Association for Pathology Informatics

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November17, 2025

David R. Wright
Director, Quality, Safety & Oversight Group (QSOG)
Centers for Medicare & Medicaid Services
7500 Security Blvd, Mailstop: C2-21-16
Baltimore, MD 21244-1850

Subject: Continuation of Remote Digital Cytology Review under CLIA Enforcement Discretion

Dear Mr. Wright,

On behalf of the Association for Pathology Informatics (API), the Association for Academic Pathology (AAPath), the American Society for Clinical Pathology (ASCP), the American Society of Cytopathology (ASC), ARUP Laboratories, Inc., the Diagnostic Medicine Consortium (DMC), the Digital Pathology Association (DPA), and Project Santa Fe, we appreciate CMS's continued support for digital review in surgical pathology, molecular, and laboratory disciplines under the CLIA remote review enforcement discretion reaffirmed in QSO-23-15-CLIA (Revised, Sept 23, 2025). This framework has enabled safe, secure, and efficient diagnostic service delivery across the nation.

However, we respectfully express concern regarding the rollback of remote digital cytology review scheduled to end six months after issuance of this memo. Unlike physical slide examination, remote digital cytology review involves no human specimen leaving the certified laboratory—only the viewing of images and metadata through a secure, audited digital system. In this sense, digital cytology operates identically to the digital review now permitted for surgical pathology, molecular and laboratory testing. The physical specimen remains within the certified laboratory; only pixels are transmitted.

Ending this flexibility risks significant negative impact on rural and underserved communities, many of which depend on remote cytology services to maintain timely cancer screening and diagnostic coverage. With a projected national shortage of pathologists and cytotechnologists, the ability to perform secure remote review is essential to sustaining equitable access to laboratory medicine.

The API urges CMS to extend the existing remote review discretion to cytology, under the same safeguards already applied to surgical pathology and molecular practice: oversight under the primary CLIA certificate, secure network access, personnel documentation, and quality assurance monitoring. This continuation would uphold CLIA's mission of accuracy and reliability while preserving access to diagnostic care for patients nationwide.
Just as remote radiology - which has been permitted for decades - and remote surgical pathology have enabled diagnostic flexibility, remote diagnostic cytology evaluation facilitates the secure and efficient transmission of data to and from the diagnostician. This approach minimizes the risks and delays associated with the physical transport of glass slides, enhancing both speed and reliability in diagnostic workflows.

We would welcome the opportunity to collaborate with CMS to establish evidence-based standards for digital and remote cytology practice that ensure both quality and operational flexibility.

Sincerely,

Lisa-Jean Clifford

Lisa-Jean Clifford
President, Association for Pathology Informatics

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