Meaningful Use Fact Sheet

PUBLIC HEALTH INFORMATION NETWORK

Reportable Lab Results

Submission of electronic data on reportable lab results to public health agencies

Background

One of the stated goals of the American Recovery and Reinvestment Act (ARRA), enacted in February 2009, is to increase the Meaningful Use (MU) of Electronic Health Record (EHR) technology among medical providers. The Centers for Medicare and Medicaid Services (CMS) established an incentive program using ARRA funds to encourage eligible providers and hospitals to adopt and use EHR technology.

To receive EHR-MU incentives, participating providers and facilities must meet various operational and public health criteria established by CMS with the Office of the National Coordinator for Health Information Technology (ONC). The incentives will be released in three stages over several years. Stage 1 MU final rule requirements have been divided into 15 core set objectives and 10 menu set objectives (where there is an option to pick 5 out of 10).

The three public health objectives in Stage 1 are submission of electronic data to public health in the context of 1) Immunizations, 2) Reportable Laboratory Results (Eligible Hospitals only), and 3) Syndromic Surveillance. Unless an Eligible Professional (EP) or Eligible Hospital (EH) has an exception for all the objectives, it is mandatory to complete at least one public health objective as part of their demonstration of the menu set in order to be a meaningful user of EHR technology.

Reportable Laboratory Results reporting for MU is the electronic exchange from laboratories to public health and is a subset of the broader Electronic Laboratory Reporting (ELR) initiative, which includes results reporting among laboratories, public health agencies, and providers, as well as the electronic transmission of test orders. For more information, visit http://www.cdc.gov/ehrmeaningfuluse/elr.html.

MU Reportable Laboratory Results reporting has many benefits, including improved timeliness, reduction of manual data entry errors, and more complete information. ELR has been promoted as a public health priority for the past several years and inclusion of MU Reportable Laboratory Results as an objective for public health will serve as a catalyst to accelerate its adoption.

The Reportable Laboratory Results objective is only applicable for EHs. The following information provides guidance on submitting MU-compliant reportable laboratory results from hospital laboratories to jurisdictional public health agencies.

The following public health information exchange policies, practices, standards, and services will support the implementation of Meaningful Use Stage 1 with respect to Reportable Laboratory Results.

Policies

In order to fulfill the public health objective of the capability to submit electronic data on reportable (as required by state or local law) laboratory results to public health agencies and actual submission according to applicable law

and practice, EHs and Critical Access Hospitals (CAH) must comply with two federal regulations:

- **CMS Final Rules EHR Incentive Program** (http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf).

  Objective: Capability to submit electronic data on reportable (as required by state or local law) laboratory results to public health agencies and actual submission according to applicable law and practice.

  Measure: Performed at least one test of certified EHR technology's capacity to provide electronic submission of reportable laboratory results to public health agencies and follow-up submission if the test is successful (unless none of the public health agencies to which an EH or CAH submits such information has the capacity to receive the information electronically).

  Exclusion: No public health agency to which the EH or CAH submits such information has the capacity to receive the information electronically.

- **ONC Final Rules Health Information Technology Standards, Implementation Specifications, and Certification Criteria for EHR Technology** (http://edocket.access.gpo.gov/2010/pdf/2010-17210.pdf)

  Reportable lab results: electronically record, modify, retrieve, and submit reportable clinical lab results in accordance with the standard (and applicable implementation specifications) specified in §170.205(c) and, at a minimum, the version of the standard specified in § 170.207(c).

Practices

Reporting on conditions of public health importance is a cornerstone of public health surveillance and includes reporting of laboratory results that may be indicative of a reportable condition. The Council of State and Territorial Epidemiologists (CSTE) determines the list of conditions that are nationally notifiable to the Centers for Disease Control and Prevention (CDC) on a voluntary basis by state public health agencies. Each state determines which conditions are reportable within its jurisdiction, including which conditions are reportable from various entities (e.g., facilities, providers, laboratories), within what time frame, to whom within the health department, by what method, and in what format. These definitions are typically available in human-readable form from the public health agency. Jurisdictions may or may not choose to be guided by CSTE position statements that include reporting criteria for the relevant conditions.

- **Certification**: For a hospital to qualify for MU incentives, it must use certified EHR technology. EHR technology can be certified as a complete or modular EHR system. ONC certification criteria specifies how to electronically record, modify, retrieve, and submit reportable clinical laboratory results in accordance with the standard (and applicable implementation specifications) specified in the final rule for Stage 1 MU. Certification must be done by an Authorized Testing and Certification Body (ATCB [see below]). EHR technologies are evaluated for certification following National Institute of Standards and Technology (NIST) test procedures to electronically record, retrieve, and submit laboratory test results containing Logical Observation Identifiers Names and Codes (LOINC) codes in HL7 v2.5.1 format to public

health and other agencies (http://healthcare.nist.gov/docs/170.306.g_LabstoPH_v1.1.pdf).

- **Attestation**: To qualify for incentives in Stage 1, the eligible providers (EHs or CAHs) must at a minimum, submit a test message to the public health entity. If the test is successful, then the EH or CAH should initiate production submission of reports. The public health agency may queue the providers for on-boarding at their convenience.

- **Communications**: Communications for MU reflects the collaboration between senders and receivers for reportable laboratory results. This section reflects those two perspectives, but recognizes that the senders and receivers of MU must work together to implement the information exchange.

    - **Public Health Agency Communications**: Public health agencies should make the following information readily available to EHs, the Regional Extension Center(s) (http://healthit.hhs.gov/portal/server.pt?open=512&objID=1495&parentname=CommunityPage&parentid=58&mode=2&in_hi_userid=11113&cached=true) and the HIT Coordinator (http://edocket.access.gpo.gov/2010/pdf/2010-17210.pdf) for the jurisdiction:

        - Conditions that are reportable in the jurisdiction (many public health agencies post this information on local webpages; http://www.cdc.gov/ehrmeaningfuluse/Jurisdiction.html);

        - Conditions that may be reported using electronic laboratory reporting;

        - Reporting requirements, including which conditions are reportable from which reporters (e.g., facilities, providers, laboratories), within what time frame, to whom within the health department, by what method (e.g., fax, phone, electronic);

        - Reporting criteria, including file format, information to include, under what condition(s) (e.g., for children < 18, for pregnant women, for an event);

        - Who to contact to arrange testing and on-boarding; and

        - Suggested pre-test validation utilities and constrained test profiles to use, if available.

    - **Hospital Communications**: Hospitals should take the following steps when implementing reportable laboratory results:

        - Contact jurisdiction to determine readiness to receive MU Reportable Laboratory Results;

        - Verify reportable conditions list, reporting requirements and criteria for jurisdiction (many public health agencies post this information on local webpages; (http://www.cdc.gov/ehrmeaningfuluse/Jurisdiction.html);

- Use pre-test validation utilities, to validate test message and if available, use jurisdiction constrained profile to test compliance of message;
- Communicate with jurisdiction's contact to arrange testing and on-boarding;
- Submit Reportable Laboratory Results test message with public health agency; and,
- Communicate results of testing to CMS.

Standards

The standards referred to below support reportable lab results transactions to public health.

- **Implementation Guides**:
  - **ELR Guide HL7 2.5.1** (http://www.hl7.org/implement/standards/product_brief.cfm?product_id=98) is the implementation guide for ELR data transactions using version 2.5.1 of the HL7 standard protocol. Adherence to this guide is required to meet the requirements for Meaningful Use Stage 1.
  - **Errata and clarifications for the HL7 Version 2.5.1 Implementation Guide** is also available for HL7 members, and for purchase by non-members. This document provides updates and clarifications that may be helpful to implementers.
- **Vocabulary**: MU Stage 1 requires use of LOINC result codes as specified in the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm).
- **Transport**: In Stage 1 of MU no specification has been mandated for secure transport. However, several tools exist to support transport of public health data. See services for a list of transport options.

Services

The standards referred to below support reportable lab results transactions to public health.

- **Vocabulary**
  - The Reportable Conditions Mapping Table (RCMT) provides a map between LOINC test codes, Systemized Nomenclature of Medicine (SNOMED) result codes and their associated reportable conditions. The RCMT is now available for use through CDC vocabulary server PHIN Vocabulary Access and Distribution System (VADS) (https://phinvads.cdc.gov) and phConnect RCMT discussion forum (http://www.phconnect.org/group/rcmt). The RCMT includes mappings for all nationally notifiable conditions that have laboratory tests. In addition, many

additional jurisdictionally reportable conditions have been mapped.

- ELR vocabulary associated with HL7 2.5.1 ELR messaging guide can be downloaded from PHIN VADS (http://phinvads.cdc.gov/vads/ViewView.action?name=Electronic%20Laboratory%20Reporting%20(ELR)%20to%20Public%20Health%20-%20HL7%20Version%202.5.1)

- **Message Translation**: Message translation is available to downgrade ELR HL7 2.5.1 messages to ELR HL7 2.3.1 and also upgrade ELR HL7 2.3.1 messages to ELR HL7 2.5.1. Translation is available to HL7 members for the Orion™ Health Symphonia Messaging and Mapping Tool, and is also available for users of Mirth Connect.

- **Transport**: Through Stage 1 of MU (October 2012 for Medicare hospitals) protocols for secure transport should be collaboratively agreed upon between the sender and the public health agency. The following are transport tools:

  - PHIN Messaging System (PHIN MS) (http://www.cdc.gov/phin/tools/PHINms/index.html) is software that securely sends and receives encrypted data over the Internet to public health information systems using Electronic Business Extensible Markup Language (ebXML) technology.

  - Nationwide Health Information Network (NwHIN) Direct (Note: In Stage 2 of MU only certain transport protocols (including Direct - http://wiki.directproject.org/) may be acceptable)

  - Secure File Transfer Protocol (SFTP)

  - Hyper Text Transfer Protocol Secure (HTTPS)

  - Virtual Private Network (VPN) e.g., Mirth Connect

  - Simple Object Access Protocol (SOAP)

  - Representational State Transfer (REST) or other Health Insurance Portability & Accountability Act (HIPAA) & Federal Information Security Management Act (FISMA) compliant transport is acceptable

- **Testing and Validation**: Public health reporters and receivers can make use of several tools and profiles to assist in testing the validity of messages. The tools are best used at different times in the testing process.

  - National Institute of Standards and Technology (NIST) Test Procedure for §170.302 (l) Public Health Surveillance (http://healthcare.nist.gov/docs/170.306.g_LabstoPH_v1.1.pdf) and testing tools (http://xreg2.nist.gov:8080/HL7V2MuValidation2011/)

    - NIST test profile for ELR used to certify EHR technology (less constrained),

- Does not contain public health agency-specific constraints on vocabulary (more constrained) For information on the NIST Healthcare Message Test Generation visit http://www.nist.gov/itl/ssd/int/hc-msg-test-gen.cfm

◦ PHIN Message Quality Framework (MQF) (https://phinmqf.cdc.gov/DownLoad.aspx) is an automated testing tool that ensures messages are adhering to standards defined in the messaging guides by: validating the structure of the message, validating that the messages are following the business rules defined for the message, and verifying that the vocabulary defined for the message is utilized. Note that PHIN MQF validates overall message construction, but may not yield identical results to the NIST test profile.

◦ National Electronic Disease Surveillance System (NEDSS) Message Subscription Service (MSS) (http://www.cdc.gov/phin/library/phin_fact_sheets/111759_NMS_NEDSS.pdf): Public Health Agencies can utilize MSS to develop a profile that includes local constraints, and hospitals can test messages against the local profile using MSS. MSS includes additional functionality including mapping of local vocabulary to standard vocabulary, message format translation, and message routing.