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118TH CONGRESS
1ST SESSION

H. R. 3795

To amend the Public Health Service Act to require the development of a diagnostic testing preparedness plan to be used during public health emergencies, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 5, 2023

Mr. PENCE (for himself, Mr. CARSON, Mr. BUCSHON, and Ms. SCHRIER) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Public Health Service Act to require the development of a diagnostic testing preparedness plan to be used during public health emergencies, and for other purposes.

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

SECTION 1. DIAGNOSTIC TESTING PREPAREDNESS PLAN.

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended by inserting after section 319F–5 of such Act (42 U.S.C. 247d–6f) the following:

"SECTION 319F–6. DIAGNOSTIC TESTING PREPAREDNESS PLAN.

''(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Preparedness and Response, and in consultation with the heads of relevant Federal agencies, shall develop not later than 1 year after the date of enactment of this section and update not less than every 3 years thereafter a plan for rapid development, authorization, scaling, procurement, and distribution of diagnostics and clinical and diagnostic laboratory testing capacity during a public health emergency declared under section 319.

''(b) PURPOSES.—The purposes of the plan under subsection (a) shall be—

''(1) to facilitate the development of diagnostics for use with respect to a novel chemical, biological, radiological, or nuclear threat or an emerging infectious disease, including any such high-throughput laboratory diagnostic, point-of-care diagnostic, or rapid at-home or point-of-use diagnostic; and

''(2) to describe the processes for rapid development, authorization, scaling, procurement, and distribution of diagnostics and clinical and diagnostic laboratory testing capacity.

''(c) PUBLIC-PRIVATE COORDINATION.—

''(1) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Preparedness

and Response, shall include within the plan under subsection (a) a plan for public-private coordination on national diagnostic testing during a public health emergency.

''(2) CONTENTS.—The plan under paragraph (1) shall be designed to facilitate coordination and collaboration among—

''(A) government agencies; and

''(B) critical private-sector diagnostic testing stakeholders, including private-sector clinical and diagnostic laboratories, diagnostic manufacturers, health care product distributors, and research laboratories.

''(d) PUBLIC AVAILABILITY.—The Secretary, acting through the Assistant Secretary for Preparedness and Response, shall make the plan under subsection (a) publicly available.

''(e) REPORTS TO CONGRESS.—Not later than 1 year after commencing implementation of the plan under subsection (a) for a public health emergency, the Secretary, acting through the Assistant Secretary for Preparedness and Response, shall submit to the Congress a report evaluating the effectiveness of activities implemented under the plan.''.

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