



COLLEGE of AMERICAN PATHOLOGISTS

May 25, 2021

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 Building
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:

On behalf of the College of American Pathologists (CAP), we appreciate your continued efforts to combat and address the ongoing impacts of the COVID-19 pandemic. As you move forward with an infrastructure package, we urge you to include some additional resources as the public health emergency continues and several challenges remain.

Pathologists are the physician specialists who diagnose disease. The CAP's members and the laboratories they direct have worked tirelessly since the coronavirus outbreak to bring new COVID-19 tests online in communities throughout the United States. Pathologists also have an integral role in the diagnosis of cancer (breast, prostate, cervical, leukemia, kidney), hepatitis, and cirrhosis. The expertise our members provide drives treatment decisions that optimize outcomes for patients. As a result of the public health crisis, many pathologists are seeing an increase in staff burnout and continued financial losses, which threaten the viability of practices. Now more than ever, patients and their treating physicians are relying on the expertise of pathologists to meet increasing diagnostic testing needs and achieve healthier outcomes for all Americans.

Laboratory Infrastructure

The CAP supports the inclusion of a \$4.5 billion pilot program for renovating and modernizing clinical laboratory infrastructure, specifically to help improve COVID-19 testing and response activities. This program must be accessible to clinical laboratories as defined in section 353 of the Public Health Service Act (42 U.S.C. 263a). To respond to the pandemic, pathologists were forced to diversify. This diversification included the development of more than one nucleic acid test method and multiple analytical platforms. These efforts took place in order to address unprecedented shortages and unmet demands for more accessible testing in their local communities. Pathologists and laboratories responded to this challenge and some now need assistance to renovate and modernize their infrastructure.

The CAP supports additional federal funding for the Centers for Disease Control and Prevention (CDC) to respond to the COVID-19 pandemic and to prepare for future



pandemics. The \$30 billion in funding outlined in the President's plan for "investments to shore up our nation's strategic national stockpile; accelerate the timeline to research, develop and field tests and therapeutics for emerging and future outbreaks; accelerate response time by developing prototype vaccines through Phase I and II trials, test technologies for the rapid scaling of vaccine production, and ensure sufficient production capacity in an emergency; enhance U.S. infrastructure for bio preparedness and investments in biosafety and biosecurity; train personnel for epidemic and pandemic response; and onshore raw materials for testing supply manufacturing and active pharmaceutical ingredients" is a strong step to control the current pandemic and ensure we are prepared for any future outbreaks. The funding should also support core public health capacity improvements in States and Territories, modernize public health data collection nationwide, train new epidemiologists and other public health experts, and build international capacity to detect, prepare for, and respond to emerging global threats.

While testing capacity in the United States has increased dramatically, there is room for further improvement. Surveys of laboratory directors have consistently reported excess overall testing and instrument capacity, but they are constrained by several limitations. Laboratory directors cite problems acquiring testing supplies, particularly test kits, plastic pipette tips (which are also used to test for other diseases, including sexually transmitted infections), specimen acquisition swabs, and transport media as great barriers to increased testing. For example, smaller health systems continue to struggle to get supplies, which limit capacity for rapid testing for triage in emergency room departments, placement in behavioral health and psychiatric programs, and testing for women who are in labor.

Support for Pathology Practices

Ongoing testing and analysis by pathologists are imperative to arresting the spread of the disease and its variants. Testing will continue to be an important component of reopening our economy and schools safely. At this juncture, it is critical that Congress expand its investments to ensure timely and accurate testing through increased testing reimbursement. Unfortunately, Medicare reimbursement rates for COVID-19 tests have failed to account for the costs and resources necessary to continue testing during the pandemic for laboratories of all sizes and localities—especially those in critical access and rural areas serving underserved populations. The current rates tend to economically disadvantage the typical primary testing providers in the acute care hospital and academic laboratory settings who are responsible for rapidly identifying and caring for COVID-19 patients in the midst of this pandemic. To confront the critical laboratory reimbursement issue, we ask Congress to work with the Biden administration to address the inadequate reimbursement rates for SARS-CoV-2 nucleic acid tests and abandon flawed Medicare payment/coverage policies. We are greatly concerned that provider laboratories cannot sustain these underpayments indefinitely, along with the other overall increased costs associated with doing business during the national public health emergency.



Health Workforce

The CAP appreciates the financial support offered to physicians, physician practices, laboratories, and medical examiner offices during this public health emergency. Congress recognized the financial strain placed on providers, and appropriated funds offering financial relief to physicians and other health care providers. We continue to support the allocation of financial support through the Provider Relief Fund and other direct funding mechanisms to keep pathology practices open, especially those meeting the needs of underserved populations, and allow these physicians to focus on the essential task of testing and ensuring proper treatment. The Medicare Accelerated and Advance Payment Program has been important to providing financial support for pathologists, especially those less equipped to weather this financial crisis. Moving forward, the CAP encourages Congress to continue to provide funding and flexibility through these programs for those who are still in need of support.

Extension of Evaluation and Management Relief

Additionally, the CAP requests that Congress extend the relief provided in the Consolidated Appropriations Act of 2021 to mitigate the impact of the Centers for Medicare and Medicaid Services (CMS) 2022 payment reductions to all non-evaluation and management (E/M) services. We continue to work with Congress and impacted physician organizations to find a long-term plan to deal with this issue. As we are still working our way through the pandemic and starting to recover, a Medicare payment cut to all pathology services in 2022 is not prudent. Without continued relief, pathologists will see payment cuts of 6% to all pathology services, following a roughly 3% cut in 2021, to help fund increases in payment for E/M services. This is on top of other economic shifts adversely affecting pathology practices related to major financial dislocations because of the pandemic. These cuts would adversely impact small and rural hospitals. Many such hospitals are already in trouble financially. The patients that they serve include some of our most vulnerable, communities of color, and economically disadvantaged populations.

While Congress has made incredible investments in testing, vaccines, and economic support to physicians and their patients to address the impact of the pandemic, the instability caused by the pandemic remains and is likely to for several years. Therefore, we urge Congress to extend the relief provided in the Consolidated Appropriations Act of 2021 for 2022. Specifically, we ask that Congress appropriate an additional \$3 billion to mitigate the impacts of cuts to pathology and other effected physician and nonphysician services beginning in 2022 and maintain the 3-year moratorium on the G2211 code. This much-needed action by Congress will provide stability to pathologists and their patients at this critical time.

Summary

As Congress works to tackle big issues in the infrastructure bill, the CAP urges you to consider our recommendations to support laboratory infrastructure, resources for testing,



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and public workforce investments in any comprehensive strategy. While Congress has made incredible investments in testing, vaccines, and economic support to physicians and their patients to address the impact of COVID-19, the instability caused by the pandemic remains and is likely to be a factor for several years. Now more than ever patients and their treating physicians are relying on the expertise of pathologists. Pathologists and the services they provide, including ensuring laboratory quality in communities across the United States, are at the foundation of our health care system. Now is not the time to erode that foundation.

We welcome the opportunity to work with you to address these issues to accelerate the discovery, development, and delivery of cutting-edge medicine and treatments for all Americans. Please contact Sarah Bogdan via email at sbogdan@cap.org or via phone at (401) 316-5144 if you have any questions regarding these comments.

Sincerely,

Patrick Godbey, MD, FCAP
President