www.nodakpharmacy.com and may be obtained by writing the North Dakota State Board of Pharmacy, by calling (701) 328-9535 or by email ndboph2@btinet.net. Also, written comments may be submitted to 1906 East Broadway, Bismarck, ND 58501 until October 5, 2015. If you plan to attend the public hearing and will need special facilities or assistance relating to a disability, please contact the North Dakota State Board of Pharmacy at the above telephone number or address at least 14 days prior to the public hearing.

Dated this 5th day of August, 2015.

Mark J. Hardy, PharmD
Executive Director

**ABBREVIATED NOTICE OF INTENT TO ADOPT AND
AMEND ADMINISTRATIVE RULES**

RELATING TO North Dakota State Board of Pharmacy regulating of the Practice of Pharmacy

TAKE NOTICE that the North Dakota State Board of Pharmacy will hold a public hearing to address proposed new N.D Admin. Code 61-02-01-19 Continuous Quality Improvement for Pharmacies and 61-04-12 Limited Prescriptive Authority for Naloxone; and proposed amendments to N.D. Admin. Code 61-03-01-04 Pharmacist Licensure Transfer; 61-04-08 Limited Prescriptive Practices; and 61-04-10 CLIA Waived Laboratory Tests at **10:00AM on Thursday, September 17, 2015, in the Board of Pharmacy conference room at 1906 East Broadway, Bismarck, ND.**

A copy of the proposed rules may be obtained by writing the North Dakota State Board of Pharmacy, calling (701) 328-9535 or by email ndboph2@btinet.net. Also, written comments may be submitted to 1906 East Broadway, Bismarck, ND 58501 until October 5, 2015. If you plan to attend the public hearing and will need special facilities or assistance relating to a disability, please contact the North Dakota State Board of Pharmacy at the above telephone number or address at least 14 days prior to the public hearing.

Dated this 5th day of August, 2015.

Mark J. Hardy, PharmD
Executive Director

Consideration of Comments for September 17, 2015 rule hearing.

- 1. Revise N.D. Admin. Code Chapter 61-02-01 to add a Continuous Quality Improvement and Policy and Procedure Requirement for retail pharmacies.**
No Comments Received
- 2. Revise N.D. Admin. Code Chapter 61-03-01 Licensure of Pharmacists to transfer a license or license reciprocity**
No Comments Received
- 3. Revise N.D. Admin Code Chapter 61-04-10 CLIA Waived Laboratory Tests**
Lauren Berton: CVS Health in support of the revised proposed language which expands current practice standards for pharmacists performing CLIA waived laboratory tests. We do ask that the board consider further expansion to allow a pharmacist designee under supervision, such as a technician or intern, to perform these tests. I have included suggested changes to language in blue below to 61-04-10-01(3), 61-04-10-02 and 61-04-10-03 to allow a pharmacist designee to perform these tests. We also request that the board add language to 61-04-10-06(1) specifically allowing LDL cholesterol testing.

Proposed Language

61-04-10-01. Definitions. For purposes of this chapter:

3. "Portfolio review" means a review by the board of a ~~pharmacist's~~ Pharmacy's records of ~~proficiency testing training logs, control testing logs, and records of patient tests performed to determine that a pharmacist pharmacy is continuously and consistently providing a service in a quality and competent manner.~~

61-04-10-02. Education requirements ~~for pharmacists to perform CLIA waived laboratory tests.~~ ~~A pharmacist~~ An individual licensed or registered by the Board must meet the following requirements in order to perform CLIA waived laboratory tests authorized by North Dakota Century Code section 43-15-25.3 or added to the list as allowed by ~~that section~~ 61-04-10-06:

61-04-10-03. Minimum quality standards required. ~~Pharmacists~~ Pharmacies performing CLIA waived laboratory tests must meet the following standards:

61-04-10-06. Exempt tests and methods. An individual licensed or registered by the board, performing the following food and drug administration-waived tests and using the following methods, is exempt from the provisions of North Dakota Century Code chapter 43-48:

1. Total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides test by any accepted method

Jeff Lindoo: Thrifty White believes it is essential that pharmacists be allowed to delegate these tasks.

- These tests are CLIA-waived, because it has been determined that they do not require the education and training of a laboratory technician to do the test. In fact, these are tests that consumers can do themselves.
- We cannot expand pharmacy practice toward pharmacists truly serving as a health care practitioner if we saddle pharmacists with requirements to perform tasks that can be delegated individuals with much less education and training and at a much lower salary level. We don't require pharmacists to count pills and put them in bottles, because we have realized that is not good use of their education & training. I believe this is the same thing.

Board Response:

The Board agrees with the addition of “LDL Cholesterol” in 61-04-10-06 (1).

The Board discussed the topic of delegation and the following is from the minutes during the September 24th public hearing.

In discussions regarding changes to the CLIA waived Tests rules, Dr. Hardy explained a past comment received from Pharmacist Jeffrey Lindoo on the involvement of Pharmacy Technicians in conducting CLIA waived Tests. Board Members agreed that while technicians certainly can assist a pharmacist in preparing the patient for the test, the actual test must be conducted by the pharmacists. There was no feeling that any language would need to be changed to account for this consensus.

Regarding Interns, we would maintain the intern can conduct the tests as long as it is done under a supervising pharmacist who is able to conduct the specific test and the intern is properly trained to conduct the test. This is a consistent stance on other duties interns are able to perform under pharmacist supervision.

Joel Kurzman: NACDS supports the proposed rules that expand the types of CLIA-waived tests that pharmacists can provide to their patients without having to comply with requirements of North Dakota Century Code chapter 43-48. This rule change will enable pharmacists and pharmacies to offer additional healthcare services that are currently provided by pharmacists and pharmacies in other states. Elsewhere in the country, pharmacists and pharmacies increasingly offer this public health service to promote prevention, early detection, and disease management. Given that millions of Americans lack adequate and timely access to primary health care, eliminating barriers to pharmacist-provided services such as CLIA-waived tests will allow pharmacists to assist physicians and other healthcare providers in meeting increased patient demand for basic healthcare services in North Dakota.

Board Response: The Board would agree with the comment.

Bridget Weidner: Staff in our office [North Dakota Department of Health] have reviewed the proposed North Dakota Board of Pharmacy rule changes to Chapter 61-04-10 CLIA Waived Laboratory Tests. We have a concern with section 61-04-10-06. Exempt tests and methods. The rule states that an individual licensed by the board, performing the following food and drug administration-waived tests and using the following methods, is exempt from the provision of the North Dakota Century Code chapter 43-48. Included in the lists of tests is Vitamin D blood test by any accepted method and genomic testing by any accepted method. These two tests are not currently food and drug administration waived tests. Since these tests are not food and drug administration waived tests, the pharmacy would not be able to perform this testing under a CLIA Certificate of Waiver.

Board Response: The Board would agree with the comments that since these two tests are not included as CLIA waived test that we will remove Vitamin D blood test and the genomic test from 61-04-10-06.

Sandra Matthey: On behalf of the North Dakota Board of Clinical Laboratory Practice, I am writing a letter of concern regarding your change to Administrative Rule § 61-04-10-06 which would allow licensed Pharmacists to perform waived laboratory testing. The Clinical Laboratory Administrative Rule § 96-02-10-01 already has a list of waived exempt tests which can be performed by non-laboratory personnel under the supervision of someone licensed by the ND Board of Clinical Laboratory Practice. The Board of Clinical Laboratory Practice carefully screens each of these tests to ensure that they are indeed waived tests and that the public is

safe to have these tests performed by non-laboratory personnel. Many of the tests in § 61-04-10-06 are not waived, the testing process is not simple, and the language is very nonspecific. In fact, the term “by any accepted method” is very broad and may lead to unsafe laboratory testing since these methods are not vetted by the Board of Clinical Laboratory Practice. We respectfully ask that you consider these concerns and perhaps defer to the language of the Administrative Rule § 96-02-10-01. The Board would be willing to discuss this with the Board of Pharmacy at your convenience.

Board Response: The Board appreciates the efforts which the Board of Clinical Laboratory Practice has put into the list in their Administrative Rules. Our Board crafted our lists of tests specifically from 96-02-10-01 Administrative Rule. There are a few key additions of tests made to the list in 61-04-10-06 which the Board felt are safe and reasonably simple to administer. Pharmacists are increasingly being called upon and educated to conduct these simple point of care tests which often are purchased at their pharmacies. We have made the following modifications to the list of tests which differ from the tests outlined in 96-02-10-01 and NDCC 43-15-25.3.

13. Nicotine or cotinine test by any accepted method urine

14. Thyroid stimulating hormone blood test by any accepted method, blood

15. Vitamin D blood test by any accepted method

16. Bone mass and bone mineral density test by any accepted method

17. Genomic testing by any accepted method

18. Drug screening tests by any accepted method urine

4. Revise N.D. Admin. Code Article 61-04 to add N.D. Admin. Code Chapter 61-04-12 Limited Prescriptive Authority for Naloxone

Joel Kurzman: Pharmacists and pharmacies have an important role to play in facilitating access to naloxone for overdose prevention purposes. Pharmacists are recognized medication experts and are oftentimes the most readily accessible healthcare provider in local communities. By enabling pharmacists to prescribe and dispense Naloxone rescue kits in accordance with a written protocol approved by the board, the proposed rules will serve to eliminate barriers that can otherwise deter individuals from obtaining naloxone for use in overdose prevention scenarios. We commend the Board for promulgating regulations that clarify and streamline the process by which pharmacists can obtain limited prescriptive authority for naloxone for this purpose.

Board Response: The Board would agree with the comment.

5. Revise N.D. Admin. Code Chapter 61-04-08 Limited Prescriptive Practices
No Comments Received



NORTH DAKOTA
DEPARTMENT *of* HEALTH

HEALTH RESOURCES SECTION
600 East Boulevard Avenue, Dept. 301
Bismarck, ND 58505-0200
Fax: 701.328.1890
www.ndhealth.gov



To: North Dakota Board of Pharmacy

From: Bridget Weidner^{BW}, North Dakota Department of Health
Division of Health Facilities CLIA Program

Subject: Chapter 61-04-10 CLIA Waived Laboratory Tests

Date: October 5, 2015

Staff in our office have reviewed the proposed North Dakota Board of Pharmacy rule changes to Chapter 61-04-10 CLIA Waived Laboratory Tests. We have a concern with Section 61-04-10-06. Exempt tests and methods. The rule states that an individual licensed by the board, performing the following food and drug administration-waived tests and using the following methods, is exempt from the provision of the North Dakota Century Code chapter 43-48. Included in the list of tests is Vitamin D blood test by any accepted method and genomic testing by any accepted method. These two tests are not currently food and drug administration waived tests. Since these tests are not food and drug administration waived tests, the pharmacy would not be able to perform this testing under a CLIA Certificate of Waiver.

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OCT 22 2015



**NORTH DAKOTA BOARD OF CLINICAL
LABORATORY PRACTICE**
P.O. Box 4103
Bismarck, ND 58502-4103
Phone: 701-530-0199
Fax: 701-224-9824

www.ndclinlab.com
ndbclp@aptnd.com

October 20, 2015

Mark Hardy, PharmD
North Dakota State Board of Pharmacy
1906 East Broadway Avenue
Bismarck, ND 58501

Re: Proposed changes to Administrative Rule 61-04-10-06

Dear Board of Pharmacy:

On behalf of the North Dakota Board of Clinical Laboratory Practice, I am writing a letter of concern regarding your change to Administrative Rule § 61-04-10-06 which would allow licensed Pharmacists to perform waived laboratory testing. The Clinical Laboratory Administrative Rule § 96-02-10-01 already has a list of waived exempt tests which can be performed by non-laboratory personnel under the supervision of someone licensed by the ND Board of Clinical Laboratory Practice. The Board of Clinical Laboratory Practice carefully screens each of these tests to ensure that they are indeed waived tests and that the public is safe to have these tests performed by non-laboratory personnel. Many of the tests in § 61-04-10-06 are not waived, the testing process is not simple, and the language is very nonspecific. In fact, the term "by any accepted method" is very broad and may lead to unsafe laboratory testing since these methods are not vetted by the Board of Clinical Laboratory Practice. We respectfully ask that you consider these concerns and perhaps defer to the language of the Administrative Rule § 96-02-10-01. The Board would be willing to discuss this with the Board of Pharmacy at your convenience. Thank you.

Sincerely,

A handwritten signature in cursive script that reads "Sandra Matthey".

Sandra Matthey, Board Chair
North Dakota Board of Clinical Laboratory Practice

INVOICE

Please Remit To:

Attorney General's Office
600 E. Blvd.
Bismarck ND 58505-0040
United States

Page: 1
Invoice No: 122015.920.0
Invoice Date: 01/19/2016
Customer Number: 920.0
Payment Terms: Due Immed
Due Date: 01/19/2016

Bill To:

Pharmacy, Board of
Howard C Anderson Jr.
P O Box 1354
Bismarck ND 58502
United States

AMOUNT DUE: 147.02 USD

147.02
Amount Remitted



For billing questions, please call 701-328-4213

Line	Adj	Identifier	Description	Quantity	UOM	Unit Amt	Net Amount
1		LEGAL SERVICE		1.00		147.02	147.02
SUBTOTAL:							147.02
TOTAL AMOUNT DUE :							147.02

ok time
[Signature]

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SEP 03 2015

North Dakota Newspaper Association

1435 Interstate Loop

Bismarck, North Dakota 58503

Phone: 1-701-223-6397 Fax: 1-701-223-8185

INVOICE

September 03, 2015

Order: 15084NNO

Invoice# 4690

Attn: ND Board of Pharmacy
PO Box 1354
Bismarck, North Dakota 58502-1354

Advertiser: ND Board of Pharmacy

Brand:

Campaign

Amount Due:

\$2,052.84

Voice: 701-328-9535 Fax: 701-258-9312

Please detach and return this portion with your payment

ND Board of Pharmacy Invoice# 4690 P.O.#:

Table with columns: Run Date, Ad Size, Rate Type, Rate, Color Rate, Total, Discount, (%), Amount after Discount, Page. Rows include various newspaper ads with subtotals for each publication.

Run Date	Ad Size	Rate Type	Rate	Color Rate	Total	Discount	(%)	Amount after Discount	Page
Grafton, Walsh County Record (Grafton, North Dakota)									
08/12/2015	5.50	Notice Display	\$6.38		\$35.09	\$0.00	(0.00%)	\$35.09	
Caption: regulating the Practice of Pharmacy									
Subtotal:	5.50		\$6.38	\$0.00	\$35.09	\$0.00		\$35.09	
Grand Forks Herald (Grand Forks, North Dakota)									
08/13/2015	5.50	Notice Display	\$13.03		\$71.67	\$0.00	(0.00%)	\$71.67	
Caption: regulating the Practice of Pharmacy									
Subtotal:	5.50		\$13.03	\$0.00	\$71.67	\$0.00		\$71.67	
Harvey, The Herald-Press (Harvey, North Dakota)									
08/15/2015	5.50	Notice Display	\$6.38		\$35.09	\$0.00	(0.00%)	\$35.09	
Caption: regulating the Practice of Pharmacy									
Subtotal:	5.50		\$6.38	\$0.00	\$35.09	\$0.00		\$35.09	
Hettinger, Adams County Record (Hettinger, North Dakota)									
08/14/2015	5.50	Notice Display	\$6.38		\$35.09	\$0.00	(0.00%)	\$35.09	
Caption: regulating the Practice of Pharmacy									
Subtotal:	5.50		\$6.38	\$0.00	\$35.09	\$0.00		\$35.09	
Jamestown Sun (Jamestown, North Dakota)									
08/12/2015	5.50	Notice Display	\$8.86		\$48.73	\$0.00	(0.00%)	\$48.73	
Caption: regulating the Practice of Pharmacy									
Subtotal:	5.50		\$8.86	\$0.00	\$48.73	\$0.00		\$48.73	
Killdeer, Dunn County Herald (Killdeer, North Dakota)									
08/14/2015	5.50	Notice Display	\$6.38		\$35.09	\$0.00	(0.00%)	\$35.09	
Caption: regulating the Practice of Pharmacy									
Subtotal:	5.50		\$6.38	\$0.00	\$35.09	\$0.00		\$35.09	
LaMoure Chronicle (LaMoure, North Dakota)									
08/12/2015	5.50	Notice Display	\$6.38		\$35.09	\$0.00	(0.00%)	\$35.09	
Caption: regulating the Practice of Pharmacy									
Subtotal:	5.50		\$6.38	\$0.00	\$35.09	\$0.00		\$35.09	
Lakota American (Lakota, North Dakota)									
08/12/2015	5.50	Notice Display	\$6.38		\$35.09	\$0.00	(0.00%)	\$35.09	
Caption: regulating the Practice of Pharmacy									
Subtotal:	5.50		\$6.38	\$0.00	\$35.09	\$0.00		\$35.09	
Langdon, Cavalier County Republican (Langdon, North Dakota)									
08/17/2015	5.50	Notice Display	\$6.38		\$35.09	\$0.00	(0.00%)	\$35.09	
Caption: regulating the Practice of Pharmacy									
Subtotal:	5.50		\$6.38	\$0.00	\$35.09	\$0.00		\$35.09	
Linton, Emmons County Record (Linton, North Dakota)									
08/13/2015	5.50	Notice Display	\$6.38		\$35.09	\$0.00	(0.00%)	\$35.09	
Caption: regulating the Practice of Pharmacy									
Subtotal:	5.50		\$6.38	\$0.00	\$35.09	\$0.00		\$35.09	
Lisbon, Ransom County Gazette (Lisbon, North Dakota)									
08/17/2015	5.50	Notice Display	\$6.38		\$35.09	\$0.00	(0.00%)	\$35.09	
Caption: regulating the Practice of Pharmacy									
Subtotal:	5.50		\$6.38	\$0.00	\$35.09	\$0.00		\$35.09	
Mandan News (Mandan, North Dakota)									
08/14/2015	5.50	Notice Display	\$6.38		\$35.09	\$0.00	(0.00%)	\$35.09	
Caption: regulating the Practice of Pharmacy									
Subtotal:	5.50		\$6.38	\$0.00	\$35.09	\$0.00		\$35.09	
Mayville, Trail Co Tribune (Mayville, North Dakota)									
08/15/2015	5.50	Notice Display	\$6.38		\$35.09	\$0.00	(0.00%)	\$35.09	
Caption: regulating the Practice of Pharmacy									

Run Date	Ad Size	Rate Type	Rate	Color Rate	Total	Discount	(%)	Amount after Discount	Page
Caption: regulating the Practice of Pharmacy									
Subtotal:	5.50		\$6.38	\$0.00	\$35.09	\$0.00		\$35.09	
Towner Mouse River Journal (Towner, North Dakota)									
08/12/2015	5.50	Notice Display	\$6.38		\$35.09	\$0.00	(0.00%)	\$35.09	
Caption: regulating the Practice of Pharmacy									
Subtotal:	5.50		\$6.38	\$0.00	\$35.09	\$0.00		\$35.09	
Valley City Times-Record (Valley City, North Dakota)									
08/12/2015	5.50	Notice Display	\$8.86		\$48.73	\$0.00	(0.00%)	\$48.73	
Caption: regulating the Practice of Pharmacy									
Subtotal:	5.50		\$8.86	\$0.00	\$48.73	\$0.00		\$48.73	
Wahpeton, The Daily News (Wahpeton, North Dakota)									
08/12/2015	5.50	Notice Display	\$8.86		\$48.73	\$0.00	(0.00%)	\$48.73	
Caption: regulating the Practice of Pharmacy									
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Watford City McKenzie County Farmer (Watford City, North Dakota)									
08/12/2015	5.50	Notice Display	\$6.38		\$35.09	\$0.00	(0.00%)	\$35.09	
Caption: regulating the Practice of Pharmacy									
Subtotal:	5.50		\$6.38	\$0.00	\$35.09	\$0.00		\$35.09	
Williston Herald (Williston, North Dakota)									
08/12/2015	5.50	Notice Display	\$8.86		\$48.73	\$0.00	(0.00%)	\$48.73	
Caption: regulating the Practice of Pharmacy									
Subtotal:	5.50		\$8.86	\$0.00	\$48.73	\$0.00		\$48.73	

Gross Advertising	\$2,052.84	Total Misc	\$0.00	Amount Paid	\$0.00
Agency Discount	\$0.00	Tax	\$0.00	Adjustments	\$0.00
Other Discount	\$0.00	Total Billed	\$2,052.84	Payment Date	
Service Charge	\$0.00	Unbilled	\$0.00	Balance Due	\$2,052.84

If you would like to pay your invoice with a credit card, please call Rhonda at 701-595-7311 or email rhondaw@ndna.com. We accept Visa, Mastercard, Discover, and AMEX. Or you can pay your bill online at www.ndna.com/billpay. Thank you!



OFFICE OF THE EXECUTIVE DIRECTOR

1906 E Broadway Ave

Bismarck ND 58501-4700

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Fax (701) 328-9536

STATE BOARD OF PHARMACY

**State of North Dakota
Jack Dalrymple, Governor
www.nodakpharmacy.com**

E-mail= Mhardy@btinet.net

**Mark J. Hardy, PharmD, R.Ph.
Executive Director**

August 4, 2015

NDCC 28-32-08.1 – Regulatory Analysis relative to amendments and creation of rules in NDAC 61
61-02-01-19 Continuous Quality Improvement
61-03-01-04 Pharmacist Licensure Transfer
61-04-08 Limited Prescriptive Practices
61-04-10 CLIA Waived Laboratory Tests
61-04-12 Limited Prescriptive Authority for Naloxone

Neither the Governor, nor a member of the Legislative Assembly has filed a written request for a Regulatory Analysis for these rules.

The above rules are not expected to have an impact on the regulatory community of \$50,000 or more. The cost directly to the North Dakota State Board of Pharmacy will be minimal, as compliance will be conducted during the current annual inspections.

There should be no effect on state revenue with the rule.

61-02-01-19 Continuous Quality Improvement – will require pharmacies to adopt and utilize a tracking system for quality related events, to improve their practices to ensure the highest level of care is administered to their patients.

61-04-12 Limited Prescriptive Authority for Naloxone – creates the administrative code based upon Senate Bill 2104 allowing a process for a pharmacist to obtain prescriptive authority to prescribe and dispense Naloxone Rescue kits to prevent overdose death.

61-03-01-04 Pharmacist License Transfer –revises the administrative code language reflecting the license transfer procedures currently in place for pharmacists licensed in another state.

61-04-08 Limited Prescriptive Practices - revise the administrative code based upon recent legislative changes in the ND Century Code set forth in Senate Bill 2173.

61-04-10 CLIA Waived Laboratory Tests - is revised to expand and modify the language to the current practice standards for those tests pharmacists are able to perform.

Mark J. Hardy, PharmD
Executive Director



OFFICE OF THE EXECUTIVE DIRECTOR
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STATE BOARD OF PHARMACY

State of North Dakota
Jack Dalrymple, Governor
www.nodakpharmacy.com

E-mail= Mhardy@btinet.net

Mark J. Hardy, PharmD, R.Ph.
Executive Director

August 4, 2015

NDCC 28-32-08.1 & 28-32-08.2 & 28-32-09 – Small Entity Economic Impact Statement, Small Entity Regulatory Analysis, Fiscal Note and Takings Assessment

**RE: 61-02-01-19 Continuous Quality Improvement
61-03-01-04 Pharmacist Licensure Transfer
61-04-08 Limited Prescriptive Practices
61-04-10 CLIA Waived Laboratory Tests
61-04-12 Limited Prescriptive Authority for Naloxone**

Although the Board of Pharmacy is exempt from the sections on Small Entity Regulatory Analysis and Small Entity Economic Impact Statements, we will provide a few comments none the less.

Since most of the entities regulated by the respective Boards are either individuals or small entities, the Boards always consider the effect on these individuals or businesses when establishing rules.

The rule on Continuous Quality Improvement will require pharmacies to adopt and utilize a program for tracking errors or Quality Related Events. Many pharmacies currently have a program they utilize to which annual costs seem to be around \$200 per year. Compliance with the rule can be obtained by utilizing an internal tracking method to which a specific program would not need to be purchased. The intention for the pharmacies is to ensure they are monitoring these events and making improvements to better their practice setting.

The other rules should not bear any impact and are mostly expansions in the practice of pharmacy based on legislative changes.

There should not be a cost or fiscal impact with either rule to state revenue and expenditures. A Takings Assessment is not required or applicable to these rules

Mark J. Hardy, PharmD
Executive Director



STATE OF NORTH DAKOTA
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JAN 19 2016

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Wayne Stenehjem
ATTORNEY GENERAL

OPINION

January 15, 2016

Dr. Mark J. Hardy
Executive Director
State Board of Pharmacy
1906 E Broadway Ave
Bismarck, ND 58501-4700

Dear Dr. Hardy:

The Office of Attorney General has examined the proposed amendments to N.D.A.C. title 61 concerning pharmacy practice, 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 nor 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 this requirement, 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

cc: Vonette Richter, Legislative Council



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Licensure Transfer



Moving? Starting a new position that requires licensure in multiple states? NABP's Electronic Licensure Transfer Program® enables licensed pharmacists to easily transfer their existing pharmacist license from one state or jurisdiction to another. Pharmacists who move out of state or practice pharmacy across state lines will find that NABP's licensure transfer program is a convenient way to achieve licensure in a new state or multiple states.

When a pharmacist applies for licensure transfer, NABP screens his or her Preliminary Application to prepare the Official Application the pharmacist will submit to the board of pharmacy. When applying to NABP, the pharmacist's license undergoes a background check and is screened through the [NABP Clearinghouse](#), a national repository of pharmacist information supplied by the state boards of pharmacy to help facilitate licensure transfer.

Each state [board of pharmacy](#) has a set of requirements that a prospective pharmacist must meet before a license to practice pharmacy is issued. Before submitting a [Preliminary Application](#) for licensure transfer, review the state's (or states') requirements for licensure transfer – some states require an appearance before the board, criminal background checks, a state transfer application, or a state law examination like the MPJE® (Multistate Pharmacy Jurisprudence Examination®). A license that is eligible for licensure transfer must be active, unrestricted, and in good standing.

Steps to Licensure Transfer

Simply stated, NABP compiles and verifies the information you provided into an official application and sends it back to you. Once you receive the Official Application you send it to the board of pharmacy, and the board issues the license if you meet their requirements. Please allow sufficient time to

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CPE Monitor is an online system being developed for pharmacists and

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complete the entire process – the time can vary depending on the applicant and the board of pharmacy. The basic steps are as follows:

- **Submit Preliminary Application to NABP**
- **NABP processes Preliminary Application**
NABP's review of the Preliminary Application addresses the pharmacist's licensure information and professional history, as well as, among other things, his or her education, practical experience, and examination record.
- **Submit Official Application to board of pharmacy**
Once the Preliminary Application is successfully processed, NABP will mail the pharmacist an Official Application. The pharmacist must submit the Official Application to the applicable board within 90 days.
- **Pass the MPJE or applicable state law examination**
Check with the board of pharmacy to determine what law examination is required. If the MPJE is a requirement, you can register for the exam at any point in the licensure transfer process.
 - **License Transfer to Utah:** To become eligible to sit for the Utah MPJE, candidates must complete and submit a [NAPLEX/MPJE Eligibility Request form](#) to NABP. There is an \$85 processing fee.
- **Issuance of license**
State boards of pharmacy issue pharmacist licenses.

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**Sixty-fourth Legislative Assembly of North Dakota
In Regular Session Commencing Tuesday, January 6, 2015**

SENATE BILL NO. 2173
(Senators Klein, J. Lee, Murphy)
(Representatives Keiser, Oversen, Weisz)

AN ACT to amend and reenact section 43-15-31.4 of the North Dakota Century Code, relating to the governance of prescriptive practices for pharmacists.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. AMENDMENT. Section 43-15-31.4 of the North Dakota Century Code is amended and reenacted as follows:

43-15-31.4. Limited prescriptive practices.

1. ~~A licensed pharmacist in an institutional setting has limited prescriptive practices to initiate or modify drug therapy following diagnosis and initial patient assessment by a licensed physician or an advanced practice registered nurse, under the supervision of the same licensed physician or advanced practice registered nurse, in accordance with this section. An institutional setting, for the purpose of this section, is a hospital, a physician clinic, a skilled nursing facility, or a swing bed facility in which a patient's medical records are readily available to the licensed physician and the licensed pharmacist.~~ The licensed physician or the advanced practice registered nurse and the pharmacist must have access to the patient's appropriate medical records. The care provided to the patient by the pharmacist must be recorded in the patient's medical records and communicated to the licensed physician or the advanced practice registered nurse.
2. ~~The licensed physician or the advanced practice registered nurse and the licensed pharmacist shall prepare a collaborative agreement concerning the scope of the pharmacist's prescriptive practices and shall update the agreement at least every two~~ four ~~years or when they modify the scope of the pharmacist's prescriptive practices. The collaborative agreement, or an amendment to the agreement, is effective when approved by the board of medical examiners or board of nursing and the board of pharmacy.~~
3. ~~The collaborative agreement may be between a medical director and pharmacist-in-charge. The medical director and pharmacist-in-charge shall report to the respective board of any physician, advanced practice registered nurse, and pharmacist covered under the agreement.~~
- 3-4. ~~If there is a change in personnel under the collaborative agreement, a pharmacist, physician, and advanced practice registered nurse under the collaborative agreement shall send immediate notice of the change to the respective licensing board of that individual. Unless necessary, a change in personnel does not necessitate board approval of the collaborative agreement.~~
5. ~~The collaborative agreement must include a provision that requires the licensed pharmacist to immediately notify the licensed physician or advanced practice registered nurse when the licensed pharmacist initiates or modifies a drug therapy.~~
- 4-6. ~~The board of medical examiners and the board of pharmacy shall jointly establish a prescriptive practices committee consisting of two physicians appointed by the board of medical examiners, one physician appointed by the North Dakota medical association, one pharmacist appointed by the board of pharmacy, and one pharmacist appointed by the North Dakota pharmaceutical association. The prescriptive practices committee shall develop and submit proposed rules concerning the implementation of this section to the board of medical examiners and the board of pharmacy. Any rules to implement this section must be jointly~~

adopted by the board of medical examiners or the board of nursing and the board of pharmacy.

President of the Senate

Speaker of the House

Secretary of the Senate

Chief Clerk of the House

This certifies that the within bill originated in the Senate of the Sixty-fourth Legislative Assembly of North Dakota and is known on the records of that body as Senate Bill No. 2173.

Senate Vote: Yeas 47 Nays 0 Absent 0

House Vote: Yeas 88 Nays 0 Absent 6

Secretary of the Senate

Received by the Governor at _____ M. on _____, 2015.

Approved at _____ M. on _____, 2015.

Governor

Filed in this office this _____ day of _____, 2015,

at _____ o'clock _____ M.

Secretary of State

**Sixty-fourth Legislative Assembly of North Dakota
In Regular Session Commencing Tuesday, January 6, 2015**

SENATE BILL NO. 2104
(Senator Anderson)
(Representative Rick C. Becker)

AN ACT to create and enact a new section to chapter 23-01 and a new subsection to section 43-15-10 of the North Dakota Century Code, relating to immunity from liability related to opioid antagonists and limited prescriptive authority for Naloxone rescue kits.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. A new section to chapter 23-01 of the North Dakota Century Code is created and enacted as follows:

Opioid antagonist prescription, distribution, possession, or use - Immunity from liability.

1. As used in this section:
 - a. "Health care professional" means a licensed or certified health care professional who is working within the scope of practice for that profession. The term may include a physician, physician assistant, advanced practice registered nurse, and pharmacist acting in the professional's scope of practice.
 - b. "Opioid antagonist" means a drug:
 - (1) That is approved by the United States food and drug administration for the treatment of a drug overdose and is recognized by the state department of health for the treatment of a drug overdose; and
 - (2) That when administered negates or neutralizes, in whole or in part, the pharmacological effects of an opioid in the body.
2. A health care professional acting in good faith may directly or by standing order prescribe, distribute, or dispense an opioid antagonist, if the health care professional provides training to:
 - a. An individual at risk of experiencing an opioid-related overdose; or
 - b. A family member, friend, or other individual in a position to assist an individual at risk of experiencing an opioid-related overdose.
3. An individual acting in good faith may receive or possess an opioid antagonist if that individual is:
 - a. An individual at risk of experiencing an opioid-related overdose; or
 - b. A family member, friend, or other individual in a position to assist an individual at risk of experiencing an opioid-related overdose.
4. An individual acting in good faith may self-administer an opioid antagonist or administer an opioid antagonist to another individual who the administering individual suspects is at risk of experiencing an opioid overdose.
5. An individual may receive, possess, or administer an opioid antagonist under subsection 3 or 4, regardless of whether the individual is the individual for or to whom the opioid antagonist is prescribed, distributed, or dispensed.

6. An individual who prescribes, distributes, dispenses, receives, possesses, or administers an opioid antagonist as authorized under this section is immune from civil and criminal liability for such action. A health care professional who prescribes, distributes, or dispenses an opioid antagonist as authorized under this section is not subject to professional discipline for such action. This section does not expand the scope of practice of a health care professional. Immunity from liability or discipline under this subsection does not apply if the individual's actions constitute recklessness, gross negligence, or intentional misconduct.

SECTION 2. A new subsection to section 43-15-10 of the North Dakota Century Code is created and enacted as follows:

To establish limited prescriptive authority for individuals to distribute opioid antagonist kits, also known as "Naloxone rescue kits." If the board establishes limited prescriptive authority under this subsection, the board shall adopt rules to establish standards that may include training, certification, and continuing education requirements.

President of the Senate

Speaker of the House

Secretary of the Senate

Chief Clerk of the House

This certifies that the within bill originated in the Senate of the Sixty-fourth Legislative Assembly of North Dakota and is known on the records of that body as Senate Bill No. 2104.

Senate Vote: Yeas 47 Nays 0 Absent 0

House Vote: Yeas 91 Nays 0 Absent 3

Secretary of the Senate

Received by the Governor at _____ M. on _____, 2015.

Approved at _____ M. on _____, 2015.

Governor

Filed in this office this _____ day of _____, 2015,

at _____ o'clock _____ M.

Secretary of State