COLLEGE of AMERICAN PATHOLOGISTS

Statement to the
Clinical Laboratory Improvements Advisory Committee
Meeting April 10, 2024

Applicability of CLIA personnel requirements to preanalytic testing

The College of American Pathologists (CAP) appreciates the opportunity to provide written comments to the Clinical Laboratory Improvement Advisory Committee (CLIAC). As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

As such, the CAP recommends that the current scope of CLIA be maintained and that personnel requirements related to the pre-analytics of testing remain outside of the scope of CLIA regulations.

At the November 2023 CLIAC meeting, CLIAC approved a recommendation to include histology under CLIA. The CAP disagreed with this recommendation as through our own monitoring and oversight of laboratories, we have no detected quality issues. Furthermore, the study cited during the last meeting was from overseas, so not necessarily reflective of laboratories in the US, but was also focused on the impact to digital pathology implementation and not a pathologist's ability to render a high-quality diagnosis. Increasing the scope of CLIA regulations is not needed, as there is no consensus supporting the assertion that there are quality issues that would warrant such an expansion. Thus, more discussion, and further study of U.S. laboratories, should take place before expanding CLIA oversight to new areas.

The CAP provides oversight for over 8000 laboratories, providing a firsthand view into how they operate. While issues do arise during the pre-analytical phase of testing, they are not the result of personnel being unqualified. Typically the pre-analytical steps that can compromise the quality of analysis are associated with the time to stabilization of tissue and time to processing the sample. This indicates that laboratory and personnel could benefit from process improvements, not increased qualifications, and our concern is that increased regulation will not solve these issues but could likely exacerbate them.

Some pre-analytic activities are appropriately within the purview of CLIA, such as Test Requests, Specimen submission, handling, and the laboratories systems quality assessment. However, instituting CLIA oversight of preanalytic testing personnel would mean increased regulatory burden for laboratories while reducing the flexibilities available to laboratory directors, who must make decisions on laboratory workflow based on the best interest of the patient balanced with the realities of constricting financial resources. Additionally, as laboratories continue to adapt to workforce challenges, automation is rapidly changing the field of laboratory medicine, and thus it may be premature to develop regulations as practices remain in flux and issues with quality have yet to be identified.

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The CAP does support increased consistency of application and interpretation of existing CLIA regulations and requirements. CLIA is appropriate and needed to regulate testing, which can be defined as producing a test result. We would support and encourage efforts to make interpretation of regulations more consistent; for example, guidance documents to address laboratory questions and consistency of surveyor interpretation from state to state on preanalytic duties that may be performed by laboratory assistants, defined as individuals that help perform testing, versus those requiring further knowledge and judgement that must be performed by qualified testing personnel. This would help laboratories remain compliant with CLIA requirements while also allowing for the use of laboratory assistants to meet workforce needs. However, regulating personnel qualifications for individuals involved in pre-analytic testing would be challenging from a functional standpoint, and unnecessary.

The CAP welcomes the opportunity to discuss our concerns and recommendations for implementation at your earliest. Please contact Andrew Northup at anorthu@cap.org or 202.297.3726.

Closing,

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