



Electronic Laboratory Reporting (ELR) On-Boarding Packet

This packet is intended to be used by potential ELR trading partners of the TN Department of Health (TDH). The documents provided here are for trading partner use only, and nothing in this document needs to be returned to TDH unless specifically requested.

<https://tn.gov/health/article/laboratory-reporting>

***TDH Mission: Protect, promote and improve the health and prosperity of people in Tennessee
TDH Vision: A recognized and trusted leader, partnering and engaging to accelerate Tennessee to one of the nation's 10 healthiest states***

ELR On-Boarding Packet

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- The ELR On-Boarding Process displays the step-by-step process that a trading partner will need to follow in order to successfully implement ELR with the Tennessee Department of Health. This was designed as a roadmap for trading partner use in navigating the process and expecting next steps.

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- The ELR On-Boarding Checklist is a companion document to the ELR On-Boarding Process. The checklist is for trading partner use only, and it does not need to be completed and returned to the Tennessee Department of Health. This document was designed to assist with on-boarding, help trading partners document their progress, and better explain what trading partners can expect from the Tennessee Department of Health. There are also some useful links contained in this document that can help with message validation and vocabulary mapping.

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- The ELR Frequently Asked Questions (FAQ's) document provides answers to the most commonly asked questions around implementing ELR with the Tennessee Department of Health. It is recommended that you look to this document first before contacting the Tennessee Department of Health with your questions, but further clarification can always be provided.

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- This document represents an excerpt from the larger ELR Trading Partner Agreement (TPA). The draft TPA will be shared with a trading partner during the early steps in the on-boarding process. The TPA remains in draft form and is not signed until ELR is in production. Information contained in this document will be useful during electronic health record (EHR) configuration and implementation. The information contained in this document accompanies the Implementation Guide, it does not replace it, and the 2 should always be used together.

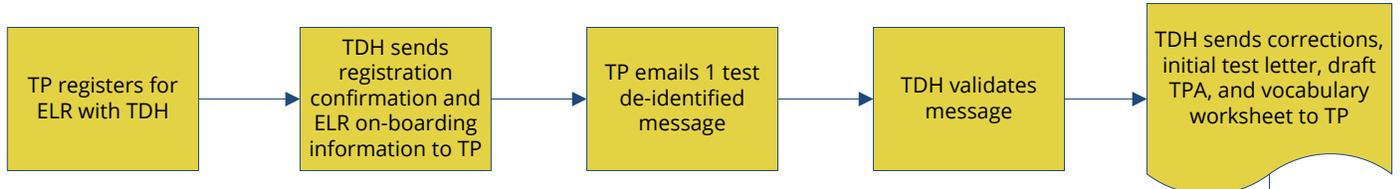
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- This document represents an excerpt from the larger ELR Trading Partner Agreement (TPA). The draft TPA will be shared with a trading partner during the early steps in the on-boarding process. The TPA remains in draft form and is not signed until ELR is in production. Information contained in this document will be useful during electronic health record (EHR) configuration and implementation. The information contained in this document accompanies the Implementation Guide, it does not replace it, and the 2 should always be used together.

For questions about any of the documents in this packet, or to get started with ELR, please contact CEDS.Informatics@tn.gov.

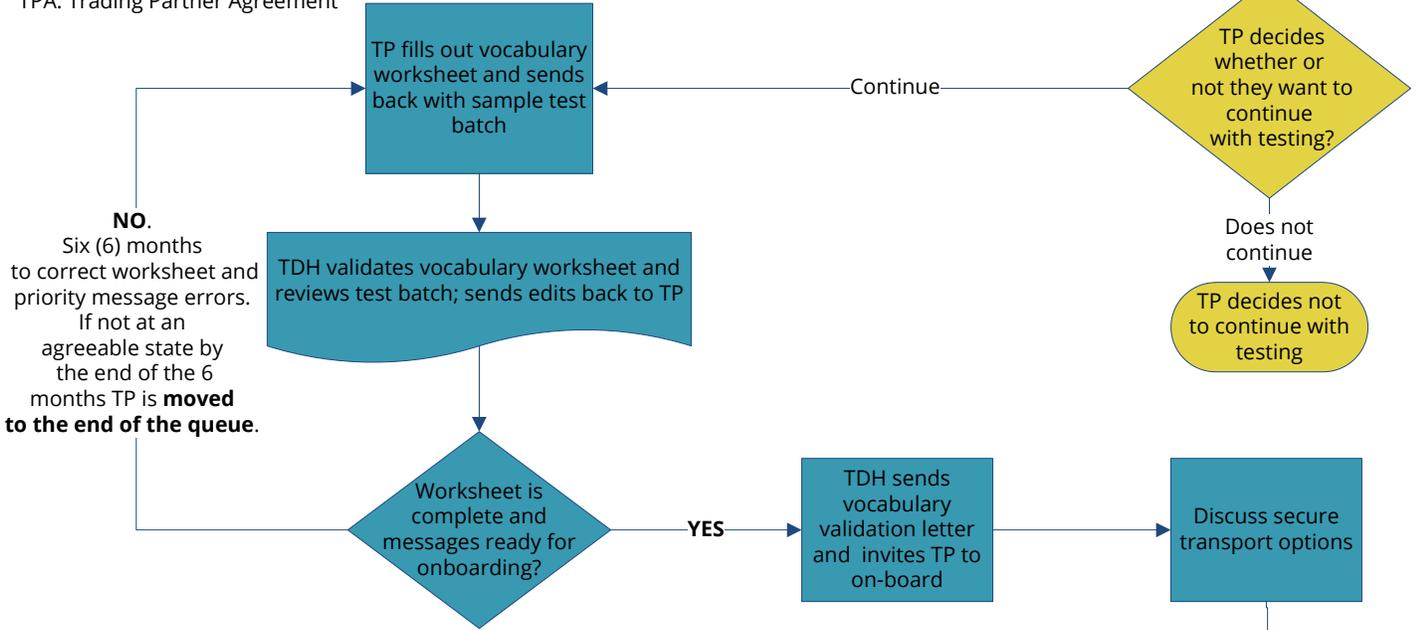
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PRE-TESTING

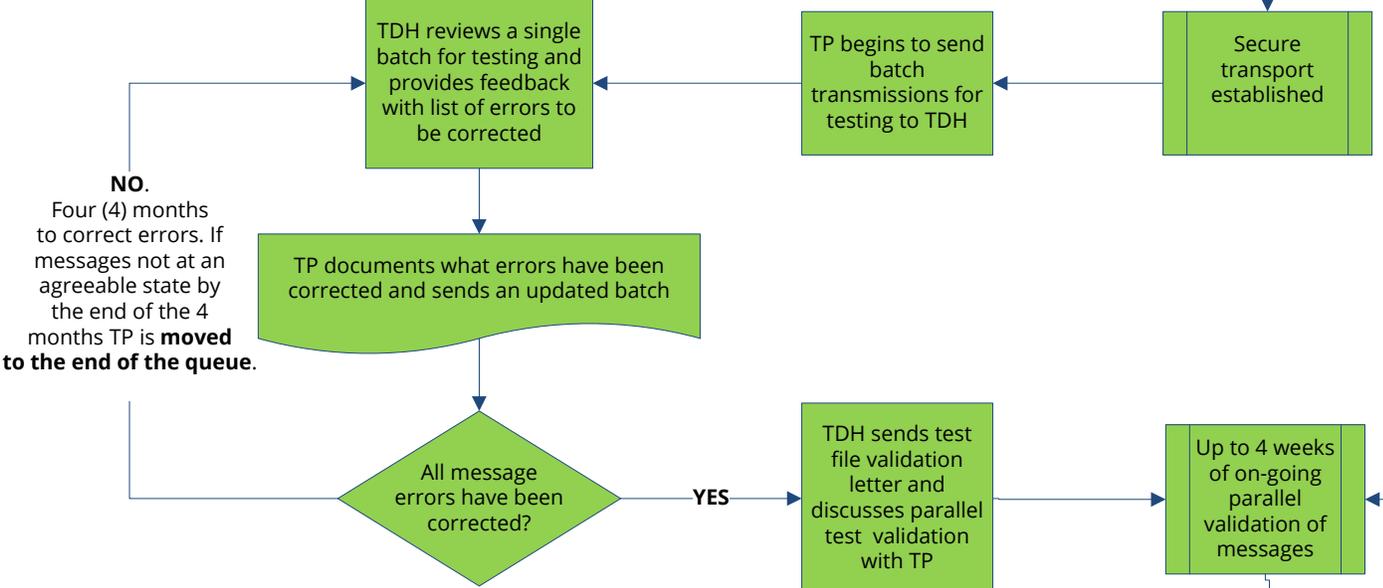


TP: Trading Partner
 TDH: Tennessee Department of Health
 ELR: Electronic Laboratory Reporting
 MU: Meaningful Use
 TPA: Trading Partner Agreement

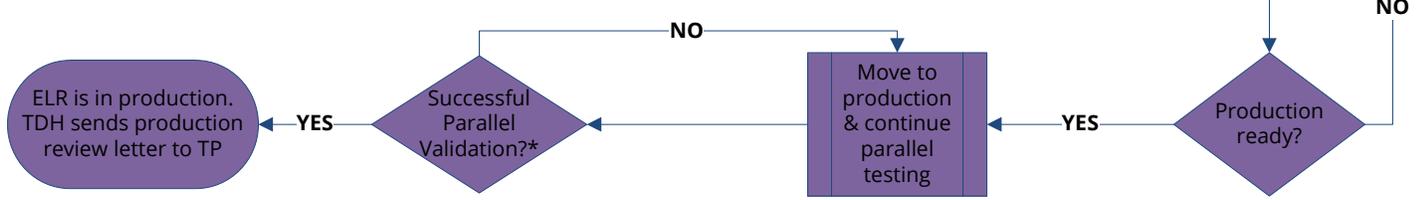
TESTING



ON-BOARDING



PRODUCTION



*Within predetermined time frame.

Tennessee Department of Health On-Boarding for HL7 2.5.1 ELR from Hospitals for Meaningful Use Process Summary:

PRE-TESTING

- In Tennessee, the Electronic Laboratory Results Reporting (ELR) on-boarding process begins when a potential trading partner (TP) registers with the Tennessee Department of Health (TDH) expressing their intent in sending laboratory information electronically to TDH.
- TDH will confirm registration and describe the ELR on-boarding protocol with the potential TP.
- The TP should obtain a copy of the Health Level Seven (HL7) Standard and HL7 Implementation Guide. (Eligible hospitals which are testing with TDH for Meaningful Use must use HL7 version 2.5.1 for messaging.)
- The TP sends the ELR staff at TDH an initial, de-identified test message through email. The ELR staff at TDH will validate the message.
- ELR staff at TDH sends the TP the corrections that need to be made to the initial message, an official letter documenting that they did send a test message to TDH, the draft Trading Partner Agreement (TPA) with Tennessee-specific requirements, and a blank vocabulary worksheet.
- A call will be held with the ELR staff at TDH and the TP to discuss whether they want to continue with on-boarding ELR, and what the next steps of that process entail. During that call the time line and business rules will be discussed.

TESTING

- If the TP decides to continue with the on-boarding process, they will need to fill out the vocabulary worksheet.
- Once complete, the TP will send the worksheet along with a sample test batch of de-identified messages through email to TDH for validation.
- The ELR staff at TDH will send edits for the worksheet and the test batch to the TP so changes can be made. **The TP will have 6 months to correct the worksheet and the priority message errors.** If the worksheet and the messages are not at a state that TDH can accept within 6 months, the TP will be moved back to the end of the queue in order to free up TDH resources to work with other partners.

- When the vocabulary worksheet is complete and the messages are ready for onboarding, TDH will send the TP an official letter documenting the completion of vocabulary validation and invite the TP to begin onboarding.

ON-BOARDING

- Secure transport will be set up for batch ELR messages.
- Once the TP is sending regular test messages for validation, TDH ELR staff will review one batch and provide the TP with feedback and a list of errors that should be corrected.
- The ELR staff at TDH will only look at further test batches when the TP has documented what errors have been corrected and sends an updated batch for validation. **The TP will have 4 months to correct all message errors.** If the test batches are not at a state that TDH can accept within 4 months, the TP will be moved back to the end of the queue in order to free up TDH resources to work with other partners engaged in ELR on-boarding.
- When all message errors have been corrected, TDH will send the TP an official letter documenting the completion of the test file validation and discuss the parallel validation process.
- There will be up to 4 weeks of on-going parallel validation of messages by the ELR staff at TDH. During this time, the TP will be required to send all lab reports currently being reported on paper to the TDH central office. The ELR staff at TDH will validate paper lab reports and ELR for completeness of ELR messaging to ensure that no paper lab reports or useful information in them is missing from ELR. As long as no problems arise during those weeks, the messages will be deemed production ready.

PRODUCTION

- Once production ready, the ELR batch messages will be sent to TDH's production surveillance systems. The TP will continue sending all paper lab reports to the TDH central office for parallel testing.
- Once it is determined that no lab reports are missing in the ELR process, TDH will send the TP an official letter documenting the successful completion of the production review. Paper lab reporting to TDH by the TP may be discontinued for those tests included in ELR, and the TPA will be signed by both TDH and the TP.

For more information, please contact: The Communicable Disease Surveillance Systems and Informatics team at CEDS.Informatics@tn.gov and please include 'ELR' in the subject line.

Electronic Laboratory Reporting (ELR) On-Boarding Checklist

Please note that the information in this document only applies to ELR in TN. The information below does not pertain to Immunization Registry updates, Cancer Case Reporting, or Syndromic Surveillance.

Introduction

The Communicable and Environmental Diseases and Emergency Preparedness Division (CEDEP) within the Tennessee Department of Health (TDH) has programmatic oversight of the diseases and conditions that are reportable to the State of Tennessee and how they are to be reported from hospitals, providers, and laboratories. This on-boarding checklist is intended for those interested in Electronic Laboratory Result Reporting (ELR), including those interested in obtaining Centers for Medicaid and Medicare Services (CMS) "Meaningful Use" funding. For more information on the ELR on-boarding process in Tennessee, helpful resources, and additional documentation, please visit:

<https://tn.gov/health/article/laboratory-reporting>

Purpose

The purpose of this document is to provide the reader with the information necessary for successful electronic laboratory reporting to TDH. The on-boarding checklist is for health systems, hospitals, laboratories and their vendors or business associates.

Useful Links

Tennessee Reportable Diseases: <https://apps.health.tn.gov/ReportableDiseases>

TDH Laboratory Reporting: <https://tn.gov/health/article/laboratory-reporting>

TDH Meaningful Use: <https://tn.gov/health/topic/meaningful-use-summary>

HL7, Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health Release 1 (US Realm) with errata: http://www.hl7.org/implement/standards/product_section.cfm?section=5

Logical Observation Identifiers Names and Codes (LOINC): <http://loinc.org/>

Systemized Nomenclature of Medicine (SNOMED):
http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html

NIST HL7 ELR 2.5.1 Validation Suite: <http://hl7v2-elr-testing.nist.gov/mu-elr/>

Pre-Registration with Public Health Agency

Before registering with TDH, these items are suggested to accelerate the on-boarding process.

Trading Partner (TP) Activity	Complete	Date
Map local lab test codes to LOINC standard vocabulary	<input type="checkbox"/> Yes	
Map local, non-numeric lab test result values to SNOMED-CT standard vocabulary	<input type="checkbox"/> Yes	
Map other local codes according to the HL7 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm)	<input type="checkbox"/> Yes	
Develop an HL7 message conformant to the HL7 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm)	<input type="checkbox"/> Yes	
Test ELR messages using the NIST HL7 ELR 2.5.1 Validation Suite	<input type="checkbox"/> Yes	
Resolve message issues found using the NIST HL7 ELR 2.5.1 Validation Suite	<input type="checkbox"/> Yes	

In addition to the Official Letters listed below, TDH will supply an Official Letter each time the Trading Partner transitions to a new phase in the on-boarding process.

Phase 1: Registration with Public Health Agency (PHA) / Pre-Testing

Trading Partner (TP) Activity	Complete	Date	TDH Response	Official Letter
Email MU.Health@tn.gov to set up account in Trading Partner Registration system.	<input type="checkbox"/> Yes		Assist trading partner in setting up Trading Partner Registration system account.	N/A
Submit registration information via Trading Partner Registration system (https://apps.tn.gov/tpr/)	<input type="checkbox"/> Yes		Send TP registration confirmation and on-boarding information	Registration Completed
Email 1 test de-identified ELR message following HL7, Version 2.5.1 ELR Implementation Guide	<input type="checkbox"/> Yes		Send TP message corrections, draft Trading Partner Agreement (TPA), and Vocabulary Worksheet	Initial Test Completed

Phase 2: Testing

Trading Partner (TP) Activity	Complete	Date	TDH Response	Official Letter
Fill out Vocabulary Worksheet including LOINC and SNOMED-CT codes and send to TDH	<input type="checkbox"/> Yes		Send TP vocabulary edits and questions	N/A
<i>If applicable:</i> send corrected Vocabulary Worksheet to TDH (iterative process - continue correcting until at an agreeable state)	<input type="checkbox"/> Yes		Invite TP to begin on-boarding and provide secure transport options	Vocabulary Validation Completed

Phase 3: On-Boarding

Trading Partner (TP) Activity	Complete	Date	TDH Response	Official Letter
Establish secure transport and test with TDH	<input type="checkbox"/> Yes		Acknowledge that transport connectivity test completed	N/A
Start sending ELR batch transmissions to TDH	<input type="checkbox"/> Yes		Send TP message corrections to be corrected	N/A
Document what errors have been corrected and send updated batch to TDH (iterative process - continue correcting until at an agreeable state)	<input type="checkbox"/> Yes		Verify all errors corrected and discuss parallel test validation with TP	Test File Validation Completed
Participate in parallel test validation process as decided during discussion with TDH	<input type="checkbox"/> Yes		Complete parallel validation and discuss moving to production with TP	N/A

Phase 4: Production

Trading Partner (TP) Activity	Complete	Date	TDH Response	Official Letter
Start sending production ELR batch transmissions to TDH and continue parallel validation	<input type="checkbox"/> Yes		Send TP any issues that need to be corrected	N/A
<i>If applicable:</i> Correct any issues found during production parallel validation	<input type="checkbox"/> Yes		Alert TP that they can stop sending paper labs for parallel validation	Production Review Completed
Stop parallel validation process	<input type="checkbox"/> Yes		Send TP the TPA	N/A
Review TPA and send TDH signed copy	<input type="checkbox"/> Yes		Send TP copy of finalized TPA	N/A

Electronic Laboratory Reporting (ELR) Frequently Asked Questions

Please note that the information in this document only applies to ELR in TN. The information below does not pertain to Immunization Registry updates, Cancer Case Reporting, or Syndromic Surveillance.

1. What constitutes ELR in TN?

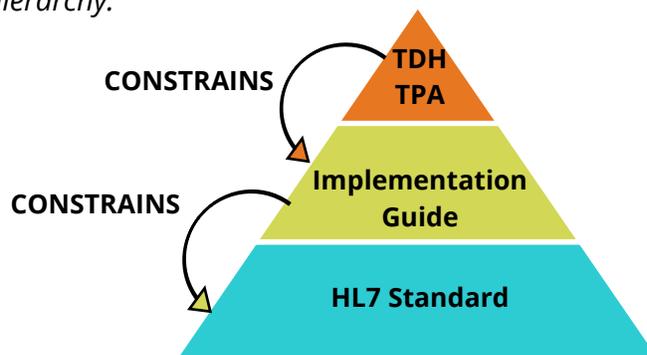
- a. In TN, ELR is the electronic submission of laboratory results thought to be indicative of a reportable condition, disease, or event, as described by the TDH, using interoperability standards (HL7 messaging). Flat file submissions, emails, and other formats are not considered to be ELR in TN, even if transmitted electronically.

2. How will TDH use the data I send in ELR messages?

- a. The ultimate goal of ELR is for the TDH surveillance systems to be able to consume that data so it can be used for public health action. TDH must ensure adequate and reliable information in those systems. Because of this, TDH will not use the data during testing in production surveillance systems. Once the ELR message content and structure is at an agreeable state, TDH will discuss moving the trading partner into production.

3. What HL7 versions can TDH currently receive for ELR?

- a. TDH is currently able to receive both HL7 2.3.1 and HL7 2.5.1 for ELR following the respective standards and implementation guides. TDH expects messages to be formatted based on the following hierarchy:



For more information on the HL7 standards and the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health Release 1 (US Realm) with errata, please visit http://www.hl7.org/implement/standards/product_section.cfm?section=5 . To obtain a copy of the Implementation Guide for transmission of Laboratory –Based Reporting of Public Health Information using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol (Dated March 2005), please contact edx@cdc.gov. Please contact TDH for a draft copy of the TDH Trading Partner Agreement.

4. Do you require the use of standard vocabulary?

- a. *Yes, we require the use of standard vocabulary and value sets, including but not limited to LOINC, SNOMED, and UCUM. LOINC codes and associated descriptions are required for all observation identifiers (OBX-3). TDH expects all coded observations values (OBX-5) to use SNOMED codes and associated descriptions. This applies to all ordinal results such as positive and reactive as well as nominal results for organism names. This does not apply to numeric or structured numeric observation values.*

5. Why am I required to submit the vocabulary worksheet to TDH?

- a. *TDH has found that vocabulary is one of the most time-intensive aspects of ELR validation. To expedite that process, TDH has worked vocabulary validation into the ELR on-boarding process. During this validation, TDH will work with your facility to ensure only reportable lab results are being sent, verify the tests that are performed in-house and those performed by reference laboratories, confirm that the LOINC and SNOMED codes being sent are valid and descriptions are accurate, check for internal consistency between LOINC code, result type, and specimen source, and work out potential content issues on the front-end.*

6. Will TDH map our local codes? If not, what tools are available for vocabulary mapping assistance?

- a. *TDH will not map local codes to standard codes. TDH will only accept local codes if sent with the corresponding standard vocabulary. The two best places to find vocabulary mapping assistance include RELMA from the Regenstrief Institute (<http://loinc.org/relma>) and CDC's PHIN VADS (Vocabulary Access and Distribution System) where you can find a wide variety of vocabulary and tools, including the Reportable Condition Mapping Tables (RCMT) (<http://phinvads.cdc.gov/vads/SearchHome.action>).*

7. What web based tools are available to assist me in validating my message structure?

- a. *TDH uses free, on-line ELR message tools to assist in validation. Examples include the NIST HL7 2.5.1 Validation Suite for certifying 2014 Edition Meaningful Use EHR technology (<http://hl7v2-elr-testing.nist.gov/mu-elr/>) and the CDC's Message Quality Framework (MQF) tool (<https://phinmqf.cdc.gov/>). TN recommends potential trading partners, including those just interested in testing for Meaningful Use, to first validate their messages using the NIST tool and make any necessary corrections, prior to submitting to TDH for testing. TDH recognizes that not all errors received from the NIST or MQF validation are of equal importance; some may be accepted by TN.*

8. What is reportable in TN?

- a. *The list of reportable diseases and events is updated annually and can be found on the TDH website: <https://apps.health.tn.gov/ReportableDiseases>. For information specific to lab events, please see the Reportable Diseases and Events Laboratory Reporting Guidance document: https://tn.gov/assets/entities/health/attachments/TN_Reportable_Events_Guidance.pdf.*

9. What methods of transport are available to send ELR to TDH?

- a. *Secure file transport protocol, or SFTP, is the preferred method of transport for ELR with TDH. This can be set up either by creating a username and password for the PTP account or by exchanging public keys, but utilizing the exchange of public keys is ideal as passwords are required to be updated often. Additional mechanisms might be available and can be discussed upon establishment. TDH does not establish secure transport with trading partners until vocabulary validation is completed and most structural message errors have been resolved. Please see the ELR on-boarding process (https://admincms.tn.gov/assets/entities/health/attachments/MU_ELROnboarding.pdf) for more information.*

10. If my lab starts to send ELR to TDH, will we have to continue sending paper lab reports?

- a. *Once the ELR has been validated against the paper lab reports being submitted for an appropriate amount of time (time frame to be determined by TDH and potential trading partner depending on volume), then TDH will permit the sender to discontinue sending paper lab reports. Paper can only be discontinued for the lab results included in ELR. If your facility is not utilizing ELR to meet all reporting obligations (e.g., not capturing results performed by reference laboratories), those lab reports will still need to be reported on paper. In the event that an ELR is not received, but TDH is notified of lab results from a provider, then TDH will require that paper/manual lab report submission from the lab resume until ELR is validated once again.*

11. Does ELR fulfill my reporting requirements to TDH?

- a. *ELR fulfills the laboratory's obligation to report reportable lab events so long as all reportable lab events are being sent via ELR. Laboratory reporting, including ELR, is not the same as case reporting by health care providers. Reporting by laboratories does not nullify the health care provider's or institution's obligation to report reportable disease and events, nor does reporting by health care providers nullify the laboratory's obligation to report reportable lab events. Laboratories are also required to send tests performed by reference labs, see question 12 below.*

12. Will my lab need to send the tests performed by reference lab facilities?

- a. *Yes, it is expected that ELR will include lab reports for tests performed in-house and by reference lab facilities with the performing organization appropriately documented in the ELR message. If you are unable to appropriately document the performing organization or utilize standard vocabulary for those labs sent to reference labs, continuance of paper lab reporting of these lab results will be expected.*

13. Is there an ELR on-boarding timeline?

- a. *This really depends on the readiness of the potential trading partner. There is not a specified timeline for how long it will take a trading partner to move into production. This depends on how engaged the trading partner is in the testing process and how many other trading partners TDH is currently on-boarding. For trading partners associated with Meaningful Use, please see the ELR on-boarding process for more information (https://admincms.tn.gov/assets/entities/health/attachments/MU_ELROnboarding.pdf).*

14. How do I get started?

- a. *The first step in the ELR on-boarding process is registering intent with TDH. To assist trading partners with tracking their progress through the ELR on-boarding process, TDH developed the ELR on-boarding checklist*

https://admincms.tn.gov/assets/entities/health/attachments/MU_ELROnboarding.pdf

This list is recommended for trading partner use, but will not be required to be completed and submitted to TDH. Before starting the on-boarding process, TDH recommends:

- i. *Mapping local lab test codes to LOINC standard vocabulary*
- ii. *Mapping local, non-numeric test result values to SNOMED-CT standard vocabulary*
- iii. *Mapping other local codes according to the HL7 2.5.1 Implementation guide: Electronic Laboratory Reporting to Public Health (US Realm)*
- iv. *Obtaining a copy of the HL7 2.5.1 Implementation guide: Electronic Laboratory Reporting to Public Health (US Realm)*
- v. *Working to develop a conformant message*
- vi. *Testing those messages using the NIST HL7 ELR 2.5.1 Validation Suite*
- vii. *Resolving message issues found using the NIST HL7 ELR 2.5.1 Validation Suite*

15. I received a letter from Tennessee Department of Health stating my facility/health system is “not a target for continued testing and validation of ELR with TDH and has been placed in the TDH ELR on-boarding queue.” What does this mean?

- a. *This letter is to inform you that you are in our ELR on-boarding queue and will be contacted in the future to continue testing and validation of ELR with TDH. We ask that you continue to report all reportable diseases and events in accord with your current reporting methods. For further information, visit our Meaningful Use website (<https://tn.gov/health/topic/meaningful-use-summary>), scroll down to the bottom section on Stage 2 to “What do the regulations say?” or reference the MU Stage 2 Final rule for details on how an eligible Professional or Hospital can meet measures.*

16. What information should I include in the message subject header (MSH)?

- a. *TDH accepts either CLIAs or OIDs in MSH-4 (Sending Facility). For MSH-5 and MSH-6, TDH will expect the OIDs below. For other MSH components please see question 17.*
- i. *[MSH-5] Receiving Application – ‘tdh-ELR^2.16.840.1.113883.3.773.1.1.3^ISO’*
 - ii. *[MSH-6] Receiving Facility – ‘TDH^2.16.840.1.113883.3.773^ISO’*

17. Does TDH accept batch or real-time message transmission for ELR?

- a. *Batch transactions will be utilized. Please see table 3-4 in the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health Release 1 (US Realm) with errata for correct Accept Acknowledgement value, Application Acknowledgement value, and Profile ID to be used in MSH-15, MSH-16, and MSH-21, respectively. TDH does not currently accept real-time message transmission for ELR. TDH does not send message or batch acknowledgements for ELR.*

18. When do we sign the Trading Partner Agreement (TPA)?

- a. *The TPA will remain in draft form and will not be signed by TDH or the trading partner until ELR is in production. TDH will share a draft version of the TPA with you early in the on-boarding process to help explain business rules. This draft TPA is a template that will be tailored for each trading partner and signed at the end of the on-boarding process.*

19. What is snapshot processing, and do I have to follow it?

- a. *Any order that results in multiple observations must follow snapshot processing rules as detailed in section 2.1.4 of the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health Release 1 (US Realm) with errata. Further information can also be found in HL7 version 2.7.1 Final Standard, Chapter 2, section 2.10.4.1. When an additional observation is made regarding a particular order, the sender must resend any previously sent observations associated with the order along with the additional information in the same message. This snapshot mode is how additions and deletions will be handled. All information in subsequent message(s) will replace the corresponding information from the previous message(s) in the receiving application. Because of this, when an observation regarding a particular order is made and an ELR message is sent, any subsequent observations obtained and sent using the same order information must include all previously sent observations for that order.*

20. If something is listed as “RE,” do I have to send it to TDH?

- a. *“RE” stands for “Required, but can be empty,” this is not the same as “Optional.” For values listed as RE, if the value is known, it is required to be sent. However, if the value is unknown, please leave the field empty. Conformant systems are required to be able to send this information, and the ability to send RE fields will be evaluated during on-boarding.*

21. Can I send more than one message type in the same file to TDH?

- a. *Although TDH encourages utilizing the same transport method for multiple business areas (e.g., ELR and Immunization Registry updates), mixed message types in 1 file will not be accepted. Separate files need to be sent to TDH for each type of message. For ELR, TDH expects only ORU_R01 messages be sent in a batch that is then sent in a file to TDH.*

22. What kind of documentation will TDH provide to me that I can use for Meaningful Use attestation?

- a. *TDH will provide official letters documenting completed steps and phases throughout the ELR on-boarding process, as noted in the ELR on-boarding checklist (https://admincms.tn.gov/assets/entities/health/attachments/MU_ELROnboarding.pdf). These letters can be used as documentation for your records. Neither TDH nor the Surveillance Systems and Informatics Program are the Meaningful Use regulators or the body which measures compliance. If you have specific questions about your attestation process, please contact representatives within those governing bodies.*

For more information, please contact the Communicable and Environmental Diseases & Emergency Preparedness (CEDEP) Surveillance Systems and Informatics Program (SSIP) team at CEDS.Informatics@tn.gov and please include ‘ELR’ in the subject line.

Tennessee Department of Health Tennessee Electronic Laboratory Reporting Business Rules

The following Business Rules will apply to this Trading Partner Agreement between the Trading Partner (TP) and the Tennessee Department of Health (TDH).

1. Specifications for this Agreement are contained in the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm) Release 1.0 (03/01/2010), with errata (10/07/2011). Additional constraints on the reference implementation guide can be found in Attachment 3.
2. The message structure required for this trading partner agreement is ORU^R01^ORU_R01 as described in the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm) Release 1.0 (03/01/2010), with errata (10/07/2011).
3. Batch processing will be utilized. Please refer to Table 3-4 in the implementation guide on Batch Abstract Message Syntax.
4. Any order that results in multiple observations must follow snapshot processing rules as detailed in section 2.1.4 of the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm) Release 1.0 (03/01/2010). Further information can also be found in HL7 version 2.7.1 Final Standard, Chapter 2, section 2.10.4.1 When an additional observation is made regarding a particular order, the sender must resend any previously sent observations associated with the order along with the additional information in the same message. This snapshot mode is how additions will be handled. All information in subsequent message(s) will replace the corresponding information from the previous message(s) in the receiving application. Because of this, when an observation regarding a particular order is made and an ELR message is sent, any subsequent observation obtained and sent using the same order information, must include all previously sent observations for that order. An example would be a culture order which results in a final result of *Salmonella* found and sent in an ELR message. If later that culture is also found to have grown *Shigella* and a new ELR message is sent, this second message must also include the original *Salmonella* result. Omitting the original *Salmonella* species result in the subsequent message would indicate that the result is deleted as part of the update that added the *Shigella* species result.
5. Acknowledgement messages will not be sent from TDH.

6. The implementation described in this agreement does not include electronic data exchange with NHSN.
7. The implementation described in this agreement refers to living subjects which does include humans who have died.
8. To determine jurisdiction for reporting: Patient address must be provided in [PID-11] (Patient Address). However, if it is unknown and left empty, then the ordering provider must be documented. If both are unknown and left empty, then the ordering facility is required. See number 9.
9. Messages are constrained to include only one patient per message. A message containing more than one PID segment will be rejected.
10. Any messages requiring more than one SPM segment per order (OBR segment) must be addressed with TDH prior to sending in production, in order for TDH to make internal processing accommodations.
11. RE fields are required, but can be empty if the information is not known. Conformant systems are required to be able to send this information.
12. Preliminary results (P), final results (F), and corrected results (C) are required to be sent by TP and should be properly documented in [OBX-11] (Observation Result Status). The State of Tennessee is required to process preliminary, final, and corrected results as determined by the State of Tennessee's reporting guidelines. (See HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm) Release 1.0 (03/01/2010), with errata (10/07/2011) Table 3-6 Interactions – Individual Transaction without Acknowledgements/Batch). Proper serialization must be followed, i.e. a final result cannot precede a preliminary result, and only a corrected result can succeed a final result.
13. Every message must contain one and only one ORC segment.
14. Parent child relationships should follow the normative content of the listed specification and parent observations should be appropriately documented in [OBR-26] (Parent Result) and [OBR-29] (Parent) of the child following the data types specified in the implementation guide. Parent/child relationships include reflex testing and drug susceptibility testing. Known errors in the examples provided in the listed specification should not be referenced as normative content.
15. SFT, PD1, PV1, PV2, TQ1, TQ2, CTD, FTI, and CTI are not required by the State of Tennessee and will be ignored if sent by trading partner. If any of these segments

are sent, the segments should be properly formed as described by the normative content. (Please see Table 4-1 in the previously referenced implementation guide)

16. [MSH-11] (Processing ID) can have the values "P" (Production), "T" (Training), or "D" (Debugging), but note that "T" and "D" will be handled in the same way.
17. Standard vocabulary is required. Such vocabulary coding systems include:
 - a. LOINC – Logical Observation Identifiers Names and Codes
 - b. SNOMED – Systemized Nomenclature of Medicine
 - c. UCUM – Unified Code for Units of Measure
18. Laboratory reporting including ELR is not the same as case reporting by health care providers. Reporting by laboratories does not nullify the health care provider's or institution's obligation to report reportable diseases and conditions, nor does reporting by health care providers nullify the laboratory's obligation to report reportable lab events.
19. It is expected that ELR will include lab reports for tests performed both in-house and by reference lab facilities with the performing organization appropriately documented in the ELR message. If you are unable to appropriately document the performing organization in the ELR message for those labs sent to reference labs, continuance of paper lab reporting of these lab results will be expected.

Tennessee Department of Health

Tennessee Electronic Laboratory Reporting

Message Format and Vocabulary

Constraints placed on the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm) Release 1.0 (03/01/2010), with errata (10/07/2011), are specified in this document. This implementation is for Electronic Lab Reporting (ELR) and not Test Order and Results (TOR) reporting or case reporting as discussed in Attachment 1. Constraints are listed below ordered by message segments. In fields where literal values are expected, the values are indicated below using single quotation marks following an equal sign (e.g. [MSH-12] Version ID = '2.5.1').

1. FHS – File Header Segment
 - a. [FHS-4] File Sending Facility – For the Universal ID we will accept a Party ID using NPI, CLIA, or OID, however the basic structure of the HD data type should be followed, i.e. Name Space ID, Universal ID (NPI, CLIA, or OID identifiers), Universal ID Type ('NPI', 'CLIA', or 'ISO').
 - b. [FHS-11] File Control ID – It is not supported and should not be sent. If it is sent, it will be ignored.

2. BHS – Batch Header Segment
 - a. [BHS-4] Batch Sending Facility – For the Universal ID, we will accept a Party ID using NPI, CLIA, or OID, however the basic structure of the HD data type should be followed, i.e. Name Space ID, Universal ID (NPI, CLIA, or OID identifiers), Universal ID Type ('NPI', 'CLIA', or 'ISO').
 - b. [BHS-11] File Control ID = It is not supported and should not be sent. If it is sent, it will be ignored.

3. MSH – Message Header
 - a. [MSH-3] Sending Application – We ask that 3.1 should be limited to 13 characters
 - b. [MSH-4] Sending Facility - For the Universal ID, we will accept a Party ID using CLIA or OID, however the basic structure of the HD data type should be followed, i.e. Name Space ID, Universal ID (CLIA or OID identifiers), Universal ID Type ('CLIA' or 'ISO')
 - c. [MSH-5] Receiving Application – Literal value 'tdh-ELR^2.16.840.1.113883.3.773.1.1.3^ISO'
 - d. [MSH-6] Receiving Facility – Literal value 'TDH^2.16.840.1.113883.3.773^ISO'
 - e. [MSH-9] Message Type = 'ORU^R01^ORU_R01'
 - f. [MSH-10] Message Control ID – 14 digit date/time stamp with a 4-6 digit sequence number for a total of 18-20 digits.

- g. [MSH-11] Processing ID - can have the values "P" (Production), "T" (Training), or "D" (Debugging), but note that "T" and "D" will be handled in the same way.
 - h. [MSH-12] Version ID = '2.5.1'
 - i. [MSH-15] Accept Acknowledgment Type = 'NE' (or left empty)
 - j. [MSH-16] Application Acknowledgment Type = 'NE' (or left empty)
4. MSA – Acknowledgement
 - a. Because of the use of BATCH processing, described in Attachment 2, TDH will not be sending acknowledgements.
 5. PID – Patient Identifier
 - a. [PID-3] Patient Identifier – Include social security number and the medical record number in addition to a patient identifier.
 - b. [PID-10] Race – Race values indicating "Hispanic" should not be included in this field, but should be reflected in the ethnicity field ([PID-22] Ethnic Group).
 6. ORC – Common Order Segment
 - a. [ORC-4] Placer Group Number – Should equal the requisition number.
 7. OBX – Observation/Result Segment
 - a. [OBX-2] Value Type – will be required and should appropriately correspond to the observation being made in [OBX-5] (i.e. a structured observation result should not be reported as TX). SN, NM, CE, & CWE data types will be expected.
 - b. [OBX-3] Observation Identifiers – will include the use of LOINC as the coding system. Local values and descriptions may also be supplied; however, LOINC codes and their associated descriptions will be required. It is expected that observation identifiers are appropriately coded to convey the actual test being performed, the method, the result yielded, and the specimen, when applicable.
 - c. [OBX-4] Observation Sub-ID – will be required for all OBX segments. When linked to a child order segment, should appropriately correspond to the observation sub-ID contained in the OBR-26 Parent Result.
 - d. [OBX-5] Observation Values – all coded observation values will include the use of SNOMED codes and associated descriptions. Local values and descriptions may also be supplied. This does not apply to numeric or structured numeric observation values.
 - e. [OBX-6] Units – UCUM codes will be expected for all quantitative observation values (NM or SN). Local values and descriptions may also be supplied.
 - f. [OBX-7] Reference Ranges – are expected for all quantitative observation values (NM or SN). We anticipate some reference ranges to be missing. To account for this, we expect abnormal flags to be in all observations and to be

used appropriately. The reference range will similarly be used to document cut point values, index values, and any other information used to interpret a quantitative observation value.

- g. [OBX-8] Abnormal Flag – Though listed as CE in the Implementation Guide, we expect this value to be supplied and to follow the appropriate codes listed in the HL70078 table. The Abnormal Flag field should be used to document the interpretation of the observation value and correspond to the information provided in [OBX-5] and [OBX-7] (observation result value and reference range, respectively).
- 8. SPM – Specimen
 - a. [SPM-4] Specimen Type – is required and will contain either SNOMED codes and descriptions or codes and descriptions from the HL70070 table or the HL70487 table.
- 9. FTS – File Trailer
 - a. [FTS-1] File Batch Count = '1'
- 10. BTS – Batch Trailer
 - a. [BTS-1] Batch Message Count – should be the total number of messages contained in the batch with a limit of 2000 messages per Batch.
- 11. Additional Comments:
 - a. Value types of ED (Encapsulated Data) and RP (Reference Pointer) will not be accepted.
 - b. Observation Identifiers: LOINC codes and their published long name descriptions or agreed upon descriptions by the signatories to this document are required.
 - c. Observation Values: SNOMED concept codes and their published descriptions or agreed upon descriptions by the signatories to this document are required for qualitative observation values.
 - d. For values listed as RE (Required but may be empty), if the value is known, then it is required to be sent. However, if the value is unknown, please leave the field empty.
 - e. Observations about a specimen will follow the SPM segment. Observations about an order will follow the OBR segment.