COLLEGE of AMERICAN PATHOLOGISTS

December 14, 2022

The Honorable Nancy Pelosi
Speaker
United States House of Representatives
1236 Longworth House Office Building
Washington, D.C. 20515

The Honorable Charles Schumer
Majority Leader
United States Senate
322 Hart Senate Office
Washington, D.C. 20510

The Honorable Kevin McCarthy
Minority Leader
United States House of Representatives
2468 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Mitch McConnell
Minority Leader
United States Senate
317 Russell Senate Office Building
Washington, D.C. 20510

Dear Speaker Pelosi, Leader Schumer, Leader McCarthy, and Leader McConnell:

The College of American Pathologists (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 we provide drives treatment decisions that optimize outcomes for patients. We play an integral role in the diagnosis of diseases such as cancer (breast, prostate, cervical, leukemia, and kidney), hepatitis, and cirrhosis. Further, pathologists are on the frontline of the current COVID-19 and mpox pandemics. We are responsible for developing and selecting new test methodologies, validating, and approving tests for patient use, and expanding the testing capabilities of the communities we serve to meet emergent needs.

We appreciate the steps Congress took to mitigate the impact of the COVID-19 pandemic. As you deliberate an end of year funding package, we urge you to consider the inclusion of additional provisions that we believe will improve the lives of Americans across the country by expanding access to health care coverage and improving access to high-quality care. The CAP hopes these additions will be included in any final legislative package passed by Congress. Specifically, we are requesting that the end of year package:

- Prevent the entire 4.5% evaluation and management (E/M) reduction to Medicare payment rates from being implemented on January 1, 2023, to allow stakeholders time to work with Congress to evaluate a potential permanent solution;
- Ensure quality laboratory testing for patients and minimize the regulatory burden on laboratories, while allowing for continued innovation in laboratory testing (S. 2209/H.R. 4128);
- Reduce administrative burden on laboratories and ensure accurate collection of private market data through statistically valid sampling from all laboratory segments (S.4449/H.R. 8188); and
- Establish state stockpiles of medical products and supplies needed during a public

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health emergency (S. 3799).

Evaluation and Management Services

As you know well, on January 1, 2023, absent congressional action, pathologists will face significant cuts in the Medicare Physician Fee Schedule (MPFS) for 2023. These cuts combined with cuts from sequestration, PAYGO, and the impact of inflation will have major consequences for Medicare patients who need access to laboratory services, such as cancer screenings, mpox, and COVID tests. **Therefore, the CAP strongly urges you to prevent the entire 4.5% reduction to Medicare payment rates from being implemented on January 1, 2023. This desperately needed relief will help provide financial stability for practices until permanent payment reforms are established.**

On top of this 4.5% MPFS payment cut, medical practices throughout the country are experiencing significant inflationary pressures. Since the MPFS is the only payment system within Medicare lacking an annual inflationary update, clinicians, many of whom are small business owners, contend with a wide range of shifting economic factors, such as staff salaries, building rent, and purchase of essential technology, when determining their ability to provide care to Medicare beneficiaries.

In short, with workforce shortages, addressing the current pandemic, preparing for future pandemics, and inflationary pressures, now is the time to invest in our nation's laboratory infrastructure, not erode it. Therefore, we urge you to stop the entirety of the upcoming 4.5% reduction.

The Verifying Accurate Leading-edge IVCT Development Act

The Verifying Accurate Leading-edge IVCT Development Act, or the VALID Act (S. 2209/H.R. 4128), is the bipartisan product of a four-year open and iterative process that has garnered input from multiple stakeholders, including the CAP. It reflects many of the policy priorities advocated by the CAP since 2009. As such, the CAP believes that the VALID Act establishes a reasonable and balanced regulatory framework that will ensure quality laboratory testing for patients and minimize the regulatory burden on laboratories while allowing for continued innovation in laboratory testing. In the CAP's view, the legislation strikes an appropriate balance and provides ample time (five years) to perfect the framework of the bill through the regulatory process, which requires continued engagement between the U.S. Food and Drug Administration (FDA) and all stakeholders.

Further, the legislation grandfathers all existing laboratory developed tests (LDTs) to allow laboratories to continue to offer tests to patients as the bill works its way through the regulatory process. Additionally, to support continued innovation and flexibility, the VALID Act includes several exemptions including: a humanitarian test exemption, sometimes referred to as rare disease tests exemption, exemptions for low-volume tests, exemptions for modified tests, exemptions for tests requiring manual interpretation, and low-risk tests. VALID also includes language directing the FDA to avoid issuing or enforcing regulations that are duplicative of

existing regulations, like the Clinical Laboratory Improvement Amendments (CLIA), and bars the FDA from infringing on the practice of medicine. The CAP opposes any attempt to weaken the legislation by issuing broad exemptions for places where tests are developed. We believe the risk-based system should provide the basis for oversight rather than the location of where the test is performed.

This legislation addresses a longstanding issue that has been recognized by the administrations of both parties. Several past FDA commissioners are pushing for Congress to pass VALID, and support for the legislation ranges from patient groups to diagnostic companies. Now is the time for Congress to implement true diagnostics reform and not allow FDA to dictate how LDTs will be regulated.

The VALID Act reflects many of the policy priorities advocated by the CAP since 2009 and the current federal approach to oversight has fueled regulatory uncertainty that jeopardizes investment in the next generation of diagnostics that will provide for improved patient outcomes. **As such, the CAP believes that the VALID Act establishes a reasonable and balanced regulatory framework that will ensure quality laboratory testing for patients and minimize the regulatory burden on laboratories while allowing for continued innovation in laboratory testing and urges its inclusion in an end of year package.**

The Saving Access to Laboratory Services Act

In 2014, Congress passed the Protecting Access to Medicare Act, or 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 labs, hospital outreach labs, and physician office labs (POLs). Unfortunately, the first round of data collection in 2017 failed to capture adequate and representative private market data, leaving out virtually all hospital outreach labs and significantly under sampling POLs. The significant under sampling led to nearly $4 billion in cuts to those labs 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 on a bipartisan basis three times to delay the next CLFS reporting periods and twice to delay cuts to maintain access to lab services for patients. However, without a sustainable solution to this problem, labs will face another round of cuts of up to 15% in January 2023, 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.4449/H.R. 8188), is a permanent solution that would set Medicare reimbursement for lab services on a sustainable path forward. SALSA will give the Centers for Medicare and Medicaid Services (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, provides a much-needed reduction in reporting

burden. By providing a gradual phase-in approach, the bill protects clinical labs, the Medicare program, and patients from the impact of dramatic rate increases or decreases.

The CAP urges Congress to include SALSA in an end of year package to allow laboratories to focus on providing timely, high quality clinical laboratory services for patients, continuing to innovate, and building the infrastructure necessary to protect the public health.

The Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act

During the COVID-19, pathologists have been on the frontline of the crisis, responsible for ensuring prompt and accurate testing for patients and health care providers alike. The CAP believes boosting U.S. genetic surveillance and viral sequencing, via partnerships with private sector laboratories, for example, is key to moving beyond the COVID-19 pandemic and effectively responding to future challenges, including novel and evolving infectious diseases, as well as seasonal threats like antimicrobial resistance and foodborne pathogens.

While testing capacity in the United States has increased dramatically, there is room for improvement. Laboratory directors continue to cite problems acquiring testing supplies, particularly test kits, medical-grade plastic pipette tips (which are also used to test for other diseases, including sexually transmitted infections), specimen acquisition swabs, and transport media as the greatest barriers to increased testing.

Establishing state stockpiles of medical products and supplies needed during a public health emergency, such as personal protective equipment, ventilators, and other medical products, is crucial. We further support improvements to the strategic national stockpile by partnering with medical product manufacturers, distributors, or other entities to increase the stockpiling and manufacturing capacity of reserve amounts of medical products to be provided during or in advance of a public health emergency.

For these reasons, the CAP urges you to include the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act, or the PREVENT Pandemics Act (S. 3799), in an end of year package. The legislation is a strong step forward to address many of the issues our health care system faced during the pandemic and changes needed to prepare for the next outbreak. We must have a clear understanding of what happened so the same mistakes do not occur again and take concerted steps to be prepared for the next pandemic.

Summary

The current pandemic has brought to the forefront the vital role of pathologists and the value that we bring to medicine. Now more than ever patients and their treating physicians are relying on the expertise of pathologists. Pathologists and the services we provide, including ensuring laboratory quality in communities across the United States, are at the foundation of

our health care system. We cannot allow this foundation to erode any further.

We thank you for considering our requests and look forward to working with you and your staff to strengthen this important legislative package. If you have any questions, concerns, or need additional information, please do not hesitate to contact Hannah Burriss, CAP Assistant Director, Legislation and Political Action, at hburris@cap.org.

Sincerely,

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