117TH CONGRESS
1ST SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

Mr. PAUL introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Verified Innovative Testing in American Laboratories Act of 2021'' or the ''VITAL Act of 2021''.

SEC. 2. LABORATORY-DEVELOPED TESTING PROCEDURES.

(a) FINDINGS.—Congress finds the following:

(1) Laboratory testing services are an integral part of medical decision making, health management, and public health surveillance.

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

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

(b) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) the Federal Government should work to—

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

(B) ensure that laboratory-developed testing procedures are accurate, precise, clinically-relevant, and monitored for continued quality performance;

(C) enable laboratory professionals to provide professional services without undue restrictions;

(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

requirements relating to qualified professionals who direct and supervise laboratories and consult on diagnosis, treatment, and management of patient care, and render opinions to clients concerning diagnosis, treatment, and management of patient care required under such section 353.

(c) AUTHORITY OVER LABORATORY-DEVELOPED TESTING PROCEDURES.—All aspects of a 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 no aspects of laboratory-developed testing procedures shall be regulated 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).

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

(1) laboratory modifications of 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);

(2) methods developed or performed, and results produced and interpreted, within a laboratory or laboratories under common ownership or within the same organization, certified as required under section 353(c) of the Public Health Service Act (42 U.S.C. 263a(c));

(3) standardized methods such as those that are available in textbooks and peer-reviewed publications; or

(4) methods in which performance specifications are not provided by the manufacturer of test systems or components.

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

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

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

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

(2) An assessment of the availability and utilization of laboratory-developed testing procedures during the 2020 COVID–19 pandemic response that includes—

(A) validation criteria and process, and average length of time from validation to achieving emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) before, and after, February 29, 2020;

(B) the number of patients and samples tested by laboratories using such testing procedures; and

(C) recommendations to ensure that during future infectious disease outbreaks, the public health system and clinical laboratories do not encounter delays to testing.