



February 19, 2026

Gregg S. Brandush, RN, JD
Director, Division of Clinical Laboratory
Improvement and Quality
Quality, Safety, and Oversight Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Remote Review of Digital Cytology Images

Dear Mr. Brandush:

It was a pleasure meeting with you and your staff on February 13 to discuss the September 23, 2025, Centers for Medicare & Medicaid Services (CMS) [memo](#) (QSO-23-15-CLIA REVISED) “...discontinuing the temporary exercise of enforcement discretion that previously allowed remote review of cytology digital slides...” We are especially grateful that CMS is willing to continue to discuss and potentially re-evaluate certain elements of the memo. As promised, we are writing a follow-up letter to recap our request that CMS revise the memo to allow pathologists to provide remote interpretations of digital cytology images.

Background/Issue

In the memo, CMS states it is discontinuing allowing the remote review of cytology digital slides by pathologists and cytologists because the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (the statute) requires “...that all cytology screening be done in a (CLIA certified) laboratory...” (See [42 U.S.C. § 263a\(f\)\(4\)\(B\)\(vi\)](#)). The memo keeps in place CMS’s enforcement discretion that remote reviews are permissible for non-cytologic images, such as for surgical pathology. CMS’s remote review policy has been instrumental to patient care as it helps optimize workflows and allows pathologists to utilize new technologies that improve and accelerate patient access to high-quality care. CMS’s new policy goes into effect six months from the date the memo was released (approximately March 23, 2026).

ASCP accepts CMS’s position that the CLIA statute requires “cytological screening” to take place within the laboratory. However, ASCP maintains that neither the statute nor the regulations prohibit the remote *diagnostic interpretation* by pathologists of digital cytology

images, which takes place after screening, when performed in accordance with the memo's requirements.

Discussion of Key Statutory Provisions

The statutory language is clear that “cytological screening” must be performed in a CLIA certified laboratory. 42 U.S.C. § 263a(f)(4)(B)(vi) outlines CLIA's requirement “...that all *cytological screening* (emphasis added) be done on the premises of a laboratory that is certified under this section.”

As should also be clear, the statute does not state that the in-laboratory requirement also applies to diagnostic interpretations performed by pathologists. First, we note that 42 U.S.C § 263a(f)(4)(B) uses several terms essential to the cytology workflow, specifically “screening,” “rescreening,” and “interpretations.” Congress's deliberate use of these three different terms means that it viewed each term as having its own separate and distinct meaning and that it did not intend for “interpretations” of cytologic specimens by pathologists to be restricted to the confines of a CLIA certified laboratory.

In addition, it bears mentioning that 42 U.S.C § 263a(f)(4)(B)(iv), which outlines the cytology proficiency testing requirement, specifically targets both “individuals involved in screening *or interpreting* (emphasis added) cytological preparations.” In contrast, however, 42 U.S.C § 263a(f)(4)(B)(iv)—both paragraphs from the same section of the statute—outlines that the “in laboratory” requirement is specific to screening; it does not add interpretations to this requirement.

Important to the issue of whether screening and interpretation are separate and distinct is how these terms have historically been understood. In cytopathology, screening and interpretations are well-recognized as distinctly different parts of the diagnostic workflow. Screening represents the initial or preliminary review. It is a broad, systematic search for any cells that look abnormal. This process, generally performed by a cytologist, involves scanning the entire slide (manually or with semi-automated tools) and highlighting cells or regions of the slide that appear atypical. Slides where abnormal cells are identified on screening are forwarded, along with the cytologist's findings, to the pathologist for diagnostic interpretation. The interpretative process involves, at a minimum, the pathologist's analysis of highlighted cells or regions. This involves reviewing cellular morphology in detail; integrating clinical context; applying diagnostic criteria (e.g., Bethesda System for reporting cervical cytology); and making a final classification or diagnosis. Additionally, at least 10% of gynecologic cytology cases screened as negative by the cytologist must be rescreened.

ASCP's Request

Accordingly, given the wording and construction of the applicable CLIA provisions, coupled with the generally recognized principle that the interpretation is substantively different from

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screening, ASCP maintains that the statute does not prohibit the interpretation by a pathologist from being performed remotely. As a result, we request that CMS clarify this fact and amend the memo to allow pathologists to perform interpretations remotely, when performed in a manner consistent with the memo.

ASCP appreciates the opportunity to provide these comments. If we can be of any assistance on this matter, please do not hesitate to contact us or Matthew Schulze, Senior Director of the ASCP Center for Public Policy, at matthew.schulze@ascp.org.

Sincerely,



Jonathan R. Genzen, MD, PhD, MBA, FASCP
Chair, Commission on Science, Technology, and Public Policy
ASCP



Alexandra (Ali) Brown, MD, FASCP
Interim Chief Executive Officer
ASCP

cc: Angelique Daubert, CMS/CCSQ

Penny Keller, CMS/CCSQ