

Aug 23, 2022

Department of Health and Human Services
Centers for Medicare and Medicaid Services
P.O. Box 8016
Baltimore, MD 21244

Re: Docket CMS-3326-P; "Clinical Laboratory Improvement Amendments Fees: Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories"

The American Society for Microbiology (ASM) is one of the oldest and largest single life science societies with more than 30,000 members in the United States and around the world whose mission is to promote and advance the microbial sciences. ASM membership includes basic, clinical and translational researchers as well as clinical microbiologists, including High Complexity Laboratory Directors across the country. ASM also provides two pathways to obtain Board Certifications for doctoral scientists who wish to pursue a career as a High Complexity Laboratory Director. As such, we write to express our concerns regarding educational standards for Laboratory Directors and the proposed increases in CLIA Laboratory fees.

ASM Supports Upholding Current Standards for Degree Requirements for High Complexity Laboratory Directorship Roles

Both the educational and professional experience required for High Complexity Laboratory Directors have historically reflected the scientific and academic rigors found in doctoral level degrees such as the Doctor of Philosophy (PhD), Doctor of Public Health (DrPh), Doctor of Medicine (MD), or Doctor of Osteopathic Medicine (DO) degree. Within the Proposed Rule, Section (B)(1) (C) lists the inclusion of the Doctorate in Clinical Laboratory Sciences (DCLS) degree. ASM opposes the inclusion of this degree in the acceptable educational requirements for a High Complexity Laboratory Director. ASM asserts that this degree program does not offer sufficient training and education to be considered equivalent to the traditional PhD, MD or DO degrees required to direct a high complexity laboratory. For example, the courses of study for a DCLS student are often short in length (3 years) and do not include a dissertation component. The programs consist of primarily virtual content with varying clinical requirements from 4 weeks to one year spread across multiple laboratory areas. The DCLS largely focuses on the application of tests along with general laboratory, not discipline specific, standards. Although there is an emphasis on laboratory management and test selection, the DCLS curriculum excludes aspects of diagnostics, assay development, test interpretation, treatment, public health and epidemiology (basic science), which are crucial elements to high complexity lab directorship roles. Given that the DCLS program lacks discipline-specific training, graduates of this program would not be satisfactory equipped, especially in a field such as microbiology where the science is evolving at a faster pace than any of the other laboratory specialties.

The DCLS training requirements for on-call, directorship experience, and clinical test development and research component are limited, making it an unsuitable program for high complexity laboratory directorships. As experienced laboratory directors attest, there is much more to running a high complexity lab than selecting the most appropriate test and performing validation. At this point in time, the American Board of Medical Microbiology (ABMM) excludes the DCLS degree for the aforementioned reasons. Individuals with a DCLS or master's level degree would not be appropriate for a position that

requires a medical director. We maintain these degrees are suitable for administrative directorships (i.e., manager), but it is through clinical fellowship training that one is properly prepared at a doctoral level for medical directorship.

Though we affirm that a graduate of a DCLS program can help with monitoring of laboratory data, testing processes, quality and efficiency, these skills are not the same as providing clinical consultation to other clinical colleagues, interpreting patient test results and developing new tests. Due to the vast educational and professional experience requirements when compared with traditional PhD, DrPH, MD, or DO programs, we respectfully request that CMS not include the Doctorate of Clinical Laboratory Sciences degree program as an acceptable/equitable credential for High Complexity Laboratory Directorship positions.

ASM is also concerned that the standards for directors of high complexity labs will also be undermined through Part 493—Laboratory Requirements. Amendment number 20 to §493.1443 paragraph (b) seeks to amend the standard definition for a laboratory director qualification. This amendment seeks to revise §493.1443 paragraph (b) and would provide master's level degree program graduates eligibility to become high complexity lab directors as well as sit for Board Certifications. Again, the educational and professional experience required for these directorships is extensive and highly specialized. Even with the additional academic and professional experience listed, a master's degree level individual would not be properly equipped to direct a high complexity laboratory. ASM requests that this amendment be excluded from the final rule.

Board Certifications ensure integrity, standardization for High Complexity Laboratory Directorship Positions

Another area of concern in this proposed rule is the dilution of standards for High Complexity Lab Directorships. Individuals must meet criteria and undergo processes based on education, experience and the ability to pass a standardized board exam. CMS is seeking to change the core requirements by including persons matriculating from a DCLS degree program, *without* board certification. This will create confusion and lower the standards currently in place with credentialing boards for Medical Laboratory Directors, resulting in degradation in overall quality of lab directorship, and the dilution of the importance of Board certification as part of CLIA high-complexity lab directorship.

The credentialing processes in place that qualify a person as a Medical Laboratory Director for High Complexity testing include a national board exam. These exams are established and have been in place for decades. Doctoral scientists must meet the acceptance criteria established by the respective board. The gatekeeper function permits additional vetting of doctoral scientists.

Specifically, 8 of the 9 laboratory certifying boards require a MD, DO, DrPH, or PhD level degree, additional experience and/or fellowship **following matriculation with a doctoral degree**. At this time the DCLS degree is not considered acceptable for qualification by the American Society for Microbiology Subcommittee on Postgraduate Educational Programs (CPEP) program, nor is it acceptable to qualify to sit for the American Board of Medical Microbiology (ABMM) exam and other professional boards as well.

ABMM diplomates, most of whom have completed CPEP or Accreditation Council for Graduate Medical Education (ACGME) fellowships, are uniquely qualified to respond to emerging infectious disease

threats. Training guidelines include developing and validating clinical tests and clinical interpretation of tests, which would not be a component of masters or DCLS level training without a clinical fellowship. The DCLS degree program has been historically recognized by the Agency to be **inequivalent** to a PhD, MD or DO degree program. For this reason, there is no justification for the changes found in the current language under Section B(1)(C) Proposed Changes to Personnel Requirements: Doctoral Degree. An individual with a DCLS degree without board certification may serve as supervisors for laboratories; however, there is a distinction between High Complexity Laboratory Directorship, as the role is far more advanced than a supervisory-only level and requires additional and highly specific education, training, and experience.

We recognize there is a clinical laboratory workforce shortage that is driving proposed changes in policy; however, the changes in this proposed rule do nothing to address the shortage of clinical laboratory scientists. We caution against any efforts to do, as they should not come at the expense of patient care by ensuring the appropriate level of education and experience is required by those professionals in leadership positions in these laboratories.

Fee increases will further harm financially challenged laboratories across the country

The proposed rule also includes an increase in laboratory fees by up to 20 percent for some of the most basic clinical laboratory tests that are essential to the health and wellbeing of Americans. This proposed increase comes at a time when clinical microbiology laboratories already face financial challenges associated with reduced reimbursement rates, increased volume and rising inflation.

When laboratory profit margins are further reduced, the result is that laboratories will offer fewer tests or will close altogether, especially in more rural areas of the country. Reducing access to clinical laboratory services ultimately harms patients and drives up the cost of care for both patients and taxpayers. Millions of Americans who are managing chronic and infectious diseases, and countless other common diseases and conditions that rely heavily on access to routine lab tests to prevent costly interventions. Across the board fee increases for all CLIA laboratories will have a detrimental impact on public health and clinical laboratory infrastructure that is needed to quickly respond to emerging and future public health threats such as we have experienced over the past two years. This is particularly true for labs who serve rural and underserved communities. In addition, laboratories are not immune to general market conditions. As supplies and labor costs continue to grow, laboratories struggle to maintain and hire essential personnel. Higher fees will continue to damage the nation's laboratory infrastructure at a time when it is needed most.

Laboratories also provide timely results daily to patients in long-term care facilities, many of whom require routine monitoring due to the increased risk of morbidity and mortality among older Americans. This same day turnaround helps identify any critical issues at an early stage, keeping patients healthier and preventing more costly interventions. Patients who are frail or reside in medically underserved communities, including rural areas, are at particular risk. These communities and patients rely on a shrinking number of smaller, local laboratories: laboratories that will face the brunt of these fee increases.

ASM recognizes the essential role of CMS' oversight of CLIA-certified, High Complexity laboratories. We urge you to reconsider proposed fee increases and the proposed changes in high complexity lab directorships requirements at this critical time for our nation's laboratories. Thank you for your

consideration of our views. If you have questions, you may contact Mary Lee Watts, ASM Director of Federal Affairs, at mwatts@asmusa.org.

Sincerely,

A handwritten signature in black ink that reads "Melissa B. Miller". The signature is written in a cursive, flowing style.

Melissa B. Miller, PhD, D(ABMM)
Chair, ASM Clinical and Public Health Microbiology Committee