



Better health through
laboratory medicine.

December 12, 2022

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:

On July 26, 2022, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule in the *Federal Register* that would recognize the Doctorate of Clinical Laboratory Sciences (DCLS) as “an acceptable doctoral degree” to perform the functions of a high-complexity laboratory director (HCLD) under CLIA. This reversal of CMS’ longstanding position is an issue of significant concern to the laboratory and medical communities.

AACC, the American Society for Microbiology, the College of American Pathologists, and other societies submitted statements during the public comment period opposing this recommendation, raising serious concerns about whether DCLS graduates have the knowledge, training, and experience to direct a high complexity laboratory, particularly as it pertains to laboratory developed tests.

Many societies noted that under CLIA, HCLDs must be board certified. None of the CLIA approved boards officially recognize the DCLS degree, although one does permit individuals with that degree to sit for their exam on a case-by-case basis. CMS’ premature action in advancing this degree, without a public dialogue, has created unnecessary rancor and confusion within our field.

The laboratory medicine community is committed to utilizing all its resources appropriately to meet patients’ needs while ensuring patient safety. AACC believes that a public dialogue between the three DCLS programs, the laboratory and medical communities, and the CMS-approved boards could provide a better understanding of the programs and insight into a path forward.

We believe the Clinical Laboratory Improvement Advisory Committee (CLIAC) is the appropriate venue for such a discussion given its history with the issue, its ongoing efforts to modernize

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CLIA, and the committee members' first-hand knowledge and understanding of the issue. AACC is willing to assist CLIAC in this endeavor if the panel would like help.

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 this matter. 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 ystine@aacc.org.

Sincerely,

A handwritten signature in cursive script that reads "Shannon Haymond".

Shannon Haymond, PhD, DABCC, FAACC
President, AACC