

## Preparing for Meaningful Use Stage 3 – an Overview

**Note that Meaningful Use has now been replaced by Promoting Interoperability. These programs are often referred to using the more general category of Incentive Programs. However, the majority of the expectations for IIS readiness remain unchanged.**

### Being Ready

Meaningful Use Stage 3 (MU3) requirements are optional for providers in 2017 but become required beginning in 2018. MU3 includes a consolidated public health reporting objective containing an optional immunization measure for the electronic exchange of immunization administration data and bi-directional patient history and forecast. Eligible Providers (EPs), Eligible Hospitals (EHs), and Critical Access Hospitals (CAHs) will be required to use 2015 certified EHR technology to meet this measure.

Preparing your Immunization Information System (IIS) for MU3 and the use of 2015 certified EHR products is a long and complex process, but the judicious use of available tools and resources will help ease the transition. This document aims to outline some of the steps required to prepare your IIS for MU3 and identify some of the available tools and resources.

### Upgrading Electronic Interfaces

The public health immunization measure and the 2015 EHR certification regulations call out the use of Release 1.5 of the Implementation Guide (IG) for Immunization Messaging and the associated addendum. These are documents published by the Centers for Disease Control and Prevention (CDC) and the American Immunization Registry Association (AIRA) which document the technical requirements of using HL7 version 2.5.1 to exchange immunization related data. IIS can expect to receive HL7 messages conformant to the Release 1.5 specification and will likely need up upgrade their existing HL7 interfaces in order to be interoperable with 2015 certified submitters. While IIS are not required to certify their conformance to Release 1.5, all IIS are expected to upgrade their interfaces to match this new specification. Note that minor deviation from Release 1.5 is allowed where required by local laws, regulations or IIS policy. It is critical that IIS technical staff understand the requirements of Release 1.5 and identify and document local variations.

Key elements of implementing Release 1.5 include the following:

- It is critical to support the messaging profiles called out by regulations. Release 1.5 documents a number of different message profiles, but not all of them are required by MU3.
  - Support for the Z22 - Send Unsolicited Immunization Update profile and the associated response profile is required
  - Support for the Z44 - Request Evaluated Immunization History and Forecast Query profile and the associated response profiles is required
  - Note that supporting the Z34 – Request a Complete Immunization History profile is not sufficient to meet MU3 requirements
  - While interfaces will likely validate incoming messages against the message profile indicated in the message, message non-conformance should not stop the exchange of

usable data. Local business rules should still determine if the data in a message is usable.

- IIS must be prepared to accept National Drug Codes (NDC) for immunization administration data (Z22 profile).
  - It is the spirit of the regulation that for new administrations all IIS will be able to accept NDC codes alone (and drive all business requirements based on the NDC code alone) and all IIS are highly encouraged to evolve their systems to meet this requirement
    - **Note that the term “alone” in the statement above is referencing accepting an NDC without an accompanying CVX for an administered dose. It is NOT meant to suggest that NDCs alone should be the ONLY code set accepted for administered doses. It is anticipated that IIS will continue to receive CVX codes for administered immunizations given in sites not participating in incentive programs, as well as for historical doses.**
  - In the short term, while IIS must be able to accept an NDC code without logging an error, local implementations may require the cognate CVX code also be sent
    - Note that 2015 EHR certification does NOT test the ability of a certified EHR to send both the NDC and CVX code for a given administration, so a local requirement for CVX may require a modification on the part of the EHR
  - Ideally, IIS should be prepared to receive both Unit of Use (vial/syringe) and Unit of Sale (packaging) NDC codes for administered doses
  - The IIS is not required to return the original NDC in responses to query messages
- Trading partners will be expecting response messages in response to all submitted messages.
  - Historically, little importance was placed on returning Acknowledgement messages in response to an immunization administration data message; however, MU3 places new emphasis on the use of Acknowledgement messages
- While certification regulations are silent on the nature of the process used to transport messages between interacting systems, the strong recommendation is to implement the SOAP standard interface defined by the CDC and referenced in IIS Functional Standards.
- It is important to test interfaces thoroughly after completing development.
  - The National Institute for Standards and Technology (NIST) has developed tools for validating messages against HL7 2.5.1 Release 1.5. These tools can be used to test message produced by the IIS to ensure they are conformant to Release 1.5.

Once the IIS is prepared to exchange Release 1.5 conformant messages, the IIS will need to have a process to engage, onboard and maintain providers meeting MU3 requirements:

- IIS must declare readiness by July 1, 2017 for the required Stage 3 MU start on January 1, 2018.
  - Note that IIS don't have to be fully ready six months in advance; rather, they should anticipate being ready 6 months from when they make their declaration.
  - Declarations of readiness for Stage 3 MU should be added to, rather than replace, any existing readiness declarations for Stage 2 MU (submission only) throughout 2017.
  - The following statement may be used as sample language for declaration of readiness:  
*The **ABC IIS** is currently ready to accept data and is capable of supporting bidirectional, real-time interfaces with EHR systems, conforming with the [CDC](#)*

*HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4*<sup>1</sup>. By 01/01/2017, the **ABC IIS** will also conform to the *CDC HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5*<sup>2</sup> and *addendum*<sup>3</sup>, including supporting Query/Response and acceptance of National Drug Codes (NDCs) for newly-administered immunizations.

- The IIS *may also choose* to voluntarily list their registry on the CMS Centralized Repository, but this should augment, not replace, the more detailed information posted on your jurisdiction’s website. To be included in the CMS Centralized Repository, submit the form found at [https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/EHR\\_CentRepos\\_Form.pdf](https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/EHR_CentRepos_Form.pdf) by October 31, 2016, and the information will be published in January 2017. The Centralized Repository will be updated by CMS annually.
- IIS must have a process to document provider requests to implement MU3 requirements.
  - Note that MU3 now emphasizes “active engagement” of providers as demonstrated by any of these options:
    - Completed registration to submit data and awaiting an invitation to begin testing and/or onboard with the IIS
    - In the testing and validation phase
    - Electronically submitting production data
  - Although providers are not required by rule to re-register for Meaningful Use Stage 3, IIS may need to track providers that move from Stage 2 (submission) to Stage 3 (submission with NDC and Query/Response) for practical/operational reasons.
  - As providers move to Release 1.5 conformant interfaces, it is important to develop a plan to retire previous versions of interfaces where possible. In particular, a definitive plan to sunset support for version 2.3.1 interfaces will simplify IIS resource distribution.

## Resource List

- MU readiness documents
  - [Promoting Interoperability Incentive Program Readiness Checklist](#)
  - [PH Agency Readiness for Meaningful Use, 2015-2018](#)
- Technical documents
  - [CDC/AIRA HL7 implementation guides](#)
  - [AIRA Technical Resources](#)
  - [Guidance for HL7 ACK Messages](#)
  - [NIST validation tool](#)
  - [SOAP Standard Interface](#)

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<sup>1</sup> <http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-4-2012-08.pdf>

<sup>2</sup> <http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf>

<sup>3</sup> <http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-addendum-7-2015.pdf>