

117TH CONGRESS
1ST SESSION

S. 1666

To clarify the authority for regulating laboratory-developed testing procedures.

IN THE SENATE OF THE UNITED STATES

MAY 18, 2021

Mr. PAUL introduced the following bill; which was read twice and referred to
the Committee on Health, Education, Labor, and Pensions

A BILL

To clarify the authority for regulating laboratory-developed
testing procedures.

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 “Verified Innovative
5 Testing in American Laboratories Act of 2021” or the
6 “VITAL Act of 2021”.

7 **SEC. 2. LABORATORY-DEVELOPED TESTING PROCEDURES.**

8 (a) FINDINGS.—Congress finds the following:

9 (1) Laboratory testing services are an integral
10 part of medical decision making, health manage-
11 ment, and public health surveillance.

1 (2) Provision of laboratory services is a profes-
2 sional health care activity, which is regulated under
3 the Public Health Service Act (42 U.S.C. 201 et
4 seq.).

5 (3) As witnessed with the 2020 COVID–19
6 pandemic, undue regulation of laboratory-developed
7 testing procedures may hamper the medical manage-
8 ment and public health response to infectious disease
9 outbreaks and pandemics, leading to delays in access
10 to testing and the ability to meet needed capacity to
11 stem community spread.

12 (b) SENSE OF CONGRESS.—It is the sense of Con-
13 gress that—

14 (1) the Federal Government should work to—

15 (A) ensure that patients receive the most
16 appropriate tests and procedures for medical
17 evaluations or treatment of clinical conditions;

18 (B) ensure that laboratory-developed test-
19 ing procedures are accurate, precise, clinically-
20 relevant, and monitored for continued quality
21 performance;

22 (C) enable laboratory professionals to pro-
23 vide professional services without undue restric-
24 tions;

(D) ensure that regulatory oversight of laboratory tests does not limit patient access, impede innovation, constrain flexibility or adaptability, or limit a test's sustainability as a result of being unduly burdensome or beyond the fiscal capacity of the laboratory to reasonably validate and perform, or the health care system to financially support;

(E) preserve the ability of the laboratory community to provide surge capacity in public health emergencies, including biological, chemical, radiological, and nuclear threats, infectious disease outbreaks, or other emergent situations; and

(F) safeguard, strengthen, and expand the existing Laboratory Response Network, including public health laboratories, sentinel laboratories, national laboratories, commercial reference laboratories, academic medical center laboratories, and hospital-based laboratories; and

(2) laboratories using laboratory-developed testing procedures should adhere to personnel requirements required under section 353 of the Public Health Service Act (42 U.S.C. 263a), including such

1 requirements relating to qualified professionals who
2 direct and supervise laboratories and consult on di-
3 agnosis, treatment, and management of patient care,
4 and render opinions to clients concerning diagnosis,
5 treatment, and management of patient care required
6 under such section 353.

7 (c) AUTHORITY OVER LABORATORY-DEVELOPED
8 TESTING PROCEDURES.—All aspects of a laboratory-de-
9 veloped testing procedures shall be regulated by the Sec-
10 retary of Health and Human Services under section 353
11 of the Public Health Service Act (42 U.S.C. 263a), and
12 no aspects of laboratory-developed testing procedures shall
13 be regulated under the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 301 et seq.), including during a public
15 health emergency declared under section 319 of the Public
16 Health Service Act (42 U.S.C. 247d).

17 (d) DEFINITION.—In this section, the term “labora-
18 tory-developed testing procedure” means a professional
19 medical service that utilizes a laboratory examination in
20 the context of clinical care or public health services and
21 that meets the standards for establishment of performance
22 specifications established by regulation under section
23 353(f) of the Public Health Service Act (42 U.S.C.
24 263a(f)) applicable to—

1 (1) laboratory modifications of test systems ap-
2 proved, cleared, or authorized by the Food and Drug
3 Administration under section 510(k), 513, 515, or
4 564 of the Federal Food, Drug, and Cosmetic Act
5 (21 U.S.C. 360(k), 360e, 360e, 360bbb-3);

6 (2) methods developed or performed, and re-
7 sults produced and interpreted, within a laboratory
8 or laboratories under common ownership or within
9 the same organization, certified as required under
10 section 353(c) of the Public Health Service Act (42
11 U.S.C. 263a(c));

12 (3) standardized methods such as those that
13 are available in textbooks and peer-reviewed publica-
14 tions; or

15 (4) methods in which performance specifications
16 are not provided by the manufacturer of test sys-
17 tems or components.

18 (e) PUBLIC MEETING.—Not later than 90 days after
19 the date of enactment of this Act, the Administrator of
20 the Centers for Medicare & Medicaid Services shall hold
21 a public meeting to solicit recommendations on updating
22 the regulations under section 353 of the Public Health
23 Service Act (42 U.S.C. 263a).

24 (f) REPORT TO CONGRESS.—Not later than 180 days
25 after the date of enactment of this Act, the Secretary of

1 Health and Human Services shall report to the Committee
2 on Health, Education, Labor, and Pensions of the Senate
3 and the Committee on Energy and Commerce of the
4 House of Representatives, the following:

5 (1) Recommendations to update section 353 of
6 the Public Health Service Act (42 U.S.C. 263a) and
7 the regulations promulgated under such section, tak-
8 ing into consideration input and recommendations
9 from the Clinical Laboratory Improvement Advisory
10 Committee, to reflect the current state of the field
11 of clinical laboratory testing.

12 (2) An assessment of the availability and utili-
13 zation of laboratory-developed testing procedures
14 during the 2020 COVID–19 pandemic response that
15 includes—

16 (A) validation criteria and process, and av-
17 erage length of time from validation to achiev-
18 ing emergency use authorization under section
19 564 of the Federal Food, Drug, and Cosmetic
20 Act (21 U.S.C. 360bbb–3) before, and after,
21 February 29, 2020;

22 (B) the number of patients and samples
23 tested by laboratories using such testing proce-
24 dures; and

1 (C) recommendations to ensure that dur-
2 ing future infectious disease outbreaks, the pub-
3 lic health system and clinical laboratories do
4 not encounter delays to testing.

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