ASSOCIATION FOR MOLECULAR PATHOLOGY
Providing global expertise in molecular testing that drives patient care
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Heather L. Stang, MS, MLS(AMT)
Senior Advisor for Clinical Laboratories
Division of Laboratory Systems
Center for Laboratory Systems and Response
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Re: AMP Comments Regarding Final Rule on the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories — CMS-3326-F

Dear Penny Keller and Heather L. Stang:

I am reaching out on behalf of the Association for Molecular Pathology (AMP) regarding, "Clinical Laboratory Improvement Amendments of 1988 Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories Proposed Rule" (CMS-3326-F). AMP is an international medical and professional association representing approximately 2,900 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 on 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.

On September 14th, 2022, AMP submitted comments on the Proposed Rule (CMS-3326-P), highlighting a few key changes that would negatively impact the laboratory community. We commend CMS on their efforts to propose changes to CLIA that reflect advancements in laboratory testing, expand the workforce, and better consider the many different professional roles that exist in today's high complexity laboratories. Specifically, we would like to thank CMS for providing information in the final rule explaining the justification for a fee increase, as well as decreasing the proposed increase to 18% after re-analysis. We appreciate that CMS did not include nursing degrees as an acceptable qualification for the position of High Complexity Laboratory Director (HCLD). We were also pleased that CMS agrees with our comments that a medical or doctoral degree should be the minimum standard required for educational qualifications for a high complexity laboratory director (HCLDs).

However, AMP is concerned that CMS expanded the personnel requirements and qualifications for HCLDs to now allow individuals with a Doctorate in Clinical Laboratory Science (DCLS) to be considered for this role. The position of a laboratory director is critical to ensuring that high quality tests are being performed, and HCLDs require highly specific training and extensive experience in order to guarantee

that laboratory operations are properly run. While DCLS programs train professionals to adequately serve as laboratory supervisors or managers (i.e., administrative directors), they do not provide adequate training to serve as HCLDs. AMP firmly believes that the requirements to obtain a DCLS degree do not provide the proper training to prepare an individual to be a qualified HCLDs. 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). Further, the final rule conflicts 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.

We would appreciate further discussion around this issue and respectfully request a meeting with you and/or your appropriate colleagues. For future scheduling and correspondence, please contact Annie Scrimenti, Associate Director of Public Policy and Advocacy at ascrimenti@amp.org.

Sincerely,

Maria E. Arcila, M.D

President, Association for Molecular Pathology