TN Department of Health

These Frequently Asked Questions were compiled in response to several memos and guidelines published by the Federal government:

- 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)

TDH expects that CMS will provide additional guidance regarding the rule change referenced above. We anticipate this guidance will outline expectations, implementation plans, schedules and other practical aspects of implementing and monitoring compliance with the rule. TDH will update these FAQs as new or updated guidance is received. Please contact ceds.informatics@tn.gov with any questions you have after reviewing this document.

I am a nursing home and I am not able to send lab results electronically, what should I do?

TDH has worked to stand up an online reporting system for nursing homes, or other similar environments that are using Point of Care testing. Please visit our website to review the fact sheet for how you can enroll in this reporting program. If you are a hospital or commercial lab who is also doing Point of Care testing, these results should be incorporated into your existing electronic data feed.

I am an Assisted Living Facility am I subject to CMS penalties?

TDH understands that the reporting requirements and penalties referred to in the new CMS rule apply to CMS certified nursing providers. However, you should refer questions regarding your current status with CMS to that agency, TDH cannot provide a definitive answer to any facility regarding their obligations under the new rule. Regardless, all clinical care and congregate living facilities are required to notify TDH of all reportable infectious disease cases under state rules. Please see questions throughout this document about how various results can be reported in order to establish your facility's reporting process.

I am reporting to the health department all of my test results but I cannot send all of the information they require or I cannot add in the newly requested data elements and order questions, will I be penalized?

TDH's current understanding is that not reporting is what will be penalized, not the method or content. If you are not reporting all of your relevant lab results to TDH, you could be subject to penalties. If you are reporting results without the minimum data elements (test performed, ordering and performing facility information, test result, and patient name and DOB) then you might not meet the reporting requirement. If you are able to report the minimum data elements but not the additional demographic and "ask on order entry" (AOE) questions, you are likely meeting the reporting requirement and will therefore not likely be penalized.

What if we cannot send the required information?

The expectation of the Federal government and State of Tennessee is that you make all reasonable efforts to collect and send the information required. This may mean making changes to your laboratory operating systems, order submission forms, and other protocols. Please refer to HL7 Version 2.5.1 Lab Order Interface Implementation Guide for more information.

What if we already collect this information and are ready to add this to our TDH reporting?

Please do not make any changes to the data files or messages you are currently sending to TDH. TDH is currently working on technical guidance to meet these requirements as well as a partner engagement roll-out plan. However, if you feel that your data files or messages meet the new requirements, email ceds.informatics@tn.gov. We will contact you about receiving test messages.

The emergency use template does not currently support the reporting of some of the HHS data requirements. TDH can only support the reporting of all HHS data requirements via HL7 electronic laboratory reporting.

We can collect and send the information but our submitters do not send us this data. What should we do?

The expectation of the Federal government is that you make all reasonable efforts to collect and send the information required. This may mean making these fields required

from submitters ordering tests from your lab. This could also require changes to your technology systems to collect and store this information. Please refer to HL7 Version 2.5.1 Lab Order Interface Implementation Guide for more information.

What if my laboratory tests specimens for multiple states?

If you already have an electronic reporting process established with TDH, we would prefer that you make updates to that established process. It is possible to onboard reporting with these new standards through the Association of Public Health Laboratories' AIMS platform in order to report to multiple states via one feed. However, you would need to maintain your current TDH reporting until this new process is vetted and validated by TDH. You cannot onboard for COVID only via AIMS if you already report more conditions to TDH via an established electronic process.

Do I need to report the "ask on order entry" (AOE) questions on all lab results I report to TDH?

In general, no, the AOE questions only apply to COVID-19 associated test orders and their corresponding results. However, pregnancy status is included in the AOE questions and is also a required field to be reported on all HIV, STD, and Hepatitis test results in Tennessee.

My lab test for other diseases and conditions besides COVID; do I need to report these?

Yes, laboratories are responsible for reporting all diseases and conditions of public health importance including conditions like *E. coli*, Lead, TB, West Nile Virus among many others. The full list of reportable diseases is available on the TDH website. Additional information on disease reporting in Tennessee can be found on our website at: https://www.tn.gov/health/cedep/reportable-diseases.html. Please contact ceds.informatics@tn.gov as soon as possible if you are not currently reporting all reportable diseases.

How do I prepare to onboard for HL7 ELR?

If you are thinking about developing the capability to send HL7 ELR messages, please refer to TDH's current requirements to ensure that you can meet these standards. Additionally, HL7 (the organization) hosts collaborative sites that maintain working guidance for HL7 standards and these pages have been updated to reflect the current requirements for COVID results.

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I am ready to onboard for HL7 ELR, what should I do?

If your facility is ready to begin reporting to TDH via HL7, please review the current requirements on TDH's website and then email ceds.informatics@tn.gov. Please keep in mind that these reporting requirements are in the process of being updated to reflect the HHS letter and its updated requirements. In your email please include your current reporting process and any other relevant details about timeline and volume of reporting. Someone from TDH will contact you about next steps.

I don't have a lab site at my clinic, do I still need to report?

If your clinic operates any type of Point of Care testing (for example the Abbott ID Now diagnostic machine or Sofia SARS Antigen FIA by Quidel) for COVID testing, you are subject to this law and must report according to these standards. If you have questions about how to report results from POC testing platforms, please contact ceds.informatics@tn.gov. If your clinic does not perform lab testing of any sort, you are still subject to TDH's general reporting requirements and must report all COVID-19 diagnoses in your clients/patients according to guidelines. Also, please see the question below about all diseases and conditions you are required to report as a healthcare provider.

I am a healthcare provider and I diagnose diseases other than COVID. Do I need to report these?

Healthcare providers are responsible for reporting all diseases and conditions of public health importance including conditions like E. coli, Lead, TB, West Nile Virus among many others. The full list of reportable diseases is available on the TDH website. Additional information on disease reporting in Tennessee can be found on our website at: https://www.tn.gov/health/cedep/reportable-diseases.html. Please contact ceds.informatics@tn.gov as soon as possible if you are not currently reporting all reportable diseases.

Does this replace the aggregate reporting that facilities have to complete for HHS/CMS?

No, as we understand the rule at this time, the requirement for facilities to submit aggregate case count data to HHS/CMS is still in place.

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