Meaningful Use Stage 2: Implications for Immunization Information Systems

Daniel W. Martin, MSPH
Public Health Analyst

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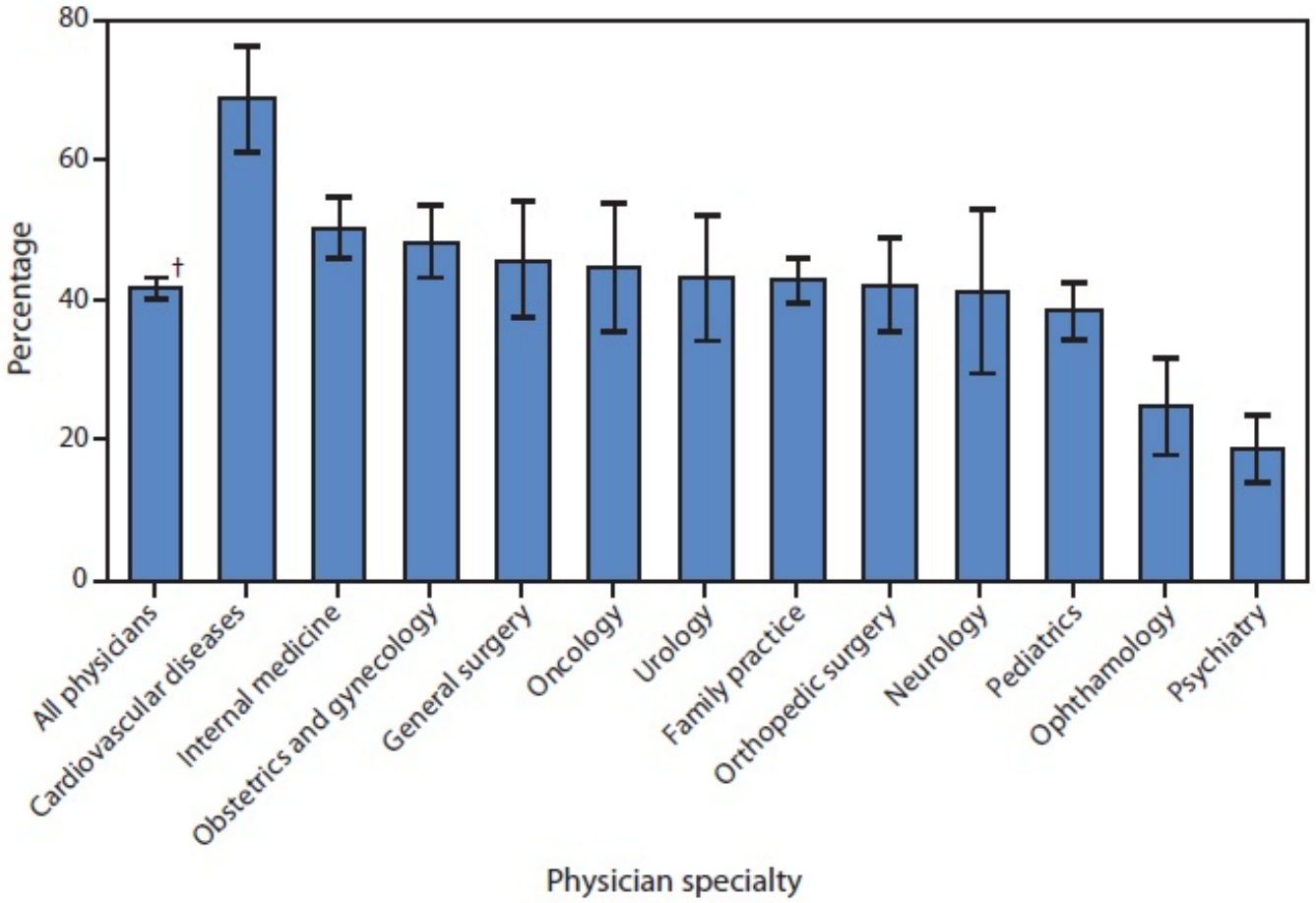
Meaningful Use Overview

- A program of the Centers for Medicare & Medicaid Services (CMS)
- Incentivizes physicians & hospitals to adopt, implement, & upgrade Electronic Health Record (EHR) systems to "certified EHR technology"
- To qualify for incentives, providers must "meaningfully use" these EHR systems

"Meaningful Use" (MU) is:

- Defined by regulations issued by CMS and the Office of the National Coordinator for Health Information Technology (ONC)
- A collection of standards for how EHR systems should function in the healthcare provider environment
- To be implemented in three stages
- Wide-ranging; immunization is only one of many issues/programs addressed
- Incentives are based on self-attestation by Eligible Hospitals/Providers (EP/EH)

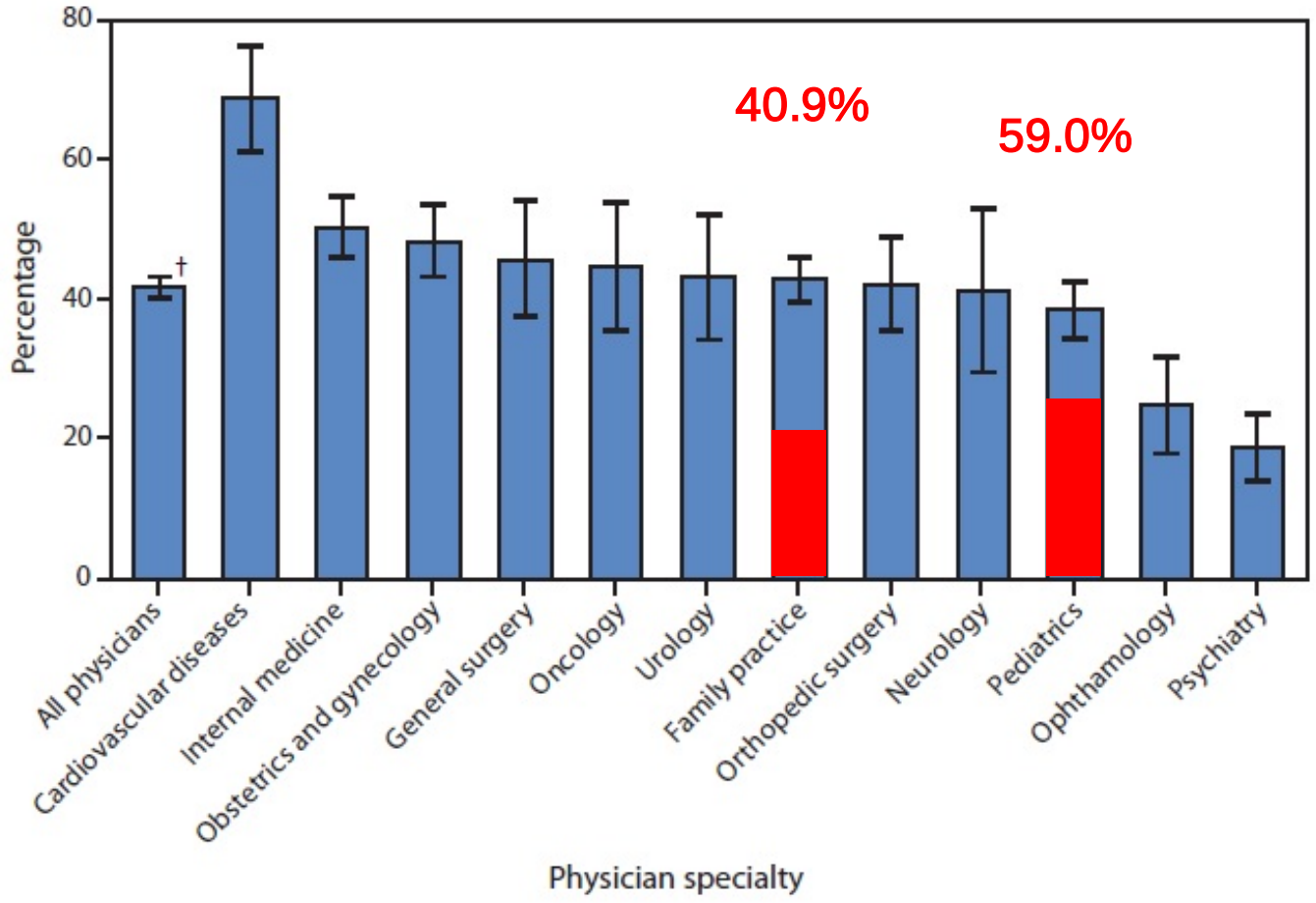
Percentage of Physicians with Electronic Health Record (EHR) Systems That Meet Federal Standards,* by Physician Specialty — Physician Workflow Survey, United States, 2011



NCHS QuickStats, reported in MMWR, 9/7/2012, V. 61, #35, p. 710

Percentage of Physicians with Electronic Health Record (EHR) Systems That Meet Federal Standards,* by Physician Specialty — Physician Workflow Survey, United States, 2011

Percentage that have attested to immunization submission Stage 1



NCHS 2011 Electronic Medical Records Supplement, unpublished data; Janey Hsaio, personal communication

Timeline of Stage 2 Rules

- NPRM published March 7
- 60-day comment period closed May 7
  - Multiple divisions within CDC commented, as did AIRA & individual grantees
- CMS & ONC revised & proposed draft final rule
- CDC commented privately on draft
- Draft Final Rule sent to OMB for review mid-July
- Final Rule published September 4, 2012
- First reporting period January, 2014

Meaningful Use Immunization Objective

- **Stage 1:**
  - Capability to submit electronic data to immunization registries of Immunization Information Systems ***and actual submission*** in accordance with applicable law and practice.
- **Stage 2:**
  - Capability to submit electronic data to immunization registries or immunization information systems ***except where prohibited***, and in accordance with applicable law and practice.

Immunization programs, their reporting providers and federal funding agencies, such as the CDC, ONC, and CMS, have worked diligently since the passage of the HITECH Act in 2009 to facilitate EPs, eligible hospitals and CAHs ability to meet the Stage 1 measure. We propose for Stage 2 to take the next step from testing to requiring actual submission of immunization data. In order to achieve improved population health, providers who administer immunizations must share that data electronically, to avoid missed opportunities or duplicative vaccinations.

CMS Final Rule, Federal Register Vol. 77, No. 171, p. 54022

"…except where prohibited…"

"…to encourage all EPs, eligible hospitals, and CAHs to submit electronic immunization data, even when not required by State/local law. Therefore, if they are authorized to submit the data, they should do so even if it is not required by either law or practice."

The default action is to submit immunization data to the IIS

CMS Final Rule, Federal Register Vol. 77, No. 171, p. 53977

Key Elements of Meaningful Use - IIS

Stage 1	Stage 2
IIS submission is "menu option"	IIS submission is "core"
Test message to IIS; ongoing submission if successful/possible	"Successful ongoing submission"
"Dummy" data permitted for test	"Actual patient data is required" for ongoing submission
HL7 2.3.1 or 2.5.1	HL7 2.5.1 only * *(including Stage 1 in 2014)*
Transport not specified	Transport as specified by Local Health Agency (LHA)
Provider attests to having made a test; may be audited but no documentation prescribed	Provider attests to ongoing submission; proof of submission provided by LHA

* HL7 2.5.1 – ONC specifically references Implementation Guide v. 1.4, see ONC Final Rule Federal Register Vol. 77, No. 171, p. 54240

"Ongoing Submission"

- **If IIS is able to accept submission**
  - CMS repository where Public Health Authorities (PHAs) can report if they're accepting submissions
  - PHAs will be asked to report in 1st 60 days of reporting period
- **If previously submitting (stage 1), then continue**
- **EP/EH who register with PHA in 1st 60 days qualify even if in an on-boarding queue**
  - EP/EH must be responsive to PHA while in-queue:

The measure will not be met if the provider--
- Fails to register their intent by the deadline; or
- Fails to participate in the on-boarding process as demonstrated by failure to respond to the PHA written requests for action within 30 days on two separate occasions.

CMS Final Rule, Federal Register Vol. 77, No. 171, p. 54021

The Grandfather Clause . . .

However, if EPs prior to CY 2014 and eligible hospitals and CAHs prior to FY2014 ***have achieved successful ongoing submission*** using EHR technology certified to the 2011 Edition EHR certification criteria (HL7 2.3.1 only) it is acceptable to continue this ongoing submission and meet the Stage 2 measure for as long as HL7 2.3.1 continues to be accepted by the immunizations information system or immunization registry.

- Already doing ongoing submission using 2.3.1
- IIS continues to support/accept 2.3.1

CMS Final Rule, Federal Register Vol. 77, No. 171, p. 54023

The question of transport…

- Public comment raised the issue with CMS/ONC
- CMS' stand is that Public Health needs to be free to specify its own standards
- Transport (for P.H.) will NOT be part of ONC certification

Public health authorities have moved to standardize transport mechanisms where feasible, and Health Information Exchanges are often facilitating the transport of data to public health. We stand by our policy that ***allows public health authorities to dictate the transport mechanism in their jurisdiction***. Further, we clarify that this is independent of the EHR certification criteria as EHR certification does not address transport for public health objectives.

CMS Final Rule, Federal Register Vol. 77, No. 171, p. 54022;
See also ONC Final Rule Federal Register Vol. 77, No. 171, p. 54240, which references CDC Expert Panel and SOAP, and ONC Rule Federal Register Vol. 77, No. 171, p. 54241re: Direct

Proof of "ongoing submission"

- NPRM suggested PHA should supply a letter to EP/EH documenting successful submission
- CDC, AIRA, and several individual registries commented
- CMS has agreed, and now provides for "any written communication (which may be in electronic format) from the PHA"

Be prepared to acknowledge submissions!

Exclusions from Immunization MU measure

1. Provider doesn't administer immunizations
2. No IIS, or IIS can't receive submissions in a format that *certified* EHR can send
3. IIS hasn't reported its capability (to CMS) in time
4. IIS can't enroll additional providers in time

Note: for (2), exclusion is not available if PHA has designated an intermediary such as an HIE to translate data to a format IIS can accept.

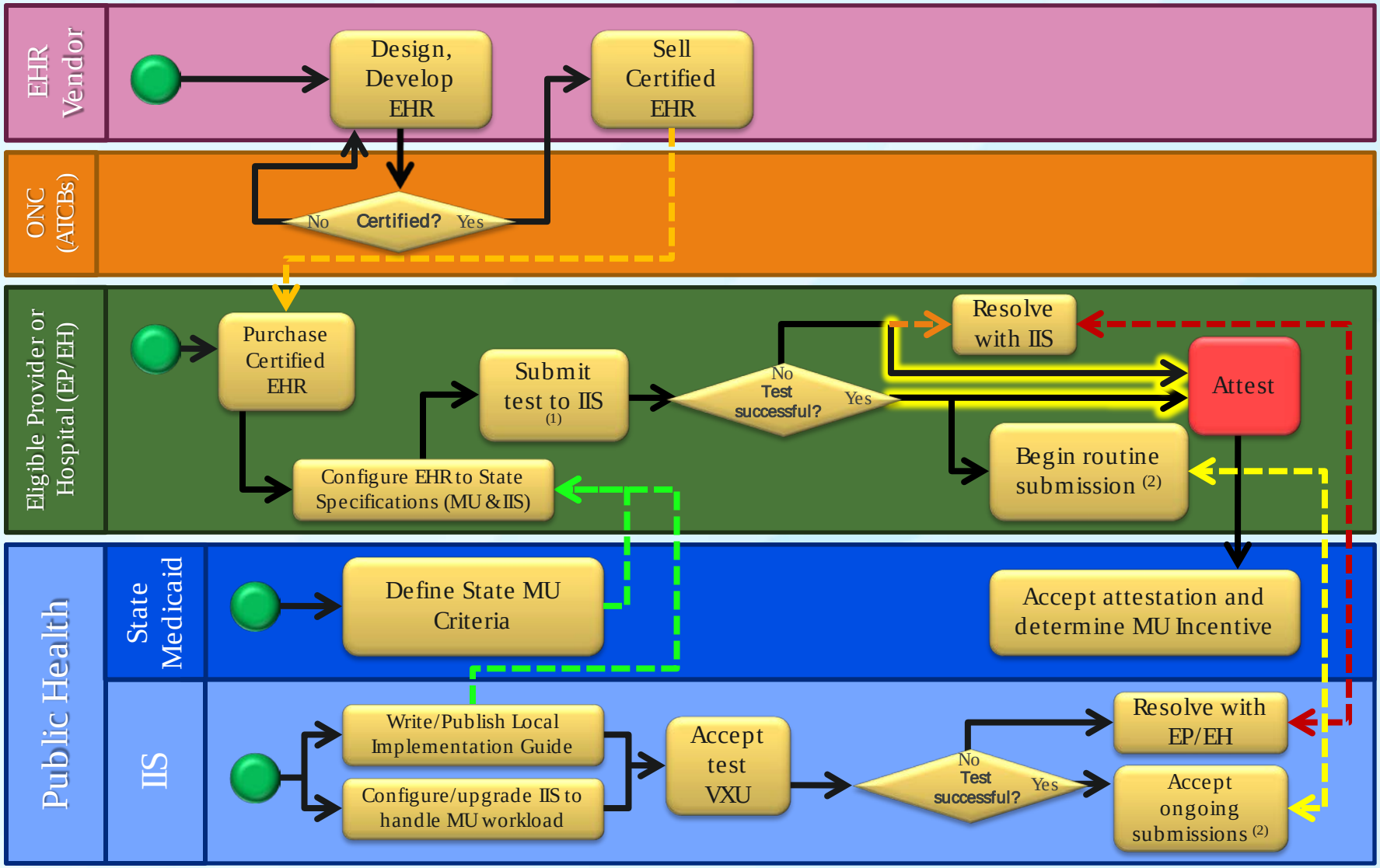
CMS Final rule, Federal Register Vol. 77, No. 171, p. 54023

Timing for Meaningful Use Attestation

1st Year	Stage of Meaningful Use										
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
2011	1	1	1	2	2	3	3	TBD	TBD	TBD	TBD
2012		1	1	2	2	3	3	TBD	TBD	TBD	TBD
2013			1	1	2	2	3	3	TBD	TBD	TBD
2014				1	1	2	2	3	3	TBD	TBD
2015					1	1	2	2	3	3	TBD
2016						1	1	2	2	3	3
2017							1	1	2	2	3

Graphic courtesy of Jason McNamara, CMS

Operational Responsibilities in Immunization MU Stage 1

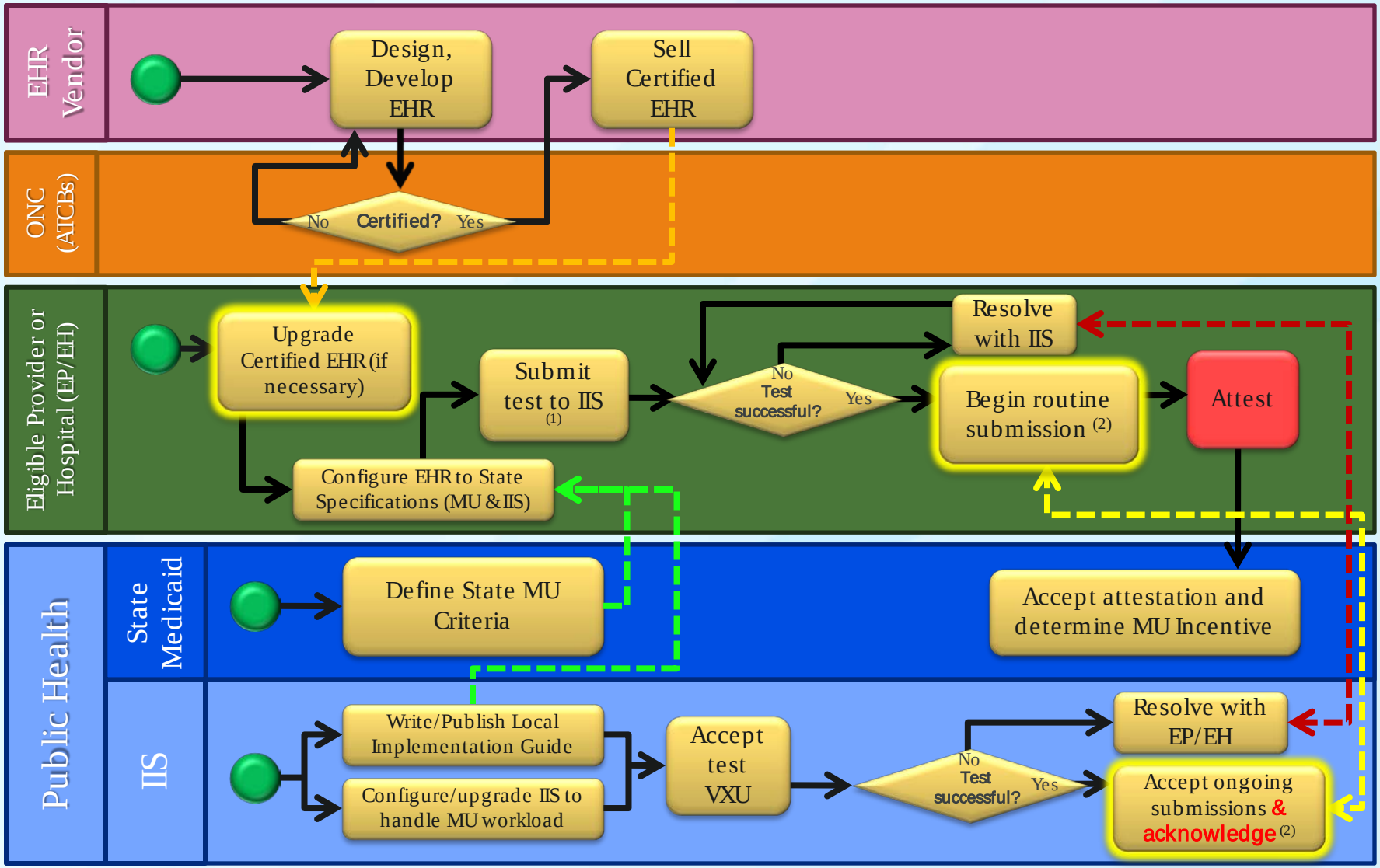


(1) If IIS is configured to accept submissions; LHA may designate alternate submission entity

(2) In accordance with local regulation and subject to IIS readiness/requirements Additional QA and configuration may be necessary before routine submission is possible.

Adapted from a schema originally presented at an AIRA Meaningful Use workshop March 27, 2011 by Mike McPherson of the Kansas Immunization Program

Operational Responsibilities in Immunization MU Stage 2



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Certification of EHR Systems

- Done by Authorized Testing and Certification Bodies (ATCB) approved by ONC
- According to NIST standards
  - ONC developed these standards for Stage 1
  - CDC (Rob Savage) & AIRA (Nathan Bunker) have helped NIST to improve test cases for Stage 2
- Ensures that Certified EHR Technology (CEHRT) meets minimum standards, including for interoperability
- ***EHR (and sometimes HIE), not IIS, is certified***
- Does not replace local on-boarding process

Certification of EHR Systems

Certification *does*	Certification *does not*
Test EHR implementation of published ***national*** standards	Test EHR implementation of ***state or local*** requirements
Test the EHR's performance of selected functions	Validate specific health care practitioner's effective use of the EHR
Test the EHR's capacity to store required data fields	Guarantee the quality of the data users put in those fields
Test EHR's production of several immunization-specific HL7 messages	Test the submission of an HL7 message to any IIS

Stage-2 Certified EHR Technology will probably be more IIS-ready than Stage 1 was, but on-boarding still matters!

Health Information Exchanges (HIEs)

An HIE can serve as a conduit for immunization data exchange with IIS

- "if serving on the behalf of the public health agency to simply transport the data, but not transforming content or message format"
- If transformation (e.g. translation into required HL7 standard) is performed by the HIE, that HIE must undergo ONC certification

In this situation, the EP, eligible hospital or CAH must still ensure the accomplishment of ongoing submission of reports ***to the actual immunization information system*** or registry (whether performed by the intermediary or not), except in situations when the PHA has explicitly designated delivery of reports to the intermediary as satisfying these requirements.

CMS Final Rule, Federal Register Vol. 77, No. 171, p. 54021

An eye to the future…

"Stage 3 is likely to enhance this functionality to permit clinicians to ***view*** *the entire immunization registry/immunization information system record and support* ***bi-directional information exchange****."*

CMS Final Rule, Federal Register Vol. 77, No. 171, p. 54022

Important References

- CDC MU website: http://www.cdc.gov/ehrmeaningfuluse/
- CMS MU website: http://www.cms.gov/EHRIncentivePrograms/
- CMS Final Rule: https://www.federalregister.gov/r/0938-AQ84
- ONC Final Rule: https://federalregister.gov/a/2012-20982
- ONC ATCB website: http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__onc-authorized_testing_and_certification_bodies/3120
- List of ONC-certified EHRs: http://onc-chpl.force.com/ehrcert

Thanks!

For more information please contact Centers for Disease Control and Prevention
Immunization Information Systems Support Branch

Dan Martin, Public Health Analyst
dwm5@cdc.gov (404) 639-0476

Janet Kelly, Operations Team Lead
izk2@cdc.gov (404) 639-8735

Gary Urquhart, Branch Chief
gau5@cdc.gov (404) 639-8277