COLLEGE of AMERICAN PATHOLOGISTS

July 7, 2023

Senator Bernie Sanders
Chairman
Senate Committee on Health, Education,
Labor and Pensions
Washington, D.C. 20510

Senator Bill Cassidy, M.D.
Ranking Member
Senate Committee on Health, Education,
Labor and Pensions
Washington, D.C. 20510

Re: Comments in Response to PAHPA Reauthorization Discussion Draft

Sent to: PAHPA2023Comments@help.senate.gov

Dear Chairman Sanders and Ranking Member Cassidy:

The College of American Pathologists (CAP) appreciates the opportunity to provide feedback and suggestions in response to the Committee's discussion draft for the reauthorization of the *Pandemic and All-Hazards Preparedness Act* (PAHPA). The CAP is the world's largest organization of board-certified pathologists and the leading provider of laboratory accreditation and proficiency testing programs. The CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. As you are aware, pathologists are physicians who specialize in the diagnosis of disease. The expertise they provide drives treatment decisions that optimize outcomes for patients. During the COVID-19 public health emergency, pathologists were on the frontline of the crisis. They were responsible for ensuring prompt and accurate testing for patients and health care providers alike.

The battle against COVID-19 highlighted critical areas of concern that must be addressed to better prepare for future pandemics. As such, the CAP offers the following recommendations for consideration during the PAHPA reauthorization process. Specifically, the CAP urges the Committee to:

- Consider policies to standardize electronic laboratory reporting and authorize funding to enhance laboratory information systems;
- Strengthen the supply chain;
- Ensure a mechanism for adequate coverage and reimbursement of tests during a public health emergency (PHE);
- Authorize funding to strengthen the laboratory workforce; and
- Set Medicare reimbursement for clinical laboratory services on a sustainable path.

Supporting Research and Laboratory Surge Capacity

Firstly, the CAP wants to thank the Committee for the inclusion of Sec. 404 of the PAHPA reauthorization discussion draft, Supporting Research and Laboratory Surge Capacity. This section is important to the CAP as it would set aside grant money to establish surge capacity biocontainment

laboratories. The CAP believes this is important as laboratories continue to prepare for future pandemics and this section supports the job creation needed for surge capacity.

Consider Policies on Electronic Laboratory Reporting and Authorize Funding to Enhance Laboratory Information Systems

The CAP believes 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 PHE. The current pandemic highlighted the need for standardized data reporting to public health agencies for officials to access comprehensive and nearly real-time data to inform decision making in their response during the PHE. As such, the **CAP supports the creation of national standardized minimum data reporting requirements and formats in which clinical laboratories would be required to report only to the state in which the laboratory is located. The minimum data required to be reported should include only those data typically available to clinical laboratories.** The same national standards could be used by state public health agencies to report data on out-of-state patients to the state public health agency of the patient's residency. Alternatively, the federal government could establish a national data hub for public health, during a PHE, for use in distributing public health-related results to various locations in a standardized format.

During the pandemic, laboratories reported disparate, burdensome, and uneven data reporting requirements. Despite the high percentage of electronic health record (EHR) adoption (80% of physician offices with certified EHRs and 93% of small rural critical access hospitals with EHRs), laboratories continue to receive paper requisitions because 1) the EHR does not have an electronic interface with the laboratory performing the test, 2) the EHR has an interface but does not have this particular test in its catalog of tests, and least commonly 3), the EHR is in a downtime. Regarding the first reason, electronic interfaces are expensive to implement and maintain, and for this reason, it is not possible for an EHR to have interfaces with all laboratories that may perform testing. Even where electronic interfaces do exist, clinical laboratories still often receive inadequate demographic and other clinical information requested by some public health laboratories and government agencies. Additionally, paper requisitions often lack adequate patient demographic information. Consequently, addressing national standards for orders through EHR changes may not result in better data collection because laboratories will continue to have challenges when receiving paper orders and the barrier of the cost of interfacing with each ordering facility.

The requirements imposed by the Department of Health and Human Services (HHS) for additional public health reporting during the pandemic created significant strain on laboratories' financial and human resources at a time when they were already stretched beyond limit. The electronic submission of laboratory results to public health agencies is not currently mandated at the federal level, and states vary on whether electronic submission is required and on the format of the electronic submission. Each interface with an EHR or with an individual state's public health agency is costly ($40,000 to $70,000 on average per interface), and each change made to an interface also

has associated costs. Further complicating the matter is the variability by states as to who is required to do the reporting, which further supports the need for national minimum standards.

Better coordination at the federal and state levels and funding for laboratories to purchase and/or enhance laboratory information systems would improve data collection and strengthen our nation's response to public health crises. **More specifically, federal funding should be made available to laboratories to fully cover the costs of installation, validation, maintenance, and any required updates of electronic public health reporting software and interfaces, as the nation's laboratories cannot continue to absorb these "unfunded mandates" during future PHEs.** Ultimately, it is the responsibility of the HHS and state (and local) agencies to develop and adopt uniform standards and common pathway solutions for reporting and sharing all public health data (and not limited to a PHE), to prevent this unreasonable burden on laboratories or other required reporting entities from occurring again.

Strengthen the Supply Chain

The CAP applauds Congress for passing the Prepare for and Respond to Existing Viruses, Emerging New Threats (PREVENT) Pandemics Act. However, the CAP believes additional work is needed. As such, the CAP urges the Committee to clarify that clinical laboratory testing capacity is a critical part of the supply chain. The PREVENT Pandemics Act authorizes the HHS to contract directly with domestic manufacturers to ensure reserve manufacturing capacity for important medical products. **The CAP believes that the Committee should clarify that this authority expressly authorizes the HHS to contract directly with clinical laboratories, including small- and medium-size laboratories, to ensure reserve testing capacity.**

Ensure Adequate Coverage and Reimbursement of Tests During a PHE

The CAP believes the Committee has an opportunity to address coverage and payment of tests during the reauthorization of PAHPA. The 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 U.S. lacks a durable policy to rapidly develop comprehensive coverage and payment to private-sector testing partners.

For example, during the pandemic, the Medicare reimbursement rates for COVID-19 tests did not adequately reflect the cost associated with providing the tests and the established processes to determine these clinical laboratory test prices were not followed. The payment rates were set without access to costs and charges for the test, and the Medicare Administrative Contractors (MACs) never revealed the methodology they used to establish payment. The cost of the reagents, supplies, and clinical labor involved to provide one of these tests, as well as the incremental equipment and other fixed capital costs, far exceeded the MAC-reported payment amounts. Many supplies and clinical labor were reported to be in erratic and short supply, resulting in higher costs for all producers.

All the laboratory cost managers we interviewed during the pandemic indicated their laboratories had to have multiple testing platforms as they struggled to keep up with the demand for testing. The

multiple platforms provided some flexibility for the continuous, but often erratic, availability of reagents and other supplies. As one laboratory platform runs low or out of supplies, others are used and brought online until needed supplies are obtained. Laboratories purchased new equipment, set up the equipment, developed protocols, proficiency tests, obtained new supply chains, trained clinical staff, ran the tests, and maintained them. Some laboratory cost managers also reported when there were insufficient testing capabilities, they also sent the tests out to large laboratories for analysis, adding an additional layer of costs and delays in test reporting. Significant costs were incurred across the country as laboratories struggled with the crisis the best they could.

Inappropriately low pricing of tests leads to unnecessary delays and complications in any crisis. During the pandemic, large, medium, and small hospital laboratories were highly involved in providing COVID-19 tests. In fact, our survey found that medium-sized hospital laboratories accounted for two-thirds of labs providing molecular COVID-19 testing.

The reimbursement rates for COVID-19 tests ranged from $35 to $100, but those rates failed to account for the costs and resources necessary to bring testing online during the national public health crisis for laboratories of all sizes and localities. The rates favored large, high-volume testing providers while economically disadvantaging many frontline and primary testing providers in small, medium-sized, and acute care hospital and academic laboratory settings who were responsible for rapidly identifying and caring for COVID-19 patients during the pandemic. These frontline providers were forced to diversify and develop multiple and expensive testing methods and manage different combinations of analytical platforms to address the unprecedented shortages and unmet demands for expanded and more accessible SARS-CoV-2 testing in their local communities. **It is critical that the established Medicare processes to determine clinical laboratory test prices are followed in the future and appropriate pricing is secured going forward.**

During the COVID-19 public health emergency, the CAP had also requested immediate national coverage for multiplex polymerase chain reaction (PCR) respiratory viral panel (RVP) tests and recommended that the Centers for Medicare and Medicaid Services (CMS) remove local coverage barriers and provide uniform national coverage for the clinical diagnostic laboratory tests that may be performed without a practitioner order. Providers needed the ability to rapidly identify the pathogen causing the patient's symptoms to ensure they were in fact COVID-19 negative, and then appropriately isolate or cohort a patient accordingly. Many respiratory pathogens presented similarly in patients, and it was difficult to differentiate between influenza, coronavirus, rhinoviruses, and many other pathogens without accurate testing. Ensuring rapid results with uniform coverage policies would have helped triage patients and minimize disease transmission during the pandemic. **Therefore, the CAP urges the Committee to consider policies to establish mechanisms to ensure adequate coverage and reimbursement of tests during a PHE.**

Authorize Funding to Strengthen the Laboratory Workforce

To ensure the health of the nation's diagnostics infrastructure, policymakers should take steps to strengthen our nation's laboratory workforce. Laboratory professionals, the physician and non-

physician workforce, are critical to efforts to identify and remediate the spread of infectious diseases, such as COVID-19. They perform approximately $13 billion laboratory tests each year, the single highest-volume medical activity affecting Americans' health care. The information these professionals provide is essential for patients to receive safe, effective, and efficient care from their providers. Recent surveys of physicians estimate that 60-70% of medical decisions regarding a patient's diagnosis and/or treatment are impacted by laboratory test results.

Unfortunately, like the physician shortage which the CAP recently submitted comments on, many laboratories currently suffer from personnel shortages and are operating at or near crisis-mode. The educational costs borne by health professionals also pose a considerable barrier to career entry for many underrepresented minority students, whose economic resources tend to be less than those of other students. Non-physician medical laboratory professionals are generally not eligible for federal workforce development programs. Therefore, the CAP urges the Committee to consider the following proposals to strengthen the laboratory workforce during the reauthorization of PAHPA:

- **Fund and expand eligibility for federal scholarship, fellowship, and loan repayment programs;**
- **Utilize federal resources to raise the visibility of careers like laboratory medicine with support of career fairs, public service announcements, etc. Programs like the Centers for Disease Control and Prevention OneLabVR, for example, could be utilized at school career fairs to educate students about medical laboratory and other careers;**
- **Provide funding to increase the availability and capacity of accredited laboratory training programs;**
- **Incentivize service as medical laboratory faculty by increasing funding for the Faculty Loan Repayment Program; and**
- **Expand the National Health Service Corps Scholarship Program to include laboratory personnel.**

Set Medicare Reimbursement for Clinical Laboratory Services on a Sustainable Path

Finally, the CAP believes setting Medicare reimbursement for clinical laboratory services on a sustainable path is necessary for maintaining laboratory operations and capacity, which is all the more important in the wake of the COVID-19 pandemic. As we plan and prepare for future pandemics, it is critical that our laboratories can focus on providing timely, high quality clinical laboratory services for patients, can continue to innovate, and build the infrastructure necessary to protect public health and the CAP believes the Committee has an opportunity to address this during the reauthorization of PAHPA.

In 2014, Congress passed the Protecting Access to Medicare Act (PAMA; P.L. 113-93) to reform the Medicare clinical laboratory fee schedule (CLFS) to a single national fee schedule based on private market data from all types of laboratories that service Medicare beneficiaries, including independent laboratories, hospital outreach laboratories, and physician office laboratories (POLs). Unfortunately,

the first round of data collection in 2017 failed to capture an adequate and representative sample of private market data, leaving out virtually all hospital outreach laboratories and significantly under sampling POLs. The significant under sampling led to nearly $4 billion in cuts to those laboratories providing the most commonly ordered test services for Medicare beneficiaries. For context, the total CLFS spend for 2020 was only $8 billion, less than 3% of Medicare Part B spending.

Congress has intervened four times on a bipartisan basis to delay the next CLFS reporting periods and three times to delay cuts to maintain access to laboratory services for patients. However, without a sustainable solution to this problem, laboratories will face another round of cuts of up to 15% in January 2024, at a time when we remain at the forefront of patient care and responding to public health disruptions and threats, such as COVID-19.

The Saving Access to Laboratory Services Act, or SALSA (S.1000/H.R. 2377), is a permanent solution that would set Medicare reimbursement for clinical laboratory services on a sustainable path going forward. SALSA will give the CMS new authority to collect private market data through statistically valid sampling from all laboratory segments for the widely available test services where previous data collection was inadequate. The bill ensures true private market rates are included and provides a much-needed reduction in the reporting burden. By providing a gradual phase-in approach, the bill protects clinical laboratories, the Medicare program, and patients from the impact of dramatic rate increases or decreases.

To ensure our laboratories are prepared to operate at full capacity during a future pandemic, the CAP urges the Committee to add SALSA to the PAHPA reauthorization.

In closing, the CAP appreciates the opportunity to respond to the PAHPA reauthorization discussion draft. Should you have questions please contact Darren Fenwick at dfenwic@cap.org.

Sincerely,

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President, College of American Pathologists