Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications

Overview for Public Health Stakeholders

Agenda

Stage 3 NPRMs

Stage 2 Experience

Beyond Meaningful Use
  S&I Framework Initiatives
  ONC Pilots
Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3

- Align all three stages of Meaningful Use into single program/rule as an option in 2017 and required for all providers in 2018
- Aligns reporting periods – full calendar year reporting for eligible professionals, eligible hospitals and critical access hospitals
- Provides simplified objectives and measures – only 8 objectives, all tied to HHS Delivery System Reform Goals

<table>
<thead>
<tr>
<th>Program goal/objective</th>
<th>Delivery system reform goal alignment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protect Patient Health Information</td>
<td>Foundational to Meaningful Use and Certified EHR Technology. Recommended by HIT Policy Committee.</td>
</tr>
<tr>
<td>Coordination of Care through Patient Engagement</td>
<td>Recommended by HIT Policy Committee. National Quality Strategy Alignment.</td>
</tr>
</tbody>
</table>

- New 2015 Base EHR Definition
- No optional/required criteria – developers should choose the criteria relevant to their purpose
- Can be used beyond CMS EHR Incentive Program

### Objective 8 - Measures and Standards

<table>
<thead>
<tr>
<th>Measure</th>
<th>Standard</th>
<th>Implementation Guide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measure 2 – Syndromic Surveillance Reporting</td>
<td>170.315(f)(2)</td>
<td>PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent, Ambulatory Care, and Inpatient Settings, Release 2.0, September 2014 (“Release 2.0”)</td>
</tr>
<tr>
<td>Measure 3 – Case Reporting</td>
<td>170.315(f)(5)</td>
<td>IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation (September 5, 2014)</td>
</tr>
<tr>
<td>Measure 5 - Clinical Data Registry Reporting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measure 6 - Electronic Reportable Laboratory Results</td>
<td>170.315(f)(3)</td>
<td>HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm), DSTU R1.1, 2014 or “Release 2, DSTU R1.1”</td>
</tr>
</tbody>
</table>
Measure 1 – Immunization Registry Reporting:

- The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

(Source: CMS Stage 3 NPRM)

Exclusions for Measure 1 – Immunization Registry Reporting:

Any EP, eligible hospital, or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure if the EP, eligible hospital, or CAH: (1) Does not administer any immunizations to any of the populations for which data is collected by their jurisdiction's immunization registry or immunization information system during the EHR reporting period; (2) operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data at the start of the EHR reporting period.

(Source: CMS Stage 3 NPRM)
§ 170.315(f)(1) (Transmission to immunization registries)

- HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5 (October 2014)
- Require NDC Codes for recording administered vaccines, require CVX codes for historical vaccines
- Require a Health IT Module presented for certification to this criterion to be able to request, access and display an immunization history and forecast from an immunization registry

(Source: 2015 Edition HIT Certification Criteria NPRM)

§ 170.315(f)(1) (Transmission to immunization registries)

- We solicit comment on whether we should allow use of NDC codes for administered vaccines as an option for certification, but continue to require CVX codes for administered vaccines for the 2015 Edition. Allowing for optional use of NDC codes for administered vaccines could provide health IT developers and health care providers an implementation period before we would consider requiring NDC codes for administered vaccines. We also solicit comment on whether we should require CVX plus the HL7 Standard Code Set MVX - Manufacturers of Vaccines Code Set (October 30, 2014 version) as an alternative to NDC codes for administered vaccines.

(Source: 2015 Edition HIT Certification Criteria NPRM)
§ 170.315(f)(1) (Transmission to immunization registries)

- We propose in a later section of this rule to include the representation of immunizations in both CVX codes and NDC codes as part of the “Common Clinical Data Set” definition for certification to the 2015 Edition. Please see section III.B.3 “Common Clinical Data Set” of this preamble for further discussion of this associated proposal. We note that this means that a Health IT Module certified to certification criteria that include the Common Clinical Data Set (e.g., the ToC criterion) must demonstrate the capability to represent immunizations in CVX codes and NDC codes. This approach ensures that health IT would be able to support a provider’s attempt to send immunization information that includes NDC information.

(Source: 2015 Edition HIT Certification Criteria NPRM)

Measure 3—Case Reporting:

- The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.

(Source: CMS Stage 3 NPRM)
Measure 3—Case Reporting:

- This is a new reporting option that was not part of Stage 2. The collection of electronic case reporting data greatly improves reporting efficiencies between providers and the PHA. Public health agencies collect “reportable conditions”, as defined by the state, territorial, and local PHAs to monitor disease trends and support the management of outbreaks. In many circumstances, there has been low reporting compliance because providers do not know when, where, or how to report. In some cases, the time burden to report can also contribute to low reporting compliance. However, electronic case reporting presents a core benefit to public health improvement and a variety of stakeholders have identified electronic case reporting as a high value element of patient and continuity of care. Further, we believe that electronic case reporting reduces burdensome paper-based and labor-intensive case reporting.

(Source: CMS Stage 3 NPRM)

Exclusion for Measure 3 – Case Reporting

Any EP, eligible hospital, or CAH meeting one or more of the following criteria may be excluded from the case reporting measure if the EP, eligible hospital, or CAH: (1) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction’s reportable disease system during the EHR reporting period; (2) operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data at the start of the EHR reporting period.

(Source: CMS Stage 3 NPRM)
§ 170.315(f)(5) Transmission to public health agencies—case reporting

We propose to adopt a certification criterion for electronic transmission of case reporting information to public health that would require a Health IT Module to be able to electronically create case reporting information for electronic transmission in accordance with the IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation (September 5, 2014) standard, which we propose to adopt at § 170.205(q)(1). As mentioned above, this standard and our proposal include compliance with other existing standards. One such standard is the CDA Release 2.0, which is a foundational standard for use in sending and receiving case reporting information.

- To note, for testing to this criterion, a Health IT Module would need to demonstrate that it can create and send a constrained transition of care document to a public health agency, accept a URL in return, be able to direct end users to the URL, and adhere to the security requirements for the transmission of this information.

(Source: 2015 Edition HIT Certification Criteria NPRM)

§ 170.315(f)(5) Transmission to public health agencies—case reporting

We recognize that the Fast Health Interoperability Resource (FHIR®) REST API and FHIR-based standard specifications will likely play a role in an interoperable health IT architecture. FHIR resources that implement SDC concepts and support the use of case reporting to public health would likely play a role in that scenario. The current HL7 FHIR Implementation Guide: Structure Data Capture (SDC), Release 1 is a “draft for comment” with a DSTU ballot planned for mid-2015. Given this trajectory, we solicit comment on whether we should consider adopting the HL7 FHIR Implementation Guide: SDC DSTU that will be balloted in mid-2015 in place of, or together with, the IHE Quality, Research, and Public Health Technical Framework Supplement. We are aware of a proposed HL7 working group known as the Healthcare Standards Integration Workgroup that will collaborate on FHIR resources considered co-owned with the IHE-HL7 Joint Workgroup within IHE. The implementation guides created from the S&I SDC Initiative is part of this joint workgroup’s area of responsibility. Therefore, we intend to work with these coordinated efforts to ensure a complementary and coordinated approach for case reporting using SDC.

(Source: 2015 Edition HIT Certification Criteria NPRM)
### Objective 8 - Measures and Standards

<table>
<thead>
<tr>
<th>Measure</th>
<th>Standard</th>
<th>Implementation Guide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measure 2 – Syndromic Surveillance Reporting</td>
<td>170.315(f)(2)</td>
<td>PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent, Ambulatory Care, and Inpatient Settings, Release 2.0, September 2014 (“Release 2.0”)</td>
</tr>
<tr>
<td>Measure 3 – Case Reporting</td>
<td>170.315(f)(5)</td>
<td>IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation (September 5, 2014)</td>
</tr>
<tr>
<td>Measure 5 - Clinical Data Registry Reporting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measure 6 - Electronic Reportable Laboratory Results</td>
<td>170.315(f)(3)</td>
<td>HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm), DSTU R1.1, 2014 or “Release 2, DSTU R1.1</td>
</tr>
</tbody>
</table>

---

### 2015 Edition NPRM: Public Comment Opportunities

Public comments will be accepted through May 29, 2015.

- Read the proposed rule: (public inspection version)  

- Public comment template for 2015 Ed Rule  

Other 2015 Edition Resources:

- Press release:  

- Fact sheet:  

- ONC regulations:  

- Contact:  
  [Michael.Lipinski@hhs.gov](mailto:Michael.Lipinski@hhs.gov)
Stage 3 NPRM: Public Comment Opportunities

Public comments will be accepted through May 29, 2015. Please consider using the comment template ONC has provided.


Other Stage 3 Resources:

- Contact: Elise.Anthony@hhs.gov to discuss specific proposals in Stage 3.

---

Full recording of NPRM overview

https://attendee.gotowebinar.com/recording/6578818239204750082
More stage 2 hospitals reported on all applicable public health measures without exclusion than did stage 1 hospitals.
Seven out of 10 eligible hospitals that administered reportable vaccinations were able to electronically submit them to a local immunization registry.

Medicare EHR Incentive Program Data through December, 2014. Includes eligible hospitals reporting to the Medicare EHR Incentive Program for Fiscal Year 2014. (N=3,969) Find this and more data on public health reporting measures at dashboard.healthit.gov

Percent of eligible hospitals, by stage of meaningful use, that reported on the immunization registry measure, 2014.

Eligible Hospitals at Stage 1
- Reporting on measure: 58%
- Did not select measure: 35%
- Local jurisdiction cannot accept: 4%
- Does not vaccinate: 3%
- N=2,158

Eligible Hospitals at Stage 2
- Reporting on measure: 88%
- Does not vaccinate: 3%
- Local jurisdiction cannot accept: 9%
- N=1,811

Medicare EHR Incentive Program Data through December, 2014. Includes eligible hospitals reporting to the Medicare EHR Incentive Program for Fiscal Year 2014. (N=3,969) “Does not vaccinate” and “local jurisdiction cannot accept” were categories for exclusion options. For stage 1, immunization registry reporting is optional; it is required in stage 2. Find this and more data on public health reporting measures at dashboard.healthit.gov
Stage Two Challenges

• Jurisdictional variation
  – Locally required fields/variation
  – Dose size, VFC
• Onboarding providers
  – Providers with incentives not necessarily the ones Public Health would prioritize
  – Immunization measure allows providers to register intent to submit data and meet the measure while awaiting invitation from Public Health to begin onboarding/validation
  – Public Health, although technically capable of accepting data, does not have resources to onboard all providers at once.

Mitigation Strategies

• Jurisdictional variation
  – Community engagement for new releases of implementation guides
  – Testing against national standards – many Stage 2 issues resolved
• Onboarding providers
  – Medicaid match (FFP) for public health resources to onboard providers with Medicaid incentives
  – ONC/CDC Community of Practice (Medicaid engagement)
  – Alignment with SIM and other payment delivery reform models
Use Case Objective: For an Immunization Information System (IIS) to respond to a transaction that contains current or historical addresses that are outside its jurisdiction by triggering a QBOP or VXU to the other jurisdiction’s IIS.
Questions

James.Daniel@hhs.gov

@jim_daniel

(Source: 2015 Edition HIT Certification Criteria NPRM)