



March 12, 2018

Centers for Medicare & Medicaid Services
Department of Health and Human Services

Re: Comments on CMS' Request for Information: Revisions to Personal Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)

Dear Regulatory Professional:

The Association of Public Health Laboratories (APHL) respectfully submits the following comments to the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) in response to the Request for Information. APHL's detailed comments on specific issues of relevance to the public health laboratory community are below and we look forward to continuing this dialogue with CMS.

Personnel Requirements:

a. Nursing Degree

- According to the National League for Nursing, in 2014 there were 710 and 1092 associate and bachelor degree programs respectively.¹ A published white paper found 34% and 45% of nurses have an associate's and bachelor's degree respectively.² However the requirements, curriculum, training are extremely variant across all programs, providing no standardization or uniformity.
 - **Bachelor of Science (BS) vs Associates Degree in Nursing (ADN) Bachelor of Science in Nursing (BSN):** There is great discrepancy between the requirements to obtain a degree in nursing and biological sciences. An ADN typically can be completed in two years while a BSN takes four. BSN is inclusive of the workload in the ADN plus social sciences, management, research, public and community health, and leadership.

After reviewing multiple nursing degree programs, there was no laboratory component found in the curriculums. Most of the coursework focuses on clinical practices, anatomy and physiology, nutrition, pharmacology, and ethics. A BSN degree does not include the scope and breadth of science coursework necessary to understand the principles behind laboratory methodology and regulatory issues that is demanded from our current workforce. A degree in biological sciences, BS, focuses on providing intensive scientific background in biological sciences. The American Society for Clinical Pathology (ASCP) has documented that nursing degrees only require a fraction of the scientific coursework required to earn a degree in biological sciences.³ For instance, a degree in biological sciences at the

¹ <http://www.nln.org/docs/default-source/newsroom/nursing-education-statistics/number-of-basic-rn-programs-total-and-by-program-type-2005-to-2014.pdf?sfvrsn=0>

² https://www.nursing.org/wp-content/uploads/2015/10/Nursing.org_State-of-Nursing_2016.pdf

³ <https://s3.amazonaws.com/ascpcdn/static/epolicy/2016/BOC-response-CMS-CLIA-Memorandum-SC.pdf>

University of Maryland requires 63 hours of natural sciences, which includes courses in biology, chemistry, and physics with almost half needed to be of upper level (300-400). However, a nursing degree at the same university only requires 16 hours of introductory level natural science courses.⁴ Nursing degrees lack a hands-on biological science laboratory component. Laboratory coursework is essential to the demonstration and application of knowledge, methods, techniques and skills taught during lecture. This is needed for basic lab technique skill competency (pipetting, measuring, aseptic technique) and enhances a body of knowledge used to understand and troubleshoot test performance.

APHL is concerned that CMS has lowered the threshold of education and training required to perform moderate and high complexity testing that will jeopardize patient safety. CMS is the regulatory body that oversees clinical and public health laboratories and it is imperative that the agency understands the skills that are needed for our laboratory workforce. Laboratory scientists must understand and apply complex scientific concepts and theories related to specific testing methods as well as fundamental mathematical and statistical concepts and practices. The CMS position not only lowers the educational standards for personnel, but also puts patients at risk and impacts the ability of laboratories to efficiently provide high quality laboratory testing to our communities. Personnel without adequate educational background require more oversight and longer training times, which reduces the efficiency of laboratory operations.

- **Recruitment of Qualified Personnel:** CMS should not look to “qualify” a BSN without looking at BSN curriculum to determine whether the BSN degree meets the requirements and qualifications both in educational coursework and training to work in a moderate and high complexity lab. Laboratories across the nation are finding it increasingly more difficult to recruit and retain qualified laboratory scientists due to low salaries, increasing workloads and the increasing Quality Assurance/Quality Control requirements in the workplace. As new and innovative technologies continue to evolve and change the scope, both the depth and breadth, of laboratory medicine, the need for higher standards of education and training becomes even more critical. As the world of laboratory science continues to progress and expand, it is imperative that the agencies that regulate our laboratories, support our profession in its efforts to ensure that all laboratory testing is performed by *qualified* individuals who possess the sufficient knowledge and competency to perform pre-analytical, analytical and post analytical analysis, reagent and material preparation, calibration of equipment, decision-making to troubleshoot, direct interventions to solve problems and extensive independent interpretation and judgement on test results.

The level of science coursework for any healthcare professional, whether a nurse, physician, pharmacist, differs based on the needs of the field one is entering. A degree in any of these areas does not qualify an individual to perform the work of another profession.

⁴ <http://www.nursing.umaryland.edu/media/son/admissions/Prerequisite-Course-List--FEB-2018.doc>

- Please find our association's [position statement](#) in response to the April 1st, 2016 CMS memorandum (S&C-16-18-CLIA) released to state CLIA survey agency directors announcing that an associate's or bachelor's degree in nursing is equivalent to an associate's or bachelor's degree in biological sciences for a moderate and high complexity laboratory.⁵ CMS should immediately rescind this directive. A BSN does not meet the minimum qualifications in educational coursework and training required for a moderate and high complexity testing personnel and technical consultants. CMS has lowered the threshold of education and training required to perform moderate and high complexity testing that will directly impact the quality of test results and jeopardize patient safety.
 1. The memorandum brought attention to the issue, causing concern in the laboratory community. A petition was circulated to oppose the equivalency policy, which to date has garnered more than 35,000 signatures.

b. Physical Science Degree

- APHL believes that a physical science degree should be recognized if the affected individual completed a sufficient amount of course work (in chemistry and biology) to otherwise be qualified to perform moderate complexity and/or high complexity testing. Rather than putting emphasis on the title of the degree earned, CMS should emphasize completion of a CMS prescribed number of course hours in chemistry, biology, or clinical laboratory science, irrespective of the actual degree earned. For example, someone who has a bachelor's degree in a discipline physical science may have completed a sufficient amount of course work in chemistry and/or biology to be qualified to perform moderate complexity and/or high complexity testing. New degrees with new requirements are introduced yearly making it difficult for public health laboratories to understand whether these individuals qualify under CLIA requirements. CMS should seek to more explicitly define acceptable minimal course requirements, similar to section 493.1489.

c. Personal Competencies

- A more stringent requirement exists for the moderate complexity general supervisor than the high complexity general supervisor when performing competency assessments for testing personnel. APHL recommends that high complexity general supervisors meet the requirements of a technical supervisor for consistency. According to the current CLIA guidelines, there is overlap of responsibilities demanded from technical supervisors and general supervisors. The recommendation is to delineate the guidelines clearer so responsibility for each can be easily identified.

⁵ <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-18.pdf>

d. Personal Experience

- For proper laboratory training, we suggest hands-on clinical laboratory work experience to include all phases of testing: pre-analytical, analytical, and post-analytical. General laboratory skills should include proper understanding of testing methodologies such as: ELISA, agglutination, slide reading, etc. There should be set percentages allocated to time spent learning all basic tasks to function in a clinical laboratory (i.e. 20% safety, 20% testing, 5% QA, 10% result interpretation, etc.) or if not percentages utilize descriptors like frequently, occasionally, rarely for qualifying tasks. Proper verification of these trainings can be a reference check form from a previous employer or educator with basic tasks defined as suggested above.

e. Non Traditional Degrees

- Similar to recognizing physical science degrees, mentioned above, APHL believes that CMS should recognize non-traditional degrees by emphasizing the need for a prescribed amount of course work in chemistry, biology, clinical laboratory science or medical technology, rather than focusing on the title of the degree earned.

PT Referral

- There should be discretion applied to Category 1 offenses. Discretion should include a full review on whether an offending employee has specific, documented training on PT performance and expectations. This should be an in-depth part of new employee orientation, not just a cursory overview, due to the severity of the penalty.

General Feedback on other areas of CLIA

Laboratory Director Requirements:

- Laboratory director qualifications, in part, states that the laboratory director must hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution. It is APHL's position that three of the listed degrees (i.e., chemistry, physical science, and biology) are much too broad in their scope to accurately identify qualified individuals on a consistently reliable basis. For an example, a degree in plant biology and a degree in microbiology are both degrees in "biology"; however, only the degree in microbiology is pertinent to performing moderate complexity or high complexity testing under CLIA.

APHL believes that the actual course work completed by the applicant is a much better indicator of whether the individual is qualified, than is the titled of the degree earned. The fact that §493.1443 does not list acceptable sub-categories of chemistry (e.g., biochemistry or clinical chemistry), biology (e.g., microbiology, bacteriology, virology, parasitology) or physical science (it is generally accepted that chemistry is a sub-discipline of physical

science) makes it critically important that more emphasis be placed on actual coursework rather than degree titles. APHL recommends that CMS focus on curriculum completed to determine whether an individual is qualified by education to perform the duties of a laboratory director when moderate complexity or high complexity testing is being performed by the laboratory that they direct.

Furthermore, for individuals that began serving as laboratory directors on or after February 24, 2003, APHL recommends that individual qualification decisions that are made by CMS approved certifying boards be final and binding with respect to whether an individual is qualified to serve as a laboratory director under CLIA 1988 and all subsequent amendments. It is unsatisfactory for CMS to overturn a board decision after an individual has been examined and found to be qualified (by the certifying board).

Molecular Detection

- APHL notes the need requirements for molecular detection as a specialty on its own or a subspecialty of microbiology/virology. This includes PCR, NAAT, and all forms of sequencing. Laboratories nationwide are conducting molecular based testing for both predisposition of conditions and diagnosis and this is currently not acknowledged by CMS.

Discrepancies in Reporting

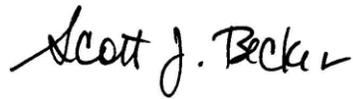
- APHL recommends that CMS address the regional discrepancies in the determination of data or test results that generate reports or data for public health purposes where the intent of the data is for epidemiological purposes. Though this has been discussed in the past, it needs to be revisited. This topic needs to be referenced in regulations.

OVERALL RECOMMENDATION:

APHL encourages CMS to work closely with public health laboratories and APHL as well as private laboratories to develop effective guidance aimed at ensuring a properly educated, adequately trained laboratory workforce is built. There needs to be continuous improvement of laboratory science through the development of relevant educational and training requirements for personnel.

APHL appreciates the opportunity to provide information to Centers for Medicare and Medicaid to help make revisions to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). For more information, please contact Peter Kyriacopoulos, APHL's Senior Director of Public Policy at peter.kyriacopoulos@aphl.org or 240-485-2766. APHL looks forward to continue conversations with CMS as modifications to CLIA are made.

Sincerely,

A handwritten signature in black ink that reads "Scott J. Becker" with a checkmark at the end.

Scott J. Becker, MS
Executive Director
Association of Public Health Laboratories

Association of Public Health Laboratories

APHL works to strengthen laboratory systems serving the public's health in the U.S. and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

Attachments:

Additional Technical Recommendations
About APHL

SUBPART K, QUALITY SYSTEM FOR NONWAIVED TESTING Subspecialty of Mycobacteriology

§493.1262 Standard: Mycobacteriology.

'(a) Each day of use, the laboratory must check all reagents or test procedures used for mycobacteria identification with at least one acid-fast organism that produces a positive reaction and **an acid-fast organism that produces a negative reaction.**'

Comments:

I believe the bolded part of this QC regulation to be in error. Modify to read 'non-acid fast organism that produces a negative reaction.'

SUBPART M, PERSONNEL FOR NONWAIVED TESTING, Laboratories Performing High Complexity Testing

§493.1445 Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.

(e) The laboratory director must—

(7) Ensure that all necessary **remedial actions** are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and that patient test results are reported only when the system is functioning properly;'

Comments:

Modify to read 'remedial and corrective actions.' Laboratories encounter situations where either remedial or corrective action is needed and must be taken or where both are needed and must be taken.

'Remedial Action is interim, immediate action taken to rectify an existing NCE or other undesirable existing situation. Attends to the immediate issue. Does NOT remove the root cause of the problem. 'Corrective Action' is action taken or planned to eliminate the root cause of an existing nonconformance or other undesirable existing situation in order to prevent recurrence.

Since these are two different actions of sorts, would like to see 'corrective action' mentioned in this particular regulation AND also the same for the equivalent moderate complexity testing director responsibilities regulation, §493.1407 (e)(7).

§493.1451 Standard: Technical supervisor responsibilities.

The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.

(b) The technical supervisor is responsible for—

(5) Resolving technical problems and ensuring that **remedial actions** are taken whenever test systems deviate from the laboratory's established performance specifications;'

Comments:

Same comments as those for §493.1445 except for the comment on moderate testing director responsibilities regulation.

§493.1463 Standard: General supervisor responsibilities.

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

(b) The director or technical supervisor may delegate to the general supervisor the responsibility for—

(1) Assuring that all **remedial actions** are taken whenever test systems deviate from the laboratory's established performance specifications;....'

Comments:

Same comments as those for §493.1451 except for the comment on moderate testing director responsibilities regulation.



About APHL

What is APHL?

APHL is the national nonprofit representing governmental laboratories that protect the public's health by detecting and monitoring health threats, such as the "H1N1" flu. Members include state, territorial and local public health labs; state environmental testing labs; state agricultural and food safety labs; and individual scientists, public health officials and academicians.

How do these 'governmental laboratories' help the American public?

Public health labs across the country work to detect, identify and monitor:

- Infectious disease outbreaks.
- Chemical contaminants in people and the environment.
- Foodborne illness clusters.

What else do they do?

- Screen newborns for genetic and metabolic conditions.
- Respond to natural disasters, industrial accidents and suspected biological, chemical or radiological terrorism.
- Support enforcement of water, food, dairy and environmental safety laws through testing.
- Monitor disease trends and develop new laboratory technologies.
- Contribute to the formulation of state and national health policies.

How does APHL support these labs?

APHL is the nexus for the country's network of laboratories with public health mandates: a hub for information exchange among members and between the APHL membership and external partners. By linking these partners, APHL safeguards the public's health. The association has longstanding relationships with the Centers for Disease Control and Prevention (CDC) and other federal health agencies. In 1999, APHL, CDC and the FBI founded the Laboratory Response Network—an integrated group of public and private sector laboratories that function as laboratory first responders to terrorism, emerging infectious disease and other public health crises.

How does APHL contribute to the formulation of state and national health policies?

APHL bridges the gap between science and public health policy through its education and advocacy program. APHL is known in Washington, DC, as an authoritative voice on laboratory-related health issues, including emerging infectious diseases, human exposure to environmental toxicants, genetic testing, terrorism preparedness and others.

Why is ongoing laboratory training critical in public health labs, and how does APHL meet that need?

Not only are technological advances making older laboratory techniques obsolete, health threats themselves are evolving at a rapid rate. The cutting-edge science practiced in public health, environmental-testing and agricultural laboratories requires a highly trained and adaptable workforce. APHL has a 20-year history

Association of Public Health Laboratories

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as a provider of high quality education. While there are other continuing education providers, APHL fills a crucial niche by focusing on topics of fundamental public health importance. Some—like rabies testing—are addressed nowhere else. Each year, the National Laboratory Training Network—co-sponsored by APHL and CDC—delivers hundreds of courses to tens of thousands of scientists on topics ranging from parasitic diseases to chemical terrorism. APHL and CDC also cosponsor two fellowship programs.

Other than training, is APHL involved with public health laboratory workforce issues?

The US is in the midst of a severe shortage of laboratory scientists, a development that threatens the operations of public health laboratories. Alarming, the shortage is most acute for technical and managerial positions at the top of the career ladder. An entire cohort of highly trained government scientists is retiring while fewer students are entering the profession. The result is a serious leadership gap.

Anticipating this challenge, in 2003 APHL launched the National Center for Public Health Laboratory Leadership. Its mission is to attract new laboratorians into public health and to prepare current and emerging laboratory leaders with the skills needed to succeed in a rapidly evolving field.

What is APHL's role in development of laboratory science and laboratory systems?

Science is the heart of the laboratory and an important focus for APHL. The association and its members routinely coordinate or collaborate in the development of new assays and testing algorithms to capitalize on

scientific advances and to find alternatives to conventional methods when needed.

Because quality laboratory practice is APHL's overarching goal, it supports the proven route to quality: a systems approach to laboratory practice that treats discrete functions and entities as part of a larger, integrated system. This applies equally to systems within individual laboratories, between partner institutions and across laboratory networks. APHL bolsters laboratory systems through model practices, research and network support.

Do APHL's efforts stop at the US border?

Because our nation's health is affected by global events, strengthening national laboratory systems worldwide is at the core of APHL's mission. APHL's Global Health Program, its largest initiative, works with national health systems in more than 20 resource-constrained nations in Asia, Africa, South America and the Caribbean to extend the reach of laboratory-based disease surveillance, advance in-country health objectives and reduce the burden of endemic diseases such as HIV/AIDS and TB. It develops and supports training programs, strategic planning, collaborations and other services to build the capacity and capability of national laboratory systems to provide accessible, quality testing services and support timely disease monitoring and response.

MORE INFORMATION

For more information on the Association of Public Health Laboratories, contact Jody DeVoll, 240.485.2753, jody.devoll@aphl.org; check our website www.aphl.org; read our blog www.aphl.org/lablog/Pages/default.aspx  and follow us on Twitter <http://twitter.com/APHL> .

To find out more about public health laboratories, view our fact sheet.

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