

## NORTH DAKOTA BOARD OF CLINICAL LABORATORY PRACTICE

**POLICY:** Clinical Laboratory Testing by persons not licensed by the North Dakota Board of Clinical Laboratory Practice

**PROCEDURE:**

1. Is the clinical laboratory test performed one of the following?

- Non-automated dipstick or tablet urinalysis
- Fecal occult blood
- Ovulation test by color comparison
- Urine pregnancy test-visual color comparison
- Erythrocyte sedimentation rate
- Blood glucose by monitoring device cleared by the FDA for home use
- Spun microhematocrit
- Hemoglobin by single analyte instrument

- a. If yes, the test can be performed under appropriate supervision by persons not licensed by the ND Board of Clinical Laboratory Practice. This includes persons not licensed by any ND health profession regulatory board as well as persons qualifying for one of the 8 exemptions in ND CC 43-48-03 as well as persons licensed by other health profession regulatory boards.

This decision is based on a Board decision April 30, 1992 where “The board determined that the CLIA waived tests were screening tests and did not require a N.D. Clinical Laboratory Practice license.” This does not apply to CLIA waived (or waived) tests per se and does not include tests that have been added to the CLIA waived list since April 30, 1992. It applies only to the tests included at the time of the board decision since they were determined to be screening tests. Board added “under appropriate supervision” at April 8, 1996 meeting.

- b. If no, the test is not on the above list a ND Board of Clinical Laboratory Practice license is required unless the person performing the tests is covered by at least one of the 8 exemptions in ND 43-38-03 or is within an overlapping scope of practice for a license by another regulatory board (see following sections 2, 3, 4 and 5).

2. Is the person performing a test in question licensed by the Board of Pharmacy?

- a. If yes, is the test one of the following CLIA **waived** tests?

- Glucose
- Cholesterol total
- HDL Cholesterol
- Triglyceride
- Glycosylated hemoglobin (Hgb A1C)
- Prothrombin time

A license from the Board of Clinical Laboratory Practice is not required to perform only the above tests by a person licensed and meeting the requirements of the Board of Pharmacy practice defined in NDCC 43-15. The law includes a process to add waived tests to this list. This list is current October 14, 2001.

3. Is the person performing a test in question licensed by the Respiratory Care Examining Board?

- a. If yes, is the test one of the following tests?  
Blood gas and electrolyte testing

This is based on an opinion in a December 27, 1996 letter from Assistant Attorney General Douglas Bahr to the ND Respiratory Care Examining Board upon that Board's request. Quoting from the opinion: "it is my opinion that a licensed respiratory care practitioner may provide respiratory care services, as defined NDCC 43-42-01(8) even if the services could also constitute clinical laboratory testing, as long as the respiratory care practitioner only represents to the public that the respiratory care practitioner is performing services as a respiratory care practitioner." This was discussed and is reflected in the minutes of the January 13, 1998 Board of Clinical Laboratory Practice meeting.

4. Is the person licensed by the Board of Medical Examiners as a Physician Assistant?

- a. Persons licensed as Physician Assistants may not provide clinical laboratory testing other than the tests listed in section 1 which do not require a license by the ND Board of Clinical Laboratory Practice.

This is based on an December 23, 1997 opinion by Attorney General Heidi Heitkamp that states following a reference to the licensing of physician assistants: "The above language provides physician assistants may not perform services otherwise regulated by licensing laws. N.D.C.C. ch. 43-48 is a licensing law regulating clinical laboratory testing. Accordingly, it is my opinion physician assistants may not perform clinical laboratory testing." This was discussed at the October 20, 1998 meeting of the Board of Clinical Laboratory Practice and is documented in the minutes.

5. Is the person licensed as a Physical Therapist?

- a. Persons licensed as Physical Therapists may not provide clinical laboratory testing other than the tests listed in section 1 which do not required a license by the ND Board of Clinical Laboratory Practice.

This is based on a decision by the Board at the January 18, 2000 meeting.

6. Is the person licensed by the Board of Nursing?

As documented in N.D.C.C. 43-48-03(2) Nurses duly and currently licensed to practice nursing and practicing with the scope of the nursing license are exempt from licensure by the Board of Clinical Laboratory Practice.

- a. Questions from CLIA surveyors (federal) and others directed to Board of Clinical Laboratory Practice office or Board members on whether a licensed nurse performing a specific clinical laboratory test(s) is practicing within the scope of practice of the nursing will be referred to the Board of Nursing.

(1). Persons making a verbal inquiry or a written request with insufficient information will be asked to submit a written request to the office of the Board of Clinical Laboratory Practice stating the name and license category of the nurse and the clinical laboratory test(s) in question.

(2). When such written questions are received the Board of Clinical Laboratory Practice office will send a letter to the Board of Nursing requesting a written opinion.

b. If the response and opinion from the Board of Nursing indicates the person is duly licensed and practicing within the scope of the nursing license the person is exempt from licensure by the Board of Clinical Laboratory Practice.

This is based on an Attorney General's opinion and discussion and direction from the Board at the February 26, 2002 meeting. A December 23, 1997 letter from Attorney General Heidi Heitkamp responded to the Board of Clinical Laboratory Practice request for clarification on the exemption for nurses. It was her opinion that which clinical laboratory tests, if any, may be performed by registered nurses, nurse practitioners, and licensed practical nurses is a mixed question of fact and law and is an issue more appropriately addressed by the Board of Nursing. This opinion was reviewed at the January 13, 1998 meeting of the Board of Clinical Laboratory Practice.

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