



September 9, 2026

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare and Medicaid
Services
Department of Health and Human
Services
7500 Security Boulevard
Baltimore, MD 21244

The Honorable Erica Schwartz, MD, MPH, JD
Director
Centers for Disease Control and Prevention
Department of Health and Human Services
1600 Clifton Road NE
MS H21-8
Atlanta, GA 30329

RE: Request for Information; Clinical Laboratory Improvement Amendments of 1988 (CLIA) Regulations; RIN 0938-AW01

Dear Administrator Oz and Director Schwartz:

On behalf of the American Academy of Family Physicians (AAFP), representing 124,500 family physicians and medical students across the country, I write in response to the Centers for Medicare & Medicaid Services' (CMS) and Centers for Disease Control and Prevention's (CDC) [Request for Information](#) (RFI) regarding potential updates to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations. The AAFP has long been engaged in CLIA policy development and implementation through its support of physician office laboratories (POLs), laboratory proficiency testing programs, laboratory accreditation activities, and prior comments submitted in response to CLIA regulatory proposals and RFIs. We support efforts to modernize CLIA requirements to reflect advancements in laboratory science, [information technology](#) (IT), and health care delivery while continuing to promote laboratory quality, patient safety, and access to diagnostic services.

Family physicians provide comprehensive, longitudinal care across a diverse range of practice settings, including many physician-owned and physician-directed laboratories. As CMS and CDC consider potential future regulatory action related to artificial intelligence (AI) and cybersecurity, among other topics, it is important that any updates recognize the diversity of CLIA-regulated laboratories and preserve the [appropriate roles of physicians](#), laboratory professionals, technology developers, and other stakeholders. Modernization efforts should strengthen laboratory quality and patient safety without imposing disproportionate burdens on POLs or shifting responsibility for technology design, performance, and security away from the entities best positioned to manage those risks.

B.6. Postanalytic Interpretation and Use of Artificial Intelligence (AI)

The AAFP [supports](#) the responsible use of AI and advanced software tools in health care, including laboratory medicine, where such technologies may improve efficiency,

enhance quality assurance activities, support interpretation of complex test results, and expand access to valuable clinical insights. AI has significant potential to support the core functions of primary care and to improve care delivery when implemented appropriately. **However, AI should be viewed as a supportive technology rather than a replacement for physician judgment, laboratory expertise, or established clinical decision-making processes.** Laboratory testing remains only one component of patient care, and laboratory findings must continue to be interpreted within the broader clinical context of the patient's medical history, physical examination, longitudinal care relationship, and other diagnostic information. Future CLIA policies should therefore preserve the distinction between laboratory analysis and reporting versus physician diagnosis and treatment decisions. **Laboratory-generated interpretations, whether produced by humans or AI-enabled systems, should not be treated as substitutes for physician clinical judgment.**

As CMS and CDC evaluate the role of AI in the postanalytic testing process, the AAFP encourages the agencies to prioritize transparency, validation, and accountability. Clinicians and laboratories should have access to sufficient information regarding AI-enabled tools to understand their intended use, limitations, performance characteristics, applicable patient populations, and known risks. Transparency is essential to maintaining physician and patient trust, and it enables meaningful evaluation of whether a tool is appropriate for a given clinical circumstance. Similarly, AI-enabled systems should be [evaluated with the same rigor](#) expected of other technologies used in health care. Future CLIA policies should focus on risk-based verification, validation, quality assurance, and ongoing performance monitoring rather than adopting prescriptive technology-specific requirements. AI systems may evolve over time through software updates or modifications to underlying algorithms, creating the potential for performance drift or unintended consequences. Laboratories should therefore be able to assess whether AI-supported systems continue to function safely and effectively throughout their lifecycle.

The AAFP also encourages CMS and CDC to recognize that not all AI applications present the same level of risk. Future oversight should be proportional to the potential patient safety implications of the tool being deployed. For example, workflow automation and administrative support functions may warrant substantially different oversight than systems used to interpret pathology results, genomic testing, or other high-complexity laboratory processes. Regulatory approaches should remain flexible enough to accommodate innovation while ensuring that higher-risk applications receive appropriate scrutiny. At the same time, future policies should clearly define responsibilities across the technology ecosystem. Developers, software vendors, device manufacturers, laboratories, laboratory directors, and physicians each play unique roles and should be accountable for activities within their control. **Physician practices and laboratories should not be expected to assume sole responsibility for the design,**

maintenance, updating, security, or performance of AI systems that they neither develop nor control. The entities that create and maintain these technologies must retain responsibility for ensuring their safety, reliability, transparency, and security.

B.8 Remote Direct Observation Competency Assessment

The AAFP supports the use of remote technologies to conduct the direct observation component of laboratory personnel competency assessments when implemented in a manner that maintains testing quality, patient safety, and effective oversight. Advances in video communication and related technologies have expanded opportunities for qualified technical consultants and supervisors to observe testing activities remotely while still evaluating competency, identifying training needs, and ensuring adherence to established laboratory procedures. As CMS and CDC consider potential future updates to CLIA requirements, remote observation should be recognized as a viable option for competency assessment when appropriate safeguards are in place.

Allowing remote direct observation could provide important operational flexibility for POLs and other laboratory settings, particularly those located in rural or underserved communities where access to qualified laboratory oversight personnel may be limited. Requiring in-person observation in all circumstances can create logistical, scheduling, and financial challenges that do not necessarily enhance testing quality. Remote assessment capabilities may help facilitate timely competency evaluations, reduce administrative burden, and improve access to qualified technical expertise while continuing to support compliance with CLIA requirements. The AAFP therefore encourages CMS and CDC to consider policies that provide laboratories with flexibility to use either in-person or remote observation methods based on their operational needs and circumstances.

At the same time, any future policies permitting remote competency assessments should include clear guidance regarding documentation, quality assurance, and accountability. Laboratories should maintain appropriate records demonstrating that competency assessments were conducted effectively and that remote observation methods allow evaluators to adequately assess the testing activities being performed. CMS and CDC should favor flexible, outcome-oriented standards rather than overly prescriptive technology requirements so that laboratories can adopt solutions that best meet their needs while ensuring consistent and reliable implementation across diverse laboratory settings.

C.3. Cybersecurity

The AAFP [strongly supports](#) efforts to strengthen cybersecurity protections across the health care system, as cybersecurity is both a patient safety issue and a matter of public

trust. Cyberattacks can disrupt laboratory operations, delay patient care, compromise sensitive health information, interfere with care coordination, and threaten the financial viability of health care organizations. Recent cybersecurity incidents have demonstrated that disruptions to health IT infrastructure can have significant downstream consequences for physician practices, laboratories, and patients. Therefore, the AAFP supports efforts to improve the protection of patient information and strengthen laboratory operational resilience against evolving cyber threats.

As CMS and CDC evaluate potential cybersecurity-related updates to CLIA, it is critical that future requirements acknowledge the wide range of laboratories subject to CLIA oversight, including POLs, independent laboratories, hospital laboratories, and large reference laboratories. We recommend against a one-size-fits-all approach, as it may inadvertently impose substantial administrative, technical, and financial burdens on smaller laboratories without meaningfully improving cybersecurity outcomes. POLs often operate with limited staffing and minimal IT resources, and requirements that may be feasible for large integrated laboratory organizations may be impractical for smaller POLs. **Any future cybersecurity framework should therefore be scalable, flexible, and commensurate with organizational size, resources, and risk profile.**

The AAFP further [encourages](#) CMS and CDC to recognize that cybersecurity responsibility must be shared across the health care technology ecosystem. Laboratories depend heavily on laboratory information systems, electronic health records, cloud service providers, medical device manufacturers, software developers, and AI vendors. Physician practices and laboratories frequently lack direct control over the architecture, code, infrastructure, and security mechanisms underlying these technologies. Therefore, cybersecurity obligations should be aligned with the ability of a stakeholder to identify, mitigate, and remediate risk. Technology developers and vendors should bear primary responsibility for the security of the systems they design and maintain. Future CLIA policies should avoid shifting responsibility for vulnerabilities or cybersecurity failures onto laboratories that lack the ability to control or modify the affected systems.

Finally, the AAFP encourages CMS and CDC to leverage existing cybersecurity resources, best practices, and federal frameworks rather than creating duplicative requirements. Continued coordination across HHS agencies and federal partners can help promote consistent expectations while minimizing unnecessary burden. Future efforts should emphasize education, technical assistance, workforce support, and quality improvement. Cybersecurity requirements should strengthen secure information sharing and laboratory operations without impeding interoperability or the timely exchange of laboratory information that physicians rely upon to care for patients.

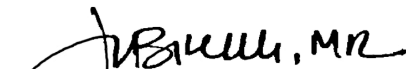
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Conclusion

Thank you for the opportunity to provide written comments on these important topics. The AAFP appreciates CMS and CDC seeking stakeholder input regarding the future of CLIA regulation in an environment increasingly influenced by advanced technologies and evolving cybersecurity threats. We support modernization efforts that improve laboratory quality, patient safety, transparency, and operational resilience while preserving the appropriate roles of physicians, laboratory professionals, and technology developers. As the agencies consider potential future rulemaking, we encourage CMS and CDC to adopt risk-based, flexible approaches that recognize the diversity of CLIA-regulated laboratories, preserve physician clinical judgment, support secure interoperability, and ensure that responsibility for technology performance and security remains with the entities best positioned to manage those risks. We look forward to continued engagement with CMS and CDC as these discussions progress. For more information or questions, please contact Mandi Neff, Senior Strategist, Regulatory and Policy, at mneff2@aafp.org.

Sincerely,



Jen Brull, MD, FAAFP
Board Chair

American Academy of Family Physicians