COLLEGE of AMERICAN PATHOLOGISTS

June 26, 2020

Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Azar:

The College of American Pathologists (CAP) is writing to obtain clarity on the Department of Health and Human Services (HHS) new guidance released on June 4th specifying clinical laboratory reporting to HHS of COVID-19 test results along with other clinical data elements. While we recognize the intentions of the guidance are to standardize data and give public health officials access to "comprehensive and nearly real-time data to inform decision making in their response to COVID-19", we would like to obtain clarity on several reporting elements and express our concerns about the burden this guidance will have on clinical laboratories.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act, requires "every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19" to report the results from each test to HHS. Given HHS is afforded the authority per the CARES Act to prescribe the method and elements for reporting, HHS should extend the deadline for implementation of this guidance until further clarity is provided to clinical laboratories and mitigation provisions are provided to address the abilities and burden of this guidance on clinical laboratories and healthcare professionals. The CAP will focus our comments on data elements clarifications and reporting burden.

Data Element Clarifications

While the guidance provides three mechanisms for clinical laboratories to report electronically, clinical laboratories will have problems collecting the required data elements outlined in the guidance. The guidance significantly expands requirements for reporting of laboratory results with some new data elements that have not historically been required and may not be in many information systems currently. Some required data elements are not tracked in many if not all information systems (e.g., FDA Unique Device Identifier, the actual zip code of the ordering provider). In addition, several data elements lack enough clarity with conflicting information regarding required vs. optional items for reporting. There is also confusion about reference laboratory reporting. Previous HHS communications regarding which reference laboratory reporting required duplicative reporting to the government had explicit instructions. Outside of complying with state laws, the HHS guidance does not address this issue which has left some clinical laboratories confused about reporting obligations.

Reporting Burden

The 24-hour reporting requirement will be difficult to comply with as some data elements may have to be amalgamated from disparate databases, especially for employee health testing. For example, employee testing data may be housed in an laboratory information system (LIS) and not transmitted to an electronic health record (EHR) for privacy reasons as mandated by law,

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patient zip codes may be in the EHR only, and employee zip codes are in a different database entirely. Also, data collection will be a significantly increased burden to clinical laboratories and front-line providers as well as to those healthcare workers responsible for data collection. The guidance requires front-line workers submitting SARS-CoV-2 orders to complete for each laboratory test order seven ask-at-order entry questions, some of which are not sufficiently defined, or which are non-value added because the data can be extracted from encounter information. Many of our healthcare workers are stressed spending significant time as required to meet testing needs amid shortages of swabs, reagents, and testing platforms.

The CAP would like to assist the HHS, Centers for Disease Control and Prevention (CDC), States, and clinical laboratories in mitigating the regulatory burden by recommending the use of structured data capture. Structured data capture can help automate and coordinate reporting to the state registries, and then flow more efficiently to the CDC within APHL AIMS, HL7, FHIR, or both. COVID-19 reporting is a critical initiative to help our country reopen so the CAP is willing to contribute our expertise in optimizing the response to this public health emergencies through efficient, standardized reporting structures. We welcome the opportunity to discuss our concerns and work with structured data to help clarify and mitigate the regulatory burden of HHS COVID-19 reporting guidance on clinical laboratories. Please contact Helena Duncan at hduncan@cap.org or 202.354.7131.

Closing,

The College of American Pathologists

Sent via email

cc: ADM Brett P. Giroir, M.D, Robert R. Redfield, MD, Michael F. Iademarco, MD, MPH (RADM, USPHS), Reynolds (Ren) M. Salerno, PhD

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