

AAPA Statement on Proposed CLIA Regulations for Gross Tissue Examination

The American Association of Pathologists' Assistants (AAPA) is deeply concerned and disappointed by proposed changes to the Clinical Laboratory Improvement Amendments (CLIA) regulations that would expand the personnel eligible to perform gross tissue examinations without establishing sufficiently specific requirements for surgical pathology education, training, and competency.

Published by the Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) on October 8, 2026, the proposed rule would allow individuals meeting broader high-complexity testing personnel qualifications to perform gross tissue examinations. It would also require technical supervisor review before a final pathology report is issued, rather than maintaining the current 24-hour review guidance. Although the proposal seeks to increase staffing flexibility and address workforce concerns, AAPA believes it does not adequately account for the specialized knowledge and clinical judgment required to examine and sample surgical specimens safely.

Gross examination is not simply specimen processing. It is a critical component of the diagnostic process. The decisions made during gross examination determine which tissue is submitted for microscopic evaluation and can directly affect diagnosis, cancer staging, and treatment. When a specimen is selectively sampled, the pathologist may never examine the original tissue. Missing a lesion, inadequately sampling a tumor, or failing to identify a relevant margin or lymph node can have serious consequences for patient care. Review after gross examination cannot replace the expertise needed to make these decisions correctly at the outset.

Pathologists' assistants are specifically educated and trained for this responsibility. Graduates of NAACLS-accredited Pathologists' Assistant programs complete specialized graduate-level didactic and clinical education in anatomy, pathology, specimen dissection, tissue sampling, and the examination of complex surgical specimens. ASCP certification further provides a nationally recognized credential for the profession. These qualifications are distinct from general laboratory science education or training focused on histologic processing.

What AAPA Is Recommending

AAPA will advocate for regulatory changes that recognize the specialized nature of surgical pathology and establish personnel qualifications that appropriately reflect specimen complexity. Our recommendations include:

- **Establish surgical pathology gross examination as a distinct CLIA specialty.** Macroscopic examination of surgical pathology specimens should be recognized as a specialized anatomic pathology discipline, comparable in principle to the recognition of cytology as a distinct specialty, rather than being addressed solely through broad high-complexity testing personnel requirements.
- **Reserve complex gross examinations for appropriately qualified professionals.** Specimens requiring selective sampling, extensive dissection, tumor assessment, margin evaluation, lymph node examination, staging, or specialized tissue triage should be handled by ASCP-certified Pathologists' Assistants, qualified pathologists, and pathology residents or fellows working within appropriate training and supervision frameworks.

- **Establish clear, complexity-based qualification standards.** Requirements should reflect the education, specialized training, documented competency, and experience needed for the specimens being examined. Appropriately trained laboratory personnel may continue to perform routine, low-complexity specimens, provided they meet defined minimum qualifications and competency requirements.
- **Maintain meaningful safeguards for diagnostic quality and patient safety.** Technical supervisor review and laboratory competency assessments are important safeguards, but they should complement—not substitute for—the appropriate qualifications of the individual performing the gross examination. Requirements must ensure that complex specimens are handled by personnel equipped to make the critical decisions involved.

Our Commitment to the Profession and the Public

AAPA supports efforts to address laboratory workforce challenges and recognizes the essential contributions of laboratory professionals across disciplines. However, staffing flexibility must not come at the expense of appropriate training and patient safety. The qualifications required to perform a task should reflect the knowledge, judgment, and potential consequences associated with that task. We are committed to engaging with CMS, CDC, laboratory leaders, pathologists, professional organizations, and our members to advocate for regulations that accurately reflect the role of Pathologists' Assistants and the specialized nature of gross tissue examination.

We encourage AAPA members to remain engaged as this rulemaking process moves forward. We will continue to communicate our concerns, provide evidence-based recommendations, and advocate for standards that protect patients, support high-quality pathology services, and recognize the specialized expertise of pathologists' assistants.

Our position is clear: the qualifications for gross tissue examination must be based on the complexity of the specimen and the expertise required to examine it safely, not solely on broad laboratory personnel classifications. Patient safety must remain central to every regulatory decision affecting surgical pathology.