ASSOCIATION FOR MOLECULAR PATHOLOGY
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September 14, 2022

Chiquita Brooks-LaSure
Administrator, Centers for Medicare
and Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Submitted Electronically via http://www.regulations.gov

Re: CMS Proposed Rulemaking on the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Program—CMS-3326-P

Dear Administrator Brooks-LaSure:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to comment on the proposed rule, "Clinical Laboratory Improvement Amendments of 1988 Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories Proposed Rule" (CMS-3326-P). AMP is an international medical and professional association representing approximately 2,600 physicians, doctoral scientists, and medical laboratory scientists (technologists) who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

As experts in molecular diagnostics, we are committed to ensuring patient access to high quality care and safety, and we welcome the opportunity to work with the Centers for Medicare & Medicaid Services (CMS) to develop future policies to modernize the CLIA Program. We commend CMS on their efforts to propose changes to CLIA to reflect advancements in laboratory testing, expand the workforce, and better consider the many different professional roles that exist in today's high complexity laboratories. Additionally, AMP appreciates that the diverse and necessary roles within a high complexity CLIA laboratory will continue to expand, and we are eager to participate in further efforts to modernize CLIA to better suit the activities and workforce of today's clinical laboratories. AMP considers the best indicator of a candidate's qualifications to be the amount of relevant training and the experience they can bring to the position, and we are concerned about several proposed changes that would allow individuals without the appropriate experience and relevant coursework to serve in various laboratory personnel roles.

<u>Concerns Regarding Proposed Changes to Laboratory Director Qualifications</u>
AMP is concerned about the proposal to expand the qualifications for Laboratory Director of a laboratory performing high complexity testing (Laboratory Director) beyond those with an MD, DO, or PhD degree to also allow for individuals with a DCLS (Doctorate in Clinical Laboratory Science) or possibly a master's degree to hold this type of position. The role of a Laboratory Director is of utmost importance to ensure that high quality testing is performed, and we believe the position requires specific training and experience in order to fill that role.

Current Requirements:
As CMS recognizes, qualified professionals with a MD, DO, or PhD have long played a crucial role in serving as a Laboratory Director ensuring patient care and safety, through the depth and rigor of their training and board certification. Qualified PhD holders obtain scientific acumen through years of troubleshooting and problem solving during a research doctoral thesis. In addition to 5-7 years of post-baccalaureate training, molecular professionals are expected to obtain at least 2 years of post-graduate training in the form of a specialty fellowship and/or active clinical laboratory practice. MD and DO Laboratory Directors have completed medical school and at least a 3-year post-doctoral clinical residency, often with one or more clinical fellowships. In addition to clinical training, laboratory professionals are required to take specific exams, and must obtain licensure and/or board certifications, depending on their training pathway or specialty. Experiential training outside of formal certification programs is essential for providing a Laboratory Director experience with a diversity of assays in active clinical operation.

Training Requirements for Doctorate in Clinical Laboratory Science:
In reviewing the training requirements for the DCLS professional doctoral degree, it does not appear that the DCLS schooling and coursework provide an equivalent training experience as physician training or a doctoral degree with a thesis and clinical fellowship(s). Our members report that at this time, DCLS programs train professionals to serve as laboratory supervisors or managers (i.e., administrative directors) but do not provide adequate training to serve as a CLIA-Laboratory Director. Further, the proposed rule change would be in conflict with existing state-level policies. For example, DCLS degree holders would currently not qualify for a Certificate of Qualification for Laboratory Director under the New York State Requirements.

Training Requirements for Master's Degree Holders:
CMS also proposes to establish an educational pathway permitting an individual with a master's degree to become a Laboratory Director. Upon our review, it is unclear if the educational pathway described is specific for DCLS graduates or if it would apply to any master's degree holder. If the proposed rule describes a separate pathway for any master's degree holder, AMP again emphasizes the rigorous training currently required for qualified professionals with an MD, DO, or PhD to serve as a Laboratory Director and does not believe a master's degree provides a comparable level of experience and education. For this reason, AMP encourages CMS to consider how individuals with an alternative degree type will obtain the relevant training and experience needed for the position before finalizing a rule that would risk having unqualified professionals to serve as Laboratory Directors.

Recommendations:
Noting AMP's significant concerns above, we recommend that the final rule exclude the proposed policy change to §493.1443 Standard; Laboratory director qualifications.

If CMS expands the qualifications for a Laboratory Director beyond those with an MD, DO, or PhD degree to individuals with a DCLS Doctorate in Clinical Laboratory Science or a master's degree, AMP requests that additional criteria and/or requirements be included such as licensure, certification by a board approved by HHS, or other metrics that document a DCLS degree-holder's qualifications for performing the duties of a Laboratory Director. Additionally, we would encourage CMS to consider a requirement for post-graduate clinical laboratory training under the supervision of a qualified Laboratory Director. These additions would ensure that individuals obtain appropriate training and experience qualifying them as a laboratory director of high complexity testing, and such requirements are consistent with the depth and breadth of training of doctoral-level practitioners.

Concerns Regarding Proposed Changes to Laboratory Testing Personnel Qualifications
AMP has similar concerns regarding the proposal to expand the standard testing personnel qualifications that must be met for performing high complexity testing to include advanced degrees in nursing. We appreciate

that CMS has emphasized training and demonstration of competency in the proposed rule, but we disagree that degrees in nursing provide the relevant and necessary coursework and experience for an individual to effectively serve as laboratory personnel without additional training, experience, and board certification specific to laboratory personnel. High complexity testing is instrumental for patient care and requires substantial foundational knowledge in addition to specific expertise in technology and laboratory procedures. AMP strongly believes that nursing training, although rigorous and thorough, does not include critical topics and experience necessary for laboratory practice, thus it would be inappropriate to expand the testing personnel qualifications as proposed.

Recommendation:

Noting AMP's significant concerns above, we recommend that the final rule exclude the proposed policy change to the standard testing personnel qualifications for high complexity testing. Instead, we once again encourage CMS to establish thresholds for professional experience and relevant coursework to support future policy changes to personnel requirements.

Concerns Regarding Proposed 20% increase in CLIA Administrative Fees

In 2019, AMP supported a 20% increase in fees to cover the cost of administering the CLIA program as required by statute. AMP acknowledges that laboratories are using more complex testing platforms, including critical laboratory developed testing procedures, and that it had been almost three decades since the fees had been increased. However, we are concerned that CLIA intends to impose an additional 20% increase in fees this year without providing transparency in how the previous increase stabilized the CLIA program, what additional resource gaps will be addressed, and how the additional funds will be utilized by the agency. Increasing administrative fees without clear goals and objectives for utilization of those resources threatens to compound financial burdens faced by laboratories struggling with numerous recent obstacles including inflation, workforce shortages, and supply chain challenges.

Recommendation:

AMP recommends that CLIA provide further justification for the proposed increase in administrative fees and calls for additional public comment on that information prior to finalizing another significant increase in fees.

We appreciate the opportunity to provide comments on this proposed rule regarding Clinical Laboratory Improvement Amendments of 1988 Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories (CMS-3326-P). Should you have any questions or require additional information, please direct your correspondence to Sarah Thibault-Sennett, Director of Public Policy and Advocacy, at sthibaultsennett@amp.org.

Sincerely,

Daniel E. Sabath, MD PhD
President, Association for Molecular Pathology