



Better health through
laboratory medicine.

March 12, 2018
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3326-NC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) January 9, 2018 *Federal Register* request for information regarding possible changes to the Clinical Laboratory Improvements Amendments (CLIA). We support the agency's efforts to update the regulations and assure the quality and accuracy of laboratory testing. Our specific comments follow.

Moderate and High Complexity Testing Personnel

CMS is considering changes to the moderate and high complexity testing personnel requirements, which would consider a bachelor's degree in nursing to be equivalent to a bachelor's degree in the biological sciences. AACC opposes this change. Although we agree that nurses are invaluable members of the healthcare team, their education and training does not delve into the depths of scientific concepts underlying clinical laboratory testing. If CMS were to deem nursing degrees as equivalent to the currently accepted degrees, nurses would be exempt from completing needed clinical laboratory training prior to performing patient testing.

AACC believes that it's important that all testing personnel be required to demonstrate they can meet all the duties and responsibilities associated with performing laboratory testing (e.g., identify analytic and pre- and post-analytic problems, determine appropriate methodologies, perform quality control, and troubleshoot problems). Such demonstration of competency is especially relevant for individuals performing point of care testing (POCT), as they are physically removed from the laboratory environment and thus do not have the benefit of direct contact with CLIA-approved lab directors and other knowledgeable testing personnel.

Whereas AACC does not believe a nursing degree by itself qualifies an individual to perform, supervise, or direct laboratory testing, nurses could demonstrate testing competency through a variety of mechanisms, such as:

- Passing a curriculum of required laboratory specific continuing education (CE) courses; and/or
- Passing a competency exam (e.g., ASCP MLS, MLT or equivalent) exam for certifying staff to work in clinical laboratories as instrument operators and testing personnel.

CMS could consider each of these options separately, or in combination, as possible methods for demonstrating compliance with the CLIA testing personnel requirements.

Physical Science Degrees

CMS is seeking input on how to define a physical science degree, since there is no universally accepted definition of what coursework is required for such a degree. The agency is concerned that such variation may permit some individuals to qualify to perform testing that are not adequately prepared to work in a laboratory. AACC shares CMS' concerns. The educational requirements for degrees in chemical, physical, and biological sciences can also vary widely across disciplines and across institutions, making it difficult to assess the extent of relevant training or education individuals with these degrees have received.

Rather than attempting to create an exhaustive list of degrees that might provide some level of relevant training, AACC proposes that CMS, in collaboration with the laboratory community, develop a list of the minimum type and amount of coursework that an individual should be required to complete to perform specific jobs (operator, technical consultant, general supervisor, etc.) at each complexity level within the clinical laboratory. Documentation of job specific competency should still be required in addition to education and experiential background for anyone working in the clinical laboratory.

Moderate Complexity Technical Consultant

CMS is also proposing that an individual with a nursing degree be deemed qualified to serve as the technical consultant for a moderate complexity laboratory. The technical consultant is "responsible for the technical and scientific oversight of the laboratory," including selecting the appropriate test methodology, establishing a quality control program, assessing testing personnel, ensuring instrument maintenance, and resolving technical, operational, and instrument-related problems," among other duties. AACC does not believe that nurses, who operate lab instrumentation or perform POCT as an adjunct to their patient care duties, have the knowledge, education, training, or experience to serve in this capacity. AACC would suggest the creation of an alternative pathway for someone with a non-traditional degree to demonstrate that they are able to fulfill the duties of the technical consultant without jeopardizing patient care.

Non-Traditional Degrees

CMS is requesting input on whether non-traditional degrees, such as a Regents Bachelor of Arts, which includes college credits for life and work experiences, as well as for the completion of various education modules (e.g., training programs, standardized exams, etc.), should be considered as equivalent to the current chemical, physical, biological, clinical laboratory science, and/or medical technology degrees required under CLIA. Although we support efforts to design and promote new methods of learning, we do not believe that CMS should accept Regents degrees (or similar type diplomas) as equivalent to the science degrees defined in the regulation.

When a student completes a standardized course of study from an accredited institution of higher learning, there is an expectation that the individual has achieved a certain level of knowledge within their field of study. As CMS acknowledges, non-traditional degrees are generally considered education, not scientific degrees. Therefore, CMS has no assurance that the individuals graduating from these programs

are knowledgeable about laboratory testing and able to perform the required tasks to work in a clinical laboratory. AACC would support the creation of a pathway, like the ones described above for nurses, that would allow these individuals to perform testing if they can demonstrate competency to perform laboratory testing at the appropriate complexity level.

General Supervisor Competency Assessment

CMS is requesting input on whether an individual that qualifies as a general supervisor of a high complexity laboratory (i.e., MD, DO, DPM or PhD, master's or bachelor's in chemical, physical, biological, clinical laboratory science or medical technology with one-year training/experience in high complexity testing, or an associate's in laboratory science or medical technology with two-years training/experience in high complexity testing) should be able to perform competency assessment of moderate complexity testing personnel. Currently, general supervisors are limited to only performing this function in high complexity laboratories, whereas technical consultants provide competency assessment in moderate complexity facilities.

AACC agrees that high complexity general supervisors should be able to perform competency assessment for both high and moderate complexity personnel in laboratories that perform both moderate and high complexity testing. Conversely, we believe that technical consultants (i.e., MD, DO, DPM or PhD or master's degree in chemical, physical, biological or clinical laboratory science or medical technology with one-year of training/experience or a bachelor's degree with two-years of training/experience in non-waived testing), by their education, training, and experience should be able to perform competency assessment of both moderate and high complexity testing personnel. Technical consultants are currently limited to only moderate complexity competency assessment.

Proficiency Testing Referral

In recent years, several clinical laboratories have inadvertently sent a proficiency testing (PT) specimen to another laboratory for testing. Frequently, this mistake was the result of laboratory personnel sending the specimen to an outside facility for reflex or confirmatory testing as specified in their standard operating procedures (SOPs). Unfortunately, the agency had little flexibility in applying sanctions, even when it was evident that the laboratory referral was not intended to circumvent the oversight process.

In response to this situation, AACC joined with others in the laboratory community in supporting the passage of the Taking Essential Steps for Testing Act, which gave the CMS greater latitude in how it applied penalties. The association suggests that CMS apply lesser sanctions to first-time offenders that send a PT sample to another facility in error, while a laboratory intentionally seeking to 'game' the system and repeat offenders should receive the maximum penalty with their CLIA certificate revoked for at least one year and the laboratory director barred from their duties for two years.

CLIA Fees

The agency states that the CLIA fees need to be updated, since the current methodology has been in place since 1992, and the last update was in 1997. AACC recognizes that the process may need to be updated and that new fees may need to be assessed for activities that were not identified in the initial rule and later modifications. We suggest that CMS develop and publish a proposed rule that specifically outlines the changes the agency wants to make, the new fees it wants to charge, the specific questions it needs answered, and provide an analysis of the potential impact of any proposed changes on differing types of laboratories. AACC believes it could provide more useful, valuable input to CMS if it had more specific information on the changes the agency believes are necessary.

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We look forward to working with you on this issue. If you have any questions, please email Vince Stine, PhD, AACC's Director of Government Affairs, at vstine@aacc.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Dennis J. Dietzen". The signature is fluid and cursive, with a prominent initial "D" and a long, sweeping tail.

Dennis J. Dietzen, PhD, DABCC, FAACC
President, AACC