AMERICAN CLINICAL LABORATORY ASSOCIATION

Chair Bernard Sanders
Senate HELP Committee
332 Dirksen Senate Office Building
Washington, DC, 20510

Ranking Member Bill Cassidy, M.D.
Senate HELP Committee
455 Dirksen Senate Office Building
Washington, DC, 20510

Senator Robert P. Casey, Jr.
Senate HELP Committee
393 Russell Senate Office Building
Washington, DC 20510

Senator Mitt Romney
Senate HELP Committee
354 Russell Senate Office Building
Washington, DC 20510

July 10, 2023

Submitted via email: PAHPA2023Comments@help.senate.gov

Re: Comments on the Pandemic and All-Hazards Preparedness Act (PAHPA) Discussion Draft

Dear Chair Sanders, Ranking Member Cassidy, and Senators Casey and Romney:

The American Clinical Laboratory Association (ACLA) appreciates the opportunity to provide these comments in response to the PAHPA Reauthorization Discussion Draft (Discussion Draft). ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers by advocating for policies that expand access to the highest quality clinical laboratory services, improve patient outcomes, and advance the next generation of personalized care. In recent years, the dedication of ACLA members has been demonstrably vital to our nation's ability to meet the public health needs imposed by the COVID-19 and Mpox public health emergencies. As such, ACLA is grateful for the opportunity to provide our insights and feedback on how the nation can be better prepared to respond to new and emerging health threats.

The Discussion Draft makes important policy proposals for strengthening the country's preparedness status for emerging health threats. In particular, ACLA appreciates the inclusion of section 404 of the Discussion Draft that aims to ensure the availability of surge capacity for clinical laboratories. However, we urge the Committee to strengthen other proposals, such as those regarding the strategic national stockpile, to ensure clinical laboratories are leveraged as a vital component of our nation's diagnostic testing infrastructure. We also have significant concerns with the data reporting policies outlined in section 205 of the Discussion Draft. In more detail below, we offer our comments on specific proposals in the Discussion Draft, as well as feedback on additional policy proposals that we urge to be considered for inclusion in the bill.

I. Sec. 404. Supporting Research and Laboratory Surge Capacity

ACLA agrees with the inclusion of section 404, which directs HHS to make awards to establish and maintain at least 12 regional biocontainment laboratories for the purpose of, among other things, "ensuring the availability of surge capacity for purposes of responding to ... biological agents," including emerging infectious diseases. As ACLA has expressed before, insufficient testing capacity—including limited staffing and on-site availability of supplies—can significantly limit access to diagnostic testing for patients. Accordingly, ensuring commercial

laboratories have access to test supplies and sufficient reserve capacity for additional testing is critical to preventing testing shortages in the face of surging demands when there is a new or emerging pathogen.

ACLA Recommendation: As a complement to the awards for biocontainment laboratories, ACLA continues to urge the Committee to strengthen the strategic national stockpile (SNS) to clarify that HHS is authorized to contract directly with independent commercial clinical laboratories for the maintenance of testing supply inventory and testing capacity. In particular, as amended by the PREVENT Pandemics Act, HHS is authorized under the SNS authorities to enter into contracts with vendors, including manufacturers or distributors of medical products, to enable (1) vendor-managed inventory of medical products, and (2) the maintenance of domestic manufacturing capacity and capabilities of medical products. We believe it would be useful to clarify this authority by expressly authorizing HHS to contract with independent clinical laboratories to maintain testing service capacity and capabilities to ensure additional reserve testing service capacity and capabilities are available.

II. Sec. 205. Pilot Program for Data Health Availability

Although ACLA agrees with the goal of improving coordination and communication among government entities to improve biosurveillance, we have significant concerns with section 205 of the Discussion Draft as proposed. As drafted, section 205(a) would direct the Secretary of HHS to "develop guidance on data elements to be reported to the Secretary pertaining to potentially catastrophic infectious disease outbreaks, in such form and manner and at such timing and frequency as determined by the Secretary," and such guidance would be applicable in states participating in the pilot program established under section 205. ACLA has concerns with this approach and believes that this section should be significantly strengthened in several ways.

ACLA Recommendation: First, although ACLA agrees in concept with the establishment of standard data reporting elements, such elements should be established by rulemaking, not guidance, to ensure there is appropriate transparency, accountability and opportunity for public input and clinical laboratories should be expressly included as members of the proposed National Public Health Data Board. During the COVID-19 pandemic, clinical laboratories experienced significant challenges in the face of new data reporting requirements. For example, when section 18115 of the CARES Act was implemented, HHS mandated that clinical laboratories report certain demographic information with test results, such as patient race and ethnicity. However, while such data elements may have public health significance, clinical laboratories do not routinely have access to this information because they typically have no direct contact with patients. Ordering health care providers who have direct contact with patients do not often share these data elements with laboratories processing specimens. Accordingly, it is crucial that new data reporting requirements are established through a notice-and-comment rulemaking process that enables clinical laboratories and other reporting entities to provide important input regarding the practical and logistical challenges and opportunities associated with such reporting. Likewise, membership for the National Public Health Data Board—proposed to be established under section 205(b) of the Discussion Draft—should be amended to expressly include clinical laboratories, and the board should be charged with making recommendations to the Secretary regarding the implementation of data and information sharing under section 310B of the Public Health Service Act (PHSA), as tentatively proposed (the brackets around this provision should be removed).

Relatedly, to the extent that any new data reporting requirements might apply to clinical laboratories as "applicable entities to report data", they should only apply with respect to data to which clinical laboratories have direct access. Therefore, if the term "applicable entities" is intended to apply to any entities other than States, it should be defined in the bill as entities that, with respect to a data element, have direct access to such data.

Second, requiring such data elements to be reported only in those states participating in the pilot program would create disparate reporting requirements for laboratories across the country, including laboratories operating in different states but under common ownership. As noted above, ACLA agrees in concept with the establishment of standard data reporting elements, but it is critical to establish a single standard among all states, not only those participating in the pilot program. If the data elements are required only in some states, they are not standardized data elements. **ACLA strongly recommends that any commercial clinical laboratory that would be subject to this pilot should be exempt from other surveillance reporting requirements set by any state, territories, municipalities, or by the federal government. In the case of a commercial laboratory with laboratory sites in multiple states, the exemption should apply across all laboratory sites owned by the same parent company.**

ACLA Recommendation: Section 205 proposes to strike the provision requiring the Secretary to "ensure that activities carried out under an award under this subsection do not unnecessarily duplicate efforts of other agencies and offices within [HHS]." There is no reason for this provision to be struck. ACLA urges the Committee to reinsert this provision to avoid the duplication of efforts across other government agencies and offices. Further, while States selected for the pilot would be responsible for reporting to the Secretary such reports of data as the Secretary may require pursuant to the proposed data guidance, States would presumably require clinical laboratories to report to them whatever data the States would need to report to the Secretary; but the use of the undefined term "applicable entities to report data" in the description of the proposed guidance suggests that entities other than States may be required to report data to the Secretary, and nothing in the bill protects clinical laboratories from having to report data elements to both the States and to the Secretary, which would be unnecessarily and harmfully duplicative. The bill should be amended to avoid duplicative efforts or obligations for both clinical laboratories and government agencies.

III. Additional Requests

Finally, ACLA continues to urge the Committee to incorporate the following policy proposals in the PAHPA Reauthorization, as discussed in our comments on the RFI.

A. National Testing Coordination Forum

ACLA Recommendation:The bill should establish an Office of the National Testing Coordination Forum (Forum) under the department of Health and Human Services, which would convene a public-private forum focused on diagnostics preparedness and response to disease emergencies. The Forum would meet regularly to provide recommendations to the HHS Secretary and Congress on both preparedness and response matters for adequate screening and diagnostic test manufacturing and laboratory capacity and collaboration between government agencies and private sector stakeholders on testing preparedness. The Forum would comprise leaders from public health-sector agencies and departments integral to diagnostic testing (e.g., CDC, CMS, FDA, NIH), and representatives of

public-sector laboratories, hospital laboratories, reference laboratories, private-sector organizations that represent diagnostic manufacturers, and healthcare product distributors.

The Forum would serve as the primary coordinating hub for public- and private-sector stakeholders to ensure real-time information sharing, swift development and scale-up of tests and testing capacity, and clear communications to the public on the state of testing. The Forum also would identify national testing challenges and provide recommendations for solving them. For example, in the earliest stages of an emergency, when access to patient samples is limited, the Forum would provide recommendations on developing and maximizing testing capacity and use and encourage the rapid development and deployment of emerging testing technologies. The Forum would also work with the US Government to establish contracting prior to a disease emergency to reserve adequate supplies and testing capacity in the event of a disease emergency.

Please note recommended legislative language for the National Testing Coordination Forum is included in Appendix A.

B. Emergency Use Authorizations (EUA) and related authorities

ACLA Recommendation: The pre-EUA and EUA processes should be refined to ensure swift access to validated testing in future emergencies. Ideally, at the beginning of a potential emergency, when a pathogen of concern is identified, certain test developers already under contract with the US Government could access patient samples and swiftly develop and launch tests for patient care in a pre-EUA environment (i.e., prior to an EUA declaration being made).

Test developer experience during this period would assist with the establishment of test validation in the event of a PHE declaration and subsequent initiation of the FDA EUA process. If an EUA declaration is made, then FDA should have the flexibility to apply the EUA to all test developers, as it did during the COVID-19 PHE, or to require notification only from LDT developers and an EUA from manufacturers, as is being done during the Mpox PHE. Should an EUA be required, FDA should allow test developers to provide notification of use of a validated test and a forthcoming submission, allowing 15 days to prepare the submission. During this stretch of time, tests could be used and pre-positioned at laboratories. Further, the agency should exercise regular test developer town hall meetings, again, as was done during COVID-19, to support test developers in preparing or updating submissions, as more is learned about a pathogen.

C. *Coverage of Tests for New Pathogens of Concern*

Significant gaps exist in coverage of tests for new pathogens of concern. To ensure robust provider and patient access to tests across all modalities (laboratory-based and point-of-care, including at-home and over-the counter tests), the rapid establishment of medical billing codes, coverage, and national payment rates is essential. While expedited processes for coding are established, the US lacks durable policy to rapidly develop comprehensive coverage and payment to private-sector testing partners.

ACLA Recommendation:: The Centers for Medicare and Medicaid Services (CMS) should develop a mechanism to swiftly set and communicate broad, national coverage and payment for testing of new pathogens of concern for public and private insurers.

ACLA Recommendation: Additionally, to ensure the health of the nation's diagnostics infrastructure, policymakers should pass The Saving Access to Laboratory Services Act (S.1000 / H.R. 2377) bipartisan, bicameral legislation that would provide for long-term sustainable and predictable Medicare reimbursement to clinical laboratories. Although the December 2022 Omnibus included a one-year delay in the pending 15% cuts in Medicare payments for about 800 laboratory tests, additional legislation is needed to ensure a sustainable pathway for Medicare payment to clinical laboratory services. Predictable and sustainable Medicare payments support patient access, innovation, and the clinical laboratory infrastructure needed to respond to public health emergencies.

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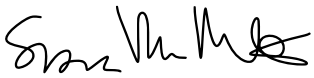
ACLA appreciates the opportunity to provide these comments on the PAHPA Reauthorization Discussion Draft. ACLA and ACLA member laboratories remain committed to serving patients and providers, and to serving as a resource in your efforts to bolster our nation's preparedness response.

If you have follow-up questions, please reach out to Holly Grosholz at hgrosholz@acla.com.

Sincerely,



Susan Van Meter
President, American Clinical Laboratory Association

Enclosure:

Appendix A: ACLA's recommended legislation language to establish a National Testing Coordination Forum

Appendix A:

118TH CONGRESS
1ST SESSION

H.

To amend title XXVI of the Public Health Service Act to create a National Testing Coordination Forum within the Office of the Secretary of Health and Human Services.

IN THE HOUSE OF REPRESENTATIVES

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

_____

A BILL

To amend title XXVI of the Public Health Service Act to create a National Testing Coordination Forum within the Office of Health and Human Services.

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 "_____ Act of 2023".

SECTION 2. CREATION OF THE NATIONAL TESTING COORDINATION FORUM.

(a) IN GENERAL.—There is established within the Department of Health and Human Services an Office of the National Testing Coordination Forum (referred to in this section as the 'Forum'). The Forum shall be headed by a Director (referred to in this section as the 'Director') who shall be appointed by the Secretary and who shall report directly to the Secretary.

(b) PURPOSE.—The Forum shall make policy recommendations to the Secretary and the U.S. Congress as part of a Federal government public health preparedness and response to a disease emergency relating to—

(1) the establishment and maintenance of adequate screening and diagnostic test manufacturing and laboratory capacity; and

(2) collaboration and coordination between government agencies and private sector stakeholders on testing preparedness.

(c) DUTIES OF THE FORUM.—

(1) RECOMMENDATIONS ON TESTING CAPACITY AND USE.—The Forum shall provide recommendations to the Secretary and the U.S. Congress on—

(A) developing and maximizing testing expertise and capacity of public health laboratories, commercial laboratories, and hospital

laboratories, both prior to a disease emergency and during a public health response to a disease emergency;

(B) encouraging the rapid development and deployment of emerging testing technologies;

(C) development of new diagnostic tests for diseases that are emerging public health threats;

(D) establishment of contracting prior to a disease emergency between the Administration for Strategic Preparedness and Response and diagnostic test manufacturers and commercial laboratories to reserve adequate supplies and testing capacity in the event of a disease emergency;

(E) making staffing resources available to public health laboratories and commercial laboratories to mitigate workforce shortages;

(F) developing use cases for different types of screening and diagnostic testing, including but not limited to laboratory testing, point-of-care testing, at-home specimen collection, and over-the-counter testing;

(G) other policies related to testing capacity and use.

(2) COMMUNICATION AND COORDINATION.—The Forum shall serve as the primary communication and coordination mechanism between the Federal government and public health laboratories, commercial laboratories, diagnostic test manufacturers, and distributors as part of a Federal government public health response to a disease emergency.

(A) The Forum shall communicate with public health laboratories, commercial laboratories, diagnostic test manufacturers, and distributors regularly about current testing plans, availability and access to pathogen samples needed for test validation, and disease emergency-related policy developments.

(B) The Forum shall advise the Secretary on communicating effectively with diagnostic testing industry stakeholders and the general public.

(3) EXPERTISE ON CLINICAL LABORATORY OPERATIONS.—The Forum shall anticipate and identify testing challenges during a disease emergency, consult with outside experts about addressing the challenges, and communicate with public and private sector laboratories about methods and resources available to mitigate challenges.

(d) MEMBERSHIP AND OPERATIONS OF THE FORUM.—

(1) MEMBERSHIP.—

(A) FEDERAL GOVERNMENT AGENCY MEMBERS.—

The Forum shall include each of the following members, or the designee of such members:

(i) The Director of the Centers for Disease Control and Prevention.

(ii) The Administrator of the Centers for Medicare & Medicaid Services.

(iii) The Commissioner of the Food and Drug Administration.

(iv) The Director of the National Institutes of Health.

(v) The Assistant Secretary for Preparedness and Response.

(vi) The Director of the Office of Pandemic Preparedness and Response Policy.

(vii) Representatives of any other Federal Agency, as the Secretary determines appropriate.

(B) MEMBERS REPRESENTING SECTORS OF THE DIAGNOSTICS TESTING INDUSTRY.—

The Director shall appoint individual members to the Forum representing trade associations and stakeholders from different sectors of the diagnostic testing industry, of whom:

(i) two individual members shall represent the commercial laboratory sector;

(ii) two individual members shall represent the public health laboratory sector;

(iii) two individual members shall represent the hospital laboratory sector;

(iv) two individual members shall represent the diagnostics manufacturing sector; and

(v) two individual members shall represent the healthcare products distributor sector.

(3) OUTSIDE INVOLVEMENT.—The Director shall ensure an opportunity for the participation in activities of the Forum of outside

advisors, interested stakeholders, and the general public.

(4) MEETINGS.—The Forum shall meet at least quarterly each year and may meet more frequently when the Secretary has made an emergency declaration under [national and public health emergency acts].

(5) QUORUM.—A majority of the members of the Forum shall constitute a quorum for purposes of voting on recommendations to the Secretary and the U.S. Congress, but a lesser number of members may meet and hold hearings.

(e) SUPPORT FROM OTHER AGENCIES.— Each department, agency, and instrumentality of the executive branch of the Federal Government, including any independent agency, is authorized to support the Director by providing the Director such information as the Director determines necessary to carry out the functions of the Director under this section.

(f) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. § App.), other than section 15 of such Act, shall apply to the Forum.

(g) PUBLICATION.—The Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Department of Health and Human Services of all policy recommendations made by the Forum under this section.

SECTION 2. CONFORMING AMENDMENTS.

(a) Section 2811-1 of the Public Health Service Act (42 U.S.C. 300hh-10a) is amended in subsection (b)—

(1) by redesignating paragraph (11) as paragraph (12); and

(2) by inserting after paragraph (10) the following: "(11) The Director of the National Testing Coordination Forum."