

Congress of the United States
Washington, DC 20515

March 25, 2020

Alex M. Azar II, MD
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

Given the President's emergency declaration that provided the Department of Health and Human Services Secretary broader authority to waive provisions of law and regulation to give doctors and hospitals "maximum flexibility to respond to the virus", we request the Secretary to direct the Centers for Medicare and Medicaid Services (CMS) to allow greater flexibility when administering the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Specifically, we are requesting a temporary waiver of the CLIA requirements regarding working remotely and to allow local pathologists and laboratories to determine what is best for their situation.

We believe pathologists and laboratories should be given the discretion to determine what is best for their staffs to manage the pandemic and a relaxation of CLIA restrictions so if needed pathologists and their staffs can work remotely. They must be able to protect their personnel by deploying appropriate protocols to ensure they are not hindered in their ability to test and treat patients. At this crucial time a disruption in this vital workforce is counterproductive to our nations' best interest and to the patient's pathologists serve.

Almost all pathologists have the infrastructure to sign-out cases from remote facilities but do not currently because of requirements under CLIA 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 diagnoses (of numerous diseases not just COVID-19) arising from a lack of in-house pathologists. Some clear examples are pathologists who are under a 14-day quarantine due to testing positive for SARS-CoV-2, but who are asymptomatic, as well as those 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 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.

Providing this waiver will serve to minimize the disruption to the workforce that is occurring while maintaining the best possible patient care. We want to make sure our constituents are getting the care they need while protecting the health care teams that are taking care of them.

cc: Seema Verma

Sincerely,



Earl L. "Buddy" Carter
Member of Congress



Bobby L. Rush
Member of Congress

Roger Marshall, M.D.
Member of Congress

Will Hurd
Member of Congress

Emanuel Cleaver
Member of Congress

Fred Upton
Member of Congress

Tony Cárdenas
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Diana DeGette
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Brian Fitzpatrick
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