Federation of American Hospitals

Charlene K. MacDonald
President and CEO

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Via electronic submission at http://www.regulations.gov

The Honorable Mehmet Oz, M.D., M.B.A.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3485-NC
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Request for Information; Clinical Laboratory Improvement Amendments of 1988 (CLIA) Regulations (CMS-3485-NC)

Dear Administrator Oz:

As the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States, accounting for approximately 20 percent of community hospitals nationally, the Federation of American Hospitals (FAH) appreciates the opportunity to respond to the Request for Information (RFI) on the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations issued by the Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC), published in the Federal Register on July 16, 2026 (91 Fed. Reg. 43,586).[1] FAH writes to add the perspective of hospital-based laboratories, which hold roughly 9,200 of the 300,700 CLIA certificates in force and furnish the testing behind emergency, surgical, inpatient, and outpatient care 24 hours a day.[2]

FAH shares the goal stated in the RFI of updating regulations promulgated in 1992 so that they reflect current laboratory science and technology while preserving the quality framework that has protected patients for more than three decades. CLIA plays a critical role in establishing standards that promote the accuracy, reliability, and quality of laboratory testing and, ultimately, protect patient safety. As laboratory medicine continues to evolve, it is important that this framework keep pace with advances in technology and changes in laboratory practice, while preserving these essential protections and minimizing unnecessary administrative burden and regulatory complexity. FAH appreciates that CMS and the CDC are seeking stakeholder input before proposing regulatory changes. FAH's comments concentrate on the matters that affect hospital-based laboratories differently from independent and reference laboratories and offer the following recommendations to inform CMS's consideration of potential future rulemaking. FAH urges CMS to:

- **Preserve pre-analytic workforce flexibility:** CMS should retain the current approach, under which hospital laboratories train pre-analytic specimen preparation staff to their assigned duties and manage histology slide preparation through their quality systems, and should condition any new personnel or certification requirement on a documented safety gap and a published workforce impact analysis.
- **Modernize CLIA around performance standards:** CMS should permit remote competency assessment, allow competency assessment by platform or method group, and provide calibration verification relief for manufacturer-calibrated test systems that do not permit user adjustment.

- **Recognize enterprise programs rather than duplicate them:** CMS should deem hospital laboratories' compliance with existing emergency preparedness, cybersecurity and biosafety frameworks, and HHS should reinstate CLIAC as the standing advisory mechanism for future CLIA updates.
- **Keep oversight of laboratory testing with CMS and the CDC:** FAH opposes any change to CLIA regulations that would create a pre-market review, submission or approval function for tests developed in-house, or that could be read to recreate the vacated FDA laboratory developed test rule through the CLIA regulations. Entities performing only computational analysis under the oversight of a CLIA-certified laboratory should not be required to hold a separate certificate.
- **Maintain the current specialty and subspecialty structure:** CMS should refrain from writing specific technologies or methods into the regulations, and any future restructuring should carry certificate categories, proficiency testing enrollment, and personnel qualifications forward without interruption to testing.

Preserve Pre-Analytic Workforce Flexibility and Keep Histology Outside CLIA

Section B.2 of the RFI seeks comment on the qualifications, education, and experience of specimen preparation personnel. In hospital laboratories, personnel performing pre-analytic specimen preparation activities receive training appropriate to their assigned responsibilities and are subject to the laboratory's policies, procedures, and applicable quality systems. The regulations do not set a separate qualification standard for pre-analytic personnel, and the histopathology standard at 42 CFR 493.1273 governs stain controls and reporting, not the qualifications of the histotechnologists who prepare slides. CMS revised the personnel requirements in subpart M in December 2023 without adding such a standard.

The Bureau of Labor Statistics projects about 22,600 openings a year for clinical laboratory technologists and technicians through 2034 against an occupation of 351,200.[3] The 2022 vacancy survey of the American Society for Clinical Pathology (ASCP) found vacancy rates of 18.0 percent in core laboratories and 13.2 percent in histology, with staff positions taking seven to 12 months to fill. The 2024 survey found rates still above pre-pandemic levels, with 10 of 17 departments reporting rising retirements.[4] A new credentialing requirement for pre-analytic work would require that hospitals and health systems remove staff from existing laboratories before new graduates could replace them. The effects would be felt first in longer turnaround times for laboratory test results used in emergency department and inpatient care, particularly at smaller and rural hospitals with fewer staffing alternatives. **FAH urges CMS not to add personnel qualification requirements for staff whose duties are limited to pre-analytic specimen preparation, and not to extend CLIA personnel or certification requirements to histology tissue processing and slide preparation, without a documented safety gap and a published workforce-impact analysis.** If CMS identifies specific pre-analytic error types, FAH recommends that it address them through the specimen handling standards at 42 CFR 493.1242, and that it publish the error data and a workforce impact analysis with any proposed rule.

Modernize CLIA Around Performance Standards

Laboratory science and technology continue to advance faster than rulemaking cycles. FAH recommends keeping CLIA technology neutral to support continuous innovation. CMS should write CLIA standards to accommodate new testing technologies and methods as they emerge. Performance standards let CLIA keep pace, supporting continuous innovation in the development and delivery of laboratory tests while holding every method to the same quality expectations. **FAH urges CMS to update CLIA around performance standards, beginning with three changes:**

- **Remote competency assessment:** FAH supports the November 2024 recommendation of the Clinical Laboratory Improvement Advisory Committee (CLIAC) that CMS permit remote direct observation for competency assessment under 42 CFR 493.1413(b)(8) and 493.1451(b)(8).[5] Any future rulemaking should propose a set of performance expectations for the observation rather than list approved devices, and should leave to the laboratory director the discretion to require in-person observation for high-risk procedures.
- **Competency assessment flexibility:** CMS should permit laboratories to assess the competency of testing personnel by testing platform, methodology, or defined group of substantially similar tests rather than test by test.
- **Calibration verification:** CMS should revise 42 CFR 493.1255 so that successful quality control and proficiency testing satisfy calibration verification for FDA-cleared or approved test systems that are manufacturer-calibrated and do not permit user adjustment.

Recognize Enterprise Programs Rather Than Duplicate Them

Hospital laboratories operate inside health systems whose safety and security programs span the whole organization. Hospitals plan and exercise under the hospital emergency preparedness conditions of participation at 42 CFR 482.15, operate under enterprise cybersecurity programs governed by the HIPAA Security Rule, and follow CDC guidance and Occupational Safety and Health Administration standards for biosafety and biosecurity. The RFI's emergency preparedness requirements questions stem from a 2025 OIG report recommending that CMS consider preparedness requirements for independent laboratories, which the 2016 emergency preparedness final rule did not reach. The hospital conditions of participation at 482.15 already require facility-wide all-hazards risk assessment, planning, training, and exercises that encompass laboratory services, and hospital laboratories participate in those exercises today. **FAH urges CMS to deem compliance with those programs and standards rather than add laboratory-specific duplicates.** FAH also urges HHS to reinstate CLIAC, which was disbanded in 2025, as the standing mechanism through which CMS and the CDC can evaluate future updates to the CLIA regulations with laboratory, hospital, and clinical stakeholders.

Keep Oversight of Laboratory Testing with CMS and the CDC

The U.S. District Court for the Eastern District of Texas vacated FDA's laboratory developed test rule on March 31, 2025, holding that laboratory developed tests are professional services furnished by laboratories rather than devices subject to FDA premarket review, and FDA did not appeal.[6] The CLIA program assigns each agency a distinct role: CMS certifies and surveys laboratories and enforces the regulations, the CDC provides scientific and technical support and manages CLIAC, and FDA categorizes tests by complexity and conducts premarket review of commercially distributed in vitro diagnostic products.[7]

The establishment and verification of performance specifications should remain a quality-system requirement that CMS evaluates through routine surveys, with the depth of review scaled to the test's complexity and how its results are used in patient care.[8] and the clinical use of the test. **FAH opposes any change to the CLIA regulations that would create a pre-market review, submission or approval function for tests developed in-house, and recommends that entities performing only computational analysis under the oversight of a CLIA-certified laboratory not be required to hold a separate certificate.** FAH likewise opposes any revision that could be interpreted to permit the regulation of laboratory developed tests in a manner the Court held to be outside FDA's statutory authority, or that similarly restricts their development or use. A separate certificate for computational analysis is unnecessary because the CLIA-certified laboratory remains responsible for establishing the performance specifications of its test systems, including any computational analysis they incorporate, under 42 CFR 493.1253(b)(2). FAH's comments on the CY 2027 Physician Fee Schedule proposed rule urge CMS to complete the definitional review begun in this RFI before finalizing payment policy that depends on where the boundary at 42 CFR 493.2 falls.[9]

Maintain the Current Specialty and Subspecialty Structure

In hospital laboratories, molecular methods are used within microbiology, hematology, pathology, and other disciplines rather than as a freestanding service, and regulatory text keyed to particular technologies would require new rulemaking each time the science advances. **FAH recommends that CMS maintain the current specialty and subspecialty structure and refrain from writing specific technologies or methods into the regulations.** If CMS nonetheless revises the specialty framework, it should provide that existing certificate categories, proficiency testing enrollment, and personnel qualifications carry forward automatically, with sufficient lead time such that no laboratory experiences an interruption in testing.

FAH appreciates the opportunity to respond to the CLIA RFI and looks forward to continuing to work with CMS and the CDC as the agencies consider updates that keep pace with laboratory science while protecting the capacity of hospital laboratories to deliver timely, accurate results for patients. Should you have any questions regarding our comments or require additional information, please contact Alyssa Keefe, SVP Head of Policy at akeefe@fah.org or (202) 624-1500.

Sincerely,

/s/
Charlene MacDonald
President and CEO

Endnotes

[1]Request for Information; Clinical Laboratory Improvement Amendments of 1988 (CLIA) Regulations, CMS-3485-NC, 91 Fed. Reg. 43,586 (July 16, 2026).

[2]Centers for Medicare & Medicaid Services, Division of Clinical Laboratory Improvement and Quality, Laboratories by Type of Facility (Exempt and Non-Exempt), CLIA database (Aug. 2026), https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/statupda.pdf.

[3]U.S. Bureau of Labor Statistics, Occupational Outlook Handbook, Clinical Laboratory Technologists and Technicians (2024-34 projections), https://www.bls.gov/ooh/healthcare/clinical-laboratory-technologists-and-technicians.htm.

[4]Garcia E, Kundu I, Kelly M, Soles R. The American Society for Clinical Pathology 2022 Vacancy Survey of medical laboratories in the United States. Am J Clin Pathol. 2024;161(3):289-304; Garcia E, Diaz J, Kundu I, Kelly M, Soles R. The American Society for Clinical Pathology 2024 Vacancy Survey of medical laboratories in the United States. Am J Clin Pathol. 2025;164(5):759-777.

[5]91 Fed. Reg. at 43,588-43,589, Section B.8.

[6]American Clinical Laboratory Association v. FDA, No. 4:24-cv-00479-SDJ (E.D. Tex. Mar. 31, 2025), vacating Medical Devices; Laboratory Developed Tests, 89 Fed. Reg. 37,286 (May 6, 2024); Medical Devices; Laboratory Developed Tests; Implementation of Vacatur, 90 Fed. Reg. 45,134 (Sept. 19, 2025).

[7]U.S. Food and Drug Administration, Clinical Laboratory Improvement Amendments (CLIA), https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia (last visited Sept. 4, 2026) (describing the respective roles of CMS, the CDC and FDA under the CLIA program).

[8] 42 CFR 493.1253; 42 CFR 493.17

[9]Federation of American Hospitals, Comments on CMS-1848-P, CY 2027 Physician Fee Schedule Proposed Rule (Sept. 14, 2026), Section II.D.3.b(61).