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

**Section 2. Definitions**

(a) ) Section 353(a) of the Public Health Service Act is amended to read as follows

-- "(a) Definitions

(1) As used in this section, the term "laboratory" or "clinical laboratory" means a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, flow cytometric, molecular, genomic, or other examination of either materials derived from the human body or information obtained through analysis of such materials, for screening purposes or for the purpose of providing information for the prognosis, diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings.

(2) In this section, the term "laboratory-developed testing procedure" –

(A) ) means a type of procedure that —

(i) is not approved, cleared, or authorized as an in vitro diagnostic product by the Food and Drug Administration under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c, 360e, 360bbb–3),

(ii) is performed by a laboratory that is certified or accredited as required under this section,

(iii) is utilized in the context of clinical care or public health services, and

(iv) meets the standards established by regulation under section 353(f) of the Public Health Service Act (42 U.S.C. 263a(f)).

(B) is applicable to procedures the involve the use of —

(i) test systems approved, cleared, or authorized by the Food and Drug Administration under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c, 360e, 360bbb–3) that have been modified by a laboratory and where the modified procedures are validated and performed, and results produced and interpreted, within same laboratory;

(ii) methods developed, validated, and performed, and results produced and interpreted, within a laboratory;

(iii) methods developed by the Centers for Disease Control and Prevention or another laboratory in a public health laboratory network coordinated or managed by the Centers for Disease Control and Prevention and performed and resulted by a clinical laboratory for which a certificate is in effect under this section and that is within a public health laboratory network coordinated or managed by the Centers for Disease Control and Prevention,

(iv) standardized methods, as determined by the Secretary, such as those that are available in textbooks and peer-reviewed publications;

(v) methods in which performance characteristics and specifications are not provided by the manufacturer of test systems or components but are established by the laboratory;

(vi) additional methods established by the Secretary.

(3) As used in this section, the term "analytical validity" means the ability of an examination or procedure to determine whether or not an analyte of interest is present in a specimen and at what concentration (if applicable), as described by the examination's or procedure's performance characteristics and performance specifications.

(4) As used in this section, the term "performance characteristic" means a property of a test that is used to describe its quality, *e.g.*, accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference range, and any other performance characteristic required for test performance.

(5) As used in this section, the term "performance specification" means a value or range of values for a performance characteristic, established or verified by the laboratory.

(6) As used in this section, "clinical validity" –

(A) means the ability of a test to diagnose or predict risk of a particular health condition or predisposition, measured by sensitivity, specificity, and predictive values, and

(B) may be established, as appropriate, with any of the following evidence—

(i) peer-reviewed scientific or medical literature;
(ii) clinical guidelines;
(iii) reports of significant human experience with an in vitro diagnostic or laboratory developed testing procedure;
(iv) case-control studies;
(v) case studies or histories;
(vi) clinical data;
(vii) consensus standards;
(viii) reference standards;
(ix) data registries;
(x) postmarket data;

(xi) real world data;
(xii) clinical trials; or
(xiii) other evidence deemed appropriate by the Secretary.

(7) As used in this section, the term “laboratory analytics” includes algorithms (including those powered by artificial intelligence or machine learning), software, mathematical formulae, clinical calculations, risk calculations, and other tools as defined by the Secretary that are used as part of a testing procedure.

**Section 3. Clarifying requirements to ensure test quality**

(a) ) Section 353(e)(2)(A) of the Public Health Service Act is amended –

(1) in clause (i), by inserting “, in accordance with subsection (h)(3),” after “qualified”; and

(2) after clause (iii) –

(A) inserting the following –

“(iv) the accreditation body agrees to 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,” and;

(B) and redesignating (iv), (v), and (vi) as (v), (vi), and (vii).

(b) Section 353(f) is amended –

(1) in paragraph (1) and (2), to read as follows --

“(1)In general
The Secretary shall issue and periodically review standards, including standards for analytical and clinical validity, to assure optimal performance, compliance, and transparency by laboratories issued a certificate under this section of accurate and reliable laboratory examinations and other procedures. Such standards shall require each laboratory issued a certificate under this section—

(A) to meet minimum requirements associated with an examination’s or procedure’s performance characteristics and specifications,
(B) to maintain a quality assurance and quality control program adequate and appropriate for validating all examinations and procedures developed, performed, or interpreted by the laboratory and ensuring the reliability of reported results,
(C) to meet requirements relating to the proper collection, transportation, and storage of specimens,

(D) to maintain records, equipment, and facilities necessary for the proper and effective operation of the laboratory,
(E) in performing and carrying out its laboratory examinations and other procedures, to use only personnel meeting such qualifications as the Secretary may establish for the direction, supervision, and performance of examinations and procedures within the laboratory, which qualifications shall take into consideration competency, training, experience, job performance, and education and which qualifications shall, as appropriate, be different on the basis of the type of examinations and procedures being performed by the laboratory and the risks and consequences of erroneous results associated with such examinations and procedures,
(F) to qualify under a proficiency testing program meeting the standards established by the Secretary under paragraph (3),
(G) to conduct alternative assessment as described under paragraph (3) if a proficiency testing program appropriate for the examination or procedure does not exist,
(H) to comply with requirements for correcting and reporting laboratory errors,
(I) to maintain best practices in developing, deploying, and maintaining laboratory analytics, and
(J) to meet such other requirements as the Secretary determines necessary to assure consistent performance by such laboratories of accurate and reliable laboratory examinations and procedures.

(2) Considerations
In developing the standards to be issued under paragraph (1), the Secretary shall, within the flexibility provided under subparagraphs (A) through (J) of paragraph (1), take into consideration—
(A) the examinations and procedures performed and the methodologies employed,
(B) the degree of independent judgment involved,
(C) the amount of interpretation involved in procedures and results analysis,
(D) the difficulty of the calculations involved in result analysis,
(E) the calibration and quality control requirements of the instruments used,
(F) the type of training required to operate the instruments used in the methodology,
(G) whether the procedure is a laboratory-developed testing procedure,
(H) the input and recommendations of 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)
(I) such other factors as the Secretary considers relevant."

(2) in paragraph (3) --

(A) in subparagraph (A), to read as follows –

"(A)The Secretary shall establish a list of analytes and methods, and associated standards, for proficiency testing programs for laboratories issued a certificate

under this section which are conducted by the Secretary, conducted by an organization approved under subparagraph (C), or conducted by an approved accrediting body. The standards shall require that a laboratory issued a certificate under this section be tested for each examination and procedure conducted within a category of examinations or procedures for which it has received a certificate, except for examinations and procedures for which the Secretary has determined that a proficiency test cannot reasonably be developed. The standards shall also require that alternative assessment for each examination or procedure is performed if a proficiency testing program for an analyte or method, as appropriate, does not exist and specify acceptable alternative assessment processes and practices. The proficiency testing or alternative assessment shall be conducted on a quarterly basis, except where the Secretary determines for technical and scientific reasons that a particular examination or procedure may be tested less frequently (but not less often than twice per year)."

(B) After subparagraph (B), inserting the following –

"(C) Regular review of list of analytes, methods, and standards
The Secretary shall review and update the list of analytes and methods for which proficiency testing is required is every two years. The Secretary shall consider the input and recommendations of 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) regarding any changes to the updated list of analytes or methods for which proficiency testing is required and the associated standards."

(C) Redesignating subparagraph (C) as (D).
(D) Redesignating subparagraph (D) as (E) and further amending by –
  (1) striking "subparagraph (C) to perform" and inserting "subparagraph (D) to perform"; and
  (2) striking "(d)(5)" and inserting "(f)".
(E) Redesignating subparagraph (E) as (F) and further amending by –
  (1) striking "(h), (i), or (j)" and inserting "(i), (j), or (k)".
(F) Redesignating subparagraph (F) as (G).

(c) ) Section 353(g) is amended –

  (1) By redesignating the section as Section 353(h)
  (2) In paragraph (2), to read as follows –

"(2) Compliance with requirements and standards
  (A) The Secretary, or the accrediting organization conducting inspections on behalf of the Secretary, shall conduct inspections of laboratories under paragraph (1) to determine their compliance with the requirements of subsection (d) and the standards issued under subsection (f).

(B) A laboratory must provide, upon request by the 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.
(C) Inspections of laboratories not accredited under subsection (e) shall be conducted on a biennial basis or with such other frequency as the Secretary determines to be necessary to assure compliance with such requirements and standards. Inspections of laboratories accredited under subsection (e) shall be conducted on such basis as the Secretary determines is necessary to assure compliance with such requirements and standards."; and

(3) After paragraph (2), by inserting the following –

"(3) Inspector training
The Secretary shall develop standards and processes for ensuring that laboratory inspectors are appropriately trained to inspect and evaluate laboratories and all examinations and procedures that would be within the inspector's responsibilities."

**Section 4. Laboratory-developed testing procedures**

(a) After Section 353(f), inserting the following –

"(g) Laboratory-developed testing procedures

(1) Authority over laboratory-developed testing procedures
Laboratory-developed testing procedures shall be regulated by the Secretary of Health and Human Services under section 353 of the Public Health Service Act (42 U.S.C. 263a), and not as a medical product under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), including during a public health emergency declared under section 319 of the Public Health Service Act (42 U.S.C. 247d).

(2) Modernizing regulations
Within two years, the Secretary shall update regulations to –

(i) reflect advances in laboratory medicine,
(ii) clarify what activities can be conducted under a single certificate or accreditation given modern laboratory care delivery, including by clarifying what kind of activities can be performed remotely, the appropriate use of additional physical locations within or across states, and allowing for the storage and retrieval of data from an external location,
(iii) promote transparency about testing information including by requiring that laboratories make summary information, in a standardized manner and format determined by the Secretary, about each of their laboratory-developed testing procedures, including information about the laboratory-developed testing procedure's performance characteristics and

specifications and information supporting clinical validity, readily available either on a website or upon request,

(iv) enhance reporting requirements associated with laboratory errors,

(v) establish requirements for laboratory-developed testing procedures described in paragraph (3),

(vi) exempt certain examinations or procedures in clinical use prior to the bill's enactment from having to comply with new regulatory requirements, as determined appropriate by the Secretary,

(vii) modernize the system and criteria for test categorization,

(viii) provide for the creation and timely evolution of standards and best practices for laboratory analytics, and

(ix) generally ensure the quality of all laboratory-developed testing procedures.

(3) The Secretary shall solicit input from the public and the Clinical Laboratory Improvement Advisory, as defined in paragraph (5),within 1 year on requirements necessary to ensure that laboratory- developed testing procedures that use methodologies, procedures, techniques, or proprietary algorithms and/or computations such that the test results cannot be tied to the methods used, or inter-laboratory comparisons cannot be performed, are analytically and clinically valid.

(4) Expertise

The Secretary shall ensure that staff responsible for promulgating and enforcing regulations pertaining to laboratory-developed testing procedures include one or more board-certified professionals who have served as a laboratory director in a clinical laboratory that performs laboratory-developed testing procedures.

(5) Clinical Laboratory Improvement Advisory Committee

(A) The Secretary shall ensure that 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) is diverse and composed of individuals with expertise, which shall include pathologists, high-complexity laboratory directors, individuals with expertise in laboratory science, laboratory analytics, and representatives from medical center, public health, and independent clinical laboratories.

(B) The Secretary shall solicit input and recommendations from the Committee on

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(i) standards established under subsection (f),

(ii) the list of analytes and methods for which proficiency testing is required under subsection (f), and

(iii) modernizing regulations to reflect advances in scientific and medical knowledge and the current standard of care including as it relates to regulations specific to laboratory-developed testing procedures, and the modification of the standards and provision of non- regulatory guidelines to accommodate technological advances, such as new test methods, the electronic transmission of laboratory information, and mechanisms to improve the integration of public health and clinical laboratory practices.

(C) Composition and terms of the advisory panel.

(i)The advisory panel shall consist of up to 20 members, including a Chair. Members shall be a diverse set of experts, knowledgeable in microbiology (including bacteriology, mycobacteriology, mycology, parasitology, virology, immunology (including histocompatibility), chemistry, hematology, pathology (including histopathology and cytology), genetic testing (including cytogenetics), laboratory analytics, and laboratory science.

(ii) The advisory panel shall consist of representatives from the fields of medical technology, bioinformatics, public health, and clinical practice, representatives from medical center, public health, and independent clinical laboratories, high-complexity laboratory directors, and consumer representatives.

(iii) Members shall be invited to serve for overlapping terms of up to four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of that term. A member may serve 180 days after the expiration of that member's term if a successor has not taken office.

(D) The advisory panel shall meet at least once per year. Meetings shall be open to the public. Notice of all meetings shall be given to the public in the Federal Register.

(E) The panel shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).

**Section 5. Public health emergencies**

(a) After Section 353(m), inserting the

following – "(o) Public health emergency waiver

authority

During any public health emergency declaration issued by the Secretary under section 319 of the Public Health Service (PHS) Act, the Secretary may waive or alter any requirements for examinations and procedures used for responding and/or providing patient care during the emergency."

**Section 6. FDA medical device requirements**

(a) After Section 353(p), inserting the

following – "(s) FDA-authorized in vitro

diagnostic products

Nothing in this section should be construed to prohibit a laboratory from opting to act as a manufacturer and seeking approval, clearance, or authorization of an assay as an in vitro diagnostic product by the Food and Drug Administration under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c, 360e, 360bbb–3)."

**Section 7. Preemption**

(a) After the newly designated Section 353(s), inserting the

following – "(t) Preemption

Except as described under subsection (p), no Federal, State, tribal, local government (or

political subdivision thereof), or government contractor may establish or continue in effect any requirement related to assessing the analytical and/or clinical validation of a laboratory- developed testing procedure for the purposes of assessing whether the procedure is reasonable and necessary for coverage and payment purposes."

**Section 8. Technical amendments**

(a) Section 353 is amended by redesignating (h), (i), (j), (k), (l), (m), (n), (o), (p), and (q) as (i), (j), (k), (l), (m), (n), (p), (q), (r), and (u).
(b) Section 353(d)(1)(C) of the Public Health Service Act is amended by striking "subsection (g)" and inserting "subsection (h)".
(c) Section 353(d)(1)(E) of the Public Health Service Act is amended by striking "subsection (i)(4)" and inserting "subsection (j)(4).
(d) The newly designation Section 353(i) of the Public Health Service Act is amended to strike each instance of "(i)" and insert "(j)".
(e) The newly designation Section 353(j)(1)(G) of the Public Health Service Act is amended to strike "(h)" and insert "(i)".
(f) The newly designation Section 353(l) of the Public Health Service Act is amended to strike each instance of "(h)" and "(i)" and insert "(i)" and "(j)" respectively.