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(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

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

Mr. PENCE introduced the following bill; which was referred to the Committee
on _____

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.

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. DIAGNOSTIC TESTING PREPAREDNESS PLAN.**

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

1 **“SECTION 319F-6. DIAGNOSTIC TESTING PREPAREDNESS**

2 **PLAN.**

3 “(a) IN GENERAL.—The Secretary, acting through
4 the Assistant Secretary for Preparedness and Response,
5 and in consultation with the heads of relevant Federal
6 agencies, shall develop not later than 1 year after the date
7 of enactment of this section and update not less than every
8 3 years thereafter a plan for rapid development, authoriza-
9 tion, scaling, procurement, and distribution of diagnostics
10 and clinical and diagnostic laboratory testing capacity dur-
11 ing a public health emergency declared under section 319.

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

14 “(1) to facilitate the development of diagnostics
15 for use with respect to a novel chemical, biological,
16 radiological, or nuclear threat or an emerging infec-
17 tious disease, including any such high-throughput
18 laboratory diagnostic, point-of-care diagnostic, or
19 rapid at-home or point-of-use diagnostic; and

20 “(2) to describe the processes for rapid develop-
21 ment, authorization, scaling, procurement, and dis-
22 tribution of diagnostics and clinical and diagnostic
23 laboratory testing capacity.

24 “(c) PUBLIC-PRIVATE COORDINATION.—

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

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

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

8 “(A) government agencies; and

9 “(B) critical private-sector diagnostic test-
10 ing stakeholders, including private-sector clin-
11 ical and diagnostic laboratories, diagnostic man-
12 ufacturers, health care product distributors,
13 and research laboratories.

14 “(d) PUBLIC AVAILABILITY.—The Secretary, acting
15 through the Assistant Secretary for Preparedness and Re-
16 sponse, shall make the plan under subsection (a) publicly
17 available.

18 “(e) REPORTS TO CONGRESS.—Not later than 1 year
19 after commencing implementation of the plan under sub-
20 section (a) for a public health emergency, the Secretary,
21 acting through the Assistant Secretary for Preparedness
22 and Response, shall submit to the Congress a report evalu-
23 ating the effectiveness of activities implemented under the
24 plan.”.