

Immunization Information Systems

Submission of electronic data to Immunization Registries or Immunization Information Systems

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 of 10). The three public health objectives in the Stage 1 menu set 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.

The immunization-specific objective for MU for Stage 1 is to test and if successful, establish a connection from the EHR to the Immunization Information System (IIS) in the provider's jurisdiction. For EHRs to connect to an IIS, providers must adopt, implement, or upgrade their EHR to ONC-certified technology capable of communicating using the Health Level 7 (HL7) standard protocol version 2.3.1 or 2.5.1. Once the upgraded EHR technology is in place, the IIS must have the capacity to accept connections and the public health agency must adhere to the necessary local implementation guidelines that govern IIS data exchange (see below). The local implementation guide establishes the interoperability requirements that are specific to each IIS. See MU Stage 1 Responsibilities for Immunization Registries (<http://www.cdc.gov/vaccines/programs/iis/meaningful-use-stage1.htm>) for specific guidance regarding IIS and MU Stage 1.

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

Policies

In order to fulfill the public health objective of capability to submit electronic data to immunization registries of IIS and actual submission in accordance with applicable law and practice; hospitals must comply with two federal regulations:

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



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Objective: Capability to submit electronic data to immunization registries of Immunization Information Systems and actual submission in accordance with applicable law and practice.

Measure: Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries and follow up submission if the test is successful (unless none of the immunization registries to which the EP or EH submits such information have 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>)

Submission to immunization registries: Electronically record, modify, retrieve, and submit immunization information in accordance with: the standard (and applicable implementation specifications) specified in § 170.205(e) (1) or § 170.205(e) (2); and, at a minimum, the version of the standard specified in § 170.207(e).

Practices

With the assumption that the IIS has the capacity to receive HL7 messages, the public health agency should enable and facilitate testing of HL7 version 2.3.1 or 2.5.1 messages from EPs and EHs in their jurisdictions. To ensure this will occur, public health agencies are expected to prepare and disseminate a time-stamped guidance document to the public. This document should specify the testing process, the timelines, the transport mechanism and the HL7 version the IIS system can accept (including any local variations in HL7 implementation guides, if applicable). The testing result has to be acknowledged as success or failure, preferably by providing a standard template-based response. For example, a failed test could include a) bad data quality and standards or b) transport version conflicts between the IIS and the EPs or EHs. These differences would still constitute meaningful use. In addition, there should be a provision to keep logs to document the testing efforts. Logs may be required for an audit by the CMS or State Medicaid agency. Before accepting production data from an EHR system to achieve full integration, additional prequalification may be necessary; this can be prioritized by the IIS programs.

To prepare an IIS for MU, the following steps and resources are helpful:

- **Provide an HL7 Local Implementation Guide**

EHR vendors and users will need the immunization registry's HL7 local implementation guide. CDC developed templates to assist local and state programs in the development of this document. In addition to the implementation guide, a standard methodology for testing and approving providers for data exchange with the IIS should be developed.

- **Review System Capacity**

Server capacity and network bandwidth to handle the increased IIS usage created by the new meaningful users must be considered. Systems that adequately support current IIS workload may be challenged with increased demand. Partial funding support for system capacity upgrades may be available through Medicaid health information technology initia-

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tives for implementation and technical support, so the Immunization Program and the State Medicaid offices are encouraged to establish a close collaboration. For information on other potential funding sources, see the CMS Whitepaper on Funding Immunization Registries (<http://www.medicaidhitechta.org/Portals/0/Users/011/11/11/ImmunRegWhitePaper.pdf>).

- **Verify Use of ONC-Certified EHR Technology**

MU requires use of an ONC-certified EHR technology. While the public health agency may choose to establish data exchange with non-certified providers for programmatic or public health reasons, such exchange does not qualify the provider for MU incentives. For details see the ONC Certified Health IT Product List (CHPL) (<http://oncchpl.force.com/ehrcert?q=CHPL>).

- **Test Messages**

Once a provider has an ONC-certified EHR technology, the next step is to send a test message to the IIS. The test message may succeed or fail. ONC certification is not a guarantee of interoperability with any specific IIS, as local regulations or standards may still require additional configuration.

- **Attestation**

To qualify for incentives in Stage 1, the eligible providers (EPs, EHs or Critical Access Hospitals (CAH)) must, at a minimum, submit a test message to the public health agency. If the test is successful, then the EP, EH or CAH should initiate production submission of reports. The public health agency may, if desired, queue the providers for on-boarding based on the public health agency's priorities.

Standards

The standards referred to below support immunization information system transactions to public health.

- **Minimum Functional Standards**

2009 version NVAC core data elements (<http://www.cdc.gov/vaccines/programs/iis/stds/coredata.htm>)

2001 version Minimum Functional Standards (<http://www.cdc.gov/vaccines/programs/iis/stds/min-funct-std-2001.htm>)
(Recommended by the Technical Working Group - Approved by CDC in 2001 and still current/relevant)

- **HL7 Standards**

HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.3 Published 8/15/2011
(<http://www.cdc.gov/vaccines/programs/iis/stds/downloads/hl7guide-08-2011.pdf>), NEW OCT 19, 2011. This document

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replaces the previous HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, Release 1.2. It contains minor updates and corrections.

Previous Versions of HL7 Implementation Guides:

HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.2 Published 2/12/2011 (<http://www.cdc.gov/vaccines/programs/iis/stds/downloads/hl7guide-02-2011.pdf>), Posted Feb 4, 2011. This document replaces the previous HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, Release 1.1. It contains minor updates and corrections.

HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.1 Published 8/15/2010 (<http://www.cdc.gov/vaccines/programs/iis/stds/downloads/hl7guide-08-2010.pdf>), Updated Sept 9, 2010. This document replaces the previous HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, Release 1.0. It contains minor updates and corrections.

HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.0 Published 5/1/2010 (<http://www.cdc.gov/vaccines/programs/iis/stds/downloads/hl7-guide-2010-prev-version.pdf>), Posted May 21, 2010. This document replaced the previous Version 2.3.1 Implementation Guides.

Version 2.2 - Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the HL7 Standard Protocol (<http://www.cdc.gov/vaccines/programs/iis/stds/downloads/hl7guide.pdf>) (Published 6/2006). This document supports legacy interfaces based on Version 2.3.1. New interfaces should be based on the Version 2.5.1 Implementation Guide. Original version in MS Word format (<http://www.cdc.gov/vaccines/programs/iis/stds/downloads/hl7guide.doc>)

- **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 following services and tools can facilitate achieving the capabilities to support MU:

- **HL7 2.5.1 Implementation Tools:**

HL7 2.5.1 Local Implementation Guide Template for Immunization Messaging, Release 1.3 Published 11/22/2011 (<http://www.cdc.gov/vaccines/programs/iis/stds/downloads/hl7-IG-Template.docx>) Posted December 9, 2011. This template is intended for IIS usage in defining their Local 2.5.1 Implementation Guide.

HL7 2.5.1 Local Implementation Guide Condensed Template for Immunization Messaging, Release 1.3 Published 11/22/2011 (<http://www.cdc.gov/vaccines/programs/iis/stds/downloads/hl7-IG-Condensed-Template.docx>) Posted

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December 9, 2011. This condensed template is an alternative template for IIS usage in defining their Local 2.5.1 Implementation Guide.

HL7 2.5.1 Local Business Rule Template for Immunization Messaging, Release 1.3 Posted December 9, 2011 (http://www2a.cdc.gov/nip/iis/TRK_RULES/trk-rules-HL7-template.asp). This template is designed to track the application of local IIS business rules during an HL7 transmission.

- **HL7 2.5.1 Test Cases**

VXU Test Cases (<http://www.cdc.gov/vaccines/programs/iis/stds/downloads/hl7-VXU-Test-Cases-10-2011.docx>) and [TXT-<http://www.cdc.gov/vaccines/programs/iis/stds/downloads/hl7-VXU-Test-Cases-10-2011.txt>] POSTED OCT 2011

- **Coding Vaccines**

CVX - Vaccines Administered (<http://www2a.cdc.gov/nip/IIS/IISStandards/vaccines.asp?rpt=cvx>) Posted Sept 2011

MVX - Manufacturers of Vaccines (<http://www2a.cdc.gov/nip/IIS/IISStandards/vaccines.asp?rpt=mvx>)

- **Mapping Alternative Codes to CVX and MVX**

CPT codes mapped to CVX codes (<http://www2a.cdc.gov/nip/IIS/IISStandards/vaccines.asp?rpt=cpt>) Posted Sept 2011

NDC codes mapped to CVX and MVX (<http://www2a.cdc.gov/nip/IIS/IISStandards/vaccines.asp?rpt=ndc>) Posted Sept 2011

Product names mapped to CVX and MVX (<http://www2a.cdc.gov/nip/IIS/IISStandards/vaccines.asp?rpt=tradenam>)
Posted Sept 2011

CVX mapped to vaccine groups (families) (<http://www2a.cdc.gov/nip/IIS/IISStandards/vaccines.asp?rpt=vg>) Posted Dec 2010

Understanding the rules for creating CVX and MVX codes (<http://www.cdc.gov/vaccines/programs/iis/stds/downloads/business-rules-508.pdf>) Updated Nov 29, 2010

- **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) 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.

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- Nationwide Health Information Network (NwHIN) Direct (Note: ONC has indicated that only certain transport protocols (including Direct - <http://wiki.directproject.org/>) may be acceptable in Stage 2)
- 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
- **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(k) Submission to Immunization Registries (http://healthcare.nist.gov/docs/170.302.k_Immunizations_v1.1.pdf) and testing tools (<http://xreg2.nist.gov:8080/HL7V2MuValidation2011/>)
 - PHIN Message Quality Framework (MQF) (<https://phinmqf.cdc.gov/>) 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.