

August 4, 2020

Jeffrey M. Zirger
Information Collection Review Office
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-D74
Atlanta, Georgia 30329

RE: CDC-2020-0062 - COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115; published in Vol. 85, No. 109, Federal Register 34633-4 on Friday, June 5, 2020.

Submitted electronically via www.regulations.gov

Dear Mr. Zirger:

UnityPoint Health (“UPH”) appreciates the opportunity to provide comments in response to the Centers for Disease Control and Prevention (CDC) proposed data collection. 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 9 regions, UPH provides care throughout Iowa, western Illinois and southern Wisconsin. On an annual basis, UPH hospitals, clinics and home health provide a full range of coordinated care to patients and families through more than 6.2 million patient visits.

UnityPoint Health respectfully offers the following comments.

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.”

DELAY: *UnityPoint Health is extremely pleased to learn of the delay in the August 1 deadline* – an announcement apparently made to state stakeholders during a national CDC call on July 30. UPH has concerns about the AOE questions as proposed, and this delay will assure that, if they are included at a later date, there is upfront supportive documentation and sufficient implementation lead time to assist infrastructure builds and clinical workflows. We are frustrated, however, with the last-minute notice and unclear messaging from the CDC that AOE questions were being delayed. Our health system expended significant time, effort and expense in order to comply to the best of our abilities with the AOE requirements. When messaging was cascaded from state agencies one day prior to the “Go Live” date in an inconsistent manner, it was confusing, and states were unable to direct us to specific CDC resources that could confirm or clarify this message. We would request that the CDC revisit how it communicates and cascades these messages in the future to enable laboratory and clinical stakeholders to receive this message in a timely and transparent manner.

AOE CONCERNS: While UnityPoint Health is confident in our ability to report on “reportable labs” data, the insufficient timeframe for infrastructure required for the collection and reporting of AOE data was troublesome. ***As the CDC contemplates laboratory reporting requirements to monitor COVID-19 testing, we encourage the CDC to require AOE reporting (or other collection that is not typically within the laboratory environment) only when there is sufficient time for providers and laboratories to develop 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.” The proposed August 1 deadline for new AOE data failed to take into consideration the need to revise physician order platforms to include these fields and to appropriately interface with the clinical laboratory platforms. Due to changing CDC requirements, we only received our EHR vendor solution in late July. 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. UnityPoint Health needs 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. As with most EHR builds, this “Go Live” process takes approximately 90 days from the date we receive the software solution.

We have been told by a state point of contact that the AOE questions are under further review and that there will be a balloted process prior to implementation. We have not seen any documentation from the CDC which describes this process. We would request further transparency, so that there is not a

repeat of recent events. In particular, ***we would encourage the CDC to post the balloted process for the AOE, along with relevant timeframes and the composition of the groups included in the balloting. At the outset, we would suggest that the balloting include groups that represent expertise in clinical workflows beyond vendor relationships.*** This balloting should not be limited to groups with expertise in interface standards and mapping.

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

- ***Unclear definitions***: Finite definitions associated with each QOE data field were not released contemporaneous with this data collection proposal and continued release during the month of July does not support a Go Live implementation date in August. ***In the future, prior to requiring reporting, platform builds and workflow restructures, we request that CDC provide detailed definitional guidance for the AOE fields and conduct a public notice period that concludes prior to implementation to enable meaningful consideration of public comments.***
- ***Interpretation of unknown (“U”) response***: In effect, these are screening questions that are being required to 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 CDC 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***: We are concerned that more fields may be included in the future. ***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 consideration of whether additional data fields should be tied to individual tests versus being collected on an aggregate basis.***
- ***Competing reporting requirements***: In reiterating our support for data-driven decisions, hospitals are being required to report upwards of 150 data fields daily to the states and federal government in relation to the COVID pandemic. ***As additional data fields are requested, we urge that they be specifically targeted, as overburdensome reporting will detract needed resources from direct patient care.***

STAKEHOLDER OUTREACH: In relation to this and other pandemic activities, ***we applaud the CDC for its initiation of the bi-weekly Clinical Laboratory COVID-19 Response Calls.*** We have found these calls to be

extremely informative and a good process to push out current information during this fast-moving environment. The shared mailbox is also a nice feature to facilitate getting a direct response from the CDC as we strive to comply with the various reporting requirements related to the pandemic.

We are pleased to provide comments on this data collection proposal and ***are grateful for the CDC's decision to delay enforcement of the AOE questions.*** As the pandemic continues and the CDC considers future reporting requirements, ***UnityPoint Health encourages the Administration to partner with stakeholders to assure realistic requirements and implementation timeframes.*** 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.

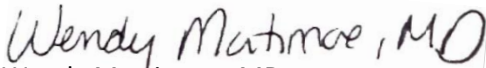
Sincerely,



Carol Collingsworth, MBA, MT (ASCP) SC
Laboratory Services Director, System Initiatives



Laura S. Smith
VP, Chief Information Officer



Wendy Mortimore, MD
Chief Medical Information Officer
Internal Medicine/Pediatrics



Cathy Simmons, JD, MPP
Executive Director, Regulatory Affairs