



Better health through
laboratory medicine.

October 19, 2020

Reynolds M Salerno, PhD
Director, Division of Laboratory Systems
Designated Federal Official, Clinical Laboratory Improvement Advisory Committee
US Centers for Disease Control and Prevention
Atlanta, GA 30333

Dear Dr. Salerno:

During several recent CLIAAC meetings, the committee or a public commenter has referenced various issues pertaining to the qualifications required of a doctoral scientist to serve as a medical laboratory director (MLD) of a high complexity laboratory. The American Association for Clinical Chemistry (AACC), one of the leading professional societies representing MLDs serving in this capacity, offers the following views on these matters.

The two issues that have arisen are: (1) what constitutes an acceptable PhD for an individual seeking to serve as a high complexity MLD; and (2) whether a CLIA-approved private accrediting body should be given responsibility for determining what is an acceptable degree. AACC outlines below its thoughts on the former, and the association opposes the latter as it would transfer authority from the Centers for Medicare and Medicaid Services (CMS) to private sector organizations.

Doctoral level MLDs of high complexity laboratories play a critical role in ensuring high quality, appropriate patient care. MLDs are responsible for overseeing all clinical and scientific aspects, and related operational aspects, of the laboratory. Their responsibilities include introducing, developing, validating, implementing, and interpreting laboratory tests. The results from these tests help physicians screen, monitor, and/or diagnose health disorders to provide care to their patients. ([see Attachment 1](#)).

MLDs must have a strong combination of technical and medical knowledge. They must have a deep understanding of laboratory methods and method limitations to ensure the quality and accuracy of laboratory results. They must also be able to understand the underlying biological processes or pathophysiology the tests are designed to assess and to apply that understanding to the interpretation of results. Doctoral level MLDs must demonstrate continued competency through continuing education and by obtaining and maintaining board certification.

The CLIA regulations specify that a PhD MLD must have a doctoral degree in a chemical, physical, biological, or clinical laboratory science. CMS has generally accepted doctoral degrees that, in addition to the required coursework, also require a written dissertation that includes a strong independent original research component that advances scientific knowledge to meet this requirement. AACC views

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the independent lab-based research component as an essential component of an acceptable doctoral degree. These qualifications ensure the MLD has the necessary knowledge base, critical thinking skills, and abilities to provide direction of a high complexity lab involved in safe and effective patient care. AACC continues to support CMS' current interpretation of an acceptable PhD and encourages the agency to maintain the stringent requirements needed to ensure MLDs have the scientific and technical expertise required for the job.

There has also been some discussion as to who should determine what is an appropriate PhD under CLIA. One suggestion is to let each of the CMS-approved certifying bodies make this decision. AACC is concerned that transferring this responsibility to private sector accrediting bodies could result in a wide range of qualifications and experience among individuals directing laboratories, thereby introducing variations in the quality of oversight across clinical laboratories. The creation of financial incentives for certifying bodies to accept less-rigorous degrees is another potential unintended consequence that could result from this change. Such outcomes would jeopardize patient care and unnecessarily increase healthcare costs ([see Attachment 2](#)).

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.

We appreciate your consideration of these matters and would welcome the opportunity to work with you to ensure CLIA-certified laboratories continue to provide the highest quality for patients. If you have any questions or would like to discuss this issue further, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at vstine@aacc.org.

Sincerely,



David G. Grenache, PhD, D(ABCC)
President, AACC