Statement to the Clinical Laboratory Improvements Advisory Committee on the Laboratory Data Exchange during COVID-19

The College of American Pathologists (CAP) appreciates the opportunity to provide comments to the Clinical Laboratory Improvements Advisory Committee (CLIAC) on the topic of Laboratory Data Exchange during COVID-19. 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.

The CAP supports clinical laboratory reporting SARS-CoV-2 results as codified in the Coronavirus Aid, Relief, and Economic Security (CARES) Act, which requires every laboratory performing SARS-CoV-2 report positive and negative results to the Secretary; however, we oppose reporting in the manner specified by the Secretary in the guidance released on June 4, 2020 and remain concerned about this unfunded mandate.

The CMS Interim Final Rule imposes new requirements on clinical laboratories for reporting SARS-CoV-2/COVID-19 test results to agencies for public health purposes. On June 4, 2020, HHS issued special requirements that, in addition to positive and negative test results, expanded the clinical data elements that laboratories are expected to report for SARS-CoV-2 tests. CMS has also indicated that it will impose civil monetary penalties (CMPs) as condition-level penalties of $1000 for the first day of noncompliance with the new reporting requirements and an additional $500 for each subsequent day up to a maximum penalty of $10,000 per day of non-compliance.

While supportive of the need for improved public health reporting regarding SARS-CoV-2/COVID-19, the CAP believes that the new rules and penalties place unworkable requirements and undue burden on laboratories during a time in which laboratories' resources must focus on performing vital SARS-CoV-2/COVID-19 testing. Accordingly, the CAP recommends that the CMS/HHS rescind its June 4 guidance regarding SARS-CoV-2/COVID-19 reporting requirements and reconsider the threatened civil monetary penalties.

1. Following release of the HHS SARS-CoV-2/COVID-19 data reporting requirements on June 4th, HHS, CDC, and state public health officials have issued multiple, complicated guidance documents that at times have also contained conflicting information. Consequently, clinical laboratories have encountered great confusion and expended significant energy in attempting to understand and to comply with the new mandates.

2. 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, HIT

vendors to establish multiple systems interfaces. These processes are costly, laborious, and time-consuming.

3. Clinical laboratories have expended great time and energy as required to meet SARS-CoV-2/COVID-19 testing needs amid shortages of swabs, reagents, and testing platforms, and have done so during this period of significant financial pressures. While the CAP understands the intent of imposing monetary penalties in order to encourage compliance, imposing new requirements and systems, and such penalties for noncompliance, further strains clinical laboratories' resources. The CAP requests that the civil monetary penalties be removed, delayed, or reduced in amount, particularly in light of the complexity of the requirements and conflicting messages from agency and other public health officials.

We continue to offer HHS, CDC, State, and clinical laboratories our assistance in mitigating the regulatory burden by discussing ways by developing tools and guidance to automate the process.