



March 9, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted via regulations.gov

Re: Request for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) [CMS-3326-NC]

Dear Administrator Verma:

On behalf of the American Association of Bioanalysts (AAB) and the National Independent Laboratory Association (NILA), please accept the following comments concerning CMS-3326-NC, the Request for Information (RFI): Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Below, AAB and NILA provide answers to the specific questions outlined in "Section II: Solicitation of Comment" of the RFI.

Section A: Clarification of Degree(s)

For moderate complexity testing personnel qualifications, a bachelor's degree in nursing satisfies the educational requirement outlined in §493.1423(b)(4)(i) of a high school diploma, but a bachelor's degree in nursing cannot stand on its own to fulfill the training requirements outlined in §493.1423(b)(4)(ii)(A-H). It is not typical that a bachelor's degree in nursing covers requirements such as implementing standard laboratory procedures; having a working knowledge of reagent stability and storage; and having skills to implement laboratory procedures and quality control measures in the laboratory. However, if an individual with a bachelor's degree in nursing can provide documentation that he/she has fulfilled these training requirements, a bachelor's degree in nursing should not preclude that individual from being able to perform moderate complexity laboratory testing. When CMS is determining appropriate qualifications for moderate complexity testing personnel, the agency needs to look beyond the degree and assess whether the individual has the appropriate training and experience to analyze patient specimens as outlined in §493.1423(b)(4)(ii)(A-H).

For high complexity testing personnel, in simple terms of semester hours required in biology and chemistry for a bachelor's degree in nursing and a bachelor's degree in a biological science, the two degrees cannot be considered equal. Under CLIA, performing high complexity laboratory testing requires at least an associate degree from an accredited institution, with a major in a laboratory science or medical laboratory technology, or education and training equivalent to an associate degree, i.e., at least 60 semester hours, including either 24 semester hours of medical laboratory technology courses or 24 semester hours of science that includes six semester hours of chemistry, six semester hours of biology and twelve semester hours of chemistry, biology or medical laboratory technology in any combination §493.1489(b)(2)(ii)(A). This ensures that high complexity testing personnel are prepared to conduct and interpret diagnostic tests, which includes proper specimen collection, handling and preparation; implementing laboratory procedures and quality control measures; and troubleshooting protocols and interpreting test results. In the case where an individual has a bachelor's degree in biological science to meet CLIA's high complexity testing educational requirements, he/she has gone through a rigorous set of degree requirements that often include laboratory components. Hence these individuals are better equipped to perform laboratory testing than nurses, whose coursework is intended to prepare them for direct patient care. While individuals with a nursing degree have gone through rigorous training, nursing degrees do not require the same number of courses in biology, chemistry, math and physics as do degrees in biological science.

An analysis of several bachelor degree programs for nursing and biological sciences shows that a bachelor's degree in nursing requires fewer semester hours of biology and chemistry than a bachelor's degree in biology, and that the biology courses that nurses are required to take have little to no application to clinical laboratory testing. See a comparison below of science credit hours required for a bachelor's degree in biology compared to a bachelor's degree in nursing from Augusta University (Georgia). Note that most biology courses for nurses are in anatomy/physiology, and the chemistry courses are in pharmacology, not organic chemistry, biochemistry, or clinical chemistry.

<i>Degree</i>	Biology/Biological Science	Chemistry	Math & Statistics	Total Science Hours
<i>Cell & Molecular Biology</i>	51	26	17	94
<i>Biology</i>	47	22	12	81
<i>Nursing</i>	18	8	6	32

Due to this difference in education and coursework, individuals with a bachelor's degree in nursing should not be considered qualified to meet the CLIA requirements for high complexity testing personnel, nor should CMS consider a bachelor's degree in nursing as a separate qualifying degree. However, if supplemented with adequate coursework in biology and chemistry to meet the requirements outlined in §493.1489(b)(2)(ii), an individual with a bachelor's degree in nursing could potentially become eligible to perform high complexity testing.

A similar situation exists for individuals with a bachelor's degree in a physical science. An analysis of Ohio State University's bachelor's degrees in Astronomy, Earth Sciences or Physics shows that an Astronomy degree requires zero courses in biology or chemistry; an Earth Science degree requires 8 semester hours of biology and 10 semester hours in chemistry; and a Physics degree requires 8 semester hours of biology and 12 semester hours in chemistry. Of these examples, none meets the 24 semester hours in biology and chemistry required for individuals

with the equivalent of an associate degree in laboratory science or medical technology. For moderate complexity testing, each of these degrees is more than equivalent to a high school diploma, but the degree does not ensure that the training requirements outlined in Section 493.1423(b)(4)(ii)(A-H) have been met. When evaluating an individual's educational requirements for moderate complexity testing, CLIA must look beyond the degree and assess whether the individual has the appropriate training and experience to analyze patient specimens as outlined in §493.1423(b)(4)(ii)(A-H).

Given the difference in course requirements between these various degrees, AAB and NILA recommend that CLIA reframe the benchmark for testing personnel qualifications from college/university degrees to a minimum standard of coursework needed to perform testing in a moderate or high complexity laboratory. As you can see from the examples above, with the nursing and physical science degrees it can be challenging to determine, from a degree title alone, if an individual is qualified to perform moderate or high complexity laboratory testing. To address this, AAB and NILA encourage CMS to establish a minimum set of coursework hours in areas that are applicable to laboratory science (e.g., biochemistry, organic chemistry, hematology, microbiology, immunology, immunochemistry, classical and molecular genetics, molecular biology, physiology, cell biology and associated laboratory courses). If an individual's degree comes into question as to whether he/she is qualified to perform moderate or high complexity testing, his/her coursework can simply be compared to the minimum coursework requirements. If the individual meets the minimum coursework requirements, then it will not matter whether the degree is in nursing, biology, astronomy, or physics. A shift to a minimum standard of coursework hours also ensures a baseline of scientific knowledge geared toward clinical laboratory testing that is not afforded by simply looking at college/university degrees.

Section B: Other Requirements for CLIA Personnel Categories

Regarding whether general supervisors should be allowed to perform competency assessments for testing personnel performing moderate complexity testing in laboratories that perform both moderate and high complexity testing, AAB and NILA believe the following: If general supervisors with an Associate's Degree can perform competency assessments on high complexity testing personnel in a laboratory performing high complexity testing, then they should easily be able to do the same for individuals performing moderate complexity testing in a laboratory that does both moderate and high complexity testing.

Section C: Proficiency Testing Referral

Regarding the feasibility of applying alternative sanctions in cases of proficiency testing (PT) referral that involve Certificate of Waiver (CoW) laboratories, AAB and NILA offer the following:

- Currently, CLIA does not require the overwhelming majority of Certificate of Waiver (CoW) laboratories to participate in Proficiency Testing. Thus, situations where a CoW laboratory is subject to CLIA sanctions for referring PT specimens to another laboratory is uncommon.
- But in the instance where a CoW participates in CLIA-required PT and refers a specimen to another laboratory, the same categories of sanctions that apply to moderate and high complexity laboratories should apply to those CoW laboratories.

An issue that was not included in this RFI, but which is **much more important** than alternative sanctions for CoW laboratories, is the **need to revise and update the list of regulated analytes requiring PT** as outlined in 42 CFR part 493, Subpart I of the CLIA regulations, since this has not been done in 26 years.

Section E: CLIA Fees

AAB and NILA believe that before an adequate and fully informed answer can be provided to CMS on changes to CLIA fees, CMS should publish a full audit of the CLIA Program's finances over the past two or more years. It is difficult to answer questions about whether CLIA's current fees are fair and reasonable without this information.

On February 14, 2018, AAB filed a Freedom of Information Act (FOIA) requesting the CLIA program's 2015 and 2016 financial results. AAB received a notice that its FOIA request was received by CMS on February 22, 2018, but as of March 9, 2018, AAB's FOIA request had not been answered. We therefore strongly recommend that no action be taken on increasing CLIA fees until a full, audited report is made public regarding the financial results of the CLIA program over the past few years.

AAB and NILA appreciate the opportunity to provide comments and recommendation to CMS to help shape revisions to CLIA. For more information, please contact Mark S. Birenbaum, Ph.D. NILA and AAB look forward to continuing conversations with CMS as modifications are made to CLIA.

Sincerely yours,



Mark S. Birenbaum, Ph.D.
Administrator

About AAB

The American Association of Bioanalysts (AAB), founded in 1957, is a professional association representing bioanalysts (clinical laboratory directors, owners, managers and supervisors), medical technologists, medical laboratory technicians, and physician office laboratory technicians. AAB is committed to the pursuit of excellence in clinical laboratory testing by enhancing the professional skills of each of its members; promoting more efficient and productive operations; and representing the interests of its members. AAB's specialized membership sections include the AAB Associate Member Section (AMS), College of Reproductive Biology (CRB), Environmental Biology and Public Health (EBPH) Section, and the **National Independent Laboratory Association (NILA)**. AAB provides a broad range of services, including representation before federal and state legislative and regulatory agencies, educational programs and publications. AAB's Proficiency Testing Service is approved under the federal CLIA regulations and is one of the largest PT providers in the United States.