July 9, 2020

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

Dear Secretary Azar:

On behalf of the National Independent Laboratory Association (NILA), whose members work in regional and community independent clinical laboratories across the United States, we write to respectfully request that the Department delay the implementation of the June 4 guidance, "COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115." While NILA understands the need for robust data to support the response to the COVID-19 pandemic, the June 4 guidance imposes requirements that many laboratories cannot feasibly implement by August 1. NILA asks that the Department delay the implementation of this guidance and work with independent laboratories and other stakeholders to develop feasible reporting requirements that provide the public health data necessary to respond to the pandemic.

NILA laboratories face several challenges implementing the June 4 guidance, including difficulty interpreting, collecting, and reporting the required data elements:

> ***Interpreting HHS reporting requirements***. The June 4 guidance requires the reporting of certain data elements that are poorly defined or inconsistent with existing laboratory data systems. Some of the required data elements, including device identifier, patient residence county, race/ethnicity, and patient age do not match existing data elements commonly used or collected by laboratories. Additionally, the Department has not provided a consistent standard for race and ethnicity values that it wishes to receive, which will lead to inconsistent data reporting among laboratories. Finally, the existing guidance is ambiguous regarding whether ask-on-order-entry questions are required to collect certain data elements. Because of the challenge and cost of implementing new ask-on-order-entry questions on such short notice, additional clarification from the Department is needed to avoid confusion and unnecessary expense.
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> ***Collecting required data elements***. Collecting required data elements is the primary challenge facing laboratories that perform SARS-CoV-2 testing. HHS guidance fails to acknowledge the need and does not create the proper incentives for clinicians to provide complete and accurate information to laboratories so that this information can be accurately and completely reported

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to public health entities. The June 4 guidance places the responsibility for reporting complete data on laboratories without a corresponding duty for attending clinicians or individuals collecting samples to provide complete data. As a result, laboratories are required to report information to which they may not have access.

Additionally, the June 4 guidance and associated FAQ does not assign clear responsibility for who must locate and complete missing patient information: "[w]hen 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 Networks (HIN) to obtain missing, required information." By attributing this responsibility to at least three separate entities, it is unclear who has the ultimate responsibility to find this information and whether a laboratory that does not have access to HIEs or HIN will be considered to have met its obligation when it makes reasonable efforts to complete the information but is unable to do so.

The guidance also does not adequately contemplate situations in which patient data is simply unattainable or the patient refuses to provide the information. Indeed, in response to the FAQ "What should we do if we are unable to capture all of the requested data," the Department directs providers, laboratories, and public health departments to find the information without contemplating that some of the information may be unattainable. While NILA understands the desire for complete and accurate data to guide pandemic response, it is unreasonable to expect that complete patient data will be available in every circumstance—particularly when the responsibility for collecting that information is not clearly assigned.

Storing and reporting required data elements. Storing and reporting required data elements is also challenging, particularly given the unique circumstances of the pandemic. To respond to the June 4 guidance, laboratories that interface with electronic health records systems must either pay a vendor out of pocket to update their technology or reassign staff to make the changes necessary to allow for the collection and transmission of the information. Given the wide variety of electronic health record systems that clinics use, laboratory interfaces must be updated to allow for data transmission from each of the electronic health record systems with which the laboratory interacts. One NILA member laboratory, for example, noted that they receive test orders from more than 200 separate clinics—each of whom has a distinct electronic health system. That laboratory, and other laboratories like it, will need to make modifications to its electronic health record system to allow for reporting from each of these entities and have a separate conversation with each clinic to ensure that the correct information is submitted to the laboratory so that the laboratory can meet reporting requirements. Similar changes are required for laboratories that use paper records in whole or in part. Importantly, many laboratories who previously received the majority of their test orders electronically may now be receiving paper orders for the majority of ordered SARS-CoV-2 tests. Many testing sites, such as those operated by government entities or "pop-up" collection sites quickly constructed to respond to the pandemic, do not use electronic records, requiring laboratories to make changes to both electronic and paper-based business processes to meet the data reporting guidance.

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While community and regional laboratories are working diligently to make changes in response to the June 4 guidance, NILA fears that many laboratories will not have the time or resources necessary to completely and accurately report all of the required data elements by August 1. Laboratories are under unprecedented strain due to the crushing demand for SARS-CoV-2 testing and years of cuts to reimbursement rates following the Protecting Access to Medicare Act, even without the imposition of additional reporting requirements. As a result, many laboratories simply lack the resources—be it time, capital, or labor—to quickly make these changes. To ensure that public health authorities have accurate and complete data to guide the pandemic response, NILA urges the Department to delay implementation of the June 4 guidance so that the Department can consult with NILA and other stakeholders to create feasible and clearly assigned data collection and reporting responsibilities.

Sincerely yours,

Mark S. Birenbaum, Ph.D.
Executive Director

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