

**Testimony SB 2202**  
**Industry, Business and Labor**  
**March 14, 2017**  
**North Dakota Department of Health**

Good morning, Chairman Keiser and members of the Committee. My name is Bridget Weidner, and I am the Clinical Laboratory Improvement Amendments (CLIA) program manager for the North Dakota Department of Health, Division of Health Facilities. I am here today to testify in opposition of SB 2202, and provide information regarding CLIA as it relates to the bill. SB 2202 was amended in committee to add language that exempts personnel performing waived tests from licensure by the N.D. Board of Clinical Laboratory Practice. The waived tests are categorized by the Food and Drug Administration (FDA) based on the criteria established by the Clinical Laboratory Improvement Act of 1988.

CLIA is a federal program with requirements related to the practice of laboratory testing. CLIA regulates all laboratories that test human specimens for the purpose of providing information for diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of human beings. CLIA mandates that laboratories meet applicable federal requirements and have a CLIA certificate based on the complexity of testing performed.

A laboratory can apply for CLIA certification in several categories, and a CLIA Certificate of Waiver is one of those categories. A Certificate of Waiver is issued to a laboratory that performs only waived tests. A laboratory with a Certificate of Waiver is not subject to routine inspections and must follow the current manufacturer's instructions for the waived test systems they are using for patient testing. A Certificate of Waiver laboratory must appoint a director; however, there are no specific educational background, training or experience qualifications. In addition, CLIA does not have qualification requirements for personnel performing the testing. Under CLIA, anybody can apply for a Certificate of Waiver, be appointed laboratory director and perform laboratory testing without any qualifications and minimal oversight.

When CLIA was first enacted, there were eight CLIA waived tests, and today there are 127 different tests classified as FDA waived. The listing of FDA waived tests can further be listed by specific test system, assay and examination. From this perspective, it takes 232 pages to print out the approximately 26,000 different test systems, assays and examinations classified as waived by the FDA. These 232

pages were printed from the FDA website just a few weeks ago. The list is continuously growing and encompasses so many different tests that an individual could set up a fairly robust lab service just with waived testing, with the exception of microbiology cultures and blood banking.

The Division of Health Facilities performed surveys in Certificate of Waiver labs for many years. The survey of Certificate of Waiver laboratories halted nationally as of October 2016. North Dakota specific data from the past 15 years shows approximately 43 percent of the laboratories were noncompliant with regulatory requirements, 42 percent were noncompliant with laboratory best practices, and only approximately 15 percent were compliant with regulatory requirements and laboratory best practices.

In summary, I oppose SB 2202, which as passed out of the Senate allows anybody to perform any of the approximately 26,000 tests categorized by the FDA as waived, without regard for training or oversight of personnel performing the testing. The information I provided to you regarding the federal CLIA program demonstrates there is very little regulation or oversight of Certificate of Waiver laboratories. Based on the results of the Certificate of Waiver surveys conducted by the Department of Health, it would be a safer option to at least limit the waived testing to one specific test.

This concludes my testimony. I am happy to answer any questions you may have.