August 3, 2022

The Honorable Xavier Becerra,
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington DC 20201

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

Mr. Dominic Mancini
Acting Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, D.C. 20503

RE: Request for Extension of 30-Day Comment Period for CMS Proposed Rulemaking on the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Program—CMS-3326-P

Dear Secretary Becerra, Administrator Brooks-LaSure, and Acting Administrator Mancini:

The undersigned organizations write to respectfully request that the Centers for Medicare and Medicaid Services extend the comment period for the recent proposed rulemaking issued concerning Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories. When the proposed rulemaking was formally published on July 26, it provided for only a 30-day comment period. A 60-day comment period is necessary to ensure that interested organizations and individuals have a meaningful opportunity to comment as required by law.

This proposed rule:

- Outlines numerous increases in funding for the CLIA program, including significant fee increases (20+ percent) for clinical laboratories, follow-up surveys, substantiated complaint surveys, and revised certificates;
- Clarifies the methodology used to determine program compliance fees.
- Amends laboratory personnel and histocompatibility regulations under CLIA, and
- Changes the CLIA requirements pertaining to alternative sanctions (including the imposition of civil money penalties, a directed plan of correction, a directed portion of a plan of correction, and onsite state monitoring) for Certificate of Waiver laboratories.

Executive Order 12866[1] directs federal agencies to "afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days." This directive is further supported by Executive Order 13563[2] which states: "To the extent feasible and permitted by law, each agency shall afford the public a meaningful opportunity to comment through the Internet on any proposed regulation, with a comment period that should generally be at least 60 days." These principles were affirmed by President Biden's memorandum "Modernizing Regulatory Review."[3]

We recognize and appreciate the goal of swift rulemaking. However, to ensure that these rules can meet the goals of quality patient care without causing unintended consequences, it is imperative that stakeholders be given sufficient time to provide comprehensive, thoughtful, and well-reasoned comments. The proposals outlined in this rule will have a profound impact on the

performance of laboratory testing and laboratory operations in the United States. Given that the rule does not outline any rationale for why an unusually brief 30-day comment period is necessary, we urge that the comment period be extended by at least 30 days to ensure that stakeholders have a real and meaningful opportunity to consider and comment on this rule.

Thank you for considering our request. If you have any questions or care to discuss further, please feel free to reach out to Matthew Schulze, Director of the Center for Public Policy for the American Society for Clinical Pathology, at (202) 735-2285 or matthew.schulze@ascp.org.

Sincerely,

American Association for Clinical Chemistry
American Association of Bioanalysts
American Association of Pathologists' Assistants
American Clinical Laboratory Association
American Medical Association
American Medical Technologists
American Society for Clinical Laboratory Science
American Society for Clinical Pathology
American Society for Clinical Pathology Board of Certification
American Society for Histocompatibility and Immunogenetics
American Society for Microbiology
American Society of Cytopathology
America's Blood Centers
Association for the Advancement of Blood & Biotherapies
Association of Genetic Technologists
Association of Medical Laboratory Immunologists
Association for Molecular Pathology
Association of Pathology Chairs
Association of Public Health Laboratories
College of American Pathologists
National Independent Laboratory Association
National Society for Histotechnology
The Joint Commission

[1] Executive Order 12866. September 30, 1993, 58 Fed. Reg. 190, Oct. 4, 1993, https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf
[2] Executive Order 13563. January 18, 2011, 76 Fed. Reg. 14, Jan. 21, 2011, https://www.reginfo.gov/public/jsp/Utilities/EO_13563.pdf
[3] Modernizing Regulatory Review. January 20, 2021. Presidential Action. Memorandum for the Heads of Executive Departments and Agencies. https://www.govinfo.gov/content/pkg/FR-2021-01-26/pdf/2021-01866.pdf