AMERICAN CLINICAL LABORATORY ASSOCIATION

By Email

March 13, 2023

Representative Richard Hudson
2112 Rayburn House Office Building
Washington, DC 20515

Representative Anna Eshoo
272 Cannon House Office Building
Washington, DC 20515

Re: Proposal for a National Diagnostics Action Plan for the United States

Dear Representatives Hudson and Eshoo:

The American Clinical Laboratory Association (ACLA) appreciates the opportunity to provide feedback and suggestions in preparation for the upcoming reauthorization of the Pandemic and All Hazards Preparedness Act (PAHPA), including by responding to the request for information (RFI) released by your offices. ACLA is the national trade association representing leading clinical laboratories, and the dedication of our members has been vital to our nation's ability to meet the pressing 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.

In addition, we are writing to provide you with a pre-print copy of our Proposal for a National Diagnostics Action Plan for the United States (NDx Action Plan), which we co-authored with the Johns Hopkins Center for Health Security. *See* Attachment A. The NDx Action Plan describes the steps that are urgently needed to prepare for future infectious disease emergencies, as well as the actions we must take at the first signs of such events. Many of the policy recommendations in our response to the PAHPA RFI are derived from this NDx Action Plan.

Since the NDx Action Plan was drafted, the PREVENT Pandemics Act was passed in the Consolidated Appropriations Act of 2023. We applaud Congress for taking this important step toward improving our nation's preparedness infrastructure, and we believe there is still more important work to be done this year. First, steps should be taken to further modernize and strengthen the supply chain for medical products, and in doing so, we encourage Congress to make clear that clinical laboratory testing capacity is a critical part of that supply chain. For example, while the PREVENT Pandemics Act authorizes HHS to contract directly with domestic manufacturers to ensure reserve manufacturing capacity for important medical products, we believe it would be useful to clarify that this authority expressly authorizes HHS to contract directly with clinical laboratories to ensure reserve testing capacity. Even if test supplies are available, patients may have trouble accessing testing services if laboratories do not have capacity to conduct additional testing. Thus, reserve capacity of clinical laboratories is critical to preventing testing shortages in the face of surging demands. Similarly, while new Strategic National Stockpile (SNS) authorities permit vendor-managed inventory practices for domestic manufacturers, we believe Congress should expressly indicate that clinical laboratories can be a site for maintaining reserves of SNS testing supplies. Reserving SNS supplies on-site at clinical

laboratories would enable rapid scaling of testing services because the supplies would already be at the locations where they are needed.

Second, as described in the RFI response, we believe that more should be done to establish a uniform and standardized system for data sharing with public health agencies, and that Congress should ensure that burdens on data providers are manageable and streamlined given the critical role that such providers play during a public health emergency. In particular, we think the data reporting provision at PHSA section 310B could be amended so that (1) reporting elements are established by regulation (rather than pronouncement by the Secretary), (2) clinical laboratories are required to report only the information they receive from ordering providers, and (3) State, local, and Tribal public health agencies cannot impose additional or different reporting requirements from the Federal requirements. ACLA has proposed legislative text to implement this approach in Attachment B.

Third, there are other significant barriers to delivering clinical testing to patients that we think Congress should address through the PAHPA reauthorization: regulatory authorization from FDA and coverage for new tests. With regard to regulatory authorization, while FDA is permitted to "expedite the development and review of countermeasures" under existing law, and has in place a process for third party review of Emergency Use Authorization (EUA) applications, we believe more can be done to help expedite access to testing. Establishing a Pre-EUA program and leveraging EUA processes can provide swift access to validated testing in future emergencies. Ideally, at the beginning of a potential emergency, when a pathogen of concern is identified, the pre-emergency bilateral response contracts with test developers that the USG had in place with select test developers would be triggered. These agreements would allow test developers covered by them to access patient samples and swiftly develop and launch tests for patient care in a Pre-EUA environment. That is, laboratory developed tests (LDTs) should be leveraged in clinical settings during this period of time. In addition, Congress should codify the policy used during the COVID-19 PHE that allows certain test developers, under limited to conditions, to offer validated tests following notification, on the condition that an application for an EUA is submitted within 15 days.

Congress also has the opportunity to address coverage of tests with the PAHPA reauthorization. As explained in the NDx Action Plan, rapid establishment of medical billing codes, coverage, and national payment rates is essential to ensuring robust provider and patient access to tests. And while expedited processes for coding are established, the US lacks durable policy to rapidly develop comprehensive coverage and payment to private-sector testing partners. Therefore, the NDx Action Plan recommends that CMS should develop a mechanism to set and communicate broad, national coverage and payment for testing of new pathogens of concern.

Finally, to ensure the health of the nation's diagnostics infrastructure, policymakers should take steps via legislation to provide for long-term sustainable and predictable reimbursement to clinical laboratories. Although the Consolidated Appropriations Act included a one-year delay in the pending 15% cuts in Medicare payments for ~800 laboratory tests, additional legislation is needed to ensure a sustainable pathway for Medicare payment to clinical laboratory services. ACLA anticipates reintroduction in this Congress of the bipartisan, bicameral Saving Access to Laboratory Services Act (SALSA) introduced in the 117th session. Predictable and sustainable Medicare payments support patient access, innovation, and clinical laboratory infrastructure.

In closing, ACLA appreciates the opportunity to respond to the PAHPA RFI and to provide you with a copy of the NDx Action Plan. 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: Proposal for a National Diagnostics Action Plan