Draft Legislation to Clarify the Clinical Laboratory Improvement Amendments (CLIA): FAQs

Why support modernizing CLIA?

Clinical laboratories and the laboratory-developed testing procedures developed and performed by their personnel are effectively regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA; Section 353 of the Public Health Service Act), in addition to state-level requirements and professional accreditation bodies. Laboratory medicine has grown and evolved significantly since CLIA was enacted nearly 35 years ago and as such, the CLIA regulations need to be updated to reflect current practices. For example, the legislation expands CLIA so that it would also incorporate facilities that perform flow cytometric, molecular, and genomic examinations and additionally, laboratories that perform "dry bench" analysis. Further, the legislation would require that standards are set for laboratory analytics that are used as part of a testing service and requires that the Secretary clarify regulations to reflect modern laboratory workflow including remote work that proved beneficial during the pandemic. Moreover, the legislation lays the foundation to provide further quality assurance that tests are accurate and reliable. Clarifying CLIA is the most streamlined, flexible, and cost-effective pathway forward for updating laboratory testing requirements in a way that protects patients and supports innovation.

How would the legislation enhance testing quality?

- The legislation requires the Secretary to develop minimum levels of standards for analytical *and* clinical validity.
- Laboratories will need to provide summary information about their tests upon request via a standardized format established by the Secretary to provide inspectors with the opportunity to review information about a test's analytical and clinical validity.
- The Secretary will develop standards and processes that ensure that laboratory inspectors are appropriately trained to inspect and evaluate laboratories and all examinations and procedures that would be within the inspector's responsibilities.
- It expands the number of tests that are subject to standardized proficiency testing, and when a proficiency testing program does not exist, it requires that all other tests are evaluated via an alternative assessment approach on a quarterly basis.
- With input from the public and the Clinical Laboratory Improvement Advisory Committee, it will create requirements specific to laboratory-developed testing procedures with elements that do not allow for interlaboratory comparisons and are not well suited to proficiency testing programs.

How does the legislation ensure that CMS has the expertise and resources to ensure the quality of laboratory tests?

CLIA allows for the use of private, non-profit third-party accreditation organizations to ensure that all clinical laboratories are complying with CLIA requirements. These third-party organizations enlist experts to support their operations and accredit laboratories in certain specialties and subspecialties. The legislation continues the role of private, non-profit third-party accreditation organizations, ensuring there are sufficient personnel to continue verifying the quality of all clinical laboratory testing. Importantly, the Secretary has existing authority to collect fees as it relates to administrating Section 353 of the Public Health Service Act.

The legislation also requires that the Secretary ensure that one or more board-certified professionals who have served as a laboratory director in a clinical laboratory that performed laboratory-developed testing procedures are on staff to promulgate and enforce the modernized regulations. In addition, it requires the input of experts on the Clinical Laboratory Improvement Advisory Committee, an advisory committee established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention), on how to clarify CLIA regulations, standards for all laboratory examinations and procedures, and updating the list of analytes and methods for which proficiency testing is required.

Are laboratories required to report laboratory errors?

Yes, CLIA requires that any clinical laboratory report patient test result errors to the authorized person ordering the test, maintain a record of those errors, ensure that all complaints and problems reported to the laboratory are documented, conduct investigations of complaints when appropriate, and issue a corrected report. (42 CFR § 493.1291) Additionally, CMS-approved accrediting organizations and state licensure programs must notify CMS within 10 days of any deficiency identified in an accredited or CLIA-exempt laboratory if the deficiency poses an immediate jeopardy to the patient or a hazard to the general public. (42 CFR § 493.555)

The legislation builds from these existing requirements by codifying the requirement to report laboratory errors to the Centers for Medicare and Medicaid Services and further requires the Secretary to enhance reporting requirements associated with laboratory errors.

How will CLIA enforce these requirements?

CLIA has existing authority to issue immediate sanctions which include directed plans of correction and civil money penalties of up to $10,000 for each violation for each day of substantial noncompliance with the requirements. Laboratories certifications may be suspended, revoked, or limited if the Secretary finds that the laboratory is not in compliance. Further, whenever the Secretary has reason to believe that continuation of any activity by a laboratory would constitute a significant hazard to the public health, the Secretary may bring suit in the

district court of the United States for the district in which such laboratory is situated to enjoin continuation of such activity.

Does the legislation allow for states and third parties to issue more rigorous requirements to ensure analytical and clinical validity?

Yes, CLIA has always served as the floor for ensuring testing quality. CLIA would continue to allow for third-party accreditation organizations and states to establish even more rigorous processes for verifying that laboratory tests are accurate and reliable.

Why is CLIA modernization a better regulatory approach than an FDA-centric approach?

As noted above, modernizing CLIA is the most streamlined, flexible, and cost-effective pathway forward for updating laboratory testing requirements in a way that protects patients and supports innovation. An FDA-centric approach would drastically alter the way laboratory services are regulated which would significantly disrupt access to localized, evidence-based patient care. It would also stifle innovation at our most prestigious institutions preventing the adoption of new scientific knowledge and limiting patient access to the most cutting-edge testing approaches. Moreover, an FDA approach duplicates already existing CLIA requirements and would require many more resources and staff at the agency to regulate the hundreds of thousands of laboratory-testing procedures that are used for patient care. This new workload would significantly stall FDA's current obligations. Even just a few thousand emergency use authorization applications – a comparatively lower number of submissions than the workload associated with FDA regulating all laboratory tests – overwhelmed FDA during the COVID-19 pandemic and forced them to prioritize review and contributed to further testing delays. Conversely, CLIA is an existing and successful framework that can support ensuring the quality of all tests without hampering clinical care.