



COLLEGE of AMERICAN PATHOLOGISTS

August 3, 2020

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

The Honorable Mitch McConnell
Majority Leader
United States Senate
317 Russell 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 Charles Schumer
Minority Leader
United States Senate
322 Hart Senate Office Building
Washington, D.C. 20510

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

On behalf of the College of American Pathologists (CAP), I appreciate your continued efforts to provide relief from the ongoing impacts of the COVID-19 pandemic. As you move forward with developing and negotiating the next relief package, the CAP urges you to include enhancements to existing programs and additional provisions to assist physicians caring for patients.

Pathologists are physicians who specialize in the diagnosis of disease. The expertise they provide drives treatment decisions that optimize outcomes for patients. Pathologists play an integral role in the diagnosis of diseases such as cancer (breast, prostate, cervical, leukemia, kidney), hepatitis, cirrhosis, and the novel coronavirus (COVID-19). 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. Further, laboratories are imposing hiring freezes, reducing benefits, furloughing employees, and cutting pay. At the same time, now more than ever patients and their treating physicians are relying on the expertise of pathologists to meet increasing diagnostic testing needs. The federal government must support pathologists and the laboratories they lead.

Support for Pathology Practices

The CAP is encouraged by Phase IV COVID-19 legislative proposals introduced in the House and Senate, which include funding to reimburse physicians and other providers of health care for expenses and lost revenue directly attributable to the public health emergency resulting from the pandemic. **We support proposals that allocate additional moneys for the Provider Relief Fund.** Legislation from the House and Senate would also utilize and improve the Medicare Accelerated and Advance Payment Program. Lowering the interest rate for loans to Medicare providers, reducing the per claim recoupment percentage, and extending the period before repayment begins are all positive steps. These changes will better ensure that pathologists can utilize this financial support and continue to focus on the essential task of testing and ensuring proper treatment of patients.



The CAP is concerned, however, that the Centers for Medicare & Medicaid Services (CMS) suspended the program in April and has not reinstated the program so physician practices can access these loans. **Therefore, the CAP urges Congress to work with the CMS to restart this program to offer loans to providers once again.**

In addition, the CAP supports House and Senate proposals to add more funding and greater flexibility to the Paycheck Protection Program (PPP) that will further relieve financial stresses on small businesses, including pathology practices and laboratories.

The CAP also urges Congress to enact targeted liability protections where health care services are provided or withheld in situations that may be beyond the control of physicians/facilities (e.g., following government guidelines, directives, lack of resources) due to COVID-19. Protections should also extend to those who provide care in good faith during the COVID-19 public health emergency (plus a reasonable time, such as 60 days, after the emergency declaration ends). These liability protections would not extend to situations of gross negligence or willful misconduct.

Support for Additional Testing Resources for Pathologists and Clinical Laboratories

Unfortunately, COVID-19 cases across the country are increasing while the nation is trying to reopen. As such, it is imperative that people have access to timely and accurate testing. Therefore, it is important that Congress include a significant financial investment in testing. Testing is a necessary and important component of reopening our economy and schools safely.

The CAP believes that the cost structure of the typical laboratory performing SARS-CoV-2 testing should be considered when these prices are determined. This will ensure that a large network of laboratories are available to perform testing as long as adequate supplies are available. The CMS previously announced payment rates of about \$36 for CDC-developed coronavirus tests, approximately \$51 for laboratories performing non-CDC tests, and \$100 for tests making use of high throughput technologies. These payment rates have caused great concern and confusion amongst providers. **We are requesting Congress allocate additional funds, as necessary and appropriate, to increase the reimbursement rate for COVID-19 tests.**

Large independent and reference laboratories have significantly different cost structures (lower costs) than do medium and small hospital laboratories. The CAP believes that the cost structures of the typical laboratory performing SARS-CoV-2 testing should be taken into account when these prices are determined. Currently, reimbursements for the tests are inadequate and the federal government should establish prices that sufficiently cover the costs of all the work and supplies involved in a test.



Furthermore, the CAP supports additional funding for contact tracing so state and local governments can fund COVID-19 testing and surveillance activities. The CAP was encouraged that both House and Senate legislative proposals include additional funds for monitoring and suppressing transmission of the coronavirus.

Improvements to the Strategic National Stockpile and Supply Chain

Many laboratories also report excess overall testing and instrument capacity but are being constrained by a variety of limitations. Laboratory directors cite problems acquiring testing supplies, particularly test kits, plastic pipette tips, and specimen acquisition swabs and transport media as the greatest barriers to increased testing. To address these supply chain issues, improvements are needed.

As such, we support inclusion of the following Senate provisions for strengthening the Strategic National Stockpile (SNS):

- Requiring the Secretary for Health and Human Services (HHS), in coordination with the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC), to consult with medical product manufacturers, suppliers, and other relevant stakeholders to identify specific supply needs, including specimen collection and transport materials, reagents, and other supplies; identify projected demand and availability of such supplies; and support activities to increase the availability of such supplies or appropriate alternatives.
- Improving and supporting 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.
- Establishing state stockpiles of medical products and supplies needed during a public health emergency, such as personal protective equipment, ventilators, and other medical products.
- Ensuring that state stockpiles will be appropriately administered and maintained by directing the Secretary to establish an auditing process and withholding funds if a state fails to submit a state stockpiling plan or meet certain benchmarks and other metrics.
- Improving the SNS 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.
- Requiring HHS to publish guidance on how states and tribes can request and access resources from the SNS.

In addition, the CAP also supports the following select provisions from the House's HEROES Act to strengthen the SNS:

- Require the HHS Secretary to ensure that contents of the SNS are in good working order and, as necessary, conduct maintenance on contents of the stockpile.
- Improve the SNS financial security by allowing the SNS to sell products to other federal departments or agencies within six months of product expiration.
- Require the SNS to develop improved transparent processes for SNS requests and identify clear plans for future communication between the SNS and states.



Support Funding to States and Local Governments for Medical Examiners

We support efforts to extend federal funds addressing the fiscal impacts of the pandemic affecting state, local, and tribal governments. While this support is needed, there should be a direct commitment that any money will assist medical examiners who are dealing with an increased volume of work and have a key role in understanding the impact of COVID-19. Our nation continues to suffer from a shortage of forensic pathologists, and state and local governments have not been able to keep up with providing the funding needed to ensure adequate resources are available to provide these services. We remain concerned that without specific designation, the money will be used for other priorities. We urge the inclusion of additional funding to the states for these important services.

Support Additional Funding for the CDC

The CAP fully supports proposals by the House and Senate to provide additional funding to the CDC. This funding will further assist federal, state, and local public health agencies prevent, prepare for, and respond to the coronavirus. In addition, the CAP supports congressional efforts to update and integrate public health systems that allow for improved preparedness for, as well as prevention and detection of future pandemics. This effort should include the input of pathologists as the laboratory experts to advise on systems for health communications and surveillance networks that will modernize public health situational awareness and bio-surveillance.

Summary

As Congress works to further address the COVID-19 pandemic, the CAP urges 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 during this national emergency.

The CAP welcomes the opportunity to work with you to address these issues to ensure Americans have access to diagnostic testing and that we take steps toward reopening the country. Please contact Michael Giuliani via email at mgiulia@cap.org or via phone at (443) 510-3039 if you have any questions regarding these comments.

Sincerely,

Patrick Godbey, MD, FCAP
President, College of American Pathologists