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July 1, 2020

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

RE: COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115

Submitted electronically via Secretary@HHS.gov

Dear Secretary Azar:

UnityPoint Health appreciates the opportunity to provide comments in response to the Health and Human Services guidance for laboratories to begin specified COVID-19 data reporting. Through more than 32,000 employees, our relationships with more than 400 physician clinics, 21 regional and 19 community network hospitals and home health services throughout our nine regions, UnityPoint Health provides care throughout Iowa, western Illinois and southern Wisconsin. On an annual basis, UnityPoint Health hospitals, clinics and home health provide a full range of coordinated care to patients and families through more than 6.2 million patient visits.

Public Law 116-136, § 18115(a), 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 such test to the Secretary of the Department of Health and Human Services (HHS). On June 4, 2020, the Secretary issued a COVID-19 laboratory data reporting guidance and frequently asked questions documents. In the June 23, 2020 letter to the Secretary from the American Clinical Laboratory Association ACLA, HHS was urged to “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.” UnityPoint Health supports this position and respectfully offers the following comments as an integrated health system with clinical and small reference laboratories.

GENERAL COMMENTS

All laboratories, defined as laboratories, non-laboratory testing locations, and other facilities or locations offering point of care testing or in-home testing related to SARS-CoV-2 shall report data for all testing completed, for each individual tested, within 24 hours of result known or determined, on a daily basis to the appropriate state or local public health agency based on the individual’s residence. Reporting includes the following seven data fields that are considered “ask on order entry” (AOE) questions:

1. First test (Y/N/U)
2. Employed in healthcare? Y/N/U
3. Symptomatic as defined by CDC? Y/N/U; if yes, then Date of Symptom Onset mm/dd/yy
4. Hospitalized? Y/N/U
5. ICU? Y/N/U
6. Resident in a congregate care setting (including nursing homes, residential care for people with intellectual and developmental disabilities, psychiatric treatment facilities, group homes, board and care homes, homeless shelter, foster care or other setting): (Y/N/U)
7. Pregnant? Y/N/U

Reporting is mandated no later than August 1, 2020.

Comment: UnityPoint Health is a strong proponent of using data to drive decisions and recognizes the importance of data collection to inform the overall real-time COVID–19 response efforts. We agree that lab data “contribute to understanding disease incidence and trends: Initiating epidemiologic case investigations, assisting with contact tracing, assessing availability and use of testing resources, and identifying of supply chain issues for reagents and other material. Laboratory testing data, in conjunction with case reports and other data, also provide vital guidance for mitigation and control activities.”

While UnityPoint Health is confident in our ability to report on “reportable labs” data, at issue is the August 1 timeframe for collection of AOE data. **We encourage HHS to consider delaying the implementation of AOE reporting to enable the development of platform and interface solutions.** As stated in the HHS COVID-19 Laboratory Data Reporting Guidance, “the data elements requested go above and beyond what has been historically requested.” This near-term deadline for new AOE data fails to take into consideration the need to revise physician order platforms to include these fields and to appropriately interface with the clinical laboratory platforms. To complicate matters, our clinical laboratories not only service our integrated health system and our internal EHRs, but three of our laboratories are reference laboratories that service a host of external customers with disparate physician order platforms. To date, our EHR vendor has estimated that their solution (e.g. standardization of order questions and interface work) will be available on July 13, impacting roughly 80% of our provider orders. Once we receive the solution, UnityPoint Health will need time to test and validate the interface, but more importantly, we will need time to revise clinician workflow and conduct training to assure that information is obtained and entered accurately and completely. For our system, this entails work with roughly 15 downstream reference laboratories and effects 31 unique lab orders. As with most EHR builds, this Go Live process takes approximately 90 days from the date we receive the software solution.

Aside from timeframe, we have general concerns related to implementation and request further guidance.

- **Unclear definitions:** To date, there are no finite definitions associated with each QOE data field. Our questions include: (1) are these fields based on self-reporting versus EHR/HIE documentation?; (2) what does “employed in healthcare” include – is this employees with exposure to patients, or does this include administrative back office functions like IT call centers, billing analysts, health plan employees, etc.?; and (3) for “symptomatic as defined by CDC,” does one symptom triggers a yes response? **Prior to requiring reporting, platform builds and**


workflow restructures, we request that HHS provide detailed definitional guidance for the AOE fields.

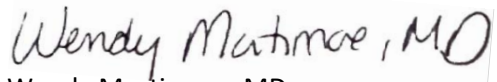
- ***Interpretation of unknown (“U”) response:*** In the absence of a data collection process due to the short implementation timeframe, it is likely that AOE fields will be completed with “U” until interfaces are established. As a result, it will be unclear whether the data is truly unknown as opposed to unreportable. We anticipate that large percentages of unknown responses will not enable public health or HHS to inform COVID responses or planning decisions. ***In the absence of delaying AOE implementation, we request that HHS issue guidance related to when a “U” is appropriate.***
- ***Implication of short-term solution:*** In effect, HHS is requesting that screening questions be embedded within the order entry process. We understand the need for these data points; however, having laboratories as the reporting nexus is out of the norm and requires extra infrastructure to be stood up for this near-term resolution. ***The seven required screening questions are more appropriately an intake or documentation workflow and should not lie within order entry and we request that HHS consider aggregate reporting for these data points.*** Mandating that these questions be answered on order entry represents a funnel workflow and creates either duplicative documentation or an unnecessary backlog of data collection within the order entry process. Once this order entry process is established, any changes to revert to an intake process will require additional data fields, workflow revisions and training and, as this data shifts location, there is a concern that reporting/tracking over time will be hampered.
- ***Additional fields:*** HHS has indicated that more fields may be included in the future. This statement is made without guidance as to the notice process for inclusion or potential timeframes for implementation. ***As there are associated time and effort considerations for additional data collection and reporting, we urge caution in issuing multiple future releases of reporting changes without clear statements of need for the requested information. Additionally, we encourage HHS to consider whether additional data fields should be tied to individual tests versus being collected on an aggregate basis.***

We are pleased to provide comments on this data collection proposal. For the reasons provided in this letter, **UnityPoint Health encourages the Administration to delay the collection of the AOE data fields.** To discuss our comments or for additional information, please contact Cathy Simmons, Government and External Affairs at cathy.simmons@unitypoint.org or 319-361-2336.


Sincerely,


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