



January 24, 2024

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare and Medicaid Services  
200 Independence Avenue, S.W.  
Washington, DC 20201

Dear Administrator Brooks-LaSure:

On December 28, 2023, the Centers for Medicare and Medicaid Services (CMS) released a final rule (FR Doc No: 2023-28170) making changes to the Clinical Laboratory Improvement Amendments (CLIA) regulations. After reviewing the final rule, our Associations have questions about the agency's decision to reverse its longstanding policy of not recognizing the Doctorate in Clinical Laboratory Science (DCLS) as an acceptable degree for serving as a high complexity laboratory director (HCLD).

The American Society for Microbiology (ASM) and the Association for Diagnostics & Laboratory Medicine (ADLM) are concerned by the agency's inadequate justification for this important policy change. The action was taken without a formal endorsement from the Clinical Laboratory Improvement Advisory Committee (CLIAC), which was the source of many of the recommendations in this final rule. What CMS describes as a minor change is a significant one, with potentially serious implications for HCLD's, and the delivery of patient care.

ASM and ADLM strongly encourage laboratory professionals to expand their knowledge and commend those who seek and obtain a DCLS degree. This is an important achievement and those with a DCLS degree are well positioned to supplement growing needs for clinical laboratory leadership in diverse settings. However, we believe that this degree, in its current form, does not qualify holders to serve as a high-complexity lab director.

Individuals directing high complexity laboratories must be able to design, validate, implement, and maintain the most complex lab tests, including laboratory developed tests (LDTs). CMS has not demonstrated that DCLS graduates have the experience or training to perform these tasks. At a time when LDTs are facing increasing scrutiny from the Food and Drug Administration and the public, CMS must ensure that HCLDs can meet these and other challenges.

Our organizations are interested in and supportive of developing pathways that would allow DCLS graduates to better utilize and strengthen their degree. However, it is incumbent on CMS to more clearly explain the rationale for their policy reversal and how they envision DCLS

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graduates to meet the duties and responsibilities of a high complexity lab director, particularly given the opposition of many accrediting and certifying bodies to this policy change.

ASM and ADLM respectfully ask that CMS suspend implementation of this provision of the final rule. That would provide time for the agency to gather more complete information about the implications of recognizing DCLS. We urge CMS to hold a public forum conducted by CLIAC to discuss and resolve the underlying concerns associated with this degree. Key stakeholders, such as the three universities that offer the degree, the CMS certifying boards, accrediting organizations, relevant professional societies, and other important parties should be invited to participate.

ASM and ADLM would like to thank you for the opportunity to engage CMS on this proposal. If you have any questions, please email Vince Stine, PhD, ADLM's Senior Director of Government and Global Affairs, at [vstine@myadlm.org](mailto:vstine@myadlm.org).

Sincerely,



Octavia M. Peck Palmer, PhD, FADLM  
President, ADLM



Virginia L. Miller, PhD  
President, ASM

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