



Better health through
laboratory medicine.

August 24, 2022

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3326-P
Mail Stop C4-26-05
7500 Security Blvd
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) July 26, 2022, proposed rule that suggests changes to the Clinical Laboratory Improvement Amendments (CLIA) regulations. While we support the agency's efforts to update the standards, we have serious reservations about several of the recommendations. Our specific comments follow.

Moderate and High Complexity Testing Personnel

CMS is proposing to add nursing as a qualifying degree under the moderate and high complexity testing personnel requirements. AACC opposes this change. Although we agree that nurses are invaluable members of the healthcare team, their education and training does not adequately address the scientific concepts that underly clinical laboratory testing. If nursing were to be added to the list of accepted degrees, CMS would be exempting these personnel from completing this 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:

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- Passing a curriculum of required laboratory specific continuing education (CE) courses; and/or
- Passing a competency exam (e.g., ASCP MLS, MLT or equivalent) 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.

High Complexity Laboratory Director

CMS is proposing to change the qualifications for a high complexity laboratory director (HCLD). Currently, the agency limits this position to certain MDs and board-certified PhDs. CMS is seeking to expand this category to include “professional doctorates” and individuals with a “master’s equivalency,” who meet certain training, experience, and certification requirements. **AACC strongly objects to these proposed changes.**

Doctorate in Clinical Laboratory Science

CMS states that a Doctorate in Clinical Laboratory Science (DCLS), which it labels as a “professional doctorate,” is equivalent to the “traditional doctorate” held by many individuals currently serving as a HCLD. The DCLS was created several decades ago and is available at three universities and, as of 2020, resulted in 15 graduates.

Historically CMS, along with the CLIA approved certifying agencies, have not recognized DCLS as an acceptable degree for taking an exam to serve as a HCLD. We are perplexed that CMS would choose to introduce this change, and a new definition of a doctoral degree, in this proposed rule. Rather, the agency should have facilitated a public forum with all the interested and affected stakeholders to discuss this suggestion.

There is general agreement within the academic and scientific communities on what differentiates a master’s degree from a PhD. A master’s is typically a course driven degree that may include a thesis, while a PhD is defined by a research component that generates new knowledge and refines an individual’s research and analytical skills. AACC agrees with CMS’ previous position—stated as recently as 2018--that the DCLS is not an acceptable PhD under CLIA.

Responsibilities of HCLD

Doctoral level HCLDs play a critical role in ensuring high quality, appropriate patient care. HCLDs are responsible for overseeing all clinical, scientific, and related operational aspects of the laboratory, including the introduction, development, validation, implementation, and interpretation of laboratory tests. The results from these tests are life changing. Providers use laboratory results to screen, monitor, and/or diagnose health disorders to treat their

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patients. Once a diagnosis is made, clinical laboratories provide the essential data that providers rely upon to perform surgeries, adjust medications, and recommend therapy. HCLDs must have a strong combination of technical and medical knowledge, including an in-depth understanding of laboratory methods and their limitations, to ensure the quality and accuracy of laboratory results. Further, the scope of methods deployed in modern clinical laboratories is becoming increasingly complex and now includes gene sequencing, flow cytometry, and mass spectrometry. HCLDs must also possess a thorough understanding of basic biologic processes and the pathophysiologic basis for a broad spectrum of disease. CLIA requires that doctoral level HCLDs demonstrate competency through continuing education (CE) and by obtaining and maintaining board certification.

Limitations of DCLS Degree

Although AACC applauds the desire of any individual to expand their knowledge and improve their skills, the DCLS falls short of meeting the requirements necessary for a person to serve as HCLD. The DCLS is a coursework driven program, which focuses primarily on laboratory management. While this skillset is important, it is only one aspect of the HCLD role. MD/DO and PhD directors typically possess 7-9 years of post-baccalaureate education and training (NSF-reported mean 6.9 years training as a PhD followed by at least two years of postdoctoral training). The DCLS curricula does not reflect the rigor of existing PhD or MD/DO programs.

Of note, a traditional PhD requires the completion of an arduous curriculum in the basic sciences as well as hypothesis-driven independent research that stimulates critical thinking and troubleshooting. It also requires experimental design and interpretation of analytical experiments. These skills are critical for HCLDs, who must also have foundational knowledge of the chemistry and technologies that underly clinical laboratory assays, if they are to effectively develop, validate, and troubleshoot assays. The DCLS does not include this research component or place sufficient emphasis on the critical evaluation of data needed to develop this expertise.

The curricula content of the DCLS professional degree program appears to be equivalent to regular continuing education requirements for a clinical laboratory scientist (CLS) maintaining ASCP certification. Further, cited thesis projects described in a recent publication on DCLS programs (Salazar et al., *Academic Pathology*, 2021; PMID: 34414258) are initiatives that a CLS could undertake in the clinical laboratory for career advancement, or be assigned to a more senior CLS. Such projects do not reflect the experimental or analytical rigor of doctoral level training and inadequately prepare individuals for the responsibilities to serve as a HCLD.

Further, the clinical training obtained during these DCLS training programs is not a suitable surrogate for the clinical training and knowledge conferred with a medical degree (MD, DO) or

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a PhD from a postdoctoral ComACC approved clinical chemistry fellowship. We believe the training outlined for the DCLS degree is commensurate with professional roles as a technical laboratory supervisor. Therefore, the DCLS is insufficient for qualifying an individual to serve as a HCLD. We recommend that CMS maintain the current doctoral level HCLD standards.

Master's equivalency degree

The agency is also proposing to permit an individual with:

- A master's equivalency and 16 of additional hours of doctoral coursework; or
- a thesis or research project; and
- certification by a CMS approved board; and
- at least 2 years of laboratory training or experience, or both; and
- laboratory experience directing or supervising high complexity testing; and
- have at least 20 hours of continuing education to serve as a HCLD

to serve as a HCLD. Once more, we fail to see how such a person is qualified to direct a high complexity laboratory. These requirements pale in comparison with existing standards for MD/DO or board-certified PhDs.

CMS uses the term of a master's equivalency throughout the document but fails to define it. Is this an individual with a master's degree or is it a person with baccalaureate degree who has taken graduate level coursework but not officially received a master's degree? Once more, the agency seems to discount the importance of research and critical evaluation skills by making the PhD optional for a person qualifying under this framework. The person defined above (master's degree equivalency) is more qualified as a supervisor than a director.

Rationale for proposed changes

AACC requests that CMS explain its rationale for lessening the qualifications for individuals serving as a HCLD. Although there is a shortage of CLS personnel at the bench, we are not aware of similar shortages at the high-complexity lab director level. Therefore, we request that the agency explain the basis for its recommendations. If CMS believes there is a staffing shortage for HCLDs, we urge it to release that data.

CLIA Fees

The agency states that the CLIA fees need to be updated, since the current methodology has been in place since 1992. 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 appreciate that CMS responded to our earlier 2018 request and provided a more detailed assessment of how it plans to increase fees. Unfortunately, given the short comment period, we have not had sufficient time to review the framework in detail.

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We are concerned, however, with the size of the proposed fee increase. The agency is recommending an increase of 20 percent with future inflationary updates. CMS does not elaborate on how it will spend these funds, nor does it consider the deep reimbursement cuts laboratories are incurring under the Protecting Access to Medicare Act (PAMA). AACC suggests that CMS consider the impact of these additional costs on the overall ability of laboratories to continue to provide services, particularly in underserved areas, before proceeding.

AACC does, however, support the nominal increase in the Certificate of Waiver (CoW) user fee. We suggest that some of the revenue be used to reinstitute the agency's two percent annual inspections of CoW facilities. Of the more than 300,000 laboratories in the United States, the vast majority are waiver laboratories that are not subject to inspection, and many have only recently entered the lab market. CMS should ensure that newer, non-traditional lab sites, such as pharmacies and home health agencies, are included in those assessments.

AACC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. AACC brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of laboratory science to advance healthcare collaboration, knowledge, expertise, and innovation.

On behalf of AACC, I would like to thank you for the opportunity to provide comments on this proposal. If you have any questions, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at vstine@aacc.org.

Sincerely,



Shannon Haymond, PhD, DABCC, FAACC
President, AACC