Draft Legislation to Clarify the Clinical Laboratory Improvement Amendments (CLIA): Section by Section Summary

Section 2. Definitions

Section 2 amends the definition of laboratory and adds several new definitions to Section 353(a) of the Public Health Service Act (PHSA):

- The definition of laboratory is updated to incorporate facilities that perform flow cytometric, molecular, and genomic examinations. The definition also is updated to include facilities that examine materials derived from the human body or from information obtained through the analysis of such materials. It is also clarified that the examination can be performed for screening purposes or to provide information for the prognosis of a health condition in addition to the other purposes listed in the current definition.
- A definition of laboratory-developed testing procedures is added.
- A definition of analytical validity is added.
- Definitions of performance characteristic and performance specification are added. These definitions are similar to the definitions currently established in CLIA regulation.
- A definition of clinical validity is added. This is the definition from the College of American Pathologist's All Common Checklist with minor modifications.
- A definition of laboratory analytics is added to clarify that certain analytics used as part of a testing procedure are subject to CLIA requirements.

Section 3. Clarifying requirements to ensure test quality

- As it relates to the approval of accreditation bodies in Section 353(e) of the PHSA:
    - This section adds language to refer to new requirements for inspector training.
    - It codifies a requirement that an accreditation body notify the Secretary within 10 days of any deficiency identified in an accredited laboratory if the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public. The term "immediate jeopardy" is defined in existing CLIA regulations.

- As it relates to the authority granted by Section 353(f) of the PHSA to set standards:
    - The language is amended to clarify that standards can pertain to analytical or clinical validity and that standards should assure consistent performance, compliance, and transparency.
    - The language is amended to clarify what the standards should require including by adding the following new requirements:
        - In addition to using proficient testing programs as appropriate, laboratories are required to conduct alternative assessments for all examinations or procedures if a proficiency testing program does not exist.
        - It codifies language requiring laboratories to comply with any requirements related to correcting and reporting laboratory errors.

        - Laboratories are required to maintain best practices in developing, deploying, and maintaining laboratory analytics.
    - The Secretary would be newly required to factor input from the Clinical Laboratory Improvement Advisory Committee (CLIAC) when developing standards.
    - Language is updated to clarify that proficiency testing requirements would apply to any analyte or method specified by the Secretary. The Secretary would also be required to regularly review and update the list of analytes and methods using input from CLIAC.

- As it relates to inspections in the newly designated Section 353(h) of the PHSA:
    - A new requirement requires laboratories to provide, upon request by an inspector, summary information and associated data, including information and documentation demonstrating the analytical and clinical validity, of each laboratory-developed testing procedure performed and resulted by the laboratory.
    - The Secretary is required to develop standards and processes related to inspector training.

Section 4. Laboratory-developed testing procedures

- Section 4 would add a new section to establish requirements for laboratory-developed testing procedures and to require that the Secretary modernize its regulations:
    - It clarifies that laboratory-developed testing procedures would be regulated under Section 353 of the PHSA and not as a medical product under the Federal Food, Drug, and Cosmetic Act.
    - The Secretary would be required to modernize regulations to:
        - Reflect advances in laboratory medicine and workflow.
        - Require that laboratories provide information to the public about their tests, including information on analytical and clinical validity. The information would be displayed via a standardized format to be established by the Secretary.
        - Enhance reporting requirements of laboratory errors.
        - With input from the public and CLIAC, establish requirements specific to laboratory-developed testing procedures with elements that do not allow for interlaboratory comparisons.
        - Exempt certain existing examinations or procedures from having to comply with any requirements as deemed appropriate by the Secretary.
        - Update the system and criteria for test complexity categorization.
        - Provide for the creation and maintenance of standards and best practices for laboratory analytics.
        - Generally, ensure testing quality.

- The Secretary is required to ensure that one or more board-certified professionals who have served as a laboratory director in a clinical laboratory that performs laboratory-

developed testing procedures are on staff to promulgate and enforce the modernized regulations.

- It is required that CLIAC fully represents the diversity of the laboratory community and clarifies its role in providing input on how to modernize CLIA regulations, standards for all laboratory examinations and procedures, and updating the list of analytes and methods for which proficiency testing is required.

Section 5. Public health emergencies

Section 5 grants authority to the Secretary to waive CLIA requirements during a public health emergency.

Section 6. FDA medical device requirements

Section 6 clarified that laboratories can opt to act as a manufacturer and seek approval, clearance, or authorization from the Food and Drug Administration for an assay as an in vitro diagnostic product.

Section 7. Preemption

Section 7 removes duplication by preventing any Federal, State, tribal, local government (or political subdivision thereof), or government contractor from requiring that the analytical and clinical validity of a test be assessed for the purpose of determining coverage and payment.

Section 8. Technical amendments

Section 8 makes updates to reflect the changes summarized above.