

119TH CONGRESS
2D SESSION

H. R. 8890

To amend the Public Health Services Act, commonly referred to as the “Clinical Laboratory Improvement Amendments” or “CLIA”, with respect to laboratory developed tests, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2026

Mr. DUNN of Florida introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Public Health Services Act, commonly referred to as the “Clinical Laboratory Improvement Amendments” or “CLIA”, with respect to laboratory developed tests, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Enhancing Clinical
5 Laboratory Innovation and Access Act of 2026” or the
6 “Enhancing CLIA Act of 2026”.

1 **SEC. 2. ENHANCED REGULATION OF LABORATORY DEVEL-**
2 **OPED TESTS.**

3 (a) AMENDMENTS TO THE PUBLIC HEALTH SERV-
4 ICES ACT, COMMONLY REFERRED TO AS THE “CLINICAL
5 LABORATORY IMPROVEMENT AMENDMENTS” OR
6 “CLIA”.—Section 353 of the Public Health Service Act
7 (42 U.S.C. 263a) is amended—

8 (1) by striking subsection (a) and inserting:

9 “(a) SCOPE OF AUTHORITY; DEFINITIONS.—

10 “(1) SCOPE OF AUTHORITY.—Laboratory oper-
11 ations shall be regulated by the Secretary under this
12 section and not under the Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 301 et. seq.).

14 “(2) DEFINITIONS.—In this section:

15 “(A) ANALYTICAL VALIDITY.—The term
16 ‘analytical validity’ means, with respect to an
17 examination or procedure performed by a lab-
18 oratory, the ability of the examination or proce-
19 dure to provide information that is accurate
20 and reliable with respect to the identification,
21 measurement, detection, or calculation of the
22 target analyte in a specimen, within a report-
23 able range.

24 “(B) APPLICABLE STANDARD.—The term
25 ‘applicable standard’ means—

1 “(i) for a laboratory developed test for
2 clinical use, that the test has a reasonable
3 assurance of analytical and clinical valid-
4 ity; and

5 “(ii) for a laboratory developed test
6 for investigational use, that the test has a
7 reasonable assurance of analytical validity.

8 “(C) CLINICAL USE.—The term ‘clinical
9 use’—

10 “(i) means that an examination or
11 procedure is used for the purpose of pro-
12 viding information for the diagnosis, prog-
13 nosis, identification, monitoring, screening,
14 prevention, or treatment of any disease or
15 impairment of, or the assessment of the
16 health of, human beings; and

17 “(ii) does not include—

18 “(I) investigational use;

19 “(II) research use; or

20 “(III) forensic use.

21 “(D) CLINICAL VALIDITY.—The term ‘clin-
22 ical validity’ means, with respect to an examina-
23 tion or procedure performed by a laboratory,
24 the ability of the examination or procedure to

1 provide information that is accurate and reli-
2 able for its stated clinical purpose.

3 “(E) DIGITAL LABORATORY DATA.—The
4 term ‘digital laboratory data’—

5 “(i) means digital data derived from a
6 laboratory examination or procedure per-
7 formed by a laboratory on materials taken
8 or derived from the human body, includ-
9 ing—

10 “(I) a digital image derived from
11 a glass slide;

12 “(II) flow cytometry plots;

13 “(III) cytogenetic karyograms;

14 “(IV) chromatographic, mass
15 spectrometric, clinical chemistry,
16 immunological, hematological and
17 microbiological data;

18 “(V) electropherograms;

19 “(VI) gel images;

20 “(VII) genetic expression, array
21 and sequencing data; and

22 “(VIII) subsequent analyses of
23 such data; and

24 “(ii) is patient-specific when it is ac-
25 companied by information that can be used

1 to identify the individual from whose speci-
2 men the information was derived.

3 “(F) INVESTIGATIONAL USE.—The term
4 ‘investigational use’ means, with respect to a
5 laboratory developed test, that the test is used
6 in a clinical investigation, at least 1 purpose of
7 which is to gather data to establish the clinical
8 validity of the test.

9 “(G) LABORATORY; CLINICAL LABORA-
10 TORY.—The term ‘laboratory’ or ‘clinical lab-
11 oratory’ means a facility for the examination of
12 materials taken or derived from the human
13 body, including analysis of patient-specific dig-
14 ital laboratory data, for clinical use or inves-
15 tigational use.

16 “(H) LABORATORY DEVELOPED TEST.—
17 The term ‘laboratory developed test’—

18 “(i) means an examination or proce-
19 dure, including an examination or proce-
20 dure that modifies an in vitro diagnostic
21 device regulated under the Federal Food,
22 Drug, and Cosmetic Act (21 U.S.C. 301 et
23 seq.), that is—

1 “(I) developed in a clinical lab-
2 oratory certified under this section to
3 perform tests of high-complexity; and

4 “(II) performed only within—

5 “(aa) the same clinical lab-
6 oratory in which it was devel-
7 oped; or

8 “(bb) another clinical lab-
9 oratory certified under this sec-
10 tion to perform tests of high-
11 complexity that is within—

12 “(AA) the same cor-
13 porate organization and has
14 common ownership by the
15 same parent corporation as
16 the developing laboratory; or

17 “(BB) a public health
18 laboratory network coordi-
19 nated or managed by the
20 Centers for Disease Control
21 and Prevention or other
22 Federal public health agen-
23 cy, if the developing labora-
24 tory is a public health lab-
25 oratory or a laboratory man-

1 aged by the Centers for Dis-
2 ease Control and Prevention
3 or other Federal public
4 health agency;

5 “(ii) does not include a protocol for an
6 examination or procedure that is commer-
7 cially distributed for performance in lab-
8 oratories not under common ownership by
9 the same parent corporation as the labora-
10 tory that developed the protocol;

11 “(iii) is not a medical device subject
12 to regulation under the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 301 et
14 seq.), even if the laboratory developed
15 test—

16 “(I) modifies the use of a device
17 that is lawfully marketed under the
18 Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 301 et seq.);

20 “(II) requires preparation or
21 modification within the laboratory of
22 equipment, reagents, instruments,
23 software, or other materials for use
24 within the laboratory;

1 “(III) includes processes, mate-
2 rials, research, or intellectual property
3 developed by third parties if the devel-
4 oping laboratory remains responsible
5 for compliance with applicable re-
6 quirements for laboratory developed
7 tests under this section; or

8 “(IV) examines a specimen that
9 was self-collected by an individual, re-
10 gardless of the setting in which the
11 specimen was collected; and

12 “(iv) is performed in a laboratory de-
13 scribed in clause (i)(II) even if software
14 used in the test is executed outside of the
15 laboratory.

16 “(I) LABORATORY OPERATIONS.—The
17 term ‘laboratory operations’—

18 “(i) means the conduct of examina-
19 tions and other procedures on material
20 taken or derived from the human body and
21 associated activities, including analysis of
22 patient-specific digital laboratory data, for
23 a purpose described in subparagraph (E),
24 including the development and perform-
25 ance of laboratory developed tests; and

1 “(ii) includes—

2 “(I) the preparation and transfer
3 of equipment, reagents, instruments,
4 software, or other materials between
5 laboratories that are under common
6 ownership by the same parent cor-
7 poration; and

8 “(II) the distribution of specimen
9 collection kits for use with laboratory
10 developed tests if the components of
11 such specimen collection kits are in-
12 tended to be used consistent with the
13 established intended uses for which
14 they may otherwise be lawfully dis-
15 tributed.

16 “(J) PERFORMANCE SPECIFICATIONS.—

17 The term ‘performance specification’ means a
18 value or range of values for a characteristic of
19 an examination or procedure, such as accuracy,
20 precision, analytical sensitivity, analytical speci-
21 ficity, reportable range, or other characteristic
22 required for test performance.

23 “(K) RESEARCH USE.—The term ‘research
24 use’ means, with respect to a laboratory devel-
25 oped test, that the test’s purpose is solely for

1 analytical development or scientific research,
2 and not for use in making clinical decisions for
3 individual patients.”;

4 (2) by adding at the end:

5 “(r) LABORATORY DEVELOPED TESTS.—

6 “(1) REASONABLE ASSURANCE OF ANALYTICAL
7 AND CLINICAL VALIDITY OF LABORATORY DEVEL-
8 OPED TESTS.—

9 “(A) STANDARD.—Beginning 2 years after
10 enactment of the Enhancing CLIA Act of 2026,
11 no laboratory may perform a laboratory devel-
12 oped test unless the test meets the applicable
13 standard.

14 “(B) ANALYTICAL VALIDITY.—For pur-
15 poses of meeting the applicable standard under
16 this section, a laboratory developed test has a
17 reasonable assurance of analytical validity if—

18 “(i) the laboratory that develops the
19 test establishes performance specifications
20 that support the ability of the test to iden-
21 tify, measure, detect, calculate, or analyze
22 1 or more analytes, biomarkers, sub-
23 stances, or other targets intended to be
24 identified, measured, detected, calculated,
25 or analyzed by the test; and

1 “(ii) the laboratory that performs the
2 test, if different than the laboratory that
3 develops the test, verifies such performance
4 specifications prior to use.

5 “(C) CLINICAL VALIDITY.—For purposes
6 of meeting the applicable standard under this
7 section, a laboratory developed test has a rea-
8 sonable assurance of clinical validity if the lab-
9 oratory that develops the test has documented
10 evidence, which may include 1 or more of the
11 following that supports the ability of the labora-
12 tory developed test to reliably and accurately
13 achieve its stated purpose—

14 “(i) peer-reviewed literature;
15 “(ii) clinical guidelines;
16 “(iii) bench studies;
17 “(iv) case studies or histories;
18 “(v) consensus standards;
19 “(vi) reference standards;
20 “(vii) data registries;
21 “(viii) postmarket data;
22 “(ix) real world data;
23 “(x) 1 or more clinical validation
24 studies; or

1 “(xi) other evidence deemed appro-
2 priate by the Secretary.

3 “(D) SUPPLEMENTAL AFFIRMATION THAT
4 STANDARD HAS BEEN MET.—

5 “(i) At any time, a laboratory may,
6 but is not required to, obtain 1 or more
7 supplemental affirmations that the labora-
8 tory developed test meets the applicable
9 standard from a third party approved
10 under subparagraph (E), pursuant to the
11 process in subparagraph (F). Subject to
12 clause (ii) of this subparagraph, such sup-
13 plemental affirmation does not expire.

14 “(ii) If a third party approved under
15 subparagraph (E) has its approval with-
16 drawn by the Secretary, a supplemental af-
17 firmation that a laboratory developed test
18 meets the applicable standard issued by
19 that third party shall remain in effect for
20 no longer than the later of—

21 “(I) 90 days after the date that
22 a third party notifies a laboratory
23 under subparagraph (E)(iv) that its
24 approval has been withdrawn; or

1 “(II) if within 60 days of receiv-
2 ing the notification under subpara-
3 graph (E)(iv) the laboratory submits
4 information to a different third party
5 requesting a supplemental affirmation
6 that the laboratory developed test
7 meets the applicable standard, the
8 date on which such approved third
9 party determines whether the labora-
10 tory developed test meets the applica-
11 ble standard under subparagraph
12 (F)(i)(II).

13 “(E) APPROVED THIRD PARTIES.—Begin-
14 ning 2 years after enactment of the Enhancing
15 CLIA Act of 2026, the Secretary shall approve
16 third parties to provide a supplemental affirma-
17 tion that a laboratory developed test meets the
18 applicable standard if—

19 “(i) the standards and procedures ap-
20 plied by the third party in determining
21 whether the laboratory developed test
22 meets the applicable standard are deter-
23 mined by the Secretary to be sufficiently
24 risk-based, rigorous, and not overly bur-
25 densome;

1 “(ii) in the case that the third party
2 determines under subparagraph
3 (F)(ii)(III)(cc) that the data and informa-
4 tion provided by the laboratory dem-
5 onstrates that the laboratory developed test
6 does not meet the applicable standard, the
7 laboratory developed test is being offered
8 with false or deceptive claims, or that it is
9 probable that the test will cause serious
10 adverse health consequences, the third
11 party agrees to notify the Secretary within
12 10 days of such determination unless the
13 laboratory stops offering, and notifies the
14 third party that it no longer offers, the
15 laboratory developed test;

16 “(iii) the third party agrees to notify
17 the Secretary at least 30 days before it
18 changes its standards and procedures for
19 determining that a laboratory developed
20 test meets the applicable standard; and

21 “(iv) if the third party has its ap-
22 proval withdrawn by the Secretary, the
23 third party agrees to notify each laboratory
24 that obtained a supplemental affirmation
25 that the applicable standard was met for

1 any laboratory developed test of the with-
2 drawal within 10 days of the withdrawal.

3 “(F) PROCESS FOR SUPPLEMENTAL AFFIR-
4 MATION BY APPROVED THIRD PARTY.—

5 “(i) If a laboratory submits informa-
6 tion to a third party approved by the Sec-
7 retary under subparagraph (E) requesting
8 a supplemental affirmation that a labora-
9 tory developed test meets the applicable
10 standard, the approved third party shall
11 within 60 calendar days of receipt of the
12 submitted information—

13 “(I) review the submitted infor-
14 mation, which may include commu-
15 nication with the laboratory; and

16 “(II) determine whether the lab-
17 oratory developed test meets the ap-
18 plicable standard and communicate
19 such determination with the labora-
20 tory as described in clause (ii).

21 “(ii) The approved third party shall
22 provide written notice to the laboratory of
23 the approved third party’s determination
24 under clause (i)(II) as follows:

1 “(I) The approved third party
2 shall notify the laboratory if the ap-
3 proved third party determines that the
4 laboratory developed test—

5 “(aa) meets the applicable
6 standard; or

7 “(bb) does not meet the ap-
8 plicable standard and subclauses
9 (II) and (III) do not apply.

10 “(II) If the approved third party
11 determines that the laboratory devel-
12 oped test does not meet the applicable
13 standard but that such determination
14 may be resolved within a reasonable
15 time—

16 “(aa) the approved third
17 party shall notify the laboratory
18 of such determination and the
19 reasons therefore, and allow the
20 laboratory to seek a teleconfer-
21 ence to discuss the finding;

22 “(bb) the laboratory shall
23 submit information dem-
24 onstrating resolution of the de-

1 termination within 60 days of re-
2 ceiving such notification; and

3 “(cc) the approved third
4 party shall make a determination
5 within 30 days of the receipt of
6 such submission of information
7 as to whether the laboratory de-
8 veloped test continues not to
9 meet the applicable standard.

10 “(III) If the approved third party
11 determines that there is a lack of
12 credible and verifiable information
13 supporting that the laboratory devel-
14 oped test meets the applicable stand-
15 ard, the laboratory developed test is
16 being offered with false or deceptive
17 claims, or that it is probable that the
18 test will cause serious adverse health
19 consequences—

20 “(aa) the approved third
21 party shall notify the laboratory
22 of such determination and the
23 reasons therefore, and allow the
24 laboratory to seek a teleconfer-
25 ence to discuss the finding;

1 “(bb) the laboratory shall
2 submit information dem-
3 onstrating resolution of the de-
4 termination within 60 days of re-
5 ceiving such notification; and

6 “(cc) the approved third
7 party shall make a determination
8 within 30 days of the receipt of
9 such submission of information
10 as to whether such determination
11 continues to apply.

12 “(iii) In the case that the third party
13 determines under subparagraph
14 (F)(ii)(I)(bb) that a laboratory developed
15 test does not meet the applicable standard,
16 the laboratory may resubmit a request for
17 supplemental affirmation by the same or
18 different third party for review without
19 prejudice at any time.

20 “(iv) In the case that the third party
21 determines under subparagraph
22 (F)(ii)(III)(cc) that there is a lack of cred-
23 ible and verifiable information supporting
24 the analytical or clinical validity of the lab-
25 oratory developed test, the laboratory de-

1 veloped test is being offered with false or
2 deceptive claims, or that it is probable that
3 the test will cause serious adverse health
4 consequences—

5 “(I) the third party will not no-
6 tify the Secretary of such determina-
7 tion if the laboratory stops performing
8 such laboratory developed test, and
9 notifies the third party that it has
10 stopped performing such laboratory
11 test, within 10 days; and

12 “(II) the laboratory may resub-
13 mit a request for supplemental affir-
14 mation by the same or different third
15 party for review without prejudice at
16 any time.

17 “(G) DEEMED SUPPLEMENTAL AFFIRMA-
18 TION.—A laboratory developed test shall be
19 deemed to have obtained a supplemental affir-
20 mation that it meets the applicable standard
21 under subparagraph (D) if it is—

22 “(i) approved by the New York State
23 Department of Health;

24 “(ii) determined to be reasonable and
25 necessary under Medicare pursuant to a

1 favorable review of a technical assessment
2 under the MolDX Program;

3 “(iii) within a category of tests identi-
4 fied by the Secretary in regulation that
5 shall be deemed to have obtained a supple-
6 mental approval.

7 “(H) FOOD AND DRUG ADMINISTRATION
8 AN APPROVED THIRD PARTY.—

9 “(i) The Food and Drug Administra-
10 tion shall be deemed an approved third
11 party under subparagraph (E).

12 “(ii) Beginning 2 years after enact-
13 ment of the Enhancing CLIA Act of 2026,
14 a laboratory may request a supplemental
15 affirmation from the Food and Drug Ad-
16 ministration that a laboratory developed
17 test for clinical use meets the applicable
18 standard.

19 “(iii) Any laboratory seeking supple-
20 mental affirmation from the Food and
21 Drug Administration under clause (ii) shall
22 pay a fee for such review that is no greater
23 than the applicable user fee for a pre-
24 market notification submission under sec-

tion 738 of the Federal Food, Drug, and
Cosmetic Act (21 U.S.C. 379j).

“(iv) If a laboratory seeks supplemental affirmation from the Food and Drug Administration under clause (ii) and pays the fee under clause (iii), the Food and Drug Administration—

“(I) shall review the information for the laboratory developed test only in accordance with the standards applied by the Secretary under subparagraph (A) and the procedure applied by approved third parties under subparagraph (F); and

“(II) shall not apply to the laboratory developed test the standards or other requirements that apply to devices or any other product regulated under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

“(2) CENTRALIZED DATABASE FOR LABORATORY DEVELOPED TESTS FOR CLINICAL USE.—Beginning 2 years after enactment of the Enhancing CLIA Act of 2026, each laboratory performing 1 or more laboratory developed tests for clinical use shall

1 submit to the Secretary the information described in
2 subparagraph (A) in accordance with the applicable
3 schedule described in subparagraph (B). Such infor-
4 mation shall be submitted electronically to the cen-
5 tralized database established by the Secretary under
6 subparagraph (C). If multiple laboratories within the
7 same corporate organization and with common own-
8 ership by the same parent corporation perform the
9 same laboratory developed test, a corporate entity
10 with common ownership of such laboratories may
11 submit the information described in subparagraph
12 (A) on behalf of such laboratories, provided that
13 each laboratory performing a laboratory developed
14 test is separately identified with respect to each lab-
15 oratory developed test it performs.

16 “(A) SUBMISSION.—For each laboratory
17 developed test performed for clinical use by the
18 laboratory, the laboratory shall submit the fol-
19 lowing information, as applicable:

20 “(i) Name and certificate number of
21 the laboratory.

22 “(ii) Name and certificate number of
23 the laboratory that developed the labora-
24 tory developed test, if different than the

1 laboratory performing the laboratory devel-
2 oped test.

3 “(iii) Name of the laboratory devel-
4 oped test.

5 “(iv) Purpose of the laboratory devel-
6 oped test, including—

7 “(I) analyte(s) measured;

8 “(II) disease(s), impairment(s) or
9 assessment(s) of the health of human
10 beings for which the laboratory devel-
11 oped test is used; and

12 “(III) for what purpose(s) the in-
13 formation from the laboratory devel-
14 oped test will be used, such as for the
15 screening, diagnosis, prognosis, or
16 other type of assessment.

17 “(v) Specimen type(s) used with the
18 laboratory developed test, which may in-
19 clude digital laboratory data.

20 “(vi) Type of examination, such as bi-
21 ological, microbiological, serological, chem-
22 ical, immuno-hematological, hematological,
23 biophysical, cytological, pathological, flow
24 cytometric, molecular, genomic, or other
25 type of examination.

1 “(vii) Summary of performance speci-
2 fications for the laboratory developed test.

3 “(viii) Whether the laboratory devel-
4 oped test modifies the use of a device that
5 is lawfully marketed under the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C.
7 301 et seq.) and, if applicable, information
8 identifying the specific device that is modi-
9 fied.

10 “(ix) Whether the test is deemed to
11 have a supplemental affirmation under reg-
12 ulations issued by the Secretary or an ap-
13 proved third party has supplementally af-
14 firmed that the laboratory developed test
15 meets the applicable standard and, if the
16 latter, the name of such approved third
17 party.

18 “(x) If the laboratory developed test is
19 first performed for clinical use by the lab-
20 oratory 2 or more years after enactment of
21 the Enhancing CLIA Act of 2026, is not
22 deemed to have a supplemental affirmation
23 under regulations issued by the Secretary,
24 and an approved third party has not sup-
25 plementally affirmed that the test meets

1 the applicable standard, a brief summary
2 of the information in paragraph (1)(B)(c)
3 that supports that the laboratory developed
4 test has a reasonable assurance of clinical
5 validity.

6 “(B) SUBMISSION SCHEDULE.—

7 “(i) TESTS OFFERED 2 OR MORE
8 YEARS AFTER ENACTMENT OF THE EN-
9 HANCING CLIA ACT OF 2026.—If the lab-
10 oratory developed test is first performed
11 for clinical use by the laboratory 2 or more
12 years after the date of enactment of the
13 Enhancing CLIA Act of 2026, the labora-
14 tory must submit the information in sub-
15 paragraph (A) for the laboratory developed
16 test by the later of—

17 “(I) 30 days after such labora-
18 tory developed test is first performed
19 for clinical use; or

20 “(II) 60 days after the central-
21 ized database described in subpara-
22 graph (C) is established.

23 “(ii) TESTS OFFERED PRIOR TO THE
24 DATE THAT IS 2 YEARS AFTER ENACTMENT
25 OF THE ENHANCING CLIA ACT OF 2026.—

1 If the laboratory developed test is first per-
2 formed for clinical use by the laboratory
3 prior to the date that is 2 years after en-
4 actment of the Enhancing CLIA Act of
5 2026, the laboratory must submit the in-
6 formation in subparagraph (A) for the lab-
7 oratory developed test by the later of—

8 “(I) 3 years after enactment of
9 the Enhancing CLIA Act of 2026; or

10 “(II) 60 days after the central-
11 ized database described in subpara-
12 graph (C) is established.

13 “(C) ESTABLISHMENT OF CENTRALIZED
14 DATABASE.—Not later than 2 years after enact-
15 ment of the Enhancing CLIA Act of 2026, the
16 Secretary shall make available a centralized
17 database that is designed to—

18 “(i) provide a transparent interface on
19 the website of the Centers for Medicare
20 and Medicaid Services for stakeholders, to
21 the extent permitted by applicable laws,
22 which may include access to—

23 “(I) information submitted by
24 laboratories under subparagraph (A);
25 and

1 “(II) information about test er-
2 rors submitted under paragraph (3);
3 and

4 “(ii) provide a secure portal for elec-
5 tronic submission of information under
6 subparagraph (A) and reports of test er-
7 rors under paragraph (3), which provides
8 protections from unauthorized disclosure of
9 information, including of—

10 “(I) trade secret or confidential
11 commercial financial information;

12 “(II) information that could com-
13 promise national security; and

14 “(III) identifiable patient data.

15 “(D) UPDATES AND CORRECTIONS.—

16 “(i) A laboratory must update or cor-
17 rect the information submitted under this
18 paragraph for a laboratory developed test
19 within 30 days of—

20 “(I) determining that an update
21 or correction is necessary to maintain
22 the accuracy of the previously sub-
23 mitted information; or

24 “(II) a request from the Sec-
25 retary to make a specific correction,

1 unless the laboratory demonstrates
2 within 21 days of such request that a
3 correction is not necessary.

4 “(ii) A laboratory may supplement or
5 modify the information submitted under
6 this paragraph for a laboratory developed
7 test when new information becomes avail-
8 able.

9 “(3) TEST ERROR REPORTING.—

10 “(A) DEFINITIONS.—In this section:

11 “(i) SERIOUS HARM.—The term ‘seri-
12 ous harm’ means a misdiagnosis or failure
13 to diagnose that results in the absence,
14 delay, or discontinuation of critical medical
15 treatment, or administration of unneces-
16 sary medical treatment, that causes death
17 or serious injury to the patient.

18 “(ii) SERIOUS INJURY.—The term ‘se-
19 rious injury’ means an injury that—

20 “(I) is life threatening;

21 “(II) results in permanent im-
22 pairment of a body function or perma-
23 nent damage to a body structure; or

24 “(III) necessitates further med-
25 ical or surgical intervention to pre-

1 clude permanent impairment of a
2 body function or permanent damage
3 to a body structure.

4 “(B) SUBMISSION OF INDIVIDUAL RE-
5 PORTS.—Beginning 2 years after enactment of
6 the Enhancing CLIA Act of 2026, a laboratory
7 shall submit a report not later than 5 calendar
8 days after becoming aware of an undetected in-
9 accurate result for a laboratory developed test
10 for clinical use that reasonably suggests—

11 “(i) that a laboratory developed test
12 caused serious harm that resulted in death;
13 or

14 “(ii) an imminent threat to public
15 health.

16 “(C) SUBMISSION OF QUARTERLY RE-
17 PORTS.—Beginning 2 years after enactment of
18 the Enhancing CLIA Act of 2026, a laboratory
19 shall submit quarterly reports that include any
20 undetected inaccurate results of which the lab-
21 oratory becomes aware for laboratory developed
22 tests for clinical use that reasonably suggest
23 that the laboratory developed test caused seri-
24 ous harm other than death. Such quarterly re-
25 ports shall be submitted not later than the end

1 of the quarter following the quarter in which
2 the laboratory becomes aware of such unde-
3 tected inaccurate results.

4 “(D) REPORT NOT AN ADMISSION.—A re-
5 port submitted by a laboratory under this para-
6 graph and the Secretary’s release of such report
7 or information does not constitute an admission
8 by the laboratory that the laboratory developed
9 test caused or contributed to serious harm.

10 “(4) REVIEW OF ANALYTICAL AND CLINICAL
11 VALIDITY.—

12 “(A) The criteria described in this sub-
13 paragraph are that a laboratory developed test
14 in clinical use—

15 “(i) does not have a supplemental af-
16 firmation under paragraph (1)(D) that the
17 applicable standard is met, and the test
18 does not meet the applicable standard; or

19 “(ii) has a supplemental affirmation
20 under subparagraph (1)(D) that the appli-
21 cable standard is met, and the test—

22 “(I) is represented for a purpose
23 that is not supported by the supple-
24 mental affirmation; and

1 “(II) does not meet the applica-
2 ble standard for such purpose.

3 “(B) Beginning 2 years after enactment of
4 the Enhancing CLIA Act of 2026, the Sec-
5 retary may issue to the developing laboratory of
6 a laboratory developed test a written request for
7 information that—

8 “(i) identifies specific scientific con-
9 cerns, based on credible and verifiable in-
10 formation, which indicate that 1 or more of
11 the criteria described in subparagraph (A)
12 apply to the laboratory developed test; and

13 “(ii) requesting information that
14 would resolve such concern.

15 “(C) Not later than 45 days after receiving
16 a request for information under subparagraph
17 (B)—

18 “(i) the laboratory—

19 “(I) may seek a teleconference
20 prior to the submission of information
21 under subclause (II) to discuss the
22 Secretary’s request; and

23 “(II) shall submit the informa-
24 tion requested pursuant to subpara-
25 graph (B), and may include in such

1 submission a request for a teleconfer-
2 ence; and

3 “(ii) the Secretary shall—

4 “(I) schedule a teleconference re-
5 quested under clause (i)(I); and

6 “(II) hold a teleconference if re-
7 quested within 10 days of the Sec-
8 retary’s receipt of the information
9 submitted under clause (i)(II).

10 “(D) Upon receiving a submission under
11 subparagraph (C), the Secretary shall—

12 “(i) review the submitted information
13 within 45 calendar days of such receipt,
14 which may include communication with the
15 laboratory; and

16 “(ii) determine whether the criteria
17 listed in subparagraph (A) apply to the
18 laboratory developed test and communicate
19 such determination with the laboratory as
20 described in subparagraph (E).

21 “(E) The Secretary shall provide written
22 notice to the laboratory of the Secretary’s de-
23 termination under subparagraph (D) as follows:

1 “(i) The Secretary shall notify the
2 laboratory if the Secretary determines that
3 the criteria in subparagraph (A)—

4 “(I) do not apply to the labora-
5 tory developed test; or

6 “(II) apply to the laboratory de-
7 veloped test and clause (ii) does not
8 apply.

9 “(ii) If the Secretary determines that
10 the criteria in subparagraph (A) apply to
11 the laboratory developed test but that such
12 determination may be resolved within a
13 reasonable time, and the laboratory devel-
14 oped test has not previously been subject
15 to this paragraph on the basis of the same
16 or substantially similar concerns identified
17 in the written request issued under sub-
18 paragraph (B)—

19 “(I) the Secretary shall notify the
20 laboratory of such a determination
21 and allow the laboratory to seek a
22 teleconference to discuss the finding;

23 “(II) the laboratory shall submit
24 information demonstrating resolution

1 of the determination within 60 days of
2 receiving such notification; and

3 “(III) the Secretary shall make a
4 determination within 30 days of the
5 receipt of such submission of informa-
6 tion as to whether the criteria in sub-
7 paragraph (A) continue to apply to
8 the laboratory developed test.

9 “(F) If the Secretary notifies the labora-
10 tory under subparagraph (E)(i)(II) or
11 (E)(ii)(III) that the criteria in subparagraph
12 (A) apply to the laboratory developed test, the
13 laboratory must—

14 “(i) cease performing the laboratory
15 developed test until the laboratory obtains
16 a confirmation from the Secretary under
17 subparagraph (G) that the criteria under
18 subparagraph (A) no longer apply to the
19 laboratory developed test; and

20 “(ii) instruct all laboratories within
21 the same corporate organization and under
22 common ownership by the same parent
23 corporation to cease performing the labora-
24 tory developed test until the developing

1 laboratory obtains the confirmation de-
2 scribed in clause (i).

3 “(G) The Secretary shall, within 30 days
4 of receiving the information described in this
5 subparagraph, provide a confirmation that the
6 criteria in subparagraph (A) no longer apply to
7 a laboratory developed test that was previously
8 issued a notification under subparagraph (F) if
9 the laboratory that developed the test submits
10 evidence that—

11 “(i) it has obtained a supplemental af-
12 firmation from an approved third party
13 under paragraph (1)(D) that the test
14 meets the applicable standard; and

15 “(ii) the criteria in subparagraph (A)
16 no longer apply to the test.

17 “(5) INVESTIGATIONAL USE.—Beginning 2
18 years after enactment of the Enhancing CLIA Act
19 of 2026, a laboratory developed test may not be of-
20 fered for investigational use unless it meets the ap-
21 plicable standard for such use and the test report
22 and all other advertising and promotional materials
23 for the test clearly state, ‘For investigational use
24 only’. Clinical validity has not yet been established.”;

1 (3) in subsection (e)(2)(A)(ii) by adding at the
 2 end “except that such standards shall not require
 3 that laboratory developed tests offered by the labora-
 4 tory have a supplemental affirmation from any ap-
 5 proved third party that the applicable standard has
 6 been met,”;

7 (4) in subsection (i)(1)(C) by inserting “or (r)”
 8 after “subsection (d)”; and

9 (5) in subsection (o) by striking the period and
 10 inserting “, except that the Secretary may not dele-
 11 gate to the Food and Drug Administration the re-
 12 sponsibility or authority for determining whether
 13 any laboratory developed test meets the applicable
 14 standard under subsection (r)(4) of this section.
 15 Notwithstanding the prior sentence, the Food and
 16 Drug Administration may provide a supplemental af-
 17 firmation that a laboratory developed test meets the
 18 applicable standard pursuant to subsection
 19 (r)(4)(F).”.

20 (b) AMENDMENTS TO THE FEDERAL FOOD, DRUG,
 21 AND COSMETIC ACT.—The Federal Food, Drug, and Cos-
 22 metic Act (21 U.S.C. 301 et seq.) is amended—

23 (1) in section 201(h)(1) by striking the period
 24 after “pursuant to section 520(o)” and inserting “or
 25 laboratory developed tests as defined in the Enhanc-

1 ing CLIA Act of 2026. For clarity, the term ‘device’
2 does not include articles intended solely for medical
3 and scientific research using materials derived from
4 the body of man or other animals, which are not in-
5 tended for any use described in subparagraphs (A)
6 through (C).’.

7 (2) in section 501(f)(1)(C) by striking the pe-
8 riod at the end and inserting “, except that this
9 paragraph does not apply to a device that is distrib-
10 uted for use with a laboratory developed test as de-
11 fined under the Enhancing CLIA Act of 2026 if the
12 device could otherwise be lawfully distributed under
13 this Act.”.

14 (3) in section 502(o) by striking the period at
15 the end and inserting, “except that this subsection
16 does not apply to a device that is distributed for use
17 with a laboratory developed test as defined under the
18 Enhancing CLIA Act of 2026 if the device could
19 otherwise be lawfully distributed under this Act.”.

20 (c) NATIONAL COVERAGE DETERMINATIONS FOR
21 LABORATORY DEVELOPED TESTS.—Section 1862(l)(1) of
22 the Social Security Act (42 U.S.C. 1395y(l)(1)) is amend-
23 ed by adding at the end, “For purposes of all existing and
24 future national coverage determinations for a clinical lab-
25 oratory diagnostic test, a supplemental affirmation from

1 any approved third party that the applicable standard has
2 been met under section 353 of the Public Health Services
3 Act (42 U.S.C. 263a et seq.), as amended by the Enhanc-
4 ing CLIA Act of 2026 shall be considered equivalent to
5 an approval or clearance under the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 301 et seq.).”.

7 (d) COMPANION DIAGNOSTICS.—If a diagnostic test
8 result is required for the approval of a drug under section
9 505 of the Federal Food, Drug, and Cosmetic Act (21
10 U.S.C. 355) or the licensure of a biologic under section
11 351 of the Public Health Service Act (42 U.S.C. 262),
12 such test result may be determined by use of a device reg-
13 ulated under the Federal Food, Drug, and Cosmetic Act
14 (21 U.S.C. 301 et seq.) or based on a laboratory developed
15 test with a supplemental affirmation from any approved
16 third party under section 353 of the Public Health Serv-
17 ices Act (42 U.S.C. 263a et seq.) as amended by this Act.

18 **SEC. 3. TRANSITION.**

19 (a) EFFECTIVE DATE.—Except as otherwise provided
20 in this section, the amendments made by this Act shall
21 take effect immediately upon enactment.

22 (b) TRANSITION AND REGULATIONS.—

23 (1) The Secretary of Health and Human Serv-
24 ices (in this subsection referred to as the “Sec-
25 retary”) shall take the following actions, and may

1 expend such funds as the Secretary determines nec-
2 essary to ensure an orderly transition—

3 (A) within 180 days of enactment, promul-
4 gate proposed regulations required under the
5 amendments made by this Act;

6 (B) within 2 years of enactment, establish
7 the centralized database for laboratory devel-
8 oped tests under section 353(r)(2) of the Public
9 Health Service Act, as added by section 2(a) of
10 this Act;

11 (C) within 2 years of enactment, promul-
12 gate final regulations to mitigate potential con-
13 flict of interest by organizations that provide
14 multiple oversight services under section 353 of
15 the Public Health Services Act (42 U.S.C.
16 263a), including accreditation of laboratories,
17 proficiency testing, and supplemental affirma-
18 tion for laboratory developed tests; and

19 (D) within 30 days of enactment, revise
20 the definition of “in vitro diagnostic products”
21 at section 809.3 of Title 21 of the Code of Fed-
22 eral Regulations, effective immediately, to clar-
23 ify that such term—

1 (i) does not include laboratory devel-
2 oped tests as defined in subsection (a) of
3 section 2 of this Act; and

4 (ii) includes protocols for use in the
5 diagnosis of disease or other conditions, in-
6 cluding a determination of the state of
7 health, in order to cure, mitigate, treat, or
8 prevent disease or its sequelae when such
9 protocols are—

10 (I) commercially distributed for
11 performance in laboratories not under
12 common ownership by the same par-
13 ent corporation as the laboratory that
14 developed the protocol; or

15 (II) commercially distributed by
16 an entity or individual that is not a
17 laboratory;

18 except that such protocols are not commer-
19 cially distributed solely because they are
20 published, including in public or scientific
21 presentations, or patented.

22 (2) APPLICABILITY OF REGULATIONS.—Not-
23 withstanding the date on which regulations are
24 issued under paragraph (1), no regulations issued
25 pursuant to the amendments made by this Act shall

1 be implemented or take effect until 2 years after en-
2 actment, except as otherwise specified in this sec-
3 tion.

4 (c) CONVERSION.—

5 (1) This subsection applies to a laboratory de-
6 veloped test as defined in subsection (a) of section
7 2 of this Act that has—

8 (A) a premarket approval under section
9 515 of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 360e), an approved humani-
11 tarian device exemption under section 520(m)
12 of such Act (21 U.S.C. 360j(m)), a clearance
13 under section 510(k) of such Act (21 U.S.C.
14 360(k)), an authorization under section
15 513(f)(2) of such Act (21 U.S.C. 370c(f)(2)),
16 an investigational device exemption under sec-
17 tion 520(g) of such Act (21 U.S.C. 360j(g)), or
18 a licensure under section 351 of the Public
19 Health Service Act (42 U.S.C. 262); or

20 (B) a premarket approval application
21 under section 515 of the Federal Food, Drug,
22 and Cosmetic Act (21 U.S.C. 360e), an applica-
23 tion for humanitarian device exemption under
24 section 520(m) of such Act (21 U.S.C.
25 360j(m)), a premarket notification under sec-

tion 510(k) of such Act (21 U.S.C. 360(k)), a de novo classification request under section 513(f)(2) of such Act (21 U.S.C. 370c(f)(2)), an investigational device exemption under section 520(g) of such Act (21 U.S.C. 360j(g)), or an application for licensure under section 351 of the Public Health Service Act (42 U.S.C. 262) pending on the date of enactment.

(2) Notwithstanding any other provision of this Act, a laboratory developed test under paragraph (1) shall be a device under section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)(1)) until—

(A) if a notification is submitted under paragraph (3)(A), the date of such notification; or

(B) if a notification is submitted under paragraph (3)(B), the earlier of—

(i) approval, clearance, authorization, exemption, or licensure of a modification to such test such that it meets the definition of device under section 201(h)(1) of such Act (21 U.S.C. 321(h)(1));

(ii) 2 years after enactment;

- 1 (iii) the date a subsequent notification
2 is submitted under paragraph (3)(A); or
3 (iv) 60 days after enactment if no no-
4 tification is submitted under paragraph
5 (3).

6 (3) For a laboratory developed test under para-
7 graph (1), within 60 days of enactment, a laboratory
8 may submit to the Food and Drug Administration a
9 notification that the laboratory—

10 (A) does not intend to modify the test to
11 meet the definition of a device under section
12 201(h)(1) of the Food, Drug, and Cosmetic Act
13 (21 U.S.C. 321(h)(1)); or

14 (B) intends to modify the test to meet the
15 definition of a device under section 201(h)(1) of
16 the Food, Drug, and Cosmetic Act (21 U.S.C.
17 321(h)(1)).

18 (4) For a laboratory developed test under para-
19 graph (1)(A), upon the applicable date in paragraph
20 (2) that such test is no longer a device, such test is
21 deemed to have a supplemental affirmation from the
22 Food and Drug Administration under section
23 353(r)(1)(D) of the Public Health Service Act (42
24 U.S.C. 263a(r)(1)(D)), as added by section 2(a) of

1 this Act, that the laboratory developed test meets
2 the applicable standard.

3 **SEC. 4. CLINICAL LABORATORY IMPROVEMENT AMEND-**
4 **MENTS (CLIA) UPDATES.**

5 (a) CLIA SPECIALTIES.—No later than 180 days
6 after enactment, the Secretary shall issue a proposed regu-
7 lation to establish new types of examinations that may be
8 performed by laboratories under section 353 of the Public
9 Health Service Act (42 U.S.C. 263a) consistent with the
10 current state of clinical laboratory science and technology,
11 including the advancements with respect to molecular
12 diagnostics, digital pathology, and next generation se-
13 quencing. Within 1 year of finalizing such regulations, the
14 Secretary must evaluate whether additional proficiency
15 testing programs should be approved for these new spe-
16 cialties under section 353(f)(3)(C) of such Act (42 U.S.C.
17 263a(f)(3)(C)).

18 (b) NOTICE OF SUBREGULATORY CHANGES.—If the
19 Centers for Medicare and Medicaid Services intend to
20 issue new or revised sub-regulatory guidance and policies
21 related to the regulation of laboratories under section 353
22 of the Public Health Service Act (42 U.S.C. 263a), includ-
23 ing new or revised State operations manuals applicable to
24 the regulation of laboratories, it must describe such pro-
25 posed action in a public report at least 90 days prior to

1 taking such action and allow an opportunity for public
2 comment.

3 (c) ENGAGEMENT WITH LABORATORIES.—The Cen-
4 ters for Medicare and Medicaid Services must hold regular
5 open door forums with clinical laboratories, no less fre-
6 quently than annually, to discuss issues related to the reg-
7 ulation of laboratories under section 353 of the Public
8 Health Service Act (42 U.S.C. 263a).

9 (d) REGULATION UPDATES.—At least once every 5
10 years, the Centers for Medicare and Medicaid Services
11 must review the regulations promulgated under section
12 353 of the Public Health Service Act (42 U.S.C. 263a),
13 and—

14 (1) issue a request for information in the Fed-
15 eral Register regarding whether updates to such reg-
16 ulations are necessary to reflect advancements in
17 laboratory science and technology; and

18 (2) establish a public docket, to remain open for
19 no less than 180 days, to solicit public comments on
20 the request for information issued under paragraph
21 (1).

○