



Colorado Department
of Public Health
and Environment

ELECTRONIC LABORATORY REPORTING IMPLEMENTATION GUIDE

Version 1.0
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Colorado Department of Public Health and Environment
ELR Implementation Guide
Version 1.0

CONTENTS

| | |
|---|----|
| Document History | 4 |
| 1.0 Introduction | 5 |
| 1.1 Technical Requirements Overview | 5 |
| 1.2 On-boarding Process Overview | 6 |
| 1.3 Meaningful Use | 7 |
| 2.0 On-boarding Process | 8 |
| Step 1: Registration | 8 |
| Step 2: Pre-testing | 8 |
| Step 3: Initial Submission | 9 |
| Step 4: In Queue | 9 |
| Step 5: Validation | 10 |
| Step 6: Production and On-going Validation | 10 |
| 3.0 Implementation Guidance and Resources | 11 |
| 3.1 Secure Message Transfer | 11 |
| 3.2 HL7 Guidance and Resources | 11 |
| 3.3 Vocabulary | 12 |
| 3.4 Rules Engine Development | 12 |
| Appendix A: Acronyms and Definitions | 15 |
| Acronyms | 15 |
| Definitions | 15 |
| Appendix B: Required Fields for ELR with HL7 2.5.1 Mappings | 16 |
| Appendix C: List of Resources for ELR Implementation | 18 |
| Appendix D: Sample Memorandum of Agreement for ELR | 19 |

DOCUMENT HISTORY

| Version | Date | Notes |
|---------|---------|---|
| 0.1 | 8/27/13 | First Draft- Dispersed for review internally and with external partners. |
| 0.2 | 9/18/13 | Collated feedback from partners and stakeholders and addressed the comments and issues. |

1.0 INTRODUCTION

This guide is intended as a resource for new laboratories wishing to on-board to electronic lab reports (ELR). ELR is defined as the automated transmission of laboratory-related data from commercial, public health, hospital, and other labs to state and local public health departments through an electronic health records (EHR) system or a Laboratory Information Management System (LIMS). This document describes the requirements, technical specifications, and process for hospital laboratories to begin submitting ELRs of reportable conditions to the Colorado Department of Public Health and Environment (CDPHE). It outlines the steps a hospital must take to on-board, the process for testing and validation, the required messaging and vocabulary standards, and provides useful resources and guidance. The process and specification are essentially the same whether the laboratory intends to submit ELRs through a Health Information Exchange (HIE) or directly to CDPHE and whether a facility intends to attest for Meaningful Use stages 1 or 2 or not.

The on-boarding process can take 9 – 12 months or more, depending on the laboratory’s availability of IT resources as well as the availability of CDPHE’s resources for validating the new ELR feed. The process requires establishment of secure transfer protocols, mapping of tests and results to national standards, and development of a rules engine for flagging reportable results, all of which can be labor-intensive. Facilities wishing to on-board should consider this when they are planning their work and allocating resources.

It should be noted that ELR does not obviate all other reporting responsibilities for hospitals. There will still be a need to report 24-hour reportable conditions (such as measles or hepatitis A), suspected outbreaks, and conditions that are syndrome-dependent (rather than laboratory result dependent) using traditional means of reporting. In addition, physicians will still be required to report conditions that they are required to report by the Board of Health regulations. For a detailed list of continuing responsibilities of facilities reporting primarily through ELR, see **Appendix D: Sample Memorandum of Agreement for ELR**.

1.1 TECHNICAL REQUIREMENTS OVERVIEW

Guidance and resources for implementation of the technical requirements can be found in **Section 3.0**.

| Requirement | Type | Validation Step |
|--|-----------------|----------------------------|
| Generate a valid HL7 2.5.1 ORU-R01 message** | Messaging | Step 2: Pre-testing |
| Transmit a secure messages directly to CDPHE via sFTP (preferred) or PHINMS, or through your HIE | Secure transfer | Step 3: Initial Submission |
| Map tests that may produce a reportable result to LOINC V2.40 | Tests | Step 5: Validation |
| Map reportable results to SNOMED CT | Results | Step 5: Validation |
| Accurately flag and transmit all reportable results | Reporting | Step 5: Validation |

1.2 ON-BOARDING PROCESS OVERVIEW

On-boarding refers to the process of moving a lab from intent to participate in ELR to on-going, production-level data submission. Once an ELR feed is validated and certified, the healthcare organization can cease its current reporting practices for all conditions that are reported based only on a laboratory result. This process is described in greater detail in **Section 2.0**.

| Step | Step Name | Description | Validation | Timeframe |
|------|---|---|---|--------------|
| 1 | Registration | Laboratories wishing to on-board for ELR must register their intent to attest on the CDPHE Meaningful Use Website. Or, if labs are wishing to on-board for ELR but not attest for Meaningful use, they should declare their intent via email to the ELR Coordinator: CDPHE_ELRL@state.so.us | N/A | N/A |
| 2 | Pre-Testing | The on-boarding laboratories will review the vocabulary and messaging standards and reporting requirements. They will generate and validate test messages using a standard tool, submitting the results to CDPHE. | HL7 2.5.1 message | 3-4 months |
| 3 | Initial Submission | Once your agency is ready to generate messages with the required standards, a test message will be sent using one of the secure methods. This HL7 message will be validated by CDPHE. Completion of Step 3 meets Meaningful Use Stage 1 attestation requirements. | Secure connection | 1-2 months |
| 4 | In Queue | If the laboratory is ready to submit on-going results, but CDPHE is not prepared to perform the validation, the laboratory may be placed on a wait-list for on-going submission and validation. Facilities placed in the queue can attest for Meaningful Use Stage 2, if that is their goal. | N/A | 0 – 6 months |
| 5 | Validation | Once your HL7 message has been validated and a secure method of transfer has been successfully tested, on-going production level data will be transferred from your system on at least a daily basis (weekdays only). These messages will be evaluated for vocabulary standards. The reports received will be matched against disease reports received from your facility from traditional methods. | LOINC Codes SNOMED CT Codes Decision Engine for flagging reportable results | 1 – 8 months |
| 6 | Production & On-going Validation | Once CDPHE is satisfied that your decision engine is appropriately flagging and reporting all reportable conditions, we will certify your feed and move your ELR feed into production. At this time, your facility can cease its previous method of reporting conditions based only on a laboratory results. | On-going validation of new tests on a quarterly basis | N/A |

1.3 MEANINGFUL USE

Facilities wishing to attest for Meaningful Use Stage 2 (MU2) for ELR must register their intent to attest with CDPHE. Please contact the CDPHE ELR Coordinator at CDPHE_ELRL@state.co.us.

Facilities wishing to attest for MU2 should note that the technology requirements and standards are somewhat different from MU1. These requirements put forth by the Centers for Medicare and Medicaid Services (CMS) are not negotiable for purposes of Meaningful Use attestation.

| MU Stage | Objective | Standards |
|----------|---|---|
| Stage 1 | ≥ 1 test of submission to public health with continued submission if successful | HL7 2.5.1 LOINC V2.27* |
| Stage 2 | Successful ongoing submission of electronic reportable laboratory results from CEHRT to a public health agency for the entire EHR reporting period. | HL7 2.5.1 LOINC V2.27* SNOMED CT |

*Newer LOINC versions are acceptable

Additional information for meaningful use is available on CDPHE's MU website, which will be available by October 1, 2013.

2.0 ON-BOARDING PROCESS

STEP 1: REGISTRATION

By the end of this step, you will have registered your intent to on-board for ELR.

You can register in two different ways, depending on your facility's intent to attest for Meaningful Use Stage 2:

- If your facility is planning to attest for Meaningful Use Stage 2, you can declare your facility's intent on CDPHE's Meaningful Use website at: www.COStage2MU.dphe.state.co.us
- If your facility is not planning to attest for Meaningful Use Stage 2, but is planning to participate in ELR, you can register your facility's intent to onboard for ELR by emailing the ELR Program at CDPHE_ELR@state.co.us. The email should contain the following information:
 - Your name, title, and contact information
 - Your facility's name and location
 - The LIS you are using, the version number, and whether it is MU certified
 - Whether you intend to attest for MU1, MU2 or both
 - The earliest date you intend to begin the onboarding process.

Once you register, you will be contacted by the ELR Program within 5 business days, at which point you will either begin the planning for the onboarding process or be placed in a queue. If your implementation is put into a queue, you will still be able to attest for the MU Stage for which you are planning to attest.

2.1.1 KICK-OFF MEETING

This meeting is an opportunity for the on-boarding lab to ask questions about the on-boarding process, requirements, or technical issues they may have before working to on-board for ELR. It establishes the relationships, the timeline, and the expectations for on-boarding. Attendees will include representatives from CDPHE, the HIE (if an HIE is being used) and should include the laboratory's Laboratory Director or designee, IT specialist who will be working on ELR, and a technical specialist from your LIS vendor (recommended). The meeting will be an hour long and can occur either face-to-face or over telephone. We ask that all parties thoroughly review this document before attending.

STEP 2: PRE-TESTING

By the end of this step:

- Your LIS will be able to generate valid HL7 messages for ELR, with all of the required fields
- Your LIS will be able to send valid LOINC and SNOMED codes
- You will have begun work on your rules engine for flagging of reportable conditions

2.2.1 CREATE TEST MESSAGES

Create at least one test message for each of the following:

1. Communicable disease report (e.g. *Salmonella*, *B. pertussis*)
2. Sexually Transmitted Disease (STI) report
3. Human Immunodeficiency Virus (HIV) report
4. Tuberculosis (TB) report
5. Blood lead report

6. Report of a culture that includes antimicrobial susceptibilities.

NOTE: If one or these do not apply to your facility, please provide justification for not including it.

Create at least one message with each of these result types:

- Coded result
- Numeric result
- Structured numeric result (if produced by your system)
- Text result (if produced by your system).

2.2.2 TEST MESSAGE VALIDATION

Validate test messages described above using both of the following:

- CDC's Message Quality Framework (MQF) tool: <http://1.usa.gov/15bb0ga>
- National Institute of Standards and Technology Meaningful (NIST) Use Tool: <http://xreg2.nist.gov:8080/HL7V2MuValidation2011/>
 - Note that the MQF and NIST are hosted on a public websites, so messages containing personally identifiable information should not be used.
 - Correct any errors and resubmit until your messages are error-free. Note that these validations also provide warnings. We will accept submissions with warnings, but not with significant errors.

Provide CDPHE with a set of MQF and NIST validation reports reflecting the messages described above.

Once all of your test messages have near error-free MQF validation reports, forward copies of the reports to CDPHE_ELR@state.co.us. CDPHE will also evaluate your LOINC and SNOMED codes to ensure that they are properly formed.

STEP 3: INITIAL SUBMISSION

Submit a de-identified HL7 message generated from your LIS to CDPHE using either a secure protocol or email. After your submission, you will receive a validation report within 5 working days. This report will either provide you with documentation that your test was successful, allowing you to move on to step 4, or detail the errors that make the message invalid. Resubmission is required if the connection is not made or the HL7 message is not valid.

You can move to the next step if:

- 1 You provide error-free MQF Validation Reports reflecting all of the required message types; AND
- 2 CDPHE successfully receives a secure HL7 message through a secure method; AND
- 3 That message contains a valid HL7 2.5.1 message, with all required fields, including valid LOINC and SNOMED codes (NOTE: SNOMED is not required for Meaningful Use stage 1 validation, but is required for stage 2).

STEP 4: IN QUEUE

We anticipate that there may be delays in moving to validation once Meaningful Use progresses and a large number of laboratories are attempting to on-board. This may require some laboratories to be placed in a queue before moving on to step 5. CDPHE will work diligently to make these delays as short as possible, and will communicate frequently with laboratories in the queue so that they understand what their status is.

STEP 5: VALIDATION

2.5.1 VALIDATION OVERVIEW

Once step 3 is completed and they have been given the OK to proceed, the on-boarding lab can begin submitting on-going reportable, production-level results to CDPHE. The purpose of this step is to ensure that CDPHE is receiving all of the laboratory reports that it would or should receive from the existing reporting methods as well as continued validation of messaging and vocabulary standards. The ELRs should appear in batch files produced at least daily, preferably at a consistent time and in the morning. This reporting will be done in parallel with established reporting methods (i.e. fax, CEDRS web portal, and phone). Once a minimum of 40 results and two weeks has passed, CDPHE will produce a validation report that reports on the criteria described below and identifies necessary changes. The report will be used to make any additional adjustments to the vocabulary, messages, or decision engine.

2.5.2 CERTIFICATION CRITERIA

| Category | Criteria |
|--------------------------|---|
| Vocabulary Standards | ≥95% of reports have valid LOINC and SNOMED CT codes |
| Reporting Sensitivity | 100% of disease reports received through established methods during parallel validation are also received through ELR. Note that this applies to a reporting period specified by CDPHE, which will restart once failed ELR reports are corrected. |
| Reporting Specificity | 90% of ELRs received are reportable conditions. |
| Timeliness | The lag time between date of result and date of report is within the timeframe specific by the Board of Health and is not substantially (i.e. 2-3 days) slower than current reporting methods.”. |
| Completeness | All required fields (see Appendix B) are ≥98% complete. |
| Test-specific validation | Each test indicative of or potentially indicative of a reportable condition is demonstrated to be properly flagged by the decision engine. The preferred method for this is entry of “dummy” cases directly into a test environment, which can generate the necessary HL7 batch file. |
| Memorandum of Agreement | A Memorandum of Agreement, signed by the appropriate officials, stating the on-going reporting responsibilities of the facility (see Appendix D) must be provided to CDPHE. |

2.5.3 TEST-SPECIFIC VALIDATION STATUS

The laboratory will send CDPHE a comprehensive list of the lab tests that are or may be indicative of reportable conditions. A dummy patient with a reportable result will then be entered into the LIS for each test. CDPHE will check the ELRs it receives against the list of reportable labs. The on-boarding lab will evaluate the tests that were not received through ELR, make changes to the rules engine, and resubmit the test report. Validation will not occur until all tests are successfully identified and transmitted.

STEP 6: PRODUCTION AND ON-GOING VALIDATION

On-going validation and corrections will be required after certification. CDPHE will continue to monitor the certified ELR feed for timeliness and completeness on an on-going basis. However, it is the laboratory’s responsibility to ensure that all reportable conditions are reported appropriately. This includes modifying the rules engine when new tests are added or there is a change to the list of reportable conditions by the Colorado Board of Health and notifying CDPHE of any major changes in LIS functionality or lab tests being offered. For a detailed list of continuing reporting responsibilities, refer to **Appendix D: Sample Memorandum of Agreement for ELR**, which must be signed prior to validation.

3.0 IMPLEMENTATION GUIDANCE AND RESOURCES

3.1 SECURE MESSAGE TRANSFER

3.1.1 HEALTH INFORMATION EXCHANGES (HIEs) AND MESSAGE ROUTING OPTIONS

Any Facility has the option of establishing a secure connection directly to CDPHE.

Facilities that are a member of a Health Information Exchange (HIE) can choose to submit ELR directly to CDPHE or through their HIE. There are two HIEs in Colorado:

- **Colorado Health Information Organization (CORHIO)** covers health facilities that are throughout the Front Range and everything east of the Continental Divide. Contact:
Kate Kiefert
kkiefert@corhio.org
720.285.3235
- **Quality Health Network (QHN)** covers health facilities on the Western Slope, west of the Continental Divide. Contact:
Vickie Ballard
vballard@qualityhealthnetwork.org
970.248.0033

Note: The interface between QHN and CORHIO for ELR is not scheduled to be complete until March 2014. Laboratories that are QHN members and are also planning to attest for Meaningful Use Stage 2 should consider this in their timelines and consider reporting directly to CDPHE if it significantly affects their Meaningful Use timelines.

3.1.2 SECURE MESSAGE TRANSFER TO CDPHE

For submission directly to CDPHE, you may send ELR messages via sFTP (preferred) or PHINMS. When you are ready to establish a secure connection, contact the ELR Coordinator (CDPHE_ELR@state.co.us) who will provide you with:

- "Connecting to CDPHE's FTP Site", which provides information for how to connect.
- "Secure External User ID Form" which will have to be completed and submitted to CDPHE in order for the necessary folders to be set up. There may be a delay of one to two weeks from the request to set up the folders.

If you are planning to submit through an HIE, please contact the HIE directly using the contact information above.

3.2 HL7 GUIDANCE AND RESOURCES

USEFUL RESOURCES FOR HL7

- HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health - <http://bit.ly/13z5mHO>
- **Appendix B: CDPHE Required Fields for ELR with HL7 2.5.1 Mappings**

The HL7 Version 2.5.1 Implementation Guide provides the specifications for laboratory results reporting to local, state, territorial and federal health agencies. In particular, it addresses messaging content and dynamics related to the transmission of Laboratory Reportable Result Messages/ELR. These are general specification for creating a valid HL7 2.5.1 message for ELR. **Appendix B** provides field requirement specific to ELR reporting in Colorado.

3.3 VOCABULARY

Review Reportable Conditions Mapping Table (RCMT): <https://phinvads.cdc.gov/vads/SearchHome.action>

The RCMT provides a map between Logical Observation Identifiers Names and Codes (LOINC) test codes, Systemized Nomenclature of Medicine (SNOMED) result codes and their associated reportable conditions.

3.4 RULES ENGINE DEVELOPMENT

The Rules engine identified laboratory results indicative of reportable conditions and flags them for submission to CDPHE. Rules engine development is one of the most challenging and time-consuming aspects of ELR on-boarding and should begin as soon as possible. The rules engine is not validated until Step 5: Validation.

While creating the rules, keep in mind that when in doubt, casting a wider net is preferable to making the rules more restrictive. We would rather see ELRs that we don't need than not get ELRs that we do. Any ELRs that are flagged and submitted that we don't need can either be identified and restricted during the validation process or filtered out once they reach CDPHE.

3.4.1 REPORTABLE CONDITIONS

Review the Colorado State Reporting Requirements:

- Conditions Reportable by all Physicians and Healthcare Providers in Colorado: <http://1.usa.gov/1aqAiw8>
- Conditions Reportable for all Laboratories Collecting Specimens or Performing Tests in Colorado: <http://1.usa.gov/14JrOuB>

There are a number of reportable conditions that are dependent on factors other than lab results to determine whether they are reportable. Please handle these as follows:

- **Varicella**- Do not flag Varicella laboratory reports.
- **Influenza- associated hospitalization**- If your system has the ability to build a rule based on hospitalization status, that is preferable. Otherwise, we will accept all influenza positives and filter them out appropriately on our end.
- **Influenza- associated deaths ≤18 years**- These should not be reported through ELR and should continue to be reported by existing methods.

ADDITIONAL INFORMATION REQUESTED

For certain diagnoses, it is extremely helpful for CDPHE to have additional information that aids in the follow-up process and assignment of case classifications according to surveillance case definitions. We request that these are provided for these conditions if it is possible to provide them. These are:

- For **All Hepatitis Viruses** and **TB**: Liver Function Tests
- For **TB, CRE, MRSA, and Gonorrhea**: antibiotic susceptibilities

3.4.2 REPORTING LABORATORY REPORTS FROM REFERENCE LABS

According to Colorado statute, clinical labs are required to report laboratory results that are sent to out-of-state referral laboratories. CDPHE therefore requires that all send-out labs be reported, even if those reports are also reported by the reference lab. This provides assurance that these tests will be reported, as well as provides CDPHE with necessary information that the referral laboratory may not have had access to, but which CDPHE requires in order to do follow-up on the reported case.

3.4.3 FIELDS USED FOR RULES ENGINES

Your LIS must have the capacity to identify reportable conditions and flag them for reporting. The flagging criteria has to be based on at least three different fields:

1. **Test Name**- Only tests that may produce a reportable result are of interest. LOINC codes should be used when possible.
2. **Test Result**- Only positive tests are of interest for many, but not for all, test types. Some tests (e.g. blood cultures) may produce different results that may or may not be reportable. Examples of test types that need not be positive include viral loads, CD4, and lead.
3. **Specimen Type**- For certain conditions, only certain specimen types are reportable. E.g., *Neisseria meningitidis* is only reportable if it is cultured from a normally sterile site.
4. **Hospitalization Status**- Influenza is only reportable if the case was hospitalized. For most laboratories, this information will not be available in their system. If it is possible to link this information to hospitalization status, that is preferred, If that is not possible, we ask that all influenza positives be reported.

3.4.4 GEOGRAPHICAL CONSIDERATIONS

There are a number of reportable conditions that are reportable in specific counties or jurisdictions. We are not asking that laboratories build rules based on patient address. We are asking that you build rules for these conditions if your facility is in that jurisdiction and apply those rules to all patients in that facility.

3.4.5 FREE TEXT RESULTS FIELDS

Laboratory Information Systems that allow for free text entering of results are a known problem for ELR. Typos- and other variations in how results are entered will prevent reportable lab results from being appropriately flagged. This will likely lead to reportable results not being reported and an inability for the ELR feed to be validated. It is highly recommended that results fields be a drop-down menu that restricts the possible entries into this field to results recognized by the decision engine.

3.4.6 SPECIFIC GUIDANCE FOR HOSPITAL-ACQUIRED INFECTIONS

Creating rules for the hospital-acquired infections (i.e. invasive VRSA and CRE (for statewide reporting) and Acinetobacter, invasive MRSA, and *C. difficile* (for laboratories in the Denver Metro Area) can be tricky. The following tables are meant to provide guidance for this work.

STATEWIDE REPORTABLE CONDITIONS

| Condition | What to send | Additional Information Requested |
|-------------|--|---|
| VRSA | Staph aureus with Vancomycin MIC ≥ 4 , or growth of Staph aureus on a Vancomycin screen plate. | Antimicrobial susceptibilities to other antibiotics tested |
| CRE | <i>E. coli</i> , <i>Enterobacter</i> spp., and <i>Klebsiella</i> spp. that test intermediate or resistant to ANY Carbapenem (Imipenem, Meropenem, Doripenem, Ertapenem) and resistant to ALL 3rd generation Cephalosporins tested (Ceftriaxone, Ceftazidime, Cefotaxime) OR positive test for carbapenemase (MHT, PCR, or disc diffusion.) | Antimicrobial susceptibilities to other antibiotics tested; results of any carbapenemase testing done (MHT, PCR, or disc diffusion) whether positive or negative. |

DENVER METRO AREA REPORTABLE CONDITIONS

| Condition | What to send | Additional Information Requested |
|----------------------------------|--|---|
| CRE | <i>E. coli</i> , <i>Enterobacter</i> spp., and <i>Klebsiella</i> spp. that test intermediate or resistant to ANY Carbapenem using the most recent MIC breakpoints (Imipenem ≥ 2 , Meropenem ≥ 2 , Doripenem ≥ 2 , Ertapenem ≥ 1) and resistant to ALL 3rd generation Cephalosporins tested using the most recent MIC breakpoints (Ceftriaxone ≥ 4 , Ceftazidime ≥ 16 , Cefotaxime ≥ 4) OR positive test for carbapenemase (MHT, PCR, or disc diffusion.) For labs using Kirby Bauer methods instead, breakpoints will be different (use zone diameters instead, and few labs use this). | Antimicrobial susceptibilities to other antibiotics tested; results of any carbapenemase testing done (MHT, PCR, or disc diffusion) whether positive or negative. |
| <i>Acinetobacter</i> | <i>Acinetobacter baumannii</i> (including baumannii complex and calcoaceticus complex) that test intermediate or resistant to ANY Carbapenem (Imipenem, Meropenem, Doripenem, Ertapenem) from an invasive site (e.g. CSF, blood, etc.) or urine. | Antimicrobial susceptibilities to other antibiotics tested |
| MRSA | Staph aureus resistant to Methicillin/Oxacillin from invasive sites (e.g. CSF, blood, etc.). | |
| <i>C. difficile</i> (CDI) | Any positive toxin test or nucleic acid test for <i>Clostridium difficile</i> (EIA, EIA antigen [GDH], PCR/nucleic acid, cytotoxin test) | All <i>C. difficile</i> testing performed on this specimen and results, including EIA, EIA antigen (GDH), PCR/nucleic acid, cytotoxin testing, and <i>C. difficile</i> culture. |

APPENDIX A: ACRONYMS AND DEFINITIONS

ACRONYMS

| | |
|------------------|--|
| AIDS | Auto-Immune Deficiency Syndrome |
| CDPHE | Colorado Department of Public Health and Environment |
| CMS | Centers for Medicare and Medicaid Services |
| CORHIO | Colorado Regional Health Information Organization |
| ELR | Electronic Laboratory Report |
| HIE | Health Information Exchange |
| HIV | Human Immunodeficiency Virus |
| HL7 | Health Level 7- a set of international healthcare informatics interoperability standards |
| LIS | Laboratory Information System |
| LOINC | Logical Observation Identifiers Names and Codes |
| MQF | Message Quality Framework |
| MU1 | Meaningful Use Stage 1 |
| MU2 | Meaningful Use Stage 2 |
| NIST | National Institute of Standards and Technology |
| PHINMS | Public Health Information Network Messaging System |
| PHIN VADS | Public Health Information Network Vocabulary Access and Distribution System |
| RCMT | Reportable Conditions Mapping Table |
| RELMA | Regenstrief LOINC Mapping Assistant |
| TB | Tuberculosis |
| QHN | Quality Health Network |
| RELMA | Regenstrief LOINC Mapping Assistant |
| sFTP | SSH (Secure Shell) File Transfer Protocol |
| SNOMED CT | Systematized Nomenclature of Medicine Clinical Terms |
| STI | Sexually Transmitted Infections |

DEFINITIONS

| | |
|--|---|
| Electronic Laboratory Reporting | The automated transmission of laboratory-related data from commercial, public health, hospital, and other labs to state and local public health departments through an electronic health records (EHR) system or a Laboratory Information Management System (LIMS). |
| Health Information Exchange | A Health Information Exchange is an organization that mobilizes healthcare information electronically across organizations within a region. |
| Meaningful Use | The Medicare and Medicaid EHR Incentive Programs provide financial incentives for the “meaningful use” of certified EHR technology to improve patient care. To receive an EHR incentive payment, providers have to show that they are “meaningfully using” their EHRs by meeting thresholds for a number of objectives. |
| On-boarding | On-boarding is the process of moving a lab from intent to participate in ELR to on-going, production-level data submission. |

APPENDIX B: REQUIRED FIELDS FOR ELR WITH HL7 2.5.1 MAPPINGS

This table defines the content fields required by CDPHE for electronic laboratory reporting. Additional requirements for forming a valid ORU-R01 message can be found in the **HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health** which can be downloaded for free at: <http://bit.ly/13z5mHO>

| Field Name | Requirement?* | HL7 Segment | HL7 Field |
|--------------------------------------|---------------|-------------|------------|
| Patient Last Name | R | PID | 5.1.1 |
| Patient First Name | R | PID | 5.2 |
| Patient Date of Birth | R | PID | 7.1 (7) |
| Patient Sex | R | PID | 8 |
| Patient Race | RE | PID | 10.2 |
| Street Address1 of Patient | R | PID | 11.1.1 |
| City Address of Patient | R | PID | 11.3 |
| County Address of Patient | R | PID | 11.9 |
| Zip Code Address of Patient | R | PID | 11.5 |
| Patient Phone Number | R | PID | 13.1 (13) |
| Patient Ethnicity | RE | PID | 22.1 |
| Patient Death Date and Time | RE | PID | 29 |
| Ordering Provider Last Name | R | ORC | 12.2.1 |
| Ordering Provider First Name | R | ORC | 12.3 |
| Ordering Facility Name | R | ORC | 21.1 |
| Ordering Provider Address: Street1** | R | ORC | 24.1.1 |
| Ordering Provider Address: Street2 | R | ORC | 24.1.2 |
| Ordering Provider Address: City | R | ORC | 24.3 |
| Ordering Provider Address: State | R | ORC | 24.4 |
| Ordering Provider Address: Country | R | ORC | 24.6 |
| Ordering Provider Address: Zip Code | R | ORC | 24.5 |
| Test Type | R | OBR | 4.4 |
| Collection Date | R | OBR | 7 |
| Order callback phone number | R | OBR | 17.1 (17) |
| LOINC Code | R | OBX | 3.1 or 3.4 |
| Test Name | R | OBX | 3.2 or 3.5 |
| Test Result | R | OBX | 5 |
| Specimen Type | R | SPM | 4 |
| Admit Date/Time | RE | PV1 | 44 |
| Message Profile Identifier | R*** | MSH | 21 |

*R: Note definitions on the following page

**We use ORC-22 (Ordering facility address) when ORC-24 is blank.

*** If sending through CORHIO, the sending facility must have a decision engine that flags and populates this field with 'CORHIOELR' in order for CORHIO to route the message to CDPHE. If this is not done or done incorrectly, CDPHE will not receive the proper messages.

REQUIRED FIELDS DEFINITIONS

R - Required: A conforming sending application shall populate all "R" elements with a non-empty value. Conforming receiving application shall process (save/print/archive/etc.) or ignore the information conveyed by required elements. A conforming receiving application must not raise an error due to the presence of a required element, but may raise an error due to the absence of a required element. Any element designated as required in a standard HL7 message definition shall also be required in all HL7 message profiles of that standard message.

RE - Required, but can be empty: The element may be missing from the message, but must be sent by the sending application if there is relevant data. A conforming sending application must be capable of providing all "RE" elements. If the conforming sending application knows the required values for the element, then it must send that element. If the conforming sending application does not know the required values, then that element will be omitted.

APPENDIX C: LIST OF RESOURCES FOR ELR IMPLEMENTATION

| Assistance with... | Resource Name | URL |
|--------------------|---|---|
| HL7 | HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health | http://bit.ly/13z5mHO |
| HL7 Validation | National Institute of Standards and Technology (NIST) HL7 Validation Tool | http://xreg2.nist.gov:8080/HL7V2MuValidation2011/ |
| HL7 Validation | CDC Message Quality Framework (MQF) | https://phinmqf.cdc.gov/ |
| LOINC | Regenstrief LOINC Mapping Assistant (RELMA) | http://loinc.org/relma |
| SNOMED | International Health Terminology Standards Development Organisation | http://www.ihtsdo.org/snomed-ct/ |
| LOINC/SNO MED | Public Health Information Network Vocabulary Access and Distribution System (PHIN VADS) | https://phinvads.cdc.gov/vads/SearchHome.action |
| Decision Engine | Conditions Reportable by all Physicians and Healthcare Providers in Colorado | http://1.usa.gov/1aqAiw8 |
| Decision Engine | Conditions Reportable for all Laboratories Collecting Specimens or Performing Tests in Colorado | http://1.usa.gov/14JrOuB |

Appendix D: Sample Memorandum of Agreement for ELR

NOTE: This is only a sample meant to provide information regarding on-going responsibilities of ELR facilities. An official memorandum will be provided upon request or once validation has begun

STATE OF COLORADO

John W. Hickenlooper, Governor
Christopher E. Urbina, MD, MPH
Executive Director and Chief Medical Officer

Dedicated to protecting and improving the health and environment of the people of Colorado

4300 Cherry Creek Dr. S. Laboratory Services Division
Denver, Colorado 80246-1530 8100 Lowry Blvd.
Phone (303) 692-2000 Denver, Colorado 80230-6928
Located in Glendale, Colorado (303) 692-3090

<http://www.cdphe.state.co.us>



Colorado Department
of Public Health
and Environment

Memorandum of Agreement

[DATE]

The Disease Control and Environmental Epidemiology Division of the Colorado Department of Public Health and Environment (CDPHE) and [AGENCY] agree that [AGENCY] will implement daily electronic laboratory reporting to CDPHE of “reportable” laboratory results as per the Colorado Board of Health regulations 6 CCR 1009-1, 6 CCR1009-7 and 6 CCR 1009-9.

Furthermore, the following operational details are agreed to:

1. [AGENCY] will report to CDPHE by phone (303.692.2700) **suspect** cases (based on clinical or laboratory suspicion) of urgent 24-hour reportable conditions including: ***meningococcal disease, measles, invasive Haemophilus influenzae (<5 years), botulism, hepatitis A, typhoid fever, plague, rubella, diphtheria, anthrax, pertussis, Mycobacterium tuberculosis, poliomyelitis, syphilis, cholera, SARS- Coronavirus, small pox, human rabies, group outbreaks, and any bioterrorism-related illness.*** After-hours, such reporting should be through the CDPHE answering service at 303.370.9395 Initials _____
2. CDPHE may need to contact [AGENCY] to obtain additional case information necessary to carry out certain mandates and activities related to disease control (e.g. documenting treatment of persons diagnosed with a sexually transmitted infection (STI)) Initials _____
3. The Laboratory Information Systems (LIS) staff of [AGENCY] will continue to transmit to CDPHE Communicable Disease Epidemiology Section the monthly line lists (which contains positive laboratory results for invasive bacterial pathogens, foodborne/enteric pathogens, MRSA, and *C. difficile*) which is necessary for CDPHE’s Emerging Infections Program grant activities and serves as an audit which may detect problems with the electronic reporting interface. Initials _____

Colorado Department of Public Health and Environment
ELR Implementation Guide
Version 1.0

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4. [AGENCY] and its LIS staff will update the electronic laboratory reporting software and processes to incorporate revisions to the list of reportable conditions passed by the State Board of Health (approximately yearly). Such revisions will be emailed by the CDPHE Electronic Laboratory Reporting Coordinator to staff designated by [AGENCY] to receive such notifications. Initials _____

 5. [AGENCY] and its LIS staff will update the electronic laboratory reporting software and processes to incorporate any new reportable tests or new/revised reportable test names or ways of reporting results adopted by [AGENCY]/ Such updates/changes will be communicated to CDPHE within 2 business days of implementation. Initials _____

 6. [AGENCY] will continue to collaborate with CDPHE to validate completeness of electronic laboratory reporting data transmissions on a regular and ongoing basis. Initials _____

 7. Regular communication will be maintained between LIS staff at [AGENCY] and CEDRS staff at CDPHE to identify and resolve reporting issues in a timely manner. Both areas will keep contact information current and any changes will be communicated in a timely manner. Initials _____

 8. If the developed and validated [AGENCY] software and processes for electronic laboratory reporting become non-functional or [AGENCY] decides to cease its use, [AGENCY] will immediately notify CDPHE and will implement "standard" methods (i.e. CEDRS, fax, phone) of notifiable disease reporting in a timely fashion to fulfill the 24-hour and seven-day state reporting requirements. Initials _____

NAME]
[TITLE]
[AGENCY]

Date: _____

Lisa Miller, MD, MSPH
State Epidemiologist
Colorado Department of Public Health and Environment

Date: _____