

Issue Brief

FEDERAL ISSUE BRIEF



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CMS Proposing Clinical Laboratory Improvement Amendments; Virtual Access, Gynecologic Cytology Proficiency Testing (PT), Personnel Qualifications, and Other Changes

The Centers for Medicare & Medicaid Services (CMS) are issuing a proposed rule to amend the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations to allow for virtual access under the CLIA certificate of the primary testing laboratory that generated the data, with the exception of the subspecialty of cytology, and the use of digital images for gynecologic cytology proficiency testing.

The rule also includes proposed changes to personnel qualification requirements and other changes pertaining to SARS-CoV-2 reporting requirements, certificate requirements, test reporting requirements, enforcement requirements, public consultation requirements, and editorial and technical updates.

The 163-page rule is scheduled to be published in the October 8 **Federal Register**. A display copy of the rule is currently available at: <https://public-inspection.federalregister.gov/2026-20613.pdf>. A 60-day comment period beginning October 8 is provided.

Comment

The rulemaking does not contain a table of contents.

The rule's introduction provides a general overview (Pages 3-4) of the actions, as shown below;

This rule encompasses four overarching areas:

- (1) Virtual access provisions that would codify the flexibility provided by prior exercises of enforcement discretion to allow pathologists and laboratory personnel to review digital laboratory data, digital results, live imaging, and digital images remotely under the CLIA certificate of the primary testing laboratory that generated the data, excluding the subspecialty of cytology;
- (2) Gynecologic cytology proficiency testing (PT) updates that would allow for the use of digital images of glass slides in PT to align with the Food and Drug Administration (FDA)-authorized digital cytology screening systems;
- (3) Personnel qualification updates that would address concerns regarding the burden associated with the qualification requirements that took effect on December 28, 2024, including removing human-only laboratory science limitations and adding qualifications for histopathology gross tissue examination personnel and Mohs dermatology laboratory directors; and
- (4) Other changes that would remove SARS-CoV-2 (the virus causing COVID-19) reporting requirements, update certificate requirements, revise regulatory text requiring establishment of the

Clinical Laboratory Improvement Advisory Committee (CLIA), update test report requirements, revise enforcement requirements, and correct editorial and technical errors.

The proposed rule aims to update CLIA regulations to reflect advances in technology, reduce regulatory burdens on laboratories, and address workforce shortages while maintaining laboratory quality and safety standards.

Provisions of the Proposed Regulations (Pages 4-100)

This is a relatively long section.

A. Proposed Changes to Allow for Virtual Access

1. Virtual Access (pp. 4-14)

Codifies flexibility CMS has allowed only through enforcement discretion, which began in the COVID-19 public health emergency. CMS reviewed survey citations from March 2023 to July 2024 and found no concerning trends tied to remote or digital review.

- New definition (§ 493.2): "virtual access" means review of digital lab data, results, live imaging, and digital images under the CLIA certificate of the primary testing lab that generated the data, over a secure connection (to the lab's systems laboratory information system (LIS), instruments, EHR, or encrypted communications).
- Test system definition: adds "live imaging, digital images" and "accurate and reliable" before "test results."
- Certificates (§§ 493.43(a)(1), 493.55(a)(3)): virtual access is treated as occurring at the primary lab wherever the person sits. The primary lab's director is responsible for all virtual testing and reporting; only qualified personnel may perform it; the lab must give CMS a list of staff using virtual access on request (and they must appear on Form CMS-209). Does not apply to Provider Performed Microscopy (PPM) certificates.
- Cytology carve-out: virtual access is not permitted in the cytology subspecialty. Remote cytology review requires a separate CLIA certificate with cytology for that location, consistent with the September 2025 revision of QSO-23-15 (enforcement discretion for remote cytology ended March 23, 2026).
- Retention (§§ 493.1101(e), 493.1105): digital images and digital data are added to storage and retention requirements. For cytology and histopathology, labs keep both the slide and the digital image where applicable. Retention periods are unchanged (cytology slides 5 years, histopathology slides 10 years).
- Confidentiality (§ 493.1231(a)): policies must ensure virtual access occurs in a confidential environment on a secure network; CMS names public places such as coffee shops as examples to prevent.

- Procedures and QC: procedure manuals must cover digital imaging and detecting inadequately prepared digital images (§ 493.1251(b)(2)); analytic control procedures must cover testing via virtual access (§ 493.1256(a)).
- Post analytic records (§ 493.1283(a)(5)): record who performed virtual testing, the software version where applicable, and the device used.
- Reporting systems (§ 493.1291(a)(2)): data transmission requirements extended to results reported via virtual access.

2. Gynecologic Cytology Proficiency Testing (pp. 14-18)

- Allows gyn cytology PT using digital images of glass slides (§§ 493.855, 493.945). Rationale: PT must use the same methodology as routine testing (§ 493.801(b)(7)), and FDA authorized the first digital cytology screening system in 2024.
- The 10- and 20-slide test sets, consensus and biopsy-confirmation standards, and scoring (+10 maximum, -5 for an incorrect response) all extend to digital images.
- New integrity requirement: HHS-approved gyn cytology PT programs must have a system to monitor the integrity of testing. College of American Pathologists (CAP) and American Society for Clinical Pathology (ASCP) currently use proctors for glass-slide PT.

3. Personnel Qualifications (pp. 18-64)

Background

The December 2023 final rule updated personnel requirements effective December 28, 2024. CMS says that stakeholders objected mainly to the lab director rules, saying the combined continuing education (CE) and experience requirements would shrink the pool of eligible directors, particularly in rural areas and for Mohs labs. CMS issued QSO-25-21-CLIA on June 23, 2025, using enforcement discretion, and said it would address the issue by rulemaking.

CMS asserts that no serious reliance interests prevent the changes, since the stricter rules were never enforced and the proposals are mostly more permissive. It rejected both full rescission of the 2023 rule (which would lose pathways for nontraditional degree holders) and a total rewrite.

Laboratory director changes

- Standard across degree types: moderate and high complexity directors need either 1 year of experience directing or supervising lab testing or 20 CE hours in lab director responsibilities ("or," not "and"), reverting to pre-2023 flexibility.
- Doctoral degree holders: remove the HHS-approved board certification requirement (§§ 493.1405(b)(3), 493.1443(b)(3)).

- Master's and bachelor's holders: rescind the additional 1-year and 2-year training or experience requirements (§ 493.1405(b)(4)(ii), (b)(5)(ii)).
- High complexity physicians: experience drops from 2 years to 1 year; a new route allows 1 year of lab training during residency or fellowship.
- Thesis or research project: no longer needs to involve human specimens (animal research counts).
- Grandfathering (§ 493.1405(b)(6)): expands to cover people who qualified as moderate or high complexity directors before December 28, 2024.
- Mohs and dermatopathology (§ 493.1443(b)(6)): new high complexity director qualifications codify QSO-25-21, allowing dermatopathology-qualified technical supervisors to serve.
- On-site requirement: the director on-site visit requirement (at least once every 6 months) is removed; directors must again be "accessible to the laboratory as needed" (§§ 493.1407(c), 493.1445(c)).
- Provider-Performed Microscopy (PPM): rescinds the director responsibility to evaluate PPM personnel competency (§ 493.1359(c), (d)), because PPM is performed by providers during a patient visit.

Other personnel changes

- New degree definitions (§ 493.2): biological, chemical, and clinical/medical laboratory science or medical technology degrees, tied to the 2020 Classification of Instructional Programs (CIP) codes. Intended to remove "human-only" laboratory science limits, citing workforce shortages and COVID-era experience.
- Rescinded definitions: "experience directing or supervising" and "laboratory training or experience."
- Gross tissue examination: codified at § 493.1489(b)(7), with qualifications at (b)(1)-(5), recognizing histotechnicians, histotechnologists, and pathologist assistants. The technical supervisor must review results before the final report is issued (current guidance: within 24 hours).
- Technical supervisors: adds the American Osteopathic Board of Dermatology and American Board of Physician Specialties as recognized boards; clarifies graduate coursework requirements.
- Blood gas: adds flexibility for blood gas personnel requirements, per the impact analysis.

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- Cleanup: corrects inadvertent omissions and cross-references; removes obsolete high school diploma-era supervision requirements (§ 493.1495(b)(7), (c)).

4. Other Changes (pp. 64-81)

- SARS-CoV-2 reporting: rescinds §§ 493.41, 493.555(c)(6), 493.1100(a)-(b), and 493.1834(d)(2)(iii). CARES Act reporting authority expired when the PHE ended on May 11, 2023.
- Certificate requirements: the multiple-site exception is expanded from hospital labs to all lab types (same campus, same lab director, single application). "Campus" is newly defined as the area adjacent to the main building plus areas within 250 yards, matching 42 CFR 413.65(a)(2). Labs must notify HHS within 30 days of an email address change.
- Test reports (§ 493.1291(c)(2)): must include the CLIA number and the lab name as it appears on the CLIA certificate. CMS cites doing business as (DBA) name confusion and its COVID-era difficulty tracing labs behind complaints.
- Enforcement: rescinds the mandatory 6-month waiting period for reinstatement after PT failure (§ 493.807(b)); labs still need two consecutive successful PT events and CMS verification. CMS cites rural access, such as a small hospital losing immunohematology testing. Removes "one of which may be on site" from § 493.807(a).
- Alternative sanctions: directed plans of correction and other alternative sanctions would no longer end when a suspension or limitation takes effect (§§ 493.1810(d)(2), 493.1832(c)(2), 493.1836(c)(3)); they run until revocation, preserving patient notification in immediate jeopardy cases. Civil money penalty provisions are unchanged, and CMPs are extended to certificate of waiver labs.
- CLIAC: "will establish" becomes "may establish" (§§ 493.2001(a), 493.17(b)), reflecting CLIAC's termination on March 31, 2025.
- Test categorization (§ 493.17): notices move from the Federal Register to FDA's CLIA database; De Novo requests are added; obsolete CDC consultation language is removed.
- PT program approval (§ 493.901(a)): the minimum of 10 participants must be CLIA-certified labs.
- PT analyte reclassification: CA 125, CEA, serum folate, and vitamin B12 move from Endocrinology to Routine Chemistry to match FDA categorization.
- Severability: CMS states the provisions can operate independently and seeks comment.

5. Regulatory Impact (pp. 94-127)

OIRA deemed the rule significant under E.O. 12866 § 3(f)(1); it is also framed under E.O. 14192 (deregulation).

- Costs: driven almost entirely by labs updating policies and procedures (\$19.0M-\$38.1M). Virtual access is voluntary; CMS estimates implementation at about \$102K-\$1.6M for one lab and ongoing costs of \$113-\$340 per year. Smaller costs fall on accreditation organizations and exempt states (\$31K-\$744K) and PT programs updating software (about \$95K-\$104K).
- Savings: come from the director provisions. Board certification and CE: \$3.8M-\$117.9M in year 1 and \$1.5M-\$90.4M per year after. CE hours: \$2.7M-\$34.0M one time. Annual director on-site travel and lodging: \$0.6M-\$1.7M. PPM competency assessment: \$0.6M-\$57.6M.
- Wide ranges: savings are very sensitive to assumptions; the high-end rests on how many directors would otherwise need board certification or CE.

Final Comments

Direction: mostly deregulatory. Restores pre-2023 director flexibility, drops director on-site visits, and removes the 6-month PT reinstatement wait. The tradeoff is less front-end screening of directors, which CMS says is offset by training, competency assessment, PT, and biennial surveys.

Safeguards added: patient notification during immediate jeopardy, CLIA number on reports, secure-network and recordkeeping requirements for virtual access, and integrity monitoring for digital cytology PT.

Likely comment issues: the cytology exclusion from virtual access; whether weakened director qualifications and the "accessible as needed" standard provide enough oversight; whether the digital PT integrity monitoring requirement is workable without a defined standard; and whether the cost savings estimates are well supported.