



*Better health through
laboratory medicine.*

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:

On March 13th, 2020 President Trump declared a National Emergency to provide the federal government with additional powers to combat the coronavirus. This emergency declaration provides the Secretary of the Department of Health and Human Services with broad authority to “immediately waive provisions of applicable laws and regulations” to provide healthcare providers with the “maximum flexibility” needed to respond to the virus and care patients.

The American Association for Clinical Chemistry (AACC) urges you to utilize this new power to direct the Centers for Medicare and Medicaid Services (CMS) to grant clinical laboratories a temporary waiver from the CLIA provision that requires that testing be performed onsite. A relaxation of this CLIA restriction would permit pathologists and laboratory staff to work remotely, thereby reducing the real possibility of a disruption to this workforce that is critical to reviewing and interpreting tests.

Many laboratory professionals have the infrastructure in place to review and interpret cases from remote facilities but cannot do so because CLIA states that tests must be performed at a CLIA-licensed facility. Therefore, each remote location would need its own CLIA license. In the current crisis, there may be times that pathologists and other laboratory personnel may not be able to be physically present (e.g. self-quarantined, supervising children at home), which could unnecessarily delay diagnoses.

Given that the number of COVID-19 cases will likely increase and peak over the next two months, it is important that pathologists and other laboratory staff be provided the flexibility to review digital slides and images and interpret data remotely. Laboratory professionals are critical to the ability of the United States to slow the spread of the pandemic by ensuring accurate and safe testing for all patients. AACC believes it is vital that laboratory professionals be able to review and interpret tests remotely, thereby ensuring continuity of patient care.

AACC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. AACC brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational

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medicine, lab management, and other areas of clinical laboratory science to advance healthcare through collaboration, knowledge, expertise, and innovation.

If you have any questions, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at vstine@aacc.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Carmen Wiley", with a stylized flourish at the end.

Carmen L. Wiley, PhD, DABCC, FAACC
President, AACC

Cc: Seema Verma
Karen Dyer