June 23, 2020

American Clinical Laboratory Association

Secretary Alex M. Azar II
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

I am writing in response to HHS's June 4 guidance, "COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115" ("Guidance"). The American Clinical Laboratory Association (ACLA) represents the commercial laboratories that have performed the majority of COVID-19 testing in this country since the pandemic began. ACLA members remain deeply concerned about the disproportionate impact of COVID-19 on underserved communities and take their role in providing test results and other information to public health authorities very seriously.

ACLA supports HHS's continued efforts to improve access to patient data to inform the nation's COVID-19 response efforts and better understand health disparities in infection and mortality rates. In order for HHS to effectively capture this data, the agency must ensure physicians and other health care providers are well educated about the critical need to collect additional data from patients at the time of specimen collection, including race and ethnicity. In addition, HHS must prioritize the importance of streamlining data reporting to reduce inaccurate or duplicative reporting to public health agencies; and ultimately, fully address the health information technology (IT) issues that impede both collection and reporting of data. Without prompt and decisive action by HHS to educate providers about the data reporting requirements as well as the necessary investment in modernizing our health IT systems, we will not meet our shared goal of providing accurate patient information to public health authorities that is critical to improving our response to COVID-19. Given the enormous provider education needed, as well as the technical challenges with implementation, we urge HHS to extend its August 1st deadline for this guidance to ensure the agency has ample opportunity to inform the provider community and provide much needed clarity to laboratories about the technical challenges of complying with the requirements.

Background

As you know, ACLA member laboratories have taken unprecedented steps to expand access to COVID-19 testing throughout the United States and have performed over 14 million COVID-19 rt-PCR tests since early March. Recognizing the critical importance of COVID-19 patient data, ACLA members have reported to public health departments all required patient information that they receive with test orders. However, as laboratories typically do not interact with patients, they can report only the information that is provided to them by ordering clinicians. It would be unethical for laboratories to delay reporting critical test results due to missing patient demographic information, particularly during a public health emergency. Unfortunately, even in cases in which labs are able to obtain additional patient information after

reporting results, many states do not accept edits or addenda to laboratory result reports after they have been submitted.

Within the Guidance, HHS acknowledges that, "the data elements requested go above and beyond what has been historically requested." The introduction of new data elements and ask-on-order-entry (AOE) questions will require significant monetary investment and coordination from laboratories, clinicians, hospitals, health systems, EHRs, and other vendors in order to be successful, at a time when the healthcare industry is under tremendous strain responding to the COVID-19 pandemic. ACLA stands ready to support the implementation of this guidance to the extent possible to achieve our shared goals of more complete reporting of patient demographic information, but unless changes to the Guidance are made, additional time beyond the August 1, 2020 effective date will be necessary for the Guidance to be implemented.

Guidance to Ordering Clinicians

ACLA strongly urges HHS to provide clear direction to clinicians ordering COVID-19 testing about providing complete patient information – including all of the data elements included in HHS's guidance – to labs when they forward the specimens they collect. The Guidance requires labs to report patient information such as sex, race, ethnicity, and address, and recommends reporting data such as pregnancy, but it does not sufficiently acknowledge the critical role ordering clinicians play in collecting this information nor include information about how HHS will inform ordering clinicians about this responsibility. HHS suggests that health information exchanges (HIE) may be a solution for filling in missing patient demographic information, but labs do not always have relationships with HIEs, and establishing connectivity to them can be resource intensive.

It is also critically important that HHS provide guidance to those who are managing non-traditional specimen collection settings, such as drive-thru testing sites, where health care providers may not be aware of their obligation to collect this extensive patient demographic data. We also urge HHS to educate providers who conduct point-of-care testing and testing within pharmacies on the requirements for direct reporting of results and patient demographic information to state and local health departments.

Streamlining Reporting Requirements

ACLA appreciates HHS's efforts to standardize and streamline reporting requirements through existing mechanisms, but the current guidance fails to consolidate the various duplicative data requests that labs are receiving from all levels of government. In recent communication with ACLA members, the Centers for Disease Control and Prevention (CDC) stated that it still will request direct data feeds from six commercial laboratories on a daily basis – even after the HHS laboratory reporting guidance takes effect. Governors' offices and HIEs also have requested data directly from labs that already are reporting to state health departments. These multiple data feeds may lead to duplicative and overlapping public health data. Furthermore, these requests place an additional burden on labs that already are expending a tremendous amount of resources to comply with regulatory requirements and expand testing

capacity. We ask that HHS clarify that labs are obligated to report COVID-19 test results only to state public health departments.

It also is concerning that the HHS guidance does not standardize results and data elements that are required to be reported across states. As the Guidance indicates, many states require reporting of additional data elements that exceed the requirements in the Guidance. For example, New Jersey has proposed requiring reporting of gender identity and sexual orientation with COVID-19 and other reportable test results, despite the lack of a standard for reporting such data. Further, the Guidance requires reporting of some data elements that states do not currently require and may be unable to accept, such as a device identifier. The Guidance also directs that data be reported "for all testing completed"; however, some states do not differentiate between "detected" and "not detected" results. We ask that HHS work with ACLA and the states toward public health reporting data elements and standards that are both uniform and practically achievable; in the immediate term, HHS should clarify whether the new requirements in the Guidance supersede and preempt state law to the extent that they differ.

Sharing Information with HIEs Raises Concerns about HIPAA Violations

ACLA members are concerned by the repeated requests from HIEs to share protected health information in patients' laboratory reports without patient authorization, even when the HIEs are neither business associates of the laboratories nor acting on behalf of state health departments. We have sought clarification from the HHS Office for Civil Rights (OCR) and the Office of the National Coordinator (ONC) on the permissibility under HIPAA of a laboratory sharing the information in such circumstances, to no avail. In many cases, these HIEs have directly referenced the Guidance as justification for requests for all results for COVID-19 tests for all patients in a state, even though the lab has already sent the results to the state health department as required by law. We understand that laboratories could share the information without a written patient authorization if it is for treatment, payment, or health care operations (TPO) purposes (45 CFR 164.506) or for public health activities (45 CFR 164.512(b)). Although ACLA member labs have asked HIEs why they need COVID-19 test results for all patients in a state when those results already have been provided to the state health department, they have been given no evidence that the HIEs are requesting the information for Treatment, Payment, Health Care Operations (TPO) purposes or on behalf of a state or federal agency for public health activities.

Where neither the lab nor the ordering provider has a business associate relationship with an HIE, and the HIE cannot document the request as fitting within an exception to the written patient authorization requirement, we do not believe there is an applicable HIPAA exception under which a lab may share results of COVID-19 tests. Absent an exception to the individual authorization requirement under HIPAA, ACLA member labs do not believe they are permitted to share such tests results with the HIE and believe that they are prohibited by law from sharing the test results with the HIE. Please confirm that our interpretation is correct.

Additionally, labs routinely provide identifiable COVID-19 test results to patients, ordering providers and state departments of health, in addition to providing de-identified results to the CDC. We are seeking confirmation that a lab's refusal to provide a duplicative set of all

COVID-19 test results for all patients in a state to an HIE does not constitute impermissible information blocking when:

- the HIE is not acting in a business associate relationship with an ordering provider or the lab;
- the lab is already providing the test results to the ordering providers, patients, and state departments of health;
- the lab would incur expenses to connect to or participate in the HIE; and
- the HIE does not provide verifiable documentation from a state indicating that the HIE is acting on behalf of a public health authority.

IT and Technical Challenges

Additionally, ACLA has the following concerns and suggestions regarding the data elements required or recommended in the HHS laboratory data reporting guidance.

Regarding required data elements:

- The Device Identifier is currently not required or supported by the majority of states and therefore not present in existing state reporting interfaces. This would require extensive programming for data feeds from instrumentation to the lab information system. There is significant complexity when the same test is being performed on multiple platforms, each of which has its own UDI (Unique Data Identifier). Additionally, Laboratory Developed Tests (LDTs) do not have device identifiers.
- The Patient Residence County called "County/Parish Code" in HL7 is a subfield of address and is not currently being sent by providers with the order, so obtaining this information would require educating the providers that it is needed and updates to EHR systems to send the correct code for the county name that is provided by the patient. Guidance would be needed on what code system should be used to represent the county. We recommend that HHS utilize the patient zip code, which is already provided, in order to obtain county information.
- Patient age should be replaced with the Patient's date of birth (DOB). State and public health agencies could calculate the patient age using the DOB and test performed date if needed.
- We need confirmation on the Race and Ethnicity tables and values to use for consistency between the laboratory order and for reporting. The HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 - US Realm references these HL7 version 2.5.1 tables below which are currently in use for state reporting. Therefore, we recommend these same tables be specifically used for the new HHS guidance.

User-defined Table 0005 - Race

Value	Description	Comment
1002-5	American Indian or Alaska Native	
2028-9	Asian	
2054-5	Black or African American	
2076-8	Native Hawaiian or Other Pacific Islander	
2106-3	White	
2131-1	Other Race	

User-defined Table 0189 - Ethnic Group

Value	Description	Comment
H	Hispanic or Latino	
N	Not Hispanic or Latino	
U	Unknown	

Regarding recommended data elements:

- The Ordering Provider address and phone number may not be the true physical location when a lab is acting as a reference lab. However, the accounts facility address is typically provided.

Regarding Ask on Order Entry (AOE) questions:

- The Guidance says (AOE) questions are recommended but not required, but the FAQs inconsistently state that they are recommended and required. The FAQs need to be clarified to indicate they are not required, but recommended. Implementation of (AOE) questions would be a huge change if required; clients, vendors and labs would have to store data, include it in a discrete field, and find a place for it in the HL7 format.

- Other options – the Guidance has an "unknown" option, but some of these questions are for sensitive and personal information. It is the patient's right not to provide this data. If (AOE) questions are to be included with "unknown" as an option, we want to emphasize that there will not be any specificity to indicate when a patient refused to respond or the ordering provider did not ask.

- The Guidance mentions a unique patient ID, and without a universal patient identifier in the industry uniqueness cannot be guaranteed.
- ACLA also recommends that if AOE questions are to be included, they should leverage an existing LOINC assigned by Regenstrief if available. However, we suggest that the CDC works with ACLA members to select the appropriate single LOINC term to be used for each ask on order entry (AOE) question. Additionally, these should be shown on the

CDC COVID website for consistency and centralization, similar to how the LIVD LOINC list is represented. Examples of LOINCs which could be centralized include:

- Date of Symptom Onset mm/dd/yy:
  - 11368-8 Illness or injury onset date and time
  - LOINC from https://loinc.org/11368-8/
- Pregnant? Y/N/U
  - 82810-3 Pregnancy status
  - LOINC answer list: Pregnant, Not pregnant, Unknown
  - LOINC from https://loinc.org/sars-cov-2-and-covid-19/

ACLA members remain committed to working with HHS to respond to the COVID-19 crisis, and specifically, to ensure we capture as accurately as possible the disproportionate impact of this crisis on communities of color. We fully recognize that our response to this pandemic and any future pandemic must be driven by data and that the data must fully capture any disparities, particularly those uncovered during a crisis of this magnitude. We look forward to working with HHS to improve the quality of data collected during COVID-19 and beyond in the most thorough, least burdensome manner possible. Thank you for your consideration of our comments.

Sincerely,

Julie Khani
President