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1. Introduction

This document serves as the Minnesota Department of Health’s (MDH) Implementation Guidebook for Electronic Laboratory Reporting (ELR). The purpose of this document is to define how findings of reportable lab results should be communicated electronically with MDH by laboratories and other health care providers.

Please note that the MDH implementation guide v2.0 is not an alternative to the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) published by HL7. It is strongly recommended that this document be read in full with reference to the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) by the trading partners. Refer to both the implementation guides before starting implementation of ELR to identify the procedures required by HL7 2.5.1 standard and MDH.

Per the Minnesota Communicable Disease Reporting Rule (Chapter 4605), laboratories and other health care providers are required to report specific communicable diseases to MDH. The list of reportable communicable diseases to MDH is provided with this guide as Appendix B.

Any facility intending to meet the ‘Meaningful Use Criteria Stage 1” has to fulfill at least one of the public health reporting requirements, electronic transmission of laboratory results (ELR), electronic transmission of immunization data, or electronic transmission of syndromic surveillance data. This guidebook provides information about the public health requirement of electronic transmission of lab results but can also be used by facilities who wish to report lab results electronically without the objective to meet meaningful use.

To meet meaningful use for ELR, Minnesota health care providers should electronically submit data from a certified electronic health record system using national standards, following the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm).

The HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) can be obtained from the HL7 website. The trading partners need to be a member or need to purchase the HL7 2.5.1 implementation guide from the HL7 website. The link to the HL7 website is provided below.

http://www.hl7.org/implement/standards/hhsifr.cfm

ELR does not replace a healthcare facility’s compliance with the Communicable Disease Reporting Rule. For example, although diseases which require immediate reporting by phone may be included in ELR they still must be immediately reported by phone (see Appendix B) and ELR cannot be the primary reporting mechanism for these diseases. Diseases that are diagnosed based on symptoms rather than laboratory results (e.g., Kawasaki disease, HUS) still need to be reported to MDH unless they are included in the ELR feed. For diseases that are determined as reportable based on a laboratory result and reporting must occur within one working day, ELR may replace paper, fax or phone based reporting if the facility is able to include enough patient information and after agreed to by MDH.
2. Definitions/ Acronyms

<table>
<thead>
<tr>
<th>CMS</th>
<th>Centers for Medicare and Medicaid Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>ELR</td>
<td>Electronic Laboratory Reporting</td>
</tr>
<tr>
<td>EHR</td>
<td>Electronic Health Records</td>
</tr>
<tr>
<td>HIE</td>
<td>Health Information Exchange</td>
</tr>
<tr>
<td>HIPAA</td>
<td>Health Insurance and Portability and Accountability Act</td>
</tr>
<tr>
<td>HL7</td>
<td>Health Level 7</td>
</tr>
<tr>
<td>LIMS</td>
<td>Laboratory Information Management System</td>
</tr>
<tr>
<td>LOINC</td>
<td>Logical Observation Identifiers Names and Codes</td>
</tr>
<tr>
<td>MEDSS</td>
<td>Minnesota Electronic Disease Surveillance System</td>
</tr>
<tr>
<td>MQF</td>
<td>Message Quality Framework</td>
</tr>
<tr>
<td>ONC</td>
<td>Office of the National Coordinator (for Health IT)</td>
</tr>
<tr>
<td>ORU</td>
<td>Observational Report – Unsolicited</td>
</tr>
<tr>
<td>PHI</td>
<td>Protected Health Information</td>
</tr>
<tr>
<td>PHIN</td>
<td>Public Health Information Network</td>
</tr>
<tr>
<td>PHINMS</td>
<td>Public Health Information Network Messaging System</td>
</tr>
<tr>
<td>PHIN VADS</td>
<td>Public Health Information Network Vocabulary Access and Distribution System</td>
</tr>
<tr>
<td>RCMT</td>
<td>Reportable Condition Mapping Table</td>
</tr>
<tr>
<td>SNOMED</td>
<td>Systematized Nomenclature of Medicine</td>
</tr>
</tbody>
</table>

3. ELR Overview

I. About ELR

ELR allows hospitals, clinics and laboratories to report lab tests and results for reportable communicable diseases through an automated and secure process. All hospitals, licensed health care providers and non-hospital based laboratories are required to report communicable disease events to MDH according to Minnesota rule. One method for reporting this information is to export data from IT systems at the hospital or lab in a standard file format and send it to MDH electronically. The national messaging standard for transmission of reportable laboratory test results to public health agencies is the HL7 Version 2.5.1. HL7 refers to a standard for healthcare specific data exchange between computer applications. The main goal of ELR is to minimize the human effort required to report cases and to improve the timeliness, completeness and accuracy of reporting which will enhance public health surveillance and increase the ability to implement prevention and control measures when necessary.
**Fig (a) ELR to MDH**: Laboratory reporting from its LIMS to MDH electronically through certified EHR technology using HL7 2.5.1 message through a secured transport mechanism. After validating the message, it is uploaded to MEDSS.
II. Why ELR?
MDH aims to support and facilitate implementation of ELR because ELR can decrease staff requirements of labs and health care providers reporting to the public health agencies and increases efficiency for both healthcare facility and public health staff. ELR decreases the burden of reporting on the laboratory by identifying reportable laboratory results, formatting results for reporting, and sending reports to MDH. Through ELR, labs can reduce paper work, decrease data entry and retrieval time, and decrease staff needed to keep records intact and updated. Additionally, it eliminates duplicate data entry, speeds up data transformation process and ensures data transmission consistency following national standards and public health reporting guidelines. Adopting ELR also guarantees data security by maintaining the patient data with compliance to HIPAA regulation that requires healthcare institutions to enact and enforce security measures so that patient information remains confidential.

Furthermore, the advantages of ELR include:
- Using ELR increases the timeliness and completeness of disease reporting. Timeliness of reporting refers to the time between the specimen collection date and the date when the health department was notified of a positive result. Completeness refers to both the information provided in the report and the proportion of diagnosed cases reported.
- ELR is useful for reporting diseases for which the diagnosis can be based on positive laboratory results for example, Chlamydia, Salmonella, etc.
- ELR aids in other communicable disease public health surveillance purposes, including tracking the volume of tests ordered, and early detection of outbreaks leading to early implementation of public health prevention and control measures.

III. ELR and ADR
Although ELR is part of meaningful use, some facilities may want to consider a feed that is similar to ELR but contains additional patient data. Automated Disease Reports (ADR) is currently in pilot testing at MDH. The difference between ELR and ADR is that ADR provides additional data elements from the patient’s chart (e.g., treatment, hospital admission and discharge) that are not included in ELR but are needed by MDH.

The benefit of ADR is that it may minimize the reporting burden for hospitals and clinics particularly for infection prevention staff, by potentially minimizing the number of call-backs from MDH for additional information. ADR is especially helpful when only minimal patient demographic data (e.g., patient address, phone number, date of birth, etc.) are stored in LIMS and additional data are necessary for public health investigations.

4. ELR and Meaningful Use
The inclusion of ELR as one of the requirements for meeting “Meaningful Use Criteria” acts as a catalyst to an increased need for public health to be able to manage a growing volume of electronic data. The federal incentive funding program offers payments for eligible hospitals and eligible providers for meeting the meaningful use criteria but not to laboratories. However, non-hospital based laboratories are required to report to MDH according to Minnesota law. Hence, MDH encourages the all labs to adopt and use the standards for electronic exchange of reports.
"Meaningful Use" is defined as the use of certified EHR technology by a provider in a meaningful manner ensuring the quality of care through electronic exchange of health information and submitting the electronic data on reportable lab results to public health agencies and actual submission in accordance with applicable law and practice. The criteria for meaningful use are staged in three different steps over the course of the next 5 years.

I. Meaningful Use for Stage 1
Stage 1 includes two sets of requirements: a set of 15 required core objectives that form a foundation for meaningful use of EHRs, and a separate menu of 10 additional elements from which providers need to choose at least five to implement. Although providers have flexibility in choosing a menu set options; at least one of the five options must be specific to public health.

Among 10 menu elements, three involve electronic reporting to public health and include:

- Immunization Reporting: Submit electronic data to immunization information system
  
  For more information about Minnesota Immunization Information Connection (MIIC)
  

- ELR: Submit reportable labs results to public health

- Syndromic Surveillance Reporting: Submit syndromic surveillance data to public health (not an option for Minnesota in Stage 1)

Additional Resources related to Meaningful Use criteria:
For more details about the Meaningful Use, visit the CMS site at

[https://www.cms.gov/EHRIncentivePrograms/30_Meaningful_Use.asp](https://www.cms.gov/EHRIncentivePrograms/30_Meaningful_Use.asp)

Also visit CDC’s website for Meaningful Use for ELR and more at:


For information about the reporting requirements to MDH for Stage 1 Meaningful Use criteria.

[http://www.health.state.mn.us/e-health/phreportmu.pdf](http://www.health.state.mn.us/e-health/phreportmu.pdf)

II. ELR Requirements for Meaningful Use
This section outlines the details about the requirements for ELR to meet the meaningful use criteria for stage 1. It focuses on one type of HL7 message, the Observational Report – Unsolicited. MDH encourages all laboratories to adopt and use these standards for ELR. The requirements for electronic message submission are message production and formatting based on common standards that make the communication possible with MDH. The participating laboratories or the trading partners shall:

- Use certified EHR technology to generate the message. If the ELR message is going to be used to meet meaningful use, participating laboratories must perform at least one test of the certified EHR technology’s capacity to submit electronic data on reportable lab results with continued submission if successful.

- Generate messages following the message format specified in the HL7 version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 and according to the specifications in the document **MDH Specifications for ELR (HL7 2.5.1)** (See Appendix A).

- Use LOINC codes to send information about tests and use coded values to send information about results.
• Send to MDH using a secure transport mechanism. Refer to the Message Transport Mechanism section of this guide for more details.

Submissions using direct data entry, message content where MDH translates local codes to LOINC codes or electronic transfer in flat file format do not qualify under the meaningful use objective.

5. Privacy and Security

HIPAA allows entities to continue reporting relationships with their public health partners and upholds state statutes (e.g., Chapter 4605 of the Minnesota State Statutes) that require disease and injury reporting to public health authorities. The HIPAA Privacy Rule permits protected disclosures without individual authorization to public health authorities. According to the HIPAA Privacy Rule, 45 CFR3 §164.512, uses and disclosures for which an authorization or opportunity to agree or object is not required. Specifically,

• **Section 164.512(a)** permits disclosure of “…protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.”

• **Section 164.512(b)** permits a covered entity to disclose protected health information to:
  “A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions…”

M.S. §144.05, subd. 1(a) and the Minnesota Communicable Disease Reporting Rules, **Parts 4605.7000 to 4605.7900** allow MDH and local public health authorities to conduct investigations on communicable diseases to protect the public’s health. Therefore healthcare providers and facilities can share medical information pertaining to a communicable disease investigation without patient authorization.

See the following link for the [HIPAA Privacy Rule and Public Health Guidance](http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm) from CDC and the U.S. Department of Health and Human Services.

MDH is obligated by statute to monitor the occurrences of diseases; respond rapidly to control outbreaks of infectious disease; develop and implement strategies for preventing and controlling diseases; and put those strategies into action in order to protect and improve the public's health. MDH, local health departments, and external trading partners will maintain the privacy of protected health information, including ELR and MEDSS information.

6. Required Communicable Disease Reporting and Reportable Conditions

The Minnesota Communicable Disease Reporting Rule ([http://www.health.state.mn.us/divs/iddep/dtopics/reportable/rule/rule.pdf](http://www.health.state.mn.us/divs/iddep/dtopics/reportable/rule/rule.pdf)) requires medical professionals to report findings of communicable diseases of public health importance to MDH. Laboratories are required to report the identification or suspected identification of a disease-causing organism or laboratory findings of public health importance to MDH. A list of communicable diseases and laboratory findings that would require reporting to MDH are listed in the **MDH Reportable Diseases Mapping Table-for ELR, Appendix B.**
Laboratories are responsible for reporting communicable diseases for specimens that are tested in their laboratories, for specimens that are sent to “reference laboratories,” and for specimens which are sent for further identification to “reference laboratories.”

The content of reports by laboratories for the individual affected or ill is defined as:

- Name
- Address
- Telephone number
- County or residence
- Age or date of birth
- Name of the attending physician and contact information
- Reporting laboratory name and contact information
- Identity or suspected identity of the organism or the laboratory findings

Moreover, additional disease specific reporting information may also be required but varies by disease.

MDH offers multiple ways of reporting infectious diseases. Any reportable disease can be reported by telephone; some diseases must be reported immediately by phone. In addition, some diseases require additional information that is not requested in the initial disease report (a.k.a. yellow card), for those diseases there may be a supplemental form requesting additional information. Use the following link for more details about various methods of disease reporting to MDH.
http://www.health.state.mn.us/divs/idepc/dtopics/reportable/forms/index.html#supplement

7. Message Structure Requirements

The MDH-ELR application will accept HL7 version 2.5.1 formatted ORU messages that conform to the CDC as well as MDH standards. Refer to the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) and the MDH Specifications for ELR (HL7 2.5.1) (See Appendix A) to create and send HL7 messages in the format as required by MDH. Both these guides should be considered when creating the message using the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) as a base and the MDH Specifications for ELR (HL7 2.5.1) as a companion document.

To qualify for meaningful use, the reportable lab results should be sent in HL7 2.5.1 data exchange format, and incorporate LOINC codes and coded results. If a sending facility is not able to send an HL7 2.5.1 message other file formats can be accepted after discussion and approval of MDH (however formats other than HL7 2.5.1 will not qualify for meaningful use).

The following section details the structure of the ORU^RO1^ORU^RO1 message profile for Electronic Laboratory Reporting to Public Health. This message profile is called the “ELR Receiver profile” in the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) guide. The ORU^RO1 message is constrained for transmitting laboratory results from the testing source to Public Health.
### Message Structure for ELR to Public Health

<table>
<thead>
<tr>
<th>Segment in Standard</th>
<th>Segment name</th>
<th>Cardinality</th>
<th>ELR Receiver Usage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSH</td>
<td>Message Header</td>
<td>[1..1]</td>
<td>R</td>
<td>The message header (MSH) segment contains information describing how to parse and process the message. This includes identification of message delimiters, sender, receiver, message type, timestamp, etc.</td>
</tr>
<tr>
<td></td>
<td>{(SFT)}</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>{PATIENT_RESULT Begin}</td>
<td>[1..*]</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td></td>
<td>[PATIENT Begin]</td>
<td>[1..1]</td>
<td>R</td>
<td>For public health reporting the patient group is required</td>
</tr>
<tr>
<td>PID</td>
<td>Patient Identification</td>
<td>[1..1]</td>
<td>R</td>
<td>The patient identification (PID) segment is used to provide basic demographics regarding the subject of the testing.</td>
</tr>
<tr>
<td></td>
<td>[PD1] Additional Demographics</td>
<td>[0..1]</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td></td>
<td>{{NTE}} Notes and Comments for PID</td>
<td>[0..*]</td>
<td>RE</td>
<td>This notes and comments (NTE) segment should contain notes or comments pertaining to the patient identified in the PID segment. It should not contain order or result related comments.</td>
</tr>
<tr>
<td></td>
<td>{{NK1}} Next of Kin/Associated Parties</td>
<td>[0..*]</td>
<td>RE</td>
<td>The next of kin (NK1) segment can be used to document the patient’s next of kin, employer, guardian, etc. Particular jurisdictions may require the NK1 segment to contain parent/guardian information when reporting lead testing results for children.</td>
</tr>
<tr>
<td></td>
<td>[VISIT Begin]</td>
<td>[0..1]</td>
<td>RE</td>
<td></td>
</tr>
<tr>
<td>PV1</td>
<td>Patient Visit</td>
<td>[1..1]</td>
<td>R</td>
<td>HL7 requires that the patient visit (PV1) segment be present if the VISIT group is present.</td>
</tr>
<tr>
<td>PV2</td>
<td>Patient Visit – Additional Information</td>
<td>[0..1]</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td></td>
<td>] VISIT End</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>] PATIENT End</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Segment in Standard</td>
<td>Segment name</td>
<td>Cardinality</td>
<td>ELR Receiver Usage</td>
<td>Description</td>
</tr>
<tr>
<td>---------------------</td>
<td>--------------</td>
<td>-------------</td>
<td>--------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>{</td>
<td>ORDER_OBSERVATION Begin</td>
<td>[1..*]</td>
<td>R</td>
<td>The order group is required and can repeat. This means that multiple ordered tests may be performed on a specimen. Snapshot processing of the result message involves processing as a snapshot all the repeats of the ORDER_OBSERVATION group together as a group. This is especially important when dealing with parent/child results (such as cultures and sensitivities) which will span multiple ORDER_OBSERVATION groups. All these must be processed from both a message sender and message receiver perspective as a single snapshot.</td>
</tr>
<tr>
<td>[ORC]</td>
<td>Order Common</td>
<td>[0..1]</td>
<td>CE</td>
<td>The common order (ORC) segment identifies basic information about the order for testing of the specimen. This segment includes identifiers of the order, who placed the order, when it was placed, what action to take regarding the order, etc. MDH-ELR requires the first ORDER_OBSERVATION group must contain an ORC segment (containing ordering facility information) if no ordering provider information is present in OBR-16 or OBR-17.</td>
</tr>
<tr>
<td>OBR</td>
<td>Observations Request</td>
<td>[1..1]</td>
<td>R</td>
<td>The observation request (OBR) segment is used to capture information about one test being performed on the specimen. Most importantly, the OBR identifies the type of testing to be performed on the specimen, and ties that information to the order for the testing.</td>
</tr>
<tr>
<td>[{NTE}]</td>
<td>Notes and Comments for OBR</td>
<td>[0..*]</td>
<td>RE</td>
<td></td>
</tr>
<tr>
<td>{</td>
<td>TIMING_QTY Begin</td>
<td>[0..*]</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>TQ1</td>
<td>Timing/Quantity</td>
<td>[1..1]</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>{[TQ2]}</td>
<td>Timing/Quantity Order Sequence</td>
<td>[0..1]</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>}</td>
<td>TIMING_QTY End</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[CTD]</td>
<td>Contact Data</td>
<td>[0..1]</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Segment in Standard</td>
<td>Segment name</td>
<td>Cardinality</td>
<td>ELR Receiver Usage</td>
<td>Description</td>
</tr>
<tr>
<td>---------------------</td>
<td>-------------------</td>
<td>-------------</td>
<td>--------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>[[]</td>
<td>OBSERVATION Begin</td>
<td>[0..*]</td>
<td>CE</td>
<td>Multiple results may be associated with an order. There will always be a single OBX in the results group. Snapshot processing: Since the OBX segment in 2.5.1 does not contain a unique instance identifier, it is assumed that the repeating observation group will contain a complete set of observations (OBXs) associated with the OBR. Where a single OBX is being updated, all the OBXs related to the OBR must accompany the updated OBX, i.e., a full snapshot is sent. Harmonized condition predicate: May be empty for OBR-25 Result statuses of “O,” “I,” “S” and “X”; otherwise, it is required. OBX related to the OBR is required unless OBR-25 contains the result status of “X” (No results available, order canceled)</td>
</tr>
<tr>
<td>OBX</td>
<td>Observation related to OBR</td>
<td>[1..1]</td>
<td>R</td>
<td>The observation/result (OBX) segment contains information regarding a single observation (analyte) result. This includes identification of the specific type of observation, the result for the observation, when the observation was made, etc.</td>
</tr>
<tr>
<td>[[NTE]]</td>
<td>Notes and Comments</td>
<td>[0..*]</td>
<td>RE</td>
<td>The notes and comment (NTE) segment may carry comments related to the result being reported in the OBX segment.</td>
</tr>
<tr>
<td>[[]</td>
<td>OBSERVATION End</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[[FTI]]</td>
<td>Financial Transaction</td>
<td>[0..*]</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>[[CTI]]</td>
<td>Clinical Trial Identification</td>
<td>[0..*]</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>Segment in Standard</td>
<td>Segment name</td>
<td>Cardinality</td>
<td>ELR Receiver Usage</td>
<td>Description</td>
</tr>
<tr>
<td>---------------------</td>
<td>-------------</td>
<td>-------------</td>
<td>-------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>{{ }}</td>
<td>SPECIMEN Begin</td>
<td>[0..*]</td>
<td>CE</td>
<td>The specimen group is required in the ORU and is used to carry specimen information that is no longer contained in the OBR segment. It also provides a place for the specimen number. Note that for ELR, the message has been constrained to support a single SPECIMEN group per OBR, meaning only a single specimen can be associated with the OBR. MDH expects all ELR messages to provide Specimen information.</td>
</tr>
<tr>
<td>SPM</td>
<td>Specimen Information related to OBR</td>
<td>[1..1]</td>
<td>R</td>
<td>The specimen information (SPM) segment describes the characteristics of a single sample. The SPM segment carries information regarding the type of specimen, where and how it was collected, who collected it, and some basic characteristics of the specimen.</td>
</tr>
</tbody>
</table>
| {{OBX}}             | Observation related to Specimen | [0..*] | RE | The Observation related to Specimen is generally used to report additional characteristics related to the specimen. It is not used to report the results of the requested testing identified in OBR-4 (Universal Service ID). The observations associated with the specimen are typically information that the ordering providing sends with the order. The laboratory forwards that information as part of the result message. One recommended value to report in the OBX related to Specimen is the age of patient at time of specimen collection. The appropriate LOINC code for this is 35659-2 (Age at specimen collection:TimeDif:Pt:^Patient:Qn). Other possible types of observations include:  
- Was specimen sent out?  
- Id of the specimen/isolate sent for testing  
- Where was the specimen sent?  
- Reason for send out?  
- Was it a specimen or isolate? Implementers need to provide a list of expected observations associated with specimen to MDH prior to production. |
8. Message Content Requirements

It is the participating laboratory’s responsibility to ensure that the messages that they are sending to MDH are compliant with both of the HL7 2.5.1 as well as the MDH standards. Guidelines for correct message content is listed in the MDH Specifications for ELR (HL7 2.5.1) (See Appendix A)

MDH’s receiving system requires the use of LOINC codes for tests and coded values for results (preferably SNOMED Codes). If the participating trading partner does not use LOINC codes, they will need to translate their local test codes to LOINC codes, prior to sending ELR messages to MDH.

If a trading partner is unable to translate their local test and local result codes to LOINC and SNOMED codes, MDH has the capability to do this translation. However, ELR messaging without LOINC codes will not meet the “Meaningful Use Criteria.” If any trading partner would like to discuss ELR messaging without the use of LOINC and SNOMED coded values, MDH should be consulted.

I. LOINC and SNOMED Mapping tool
CDC has developed a tool called RCMT that will assist the laboratories to map reportable conditions with their associated LOINC lab tests and SNOMED lab results. The RCMTs include LOINC-to-condition and SNOMED-to-condition mapping tables. Unlike the previous mapping tables like Dwyer and Notifiable Condition Mapping Tables (NCMT), the RCMT will be simpler and more comprehensive.

PHIN VADS allows users to download and navigate the entire RCMT or subsets of RCMT (e.g. TB specific RCMT). Additionally future maintenance of the RCMT will be supported by the RCMT workgroup and CDC vocabulary /PHIN VADS team. Further information can be obtained from the link given below:

External trading partners must provide a complete list of reportable test and result codes to MDH prior to file submission. This list can be provided to MDH using the format MDH Test Result Mapping Template (See Appendix C) or equivalent. Each laboratory is also responsible for notifying MDH of any future changes to this list using a process defined during the implementation (see section 11. ELR Implementation Process)
9. Message Transport Mechanism

When an eligible laboratory is successful in sending valid test messages to MDH, it should institute regular reporting to MDH according to applicable national standards and practices through a secured transport mechanism. PHINMS (Public Health Information Network- Messaging System) is currently the preferred way of receiving data at MDH. It is a secure file transfer system that is free of charge from the CDC and is available in Windows, Solaris or Linux versions. MDH has staff available to help install and configure PHINMS and has developed instructional files to help new teams walk through the procedures.

Messages are encrypted from the sending PHINMS to the receiving PHINMS. PHINMS guarantees the delivery (once and only once) and automates the sending (reties until success - queue management). For more information, visit PHINMS home page at www.cdc.gov/phin/tools/PHINMS/index.html

MDH acknowledges that PHINMS might not be the optional transport mechanism in the future. Trading partners might want to consider any of the following options before deciding on the message transport mechanism to use:

- If the facility has the capability to push data to any of the HIEs in Minnesota, MDH will be able to receive the data via the HIE in the future; different options can be discussed.
- If the facility has the capability to push data using the NwHIN Direct protocol, MDH will be able to receive it in the future.
- If the facility has the capability to send data using NwHIN CONNECT (Nationwide Health Information Network), MDH will be able to receive it in the future.

10. Responsibilities

I. Responsibilities of MDH

MDH is committed to providing support and assistance to laboratories throughout the evaluation, implementation and maintenance processes for ELR. MDH is expected to fulfill the following responsibilities:

- Provide MDH ELR staff contact information to the participating laboratories.
- Provide ELR implementation guidelines and specifications to participating laboratories.
- Collaborate with participating laboratory personnel to develop and implement ELR at the participating laboratory.
- Collaborate with the participating laboratory personnel and CDC personnel to assist in the installation of the national standard for messaging, evaluate the data transfer and monitor the transfer process.
- Provide guidance and support to participating laboratories in identification of tests and test data to report to MDH.
II. Responsibilities of Reporting Laboratories

External trading partners must submit a completed MDH-ELR online registration form to MDH (see section 11.II.a) and are expected to fulfill the following responsibilities:

- Obtain the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) from the HL7 Website through membership or purchase. MDH is **NOT** allowed to provide the HL7 2.5.1 Implementation Guide. The link to the HL7 website is provided below. [http://www.hl7.org/implement/standards/hhsifr.cfm](http://www.hl7.org/implement/standards/hhsifr.cfm)
- Identify a team of individuals to implement ELR at their institution and provide contact information to the MDH-ELR staff for those individuals.
- Collaborate with the MDH-ELR staff, HIE staff, and MDH communicable disease epidemiology and IT staff to develop and implement ELR at their site.
- Provide MDH-ELR staff with the correct format of the message.
- The sending laboratory must provide the data in the desired structure according to the guides provided.
- Collaborate with the MDH-ELR staff to:
  - Coordinate timelines to begin the implementation.
  - Provide MDH-ELR staff with local test codes and result codes spreadsheet mapping to LOINC and result codes.
  - Follow the *ELR Implementation Process* included in this guide, *MDH Implementation Guide for ELR*, to verify the messaging format and to assure all the requirements are met.
  - Develop a protocol to update the Test/ Result spreadsheet as laboratory tests are added, deleted, or modified.
  - Develop a protocol for monitoring the transport of the message.
  - Coordinate the file sending schedule with MDH-ELR team to make the sending and receiving process more efficient.
  - Identify a contact person responsible for transport monitoring and validation of the message and provide the contact information to MDH-ELR Staff.
11. ELR Implementation Process

In order to participate in the ELR process with MDH, all laboratories and trading partners must follow the process described below. Each of the steps listed requires an approval from MDH in order to move forward to the next step.

I. Use a Certified EHR System (for Meaningful Use)
   If the facility does not intend to meet meaningful use requirements, this step can be skipped. Go to section (II).

   If the facility is implementing ELR with the objective to meet meaningful use, they should have a certified EHR system in use. If the facility has new EHR technology or have developed their own EHR systems or products, they need to be tested and certified. To obtain the CMS EHR Certification number for the facility’s EHR system or product, please visit either of these two websites:
   http://onc-chpl.force.com/ehrcert
   https://www.cms.gov/EHRIncentivePrograms/25_Certification.asp

II. Message Creation and Pre-testing
   The message creation and pre-testing phase initiates the process for ELR to MDH. Laboratories that intend to meet Stage 1 Meaningful Use Criteria must at least complete the implementation and test phase. Stage 1 Meaningful Use Criteria requires the laboratories to send at least one valid test message to public health agencies.
   a. Complete the MDH-ELR Online Registration Form
      To participate in the MDH-ELR project, the first step the laboratory must do is to complete the MDH ELR Registration form. All the information filled in the registration form is expected to be accurate. Once MDH receives the completed registration form, it will be reviewed and verified. The form may be downloaded from the MEDSS MDH Electronic Laboratory Reporting web page: http://www.health.state.mn.us/medss/elr.html
b. **Receive Acknowledgement from MDH**

Upon verification of the registration form, the laboratory is merely registered for the MDH-ELR process. MDH will reach out to the contact person from the completed online registration form for further steps. After approval to start the ELR process, MDH will coordinate/schedule the next steps listed below.

c. **Set up a Transport Mechanism**

This phase will be initiated by MDH by contacting the person in charge for transmission in the laboratory. During this phase, the personnel from MDH and the laboratory, handling the message transport system, will set up a secure message transport mechanism between the facility and MDH. MDH personnel will be available to help and have developed instructional files to help new teams walk through the procedures.

See section *Message Transport Mechanism* of this guide for more details about what transport mechanism to use.

If the facility intends to send test messages that contain fake data the facility can choose to setup the secure transport mechanism during the onboarding process. In this case test messages can be sent via email. If testing is being done with real data it has to be treated as protected health information (PHI), and the test messages must be sent through a secure transport mechanism.

It is our experience that the selection and installation of a secure transport mechanism could take time to complete and we strongly encourage the facilities to start discussing transport mechanisms with MDH during the message creation phase.

d. **Construct the MDH-ELR HL7 Test Message**

For meaningful use criteria, the message should be generated from the certified EHR and constructed in accordance to both national standards and MDH requirements. See section *Message Structure Requirements* and *Message Content Requirements* sections in this document for more details on how to create a valid test message.

e. **Verify the Structure of the Test Message**

The structure of the test messages that are created by the laboratory should be verified before they start testing with MDH. MDH recommends and expects senders to use the PHIN Message Quality Framework (MQF) tool to validate their messages before sending any messages to MDH for testing purposes.

PHIN MQF is a tool that can be used by the sending laboratories to validate HL7 messages against the guide. This application is designed to assist other CDC Public Health systems and partners in promoting the use of data and information system standards to advance the development of efficient, integrated, and interoperable surveillance systems at federal, state and local levels. MQF allows users to upload a test message and view a detailed validation report immediately after the message has been submitted. In case of error occurrence, the user may edit the message and resubmit the message until all errors have been resolved. For more details about how to use this tool, visit the link https://phinmqf.cdc.gov/

Follow the link for MQF application overview and a complete list of support specifications http://www.cdc.gov/phin/resources/certification/MQPtool-overview.html
III. Testing

i. Send the Test File to MDH

The test files should be sent to MDH using the secure transport mechanism identified during the implementation phase. MDH will accept fake or real data in the test files. Once received at MDH all of the test data will be considered PHI and pulled into a separate validation system with limited access.

If the facility is testing with fake data the test messages can be sent via email if the transport mechanism has not yet been implemented. If testing is being done with PHI, then transport must be done through a secured transport mechanism.

Before any test data is sent to MDH a notification should be emailed to Health.MDHELR@state.mn.us. The email should contain the following information:

- Name of Facility ready to send the test file
- Date the test file will be sent
- Transport mechanism used

ii. Validation and Approval by MDH

Only after the format and content of the test messages has been approved by MDH, will your laboratory be able to proceed to the onboarding step. MDH will validate the message using both the national standard for messaging i.e., HL7 2.5.1 standard, and the MDH standard. After validation, MDH will send an acknowledgement of the outcome of the test submission with information about a pass or a fail.

<table>
<thead>
<tr>
<th>Successful data submissions for ELR for Meaningful Use include those with all of the following characteristics:</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Submitted from a certified EHR technology</td>
</tr>
<tr>
<td>✓ Follows the HL7 2.5.1 Implementation Guide for Electronic Laboratory Reporting to Public Health, Release 1 (US Realm)</td>
</tr>
<tr>
<td>✓ Includes LOINC codes for tests</td>
</tr>
<tr>
<td>✓ Passes content validation as defined in the MDH Implementation Guide v.2.1 for ELR.</td>
</tr>
</tbody>
</table>

Submissions using direct data entry, message content where MDH translates local codes to LOINC codes or electronic transfer in flat file format do not qualify under the meaningful use objective.

Facilities seeking to meet Meaningful Use objectives must continue to the onboarding phase after test messages pass validation. During the validation and approval step, feedback on the message will be provided by MDH and the facility will have the opportunity to make changes and repeat the test submissions until the message is approved. ELR meaningful use objectives for Stage 1 are met after this process step has been completed.
IV. Attestation

MDH will provide the facility with a confirmation that they have completed the testing step and the outcome (pass or fail). For Meaningful Use Stage 1, the facilities are responsible for conveying the information about meeting the meaningful use criteria using the CMS’ Web-based system to CMS and get attested.

For more details about the Medicare and Medicaid EHR Incentive Program, registration and attestation, visit following links.
For registration: http://www.cms.gov/EHRIncentivePrograms/20_RegistrationandAttestation.asp
For Attestation: https://ehrincentives.cms.gov/hitech/login.action
For detailed information about registration and attestation:
https://www.cms.gov/EHRIncentivePrograms/32_Attestation.asp

V. In-Queue

Due to the resources and time required to move through the onboarding process MDH will prioritize and sometimes queue facilities that have completed the implementation and successfully passed the testing phase before they are moved into the validation and production phase.

If the facility wants to complete the implementation and testing step to meet meaningful use but is not ready to move on to the onboarding process, it can request MDH to place it in the ‘On-Hold’ area in the queue by emailing MDH at Health.MDHELR@state.mn.us.

VI. Onboarding

i. Set up a Transport Mechanism

If a secure transport mechanism was not selected and installed during previous phases it must be completed before any real data can be sent to MDH. Staff members from both MDH and your facility responsible for handling the message transport system will ensure that a secure message transport mechanism is identified and installed in the implementation step. This step includes decisions about the time frame for data transmission, discussions regarding standard operating procedures and implementation of a daily ongoing daily transfer processes. MDH personnel will be available to help and have developed instructional files to help new teams walk through the procedures.

MDH expects daily transfers of ELR messaging once facilities are in production. Empty files are expected on days when there are no reports to send. During this step, methods of message monitoring must be agreed upon between MDH and the facility to ensure problems with the message transport will be identified in a timely manner. MDH also requests that reporting facilities inform MDH about messages sent for MDH monitoring purposes. This could be a daily report including name of sending facility, time of transaction, number of messages sent, and number of test/results identified.

ii. Include the Correct Tests/Results in the Message

To be able to use ELR in production for reporting to MDH, all tests and results which would support the diagnosis of any of the reportable diseases on the MDH reportable communicable diseases list must be included in the message. MDH has provided a list of reportable diseases specific to MDH with supplemental information about what laboratory tests and results would be used to identify each disease (See Appendix B for the list).
For more information about what to include in the message see sections Message Structure Requirements and Message Content Requirements in this document as well as Appendix A.

During this step the facility is encouraged to review the existing list of tests and result codes used in their EHR and identify which ones should be included in ELR messages to MDH. Participating Laboratories can use Appendix (C), MDH Test Result Mapping Template, as a template for test, result, and disease mapping for facility. MDH staff is available to assist during this process step.

Once the sending facility has identified and mapped the lab tests and results used to identify reportable conditions to the reportable diseases, this mapping table should be provided to MDH. This table will be used by MDH to ensure the information sent will be provided to the correct epidemiology program areas at MDH as well as ensuring the use of the correct codes for the ELR messages.

The mapping table should be sent to Health.MDHEL@state.mn.us. Trading partners are asked to use the following naming convention for their mapping document: “Test Result and Disease Mapping Table for Facility Name” (where Facility Name is replaced with the actual name of the trading partner’s facility).

iii. Start Sending Verification Files with Real Data
The verification files containing real data should be sent using the timeframe and interval agreed upon in the previous step. The messages should preferably match what will be sent once in production.

A set of data from the past month would be acceptable as verification data, or the facility could choose to send verification data daily in addition to continue the existing disease reporting method. Note that the existing reporting method cannot be turned off during this process step, existing reporting must continue until MDH gives the OK to change over to ELR.

iv. Content and Structure Validation by MDH
The data received from the facility will be reviewed and validated by MDH staff, both for structure and content. The period of time required to review the content of the data varies with respect to the volume and types of reported diseases and conditions.

MDH expects the reporting facility to notify MDH of changes to tests, results, formats and reporting processes. In addition a method for how to inform MDH of the changes must be agreed upon.

v. Production
A facility can start sending production data after the content and structure have been approved by MDH. However, existing reporting mechanisms (such as paper based reporting, etc.) must continue for at least 90 days after messaging has moved into production. During this 90 day period, MDH will compare the existing reports to the new electronic reports and determine if the old process can be turned off. If an acceptance cannot be reached within the first 90 days, a new 90 day period will start.
12. Appendix A: MDH Specifications for ELR (HL7 2.5.1)

Appendix A is provided in both PDF and Excel format to offer flexibility to external trading partners and may be downloaded from the MEDSS MDH Electronic Laboratory Reporting web page: http://www.health.state.mn.us/medss/elr.html

13. Appendix B: MDH Reportable Diseases Mapping Table for ELR

Appendix B may be downloaded from the MEDSS MDH Electronic Laboratory Reporting web page: http://www.health.state.mn.us/medss/elr.html

14. Appendix C: MDH Test Result Mapping Template

Appendix C may be downloaded from the MEDSS MDH Electronic Laboratory Reporting web page: http://www.health.state.mn.us/medss/elr.html

MDH ELR email Address

Support mailbox for ELR Messaging to MDH: Health.MDHELRLR@state.mn.us