



COLLEGE of AMERICAN PATHOLOGISTS

February 19, 2021

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

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

Dear Majority Leader Schumer and Minority 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. Despite approaching a year of crisis, the public health emergency continues and many of the challenges we have outlined previously remain. As you move forward with the next relief package, we urge you to include increased resources for testing, enhancements to existing relief programs, and additional provisions to support physicians and laboratories.

As pathologists are the physician specialists who diagnose disease, CAP 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 play an integral role in the diagnosis of cancer (breast, prostate, cervical, leukemia, kidney), and medical diseases such as hepatitis and cirrhosis. The expertise our members provide drives treatment decisions that optimize outcomes for patients. Yet, the pressures faced by pathologists and the rest of the laboratory workforce have increased over the course of the pandemic. As a result of the public health crisis, many are seeing an increase in staff burnout and continued financial losses, which threatens 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.

Resources for Testing

Unfortunately, COVID-19 remains uncontrolled across the country while the nation is trying to reopen. Further, despite the development of much needed vaccines, several more contagious strains of COVID-19 are spreading rapidly, including in the United States. Testing and analysis by pathologists is imperative to arresting the spread of the disease and its variants. At the same time, testing is also a necessary and important component of reopening our economy and schools safely. As such, it is critical that Congress expand its investments to ensure timely and accurate testing and increased testing reimbursement. Specifically, the CAP supports funds for an expansion of testing and would emphasize that these funds should be used for a broad range of tests, including SARS-CoV-2 nucleic acid tests, for a variety of communities and settings.

We also support funding to increase our country's "sequencing, surveillance, and outbreak analytics capacity at the levels demanded by the crisis." It is critical for the United States to increase viral sequencing and genomic surveillance to respond to the evolving challenges of



the pandemic. As you know, three new SARS-CoV-2 variants have emerged in our nation and it is crucial for the U.S. to identify, track and trace to mitigate the impact of these emerging strains. Congress needs to support and expand funding to boost viral sequencing and genomic surveillance.

Further, the CAP urges Congress to work with the Centers for Medicare & Medicaid Services (CMS) and increase reimbursement for COVID-19 testing. Medicare reimbursement rates for COVID-19 tests have failed to account for the costs and resources necessary to continue testing during the national public health crisis for laboratories of all sizes and localities. The current rates tend to preferentially favor the large, high volume testing providers while economically disadvantaging the typical testing providers in the local 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. In fact, a majority of these frontline providers have been forced to diversify and develop more than one nucleic acid test method and multiple analytical platforms to help address the unprecedented shortages and unmet demands for expanded and more accessible testing in their local communities. Additional recent policies, CMS-2020-1-R and CMS-2020-2-R2, cut the payment for certain high-throughput COVID-19 tests by 25 percent, while requiring laboratories to meet a number of additional reporting requirements to make up the difference. In practice, the policy penalizes laboratories for issues related to supply shortages and other factors outside its control.

The CAP also has requested immediate national coverage for multiplex polymerase chain reaction (PCR) respiratory viral panel (RVP) tests and recommends that the CMS provide uniform national coverage for the clinical diagnostic laboratory tests that may be performed without a practitioner order, by removing a local coverage barrier during the COVID-19 public health emergency. Providers need the ability to rapidly identify the pathogen causing the patient's symptoms to ensure they are in fact COVID-19 negative, and then appropriately isolate or cohort a patient accordingly. Many respiratory pathogens present similarly in patients and it is difficult to differentiate between influenza, coronavirus, rhinoviruses, and many other pathogens without accurate testing. Ensuring rapid results with uniform coverage policies is essential to triaging patients and minimizing disease transmission.

To confront these critical laboratory reimbursement issues, the CAP urges Congress to work with the administration to address the inadequate reimbursement rates for SARS-CoV-2 nucleic acid tests and abandon flawed CMS 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.

Ongoing Support and Flexibility for Health Care Providers

As the public health emergency continues, physicians, physician practices, laboratories, and medical examiner offices remain stressed and in need of ongoing support and flexibility. The shift in health care priorities, increase in non-reimbursable expenses, and disruption of non-essential surgeries and other procedures continues to result in significant financial losses



that threaten the viability of many small and mid-size physician practices. Throughout 2020, Congress recognized the financial strain placed on providers, and appropriated funds offering financial relief to physicians and other health care providers. The CAP continues to support the allocation of additional financial support through the Provider Relief Fund and other direct funding mechanisms to keep pathology practices open and available to patients, while allowing providers to focus on the essential task of testing and ensuring proper treatment. Specifically, we support the Senate's recent efforts to replenish the Provider Relief Fund by \$35 billion, with 20 percent set aside for rural hospitals.

The CAP appreciates the efforts by Congress to improve other financial relief programs, including the Paycheck Protection Program (PPP) and Medicare's Accelerated and Advance Payment Program. These programs have been important to providing financial support for pathologists, especially those less equipped to weather this financial crisis, for example, with limited ready access to capital. The positive changes Congress made to the Accelerated and Advance Payment Program will be critical for these practices, as is the flexibility and clarification provided regarding the PPP. Moving forward, the CAP encourages Congress to continue to provide funding and flexibility through the PPP for those who still need it.

To further support frontline physicians, the CAP has requested that Congress provide federal student loan forgiveness for residents and physicians, as well as tuition relief to medical students who provide care for patients with COVID-19. Additionally, the CAP also supports H.R. 315, the Medicare Sequester COVID Moratorium Act, to extend the current suspension of the two percent across-the-board Medicare sequester for the duration of the COVID-19 public health emergency.

Improvements to the Strategic National Stockpile and Supply Chain

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 as they are being 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 the greatest 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 psych programs, and testing for women who are in active labor.

As such, the CAP supports the proposal to invest \$30 billion into the Disaster Relief Fund and to provide 100 percent federal reimbursement for critical emergency response resources to states, local governments, and Tribes, including deployment of the National Guard. We also support the provision of an additional \$10 billion investment in expanding domestic manufacturing for pandemic supplies and any efforts to fully use the Defense Production Act.



Vaccines

Regarding vaccination efforts, the CAP can serve as a resource to reinforce guidance and best practices from the CDC and other agencies. For example, following the approval of the COVID-19 vaccine in December the CAP issued a statement encouraging its members to take advantage of access to the vaccine and complete the course for inoculation. And, the CAP has issued guidance to the public on serology testing. Each communication focuses on the facts, evidence, and scientific rationale for public health guidance to assist state and local governments and an informed citizenry to make the right decisions.

The CAP also supports congressional efforts to invest in vaccine distribution and guarantee all Americans have access to the vaccine without patient cost sharing. Specifically, the CAP supports the \$20 billion for a national vaccination program outlined in the American Rescue Plan. Additionally, the CAP urges Congress to do everything in its power to support improvements to sustained manufacturing surge capacity and capabilities to produce needed medical countermeasures, such as vaccines and therapeutics, to respond to public health threats like COVID-19 in the future.

Public Health Workforce

We support the provision to include \$7.6 billion to HHS for efforts related to establishing, expanding, and sustaining a public health workforce, and to make awards to state, local, and territorial public health departments. Workforce investments that include lab personnel are an important piece of our ability to address the pandemic. Additionally, urge the committee to include support for medical examiners. Medical examiner offices have faced unprecedented challenges to complete death investigations and examinations. Forensic pathology services have had a key role in understanding the effects of COVID-19 and informed treatments as the country progressed throughout 2020. As deaths increased, medical examiners and coroners further assisted communities in this public health crisis with their expertise in handling the dead by, for example, meeting needs for increased body transport and storage. The CAP encourages Congress to support efforts to extend federal funds addressing the fiscal impacts of the pandemic, which include support for medical examiner services that are often overlooked.

Financial Support for Frontline Providers

The CAP urges Congress to fund and expand hazard pay measures available for health care providers. Further, the CAP asks that the hazard pay provisions include the full range of staff and providers within pathology and laboratory medicine, including physicians and laboratory personnel working in hospitals and independent labs as well as those providers involved in forensic pathology and death investigations. The CAP also supports emergency funding for state, local, and territorial governments to keep frontline health workers “on the job and paid, while also effectively distributing the vaccine, scaling testing, reopening schools, and maintaining other vital services.”



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Summary

As Congress works to further address the COVID-19 pandemic, we urge you to consider our recommendations to support testing services and laboratory frontline providers in any comprehensive strategy. The current pandemic has brought to the forefront the vital role of pathologists and the value that they bring to medicine. Pathologists are integrally involved in direct mitigation of the COVID-19 crisis including testing for accurate and timely diagnosis, as well as work on potential cures. 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. We cannot allow this foundation to erode any further.

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