

June 17, 2020

TDH Response and Clarification Regarding  
HHS Letter: COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115

Health and Human Services (HHS) recently sent out a letter titled [COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115](#) (June 4, 2020). This letter was 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 strained trying to care for patients and communities while at the same time monitor exposed individuals and track the spread of disease to inform control measures. These efforts 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. This HHS letter aims to address one of those areas for improvement which is to further define the minimum data elements for reporting, entities responsible for reporting, and methods by which that information can be submitted electronically.

*The HHS letter does not require reporters to create an additional reporting process.* The letter supports 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 letter supports current TDH policy and procedures for required data elements and result types for most infectious diseases.* The 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 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](#).

August 1, 2020 was the deadline listed in letter, but TDH has been reassured by the Centers for Disease Control and Prevention (CDC) that there will be no monetary penalties for not meeting this deadline as long as we can all show that we are making reasonable progress towards these goals. TDH is working on a roll out plan for onboarding and testing the new message and template formats. This HHS guidance is evolving and we expect to receive further clarification on these specifications from HHS and the CDC in the coming weeks. We will continue to reach out to our reporting partners as more information is known.

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](mailto: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](mailto: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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State Epidemiologist