



August 26, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3326-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted Electronically via regulations.gov

**RE: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees;
Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver
Laboratories (CMS-3326-P)**

Dear Ms. Brooks-LaSure:

AABB appreciates the opportunity to submit comments in response to the Centers for Medicare & Medicaid Services (CMS) Clinical Laboratory Improvement Amendments of 1988 (CLIA) proposed rule. AABB is an international, not-for-profit association representing institutions and individuals involved in transfusion medicine and biotherapies. The association is committed to “improving lives by making transfusion medicine and biotherapies safe, available and effective worldwide.” AABB works toward this vision by developing and delivering standards, accreditation, and educational programs that optimize patient and donor care and safety. AABB individual membership includes physicians, nurses, scientists, researchers, administrators, medical laboratory scientists and technologists, and other health care providers. AABB’s comments focus on CMS’s proposals related to the delegation of competency assessments and testing personnel qualifications.

Clarification Related to Delegation of Competency Assessments

AABB strongly supports CMS’ proposal to revise the language under 42 CFR 493.1463(b)(4) to clarify that the director or technical supervisor may delegate to the general supervisor “evaluating and documenting the competency of all testing personnel.” AABB commends CMS for explicitly acknowledging that the general supervisor may perform both the semi-annual and annual competency assessments. We encourage CMS to revise the related sub-regulatory guidance to reflect this clarification.

Proposed Changes to Testing Personnel Qualifications

AABB recognizes that CMS’ proposal to expand testing personnel qualifications is, in part, intended to help alleviate the shortages of laboratory personnel across the United States.

However, adding a nursing degree without additional laboratory training or education to the testing personnel qualifications for high complexity testing is not the right approach.¹

Critical shortages of laboratory professionals, such as medical laboratory scientists/medical technologists, jeopardize patients' access to high-quality care. Additionally, the current capacity to collect and test blood and cellular materials are limited by workforce shortages impacting entry-level, front-line staff, such as phlebotomists and blood processing staff. These workforce shortages are consistent with vacancies experienced in medical laboratories throughout the United States.²

The COVID-19 pandemic has exacerbated pre-existing workforce challenges impacting laboratories, including blood collectors, blood banks, and biotherapies laboratories. In addition to current workforce shortages, the pipeline of individuals entering the field will not meet the needs of the future. While AABB has great respect for the nursing profession, AABB does not support CMS' proposal to include nursing degrees in the CLIA high complexity testing personnel requirements; nurses typically lack the required laboratory expertise for high complexity testing, and the field of nursing is also facing a shortage of front-line staff that the COVID-19 pandemic has worsened.³

Rather, AABB encourages CMS to consider solutions to bolster the current laboratory workforce and strengthen the pipeline of skilled laboratory professionals. AABB suggests that CMS collaborate with the Centers for Disease Control and Prevention (CDC), the Health Resources & Services Administration (HRSA), and other federal agencies to enhance the workforce needed to support laboratories, including blood and biotherapy laboratories, by creating a grant and training program that will: (1) address immediate staffing shortages; (2) create a pipeline for the laboratory workforce; and (3) promote professional development opportunities to support laboratory personnel retention long term. Such a program is aligned with and would complement existing workforce efforts led by CMS, CDC, HRSA, and other federal agencies.⁴ AABB would welcome the opportunity to work with CMS, CDC, HRSA, and other laboratory organizations to help define a program to strengthen the laboratory workforce.

Thank you for the opportunity to provide comments on the proposed rule. If you have any questions or need additional information, please contact Susan N. Leppke at 301.547.3962 or via email at sleppke@aabb.org.

¹ See joint comments submitted in response to "Request for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA); CMS-3326-NC" (submitted March 12, 2018). Available at https://www.aabb.org/docs/default-source/default-document-library/positions/comments180312.pdf?sfvrsn=5f438cf4_6.

² Edna Garcia, MPH, Iman Kundu, MPH, Melissa Kelly, PhD, Ryan Soles, MS, The American Society for Clinical Pathology's 2018 Vacancy Survey of Medical Laboratories in the United States, *American Journal of Clinical Pathology*, Volume 152, Issue 2, August 2019, Pages 155–168, <https://doi.org/10.1093/ajcp/aqz046>.

³ American Nurses Association, Nurses in the Workforce. Available at <https://www.nursingworld.org/practice-policy/workforce/>.

⁴ HRSA Health Workforce funding. Available at <https://bhw.hrsa.gov/funding>.

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Sincerely,

Debra BenAvram
Chief Executive Officer
AABB