COLLEGE of AMERICAN PATHOLOGISTS

Statement to the Clinical Laboratory Improvements Advisory Committee on the Application of Regulations during the COVID-19 Pandemic

The College of American Pathologists (CAP) appreciates the opportunity to provide comments to the Clinical Laboratory Improvements Advisory Committee (CLIAC) on the topic of Application of Regulations during the COVID-19 pandemic. 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 for excellence in the practice of pathology and laboratory medicine worldwide. Regulatory flexibility is needed to respond to pandemics. Since the beginning of this crisis, the federal response has improved greatly with better coordination and alignment of regulatory changes.

A swift process for the relaxation of Clinical Laboratory Improvement Amendments (CLIA) restrictions will allow laboratories the necessary discretion to determine what is best for their staffs to manage the pandemic. During the COVID-19 crisis, laboratories sought to employ appropriate protocols to reduce the risk of infection among their own teams and to avoid hindering their ability to test and treat patients. The CAP specifically requested a temporary waiver of CLIA requirements so pathologists and other licensed health care professionals could utilize remote review and sign out. Further, the CAP requested the agency postpone inspections of accredited laboratories, which would allow personnel to devote the necessary time to fully verify and validate new coronavirus testing assays and redesign operations to accommodate emerging technologies and testing. We are pleased that both these issues were addressed, but they may not have been addressed were it not for appeals from the CAP and Congress.

As the CAP recommended during the October 2020 CLIAC meeting, once a public health emergency (PHE) is declared certain regulatory requirements should be waived or reduced. For example, the Food and Drug Administration (FDA) emergency use authorization is acted upon the PHE declaration. A similar process should be in place for CLIA to allow laboratories the necessary discretion to determine what is best for their staffs to manage the pandemic. Moreover, given the infectiousness of COVID-19 and to meet the demand for COVID-19 testing of symptomatic patients, clinical laboratories established specimen collection drive-through testing locations. While we welcomed the CMS providing flexibility on site locations, the waiver was granted on March 26, 2020 – two weeks after the national emergency declaration, delaying critical testing. Importantly, while we support efforts to streamline administrative procedures for personnel, the CAP strongly believes the current CLIA personnel requirements for testing should be maintained.

The federal agencies should collaborate on guidance to ensure consistency. For instance, clinical laboratories had difficulties managing the differing COVID-19 reporting policy guidance that were released by federal agencies. The Department of Health and Human Services (HHS) released the SARS-CoV-2/COVID-19 data reporting requirements on June 4. The HHS, Centers for Disease Control and Prevention (CDC), and state public health officials have issued multiple, complicated guidance documents that at times contained conflicting information. Consequently, clinical laboratories encountered great confusion and expended significant energy in attempting to understand and to comply with the new mandates.

In addition, certain technical aspects of the requirements pose challenges and barriers to laboratories' compliance. The requirements added numerous clinical data elements, beyond the actual test results, to the data that laboratories must report. The data elements are often not available to the laboratory nor within its information systems or its scope of operations. A related example is the guidance specifies that

clinical laboratories report to the department of public health of the state or locale in which the patient resides (regardless of where the laboratory is located). For many clinical laboratories, meeting these requirements will necessitate working with public agencies and, frequently, health information technology vendors to establish multiple systems interfaces. These processes are costly, laborious, and time-consuming. To successfully combat these challenges, consistent regulatory guidance is needed to support these efforts.

Thank you for the opportunity to comment and the CAP looks forward to working with CLIAC, federal officials, and the clinical laboratory community to develop solutions for COVID-19 and any future pandemics.