Sec. 1 Short title: Promoting Excellence in In Vitro Diagnostic Validation Act

Sec. 2

(a) Findings. -- Congress makes the following findings:

(1) Reliable and timely in vitro diagnostic products, in particular advanced personalized diagnostics, offer enormous promise to improve the diagnosis of disease, better guide treatment decisions, and improve overall patient outcomes.
(2) Regulatory oversight must strike the right balance between ensuring patient safety, fostering innovation, and encouraging the incorporation of rapidly advancing scientific methods and knowledge into diagnostic development and clinical care.
(3) Any changes to the current regulatory pathways have the potential to create delays in patient access, overwhelm regulatory agencies, duplicate existing requirements, and lead to other unintended consequences.
(4) Requiring premarket review of diagnostics currently offered under enforcement discretion is a major shift in policy and one that is best assessed first through a pilot program rather than permanent authorization.

Sec. 3

The Federal Food, Drug, and Cosmetic Act is amended by inserting the following after XXX:

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(?) Pilot certification program on excellence in in vitro diagnostic validation

Commented [A1]: This would depend on where the text is inserted.

(1) In general --
The Secretary shall establish a voluntary pilot program to certify in vitro diagnostic test developers meeting criteria specified by the Secretary regarding the developer’s ability to ensure the analytical and clinical validity of in vitro diagnostic tests for a designated scope of testing methodologies and techniques.

(2) Excellence Appraisal. - For the purpose of certifying in vitro diagnostic developers, the Secretary shall conduct an appraisal of any developer voluntarily seeking to demonstrate that the developer has well-established methodologies and adequate validation procedures and processes appropriate for the full scope of testing approaches that the developer proposes would fall within its certification. As part of an appraisal, an in vitro diagnostic test developer is required to submit to the Secretary:
    (A) A proposed description of the scope of techniques, technologies, and test types that would fall under the developer’s certification order;
    (B) Information, as specified by the Secretary, about one or more in vitro diagnostic tests in order to adequately demonstrate competence for the development and validation of in vitro diagnostic tests using the same or similar methodologies; and
    (C) A description of the developer’s procedures for analytical validation, including all procedures for validation, verification, and acceptance criteria, and an explanation as to how such procedures, when used, provide a reasonable assurance of analytical validity

Commented [A2]: From NYSDOH’s definition of well-established

of in vitro diagnostic tests that would fall within the proposed scope of the certification order.

(D) A description of the developer's procedures for affirming or establishing clinical validation and an explanation as to how such procedures, when used, provide a reasonable assurance of clinical validity of in vitro diagnostic tests within the proposed scope of the technology certification order. Evidence for clinical validity may include:
  (i) peer-reviewed literature;
  (ii) clinical guidelines;
  (iii) reports of significant human experience with an in vitro clinical test;
  (iv) bench 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; and
  (xiii) data collected in countries other than the United States if such data are demonstrated to be adequate for the purpose of making a regulatory determination under the applicable standard in the United States.

(E) A description of the developer's procedures for affirming or establishing analytical and clinical validity of a modification to an in vitro diagnostic test that falls within the proposed scope of the certification.

(F) Information, including information applicable to paragraph (8) as appropriate, demonstrating that the developer meets applicable test design and quality requirements.

(G) A complete list of eligible in vitro diagnostic tests that would be immediately introduced into interstate commerce upon the issuance of a certification order.

(H) Any other information specified by the Secretary in guidance.

(3) Certification Authority. -- If the Secretary determines that the developer has well-established methodologies and adequate validation procedures and processes in place to ensure the analytical and clinical validity of in vitro diagnostic tests for a designated scope of testing methodologies and techniques, the Secretary may issue a certification order to such developer.

(4) Exemption. -- Upon the Secretary issuing a certification order, an in vitro diagnostic test is considered authorized for introduction for interstate commerce and is exempt from other premarket review requirements under section 515, or under section 510(k), of such Act if
  (A) the in vitro diagnostic test is within the scope of a developer's certification; and
  (B) the in vitro diagnostic test is an eligible test under paragraph (6).

(5) Risk-Based Approach. –
  (A) In General. -- The Secretary shall establish a risk-based approach for authorizing eligible tests that are exempt from premarket review and developed by a certified developer under the pilot program such that:

(i) For each test deemed to be high risk, certified developers are required to submit additional information for a postmarket, streamlined review to provide further assurance of the analytical and clinical validity of the in vitro diagnostic test.
(ii) Each test deemed not to be high risk is considered authorized as part of a certification order without additional postmarket review.

(B) For the purpose of the pilot program, an in vitro diagnostics test is high risk if
(i) Taking the medical context into consideration, the test is used to diagnose or monitor a disease, or inform a patient's eligibility for a specific therapy to treat a disease, and the disease is associated with significant morbidity or mortality; and,
(ii) The test uses 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.

(6) Eligibility. – An in vitro clinical test is not eligible for exemption from premarket review under subsection (?)(4), if such test is—
(A) a component or part of an in vitro diagnostic test as described under XXX;
(B) an instrument under XXX;
(C) a specimen receptacle under XXX; or
(D) an in vitro clinical test, including reagents used in such tests, intended for use for testing donors, donations, and recipients of blood, blood components, human cells, tissues, cellular-based products, or tissue-based products.

(7) Preventing Duplication with the Clinical Laboratory Improvement Amendments. -- For the purpose of the pilot program, information demonstrating compliance with requirements under section 353 of the Public Health Service Act may be used to demonstrate compliance with test design and quality requirements under section 820 of title 21 of the Code of Federal Regulations.

(8) List of Standard Methods. – The Secretary shall --
(A) Establish, maintain, and update, as appropriate, a list of methodologies and assays that have an established record of reliability and clinical validity, and which employs a standardized protocol that is universally applied in laboratories that utilize the method for the analyte, such application being consistent with industry standards recognized by leading authorities in laboratory science.
(B) Establish a streamlined process for any developer requesting a certification order that covers one or more methodologies or assays included on the list described in subparagraph (A).

(9) Annual Reporting and Maintain Requirements. – As part of the pilot program, the Secretary shall establish annual reporting and maintenance requirements for holders of a certification order in guidance.

(10) Temporary Holds.—
(A) In General.—Upon one or more findings under subparagraph (D) and after promptly notifying the developer of such findings, the Secretary may issue a temporary hold
(i) prohibiting any holder of a certification order from introducing into interstate commerce an in vitro diagnostic test that was not previously authorized for introduction into interstate commerce; or

(ii) prohibiting any holder from continuing to market, sell, or perform any specific in vitro diagnostic test that is the subject of the temporary hold.

The temporary hold must identify the grounds for the temporary hold under subparagraph (D) and the rationale for such finding, and may only remain in place until the Secretary responds to a written request under subparagraph (C).

(B) The Secretary shall not place a temporary hold under this subsection unless the Secretary has promptly notified the developer of such hold and provided 30 calendar days for the developer to come into compliance with or resolve the findings under subparagraph (D).

(C) Any written request to the Secretary from the holder of a certification order that a temporary hold under subparagraph (A) be removed shall receive a decision, in writing and specifying the reasons therefore, within 90 days after receipt of such request. Any such request shall include information to support the removal of the temporary hold.

(D) Grounds for Temporary Hold.—A temporary hold under this subsection may be instated upon a finding or findings that the holder of a certification order or the in vitro diagnostic test—

(i) Is not in compliance with any maintenance or annual reporting requirements;
(ii) labels or advertises one or more in vitro diagnostic with false or misleading claims;
(iii) Is no longer an eligible in vitro diagnostic test;
(iv) the Secretary determines there is insufficient valid scientific evidence to support the analytical validity or the clinical validity of such in vitro clinical test; or
(v) the Secretary determines that such in vitro clinical test has caused serious adverse health consequences.

(11) Withdrawals. – The Secretary may, after due notice and opportunity for informal hearing, issue an order withdrawing approval of an in vitro diagnostic test authorized under the pilot program, or a certification order issued under the pilot program, if the Secretary finds that—

(A) the application, supplement, or annual report contains materially false or misleading information or fails to reveal a material fact;
(B) such holder fails to correct materially false or misleading labeling or advertising upon the request of the Secretary;
(C) in connection with a certification, the holder provides materially false or misleading information to the Secretary; or
(D) the holder of such certification order fails to correct the grounds for temporary hold within a timeframe specified in the temporary hold order.

(12) Implementation and Reporting. --

(A) Public meeting. --

The Secretary shall publish in the Federal Register a notice of a public meeting to be held no later than 90 days after enactment, to discuss and obtain input and recommendations from stakeholders regarding the goals and scope of, and a suitable framework, procedures, and requirements for, the pilot program under this subsection.

(B) Pilot program guidance. --

The Secretary shall—

(i) Not later than 180 days after enactment, issue draft guidance regarding the goals and implementation of the pilot program under this subsection; and
(ii) not later than September 30, 2023, issue final guidance with respect to the implementation of such program.

Guidance shall include a detailed framework, procedures, and requirements for the pilot program including a timeline for issuing certification decisions, a detailed description of the risk classification system, and information about other applicable requirements under Chapter 5 of the Federal Food, Drug, and Cosmetic Act that would apply to any in vitro diagnostic tests authorized as part of the pilot program including requirements pertaining to labeling and adverse event reporting.

(C) Pilot program initiation. -- Not later than September 30, 2024, the Secretary shall initiate the pilot program under this subsection.

(D) Public Report. -- The Secretary shall make available on the internet website of the Food and Drug Administration an annual report on the progress of the pilot program under this subsection.

(E) Report to Congress. – The Secretary shall report to Congress no later than January 1, 2026 on the progress of the pilot program, uptake and interest in the certification program, number and type of in vitro diagnostics authorized under a certification order, any safety issues encountered, other metrics to assess the success of the program in both assuring safety and effectiveness of in vitro diagnostics as well as the advancement of innovation in the field, and recommendations for continued authorization of the pilot program.

(13) Sunset.

As of October 1, 2027—

(A) The authority of the Secretary to issue new certification orders under paragraph (3) shall cease to have force or effect.

(B) The Secretary may —
(i) may accept continue to require annual reporting and maintenance requirements for a certification order issued before October 1, 2027.
(ii) may continue to recognize the authorization of in vitro diagnostics tests that fall within the scope of a certification order issued before October 1, 2027.

(C) The Secretary may take actions in accordance with paragraphs (10) and (11) for any existing certification orders issued before October 1, 2027 and the in vitro diagnostics tests that fall within the scope of such certification orders.

(14) Definitions. – For the purposes of the pilot program,

(A) The term 'analytical validity' means with respect to an in vitro diagnostic test, the ability of the test to sufficiently identify, measure, detect, calculate, or analyze one or more analytes, biomarkers, substances, or other targets intended to be identified, measured, detected, calculated, or analyzed by the test.
(B) The term 'clinical validity' means the ability of an in vitro diagnostic test to achieve the purpose for which it is intended.