



# Association of Pathology Chairs

## Promoting Excellence In Academic Pathology

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The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

***RE: CMS-3326-P, Clinical Laboratory Improvement Amendments (CLIA) Fees: Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories: Proposed Rule (Vol. 87, No. 142), July 26, 2022.***

Dear Administrator Brooks-LaSure:

The Association of Pathology Chairs (APC) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule on Clinical Laboratory Improvement Amendments (CLIA) Fees, Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories. APC is a non-profit organization that represents academic departments of pathology and laboratory medicine in North America. APC's membership includes department chairs, pathology residency program directors, program coordinators and department administrators, and medical student education directors. Our departments' faculty and staff are responsible for training the majority of CLIA laboratory directors and pathologists in the United States, as well as running high-complexity labs within academic health systems.

While we appreciate CMS's effort to update several components of the CLIA regulations to ensure high quality laboratory testing, we are seriously concerned about the proposed changes to the **testing personnel requirements**. The proposed rule would equate nursing degrees to clinical laboratory science, biology, and chemistry degrees, which means that individuals with a nursing degree would not be required to meet the coursework or clinical training requirements needed to qualify as high complexity testing personnel. We do not support the proposed rule for the following reasons:

- High-complexity testing classified by CMS requires relevant knowledge, technical expertise, and training that are not offered in nursing programs. Allowing unqualified personnel to perform high-complexity testing would jeopardize the quality and safety of clinical laboratory tests.

- A degree equivalency algorithm should be able to accurately assess whether a degree holder has, as CMS states, “sufficient educational background, i.e., coursework, to be qualified to gain the subsequent training and experience to competently perform their roles.” We would support this approach to identify the requisite coursework to be eligible to perform high-complexity laboratory testing. A nursing degree lacks the comparable scientific coursework. CMS is not proposing a specific training regimen to remediate this deficiency.
- Point-of-care testing is significantly different from moderate and high complexity testing. CMS reasons that “nurses perform the majority of the point of care testing in many different scenarios. We do not have any reason to believe that nurses would be unable to accurately and reliably perform moderate and high complexity testing with appropriate training and demonstration of competency”. However, point-of-care tests are mostly simple waived tests performed at the patient’s bedside, for which there are no CLIA personnel requirements. Thus, we disagree with CMS’ rationale.
- There is an ongoing severe nurse shortage in the country. Encouraging nurses to perform high-complexity tests, for which they are not trained, would exacerbate that crisis by drawing nurses’ time and attention away from other tasks, which would also have a negative impact on patient care. Additionally, the current average salary of laboratory personnel is lower than the average nurses’ salary. Thus, there is an economic argument for building the laboratory workforce to perform high-complexity tests versus expanding the nursing workforce, which is inadequately trained to do this work.

APC is equally committed and fully shares with CMS their goal of clinical test quality and optimal patient care. The proposed rule on testing personnel requirements does not support the goal. We strongly and respectfully request that CMS reconsider the proposed changes on testing personnel requirements.

Thank you for your consideration.



Dani S. Zander, MD  
President, Association of Pathology Chairs