



COLLEGE of AMERICAN  
PATHOLOGISTS

March 20, 2020

The Honorable Mitch McConnell  
Senate Majority Leader  
U.S. Senate  
317 Russell Senate Office Bldg.  
Washington, D.C. 20510

The Honorable Chuck Schumer  
Senate Minority Leader  
U.S. Senate  
322 Hart Senate Office Bldg.  
Washington, D.C. 20510

Dear Leader McConnell and Minority Leader Schumer:

*RE: Phase III – Coronavirus Aid, Relief and Economic Security (CARES) Act*

The College of American Pathologists (CAP) urges the inclusion of needed relief for pathologists by requiring the CMS to grant a temporary waiver of CLIA rules requiring pathologists to be on site to read-out their cases in order to protect the laboratory workforce during this national health emergency. Furthermore, there is a need for financial support for pathologist and laboratories on the front-line of this crisis.

We also would like to express support for specific provisions included in the Phase III Cares Act released on March 19 that would improve the availability and access of COVID-19 diagnostic tests for American citizens.

As the world's largest organization of board-certified pathologists and 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.

We believe all laboratories should be given the discretion to determine what is best for their staffs to manage the pandemic and a relaxation of Clinical Laboratory Improvement Amendments (CLIA) restrictions so if needed pathologists and their staffs can work remotely. We must protect our personnel by deploying appropriate protocols to ensure we are not hindered in our ability to test and treat patients. At this crucial time a disruption in our workforce is counterproductive to our best interest and especially to the patients we serve.

Almost all pathologists have the infrastructure to sign-out cases from remote facilities but do not currently because of requirements under CLIA'88 that state that tests must be performed at a CLIA-licensed facility. Remote sign out currently requires each remote location to have its own CLIA license. During the COVID-19 crisis many pathologists may not be able to be physically present which will unnecessarily delay the diagnoses arising from a lack of in-house pathologists. Some clear examples are those who are under a 14-day quarantine due to testing positive for SARS-CoV-2, but who are asymptomatic. Those who return from a country where the infection is more widespread or who have known significant exposure. As well as pathologists who must remain home to supervise children who cannot be in school or day care.

It is unwise and unnecessary to overburden the remaining pathologists with excess work due to staffing shortages, thereby increasing the risk of burnout, medical error and further shortages in staffing due to exposure. The number of COVID-19 cases will increase and peak over the next two months and will stretch existing healthcare systems to their limits. Pathologists are critical to the ability of the United States to succeed in slowing the spread of the pandemic by ensuring



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accurate and safe testing for all patients. All these pathologists would still be able to remotely sign-out cases thereby ensuring continuity of patient care.

We need the congress to ensure the CMS grants this CLIA waiver during this health care crisis.

The CAP also supports the establishment of a fund up to \$5 billion to support pathology and laboratory front line providers. It should provide help for pathologists and laboratories performing COVID-19 testing services, such as support for laboratory personnel, uncompensated testing, capital and supplies, research and development, and other costs associated with testing.

In addition, the CAP applauds the Senate for including health care provisions in the bill to ensure that both patients have access to and ensure laboratories can provide needed COVID-19 diagnostic testing. Specifically, the emergency use of laboratory developed tests, pricing for diagnostic testing, and coverage of diagnostic testing are strong steps in helping pathology care for patients.

Sincerely,

John Scott  
Vice President,  
College of American Pathologist