TN Department of Health

September 3, 2020

TDH Response and Clarification Regarding
HHS and CMS Guidance Regarding COVID-19 Laboratory Results Reporting

Several memos, regulations, and press releases have been publicized over the past several months regarding COVID-19 laboratory result reporting to Federal, state, and local officials. This memo is intended to summarize the Tennessee Department of Health's current understanding of the implications of these new policies on facilities providing clinical care or laboratory testing in Tennessee. TDH's understanding will likely change as further clarification is received from Federal partners.

The documents referenced in this summary focus on:

- Health and Human Services (HHS) letter titled *COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115* (June 4, 2020).
- HHS guidance and FAQ document titled *COVID-19 Guidance for Hospital Reporting and FAQs For Hospitals, Hospital Laboratory, and Acute Care Facility Data Reporting Updated July 29, 2020* (July 29, 2020)
- Centers for Medicare & Medicaid Services (CMS) new *Interim Final Rule with a Comment Period (CMS-3401-IFC)* (August 25, 2020)

These memos, letters, and rules are intended to support and compel the electronic reporting of laboratory results for all COVID test and result types. Throughout the current pandemic, our healthcare and public health systems have been occasionally hindered by the manual flow of data and information on COVID-19 cases and exposed individuals through multiple agencies, jurisdictions, and facilities. Although TDH, and other states, have implemented Emergency Use Templates or other similar CSV file formats, these file formats often require significant manual work on behalf of facilities as well as TDH. These documents aim to address one of the areas for improvement: to further define the minimum data elements for reporting, entities responsible for reporting, and methods by which that information can be submitted electronically. Additionally, the CMS interim final rule codifies penalties associated with not meeting these previously outlined reporting requirements, content quality, and timelines.

The documents do not require reporters to create an additional reporting process. These policies support currently existing state and Federal laws which require diseases or conditions of public health importance be reported to state and local health departments. In addition to COVID-19 reporting, Tennessee requires the reporting of 80 diseases and conditions. For further information on current rules and requirements for reporting, please see the TDH website at: https://www.tn.gov/health/cedep/reportable-diseases.html.

The documents support current TDH policy and procedures for required data elements and result types for most infectious diseases. The June 4th letter requires that facilities include specific data elements in their lab and case reports to TDH. The vast majority of these fields are already included in TDH reporting rules and requirements. The letter also requires the reporting of negative COVID-19 tests, this is also in

line with current TDH policy. Negative test results are also required to be reported for some other conditions, such as Hepatitis panels, which are outlined in the detailed laboratory guidance from TDH. These negative results should follow the same reporting specifications for completeness and quality as positive results.

The June 4th letter expands the type of accompanying data requested for COVID-19 tests, called ask at order entry (AOE) questions.

These are new requirements and have not been included in previous TDH rules or requirements. The listed AOE questions apply to COVID-19 only, but TDH does require pregnancy status be reported on STD, HIV, and Hepatitis results. If your organization needs to make system changes to accommodate these AOE questions, it would be beneficial to consider the relevance of these questions for the other reportable diseases or conditions. If you have other questions about how order interfaces can be implemented within your facility, please see HL7 Version 2.5.1 Lab Order Interface Implementation Guide.

TDH is currently participating in all COVID-19 related data reporting processes. If you are currently reporting all of your lab results via a compliant HL7 message feed, then you meet the spirit of the above referenced documents which require Federal reporting of COVID results and should not be subject to penalties.

If you are currently reporting your lab data via the emergency use template, you are likely compliant with the most recent rule change. The final decision on compliance with the most recent CMS requirement for reporting lies with CMS. TDH expects that CMS will develop and distribute additional guidance regarding the recent rule change. This is when CMS provides clarification on their expectations and how they will implement monitoring and other similar practical issues. TDH is not aware of a due date for this guidance from CMS.

If you are not reporting via HL7 ELR standards nor the emergency use template then your facility is not compliant according to the most recent guidance. In order to assist facilities performing Point of Care testing only, such as nursing homes, TDH has established an online portal to support record level data reporting to TDH. We anticipate that this method will meet the requirements of the most recent guidance. Nursing homes are also able to report Point of Care or commercial testing results via a soon-to-be deployed module within the National Healthcare Safety Network (NHSN) system. Please contact the CDC if you are interested in this option.

Even though the guidance on COVID-19 lab result reporting is evolving, Federal authorities have been clear in their focus on implementing rapid, electronic, automated data feeds. TDH recommends that facilities not currently able to send HL7 ELR lab messages consider developing or implementing interfaces capable of meeting these requirements.

TDH is requesting the following from reporting partners at the current time:

- Continue to report all COVID-19 test results via your currently established route (fax, emergency use template, or HL7 ELRs).
- Review your facility's current reporting streams for completeness of the required data fields,

particularly patient demographic and address/contact information. If these fields are not routinely collected, or are frequently unknown, work to improve data quality.

- If you are not currently reporting COVID-19 results, please email ceds.informatics@tn.gov to establish a reporting process.
- For non-HL7 ELR partners, assess HL7 capabilities and prepare for onboarding by reviewing TDH electronic reporting requirements at https://www.tn.gov/health/cedep/laboratory-reporting.html.
- Review your laboratory test menu and determine if there are other reportable diseases or conditions that you should also be reporting but are currently not. If you identify that you are not in compliance with TDH reporting rules, please email ceds.informatics@tn.gov to assess next steps.
    - We will not be adding new diseases or conditions to the current emergency use template, but we need to be aware of your total reporting volume so that we can appropriately prioritize your facility for HL7 ELR onboarding.

Thank you for your partnership during this critical time.

In partnership,

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