

## 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 24<sup>th</sup> 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