July 22, 2020

Secretary Alex M. Azar II
US Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar:

The American Association for Clinical Chemistry (AACC) is commenting on the Department of Health and Human Services (HHS) June 4, 2020 guidance *"COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115"* and its corresponding frequently asked questions document. AACC supports your efforts to collect additional data to develop more effective strategies for addressing the COVID-19 pandemic. We are concerned, however, about the short timeframe for adopting these data reporting changes, particularly since there are several issues that need to be addressed before it takes effect. AACC recommends that you delay the August 1st implementation date until these issues are resolved.

Collection of Data

The guidance states that all laboratories must collect and report data regarding SARS-CoV-2 to the appropriate state or local health department. In a footnote on page two, it clarifies that "facilities collecting specimens may be directed by laboratories to provide the information required to be reported by laboratories." AACC asks that HHS clearly describe to collecting facilities the information they are required to obtain along with the specimen collection.

Data Reporting Requirements

HHS recognizes "that the data elements requested go above and beyond what has been historically requested." AACC agrees. Laboratories do not collect and report several of these data elements, such as device identifier and patient residence county. In addition, the "ask on order entry" questions are entirely new and will require significant changes to electronic health records systems.

Furthermore, multiple "ask on order entry" questions may result in incorrect or incomplete answers that are misleading or not useful. Many laboratories already use order questions (e.g., indicate for testing) to allow for appropriate routing of tests and to perform essential data tracking and analysis. Additional ask on order questions risk disruption of these processes or may result in physicians ignoring these questions.

HHS also needs to provide greater clarity regarding which requirements are mandatory and which are optional. In the guidance, the Department states that "ask on order entry" information "should be collected," but in the Q&A document it states that this data "must" be reported. HHS should correct this inconsistency in a revised document.

Also, the document states that "when information is not available, ordering health care providers (or their designees), laboratories performing SARS-CoV-2 and associated tests, and State Public Health departments should consider leveraging resources like state or regional HIEs and National Health Information (HIN) to obtain missing, required information." The guidance implies that three different entities are responsible for obtaining this data. AACC recommends that HHS clarify who is ultimately responsible in order to prevent a duplication of effort.

Needs to Standardize and Streamline Reporting Requirements

AACC recognizes the value of patient information associated with test results for making health policy, particularly during the current pandemic. Unfortunately, there is no standard list of data elements that are required to be reported and no single entity to receive this information. Currently clinical laboratories must report patient information to CDC, state and local health departments, and other entities, and the new HHS requirements will add to that complexity. These often overlapping and duplicative requirements divert limited laboratory resources to fulfilling administrative responsibilities rather than providing patient care. AACC recommends that HHS work with these oversight bodies and the laboratory community to streamline this process.

Implementing and reporting this information is going to be costly and time-consuming and will require more staff to accomplish. Most if not all clinical laboratories will not be able to modify their electronic health records systems before the August 1st implementation. Hence, AACC's recommendation mentioned above that HHS delay the effective date and work with the healthcare community to obtain the data it needs.

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

We look forward to working with you on this important issue. To facilitate these interactions, or if you have any questions, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at vstine@aacc.org.

Sincerely,

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