The Office of the National Coordinator for Health Information Technology

Medicare and Medicaid Programs: Electronic Health Record Incentive Program -- Stage 3 and Modifications to Meaningful Use in 2015 through 2017

and

2015 Edition Health Information Technology Certification Criteria, 2015 Edition Base Electronic Health Record Definition, and ONC Health IT Certification Program Modifications

Overview for Public Health Stakeholders

October 15, 2015

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CMS Rule

Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 and 2017

- Align all three stages of Meaningful Use into single program/rule
  - All providers would meet Stage 3 requirements starting in 2018
  - Phased-in timelines that allows some providers to continue to meet Stage1 and Stage 2 requirements in 2017
- Aligns reporting periods – calendar year reporting for eligible professionals, eligible hospitals and critical access hospitals
  - Full year reporting periods
  - Allows 90 day reporting periods for first time attesters in 2017 only
- Provides simplified objectives and measures –
  - Modification: Objective 10: Public Health and Clinical Data Registry Reporting
  - Stage 3:Objective 8: Public Health and Clinical Data Registry Reporting

ONC Rule

2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications

- 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

Mod Rule: Objective 10: Public Health and Clinical Data Registry Reporting

- NPRM Proposed Objective: The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.
  - Six possible measures to meet the objective
    - Eligible professionals must meet three measures
    - Eligible Hospitals and Critical Access Hospitals must meet four measures
- Final Rule Objective: Unchanged
  - Six possible measures to meet the objective
    - Eligible professionals must meet TWO measures
    - Eligible Hospitals and Critical Access Hospitals must meet THREE measures

Mod Rule: Measures for Objective 10

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PUBLIC HEALTH AND CLINICAL DATA REGISTRY REPORTING OBJECTIVE		
Measure	Maximum times measure can count towards objective for EP	Maximum times measure can count towards objective for eligible hospital or CAH
Measure 1 – Immunization Registry Reporting	1	1
Measure 2 – Syndromic Surveillance Reporting	1	1
Measure 3 – Case Reporting (Dropped)		
Measure 4 - Public Health Registry Reporting Measure 5 - Clinical Data Registry Reporting (Now Specialized Registries Includes Cancer for EP)	2	3
Measure 6 - Electronic Reportable Laboratory Results	n/a	1

Stage 3 Rule: Objective 8: Public Health and Clinical Data Registry Reporting

- NPRM Proposed Objective: The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.
  - Six possible measures to meet the objective
    - Eligible professionals must meet three measures
    - Eligible Hospitals and Critical Access Hospitals must meet four measures

- Final Rule Objective: Unchanged

Stage 3: Measures for Objective 8

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PUBLIC HEALTH AND CLINICAL DATA REGISTRY REPORTING OBJECTIVE		
Measure	Maximum times measure can count towards objective for EP	Maximum times measure can count towards objective for eligible hospital or CAH
Measure 1 – Immunization Registry Reporting	1	1
Measure 2 – Syndromic Surveillance Reporting	1	1
Measure 3 – Case Reporting	1	1
Measure 4 - Public Health Registry Reporting	3	4
Measure 5 - Clinical Data Registry Reporting	3	4
Measure 6 - Electronic Reportable Laboratory Results	n/a	1

State Flexibility for Stage 3 of Meaningful Use

- Consistent with our approach under both Stage 1 and 2, we propose to continue to offer states flexibility under the Medicaid EHR Incentive Program in Stage 3 by adding a new provision at § 495.316(d)(2)(iii) subject to the same conditions and standards as the Stage 2 flexibility policy. Under Stage 3, state flexibility would apply only with respect to the public health and clinical data registry reporting objective outlined under section II.A.1.c.(1).(b).(i). of this proposed rule.
- For Stage 3 of meaningful use, we would continue to allow states to specify the means of transmission of the data and otherwise change the public health agency reporting objective as long as it does not require functionality greater than what is required for Stage 3 and included in the 2015 Edition proposed rule elsewhere in this issue of the Federal Register.

Mod Rule: Exclusions/Total number of measures required for EH/CAH

- For eligible hospitals and CAHs, we proposed that an exclusion for a measure does not count toward the total of three measures. Instead, in order to meet this objective, an eligible hospital or CAH would need to meet three of the total number of measures available to them. If the eligible hospital or CAH qualifies for multiple exclusions and the total number of remaining measures available to the eligible hospital or CAH is less than three, the eligible hospital, or CAH can meet the objective by meeting all of the remaining measures available to them and claiming the applicable exclusions. If no measures remain available, the eligible hospital or CAH can meet the objective by claiming applicable exclusions for all measures. An eligible hospital or CAH that is scheduled to be in Stage 1 in 2015 must report at least two measures unless they can —either;-- (1) exclude from all but one available measure and report that one measure; or (2) can exclude from all available measures. Available measures include ones for which the eligible hospital or CAH does not qualify for an exclusion.

Adopted as proposed.

Mod Rule: Exclusions/Total number of measures required for EP

- For EPs, we proposed that an exclusion for a measure does not count toward the total of two measures. Instead, in order to meet this objective an EP would need to meet two of the total number of measures available to them. If the EP qualifies for multiple exclusions and the remaining number of measures available to the EP is less than two, the EP can meet the objective by meeting the one remaining measure available to them and claiming the applicable exclusions. If no measures remain available, the EP can meet the objective by claiming applicable exclusions for all measures. An EP who is scheduled to be in Stage 1 in 2015 must report at least one measure unless they can exclude from all available measures. Available measures include ones for which the EP does not qualify for an exclusion.

- Adopted as proposed.

Active Engagement (page 425)

- Active engagement means that the provider is in the process of moving towards sending "production data" to a public health agency or clinical data registry, or is sending production data to a public health agency or clinical data registry.
- We noted that the term "production data" refers to data generated through clinical processes involving patient care and it is used to distinguish between this data and "test data" which may be submitted for the purposes of enrolling in and testing electronic data transfers.
- We proposed that "active engagement" may be demonstrated by any of the following options:
  - Option 1 – Completed Registration to Submit Data:
  - Option 2 - Testing and Validation
  - Option 3 – Production

Completed Registration to Submit Data: (page 425-26)

- The EP, eligible hospital, or CAH registered to submit data with the PHA or, where applicable, the CDR to which the information is being submitted; registration was completed within 60 days after the start of the EHR reporting period; and the EP, eligible hospital, or CAH is awaiting an invitation from the PHA or CDR to begin testing and validation. This option allows providers to meet the measure when the PHA or the CDR has limited resources to initiate the testing and validation process. Providers that have registered in previous years do not need to submit an additional registration to meet this requirement for each EHR reporting period

Testing and Validation: (page 426)

- The EP, eligible hospital, or CAH is in the process of testing and validation of the electronic submission of data. Providers must respond to requests from the PHA or, where applicable, the CDR within 30 days; failure to respond twice within an EHR reporting period would result in that provider not meeting the measure.

Production: (page 426)

- The EP, eligible hospital, or CAH has completed testing and validation of the electronic submission and is electronically submitting production data to the PHA or CDR

Active Engagement (page 428)

We thank the commenters for their input and note the following clarifications of intent and purpose for the change from “ongoing submission” to “active engagement.” We received feedback from a variety of stakeholders that the "ongoing submission" structure created confusion. This feedback highlighted that providers are unsure of how ongoing submission could be achieved and whether periodic, continuous, or episodic reporting was generally required. We found that the wide variation among potential provider reporting scenarios and submission processes contributed to the difficulty in defining “ongoing submission” in a fair and universally applicable manner. Therefore our change to **“active engagement” is intended to more clearly identify the progression of the requirement as well as providing a basis for defining the actions required by the provider in each step of the process**. In a sense, the active engagement options are a clarification of the more basic concept of reporting which is that the provider is taking action and in communication with a public health agency in order to register, test and submit data in a progression which results in the provider successfully reporting relevant data to the public health agency.

The active engagement requirement clarifies what is expected of a provider who seeks to meet the measures within this objective and **renames the requirement to better describe the provider’s role in meeting each option** within the structure. There is an intentional similarity between some of the broad descriptions of the Stage 2 “ongoing reporting” and the requirements for the “active engagement” options. This is both **to provide continuity and to define a more comprehensive progression for providers in meeting the measure**. For example, in the Stage 2 rule (77 FR 54021), we generally stated that a provider could register their intent to submit data to successfully meet a measure in the public health objective. This concept is defined with additional guidance in the Stage 3 proposed rule as Active Engagement Option 1: Completed Registration to Submit Data.

For the commenters discussing the submission of production data as defined in Action Engagement Option 3: **Production, we note that under this option a provider only may successfully attest to meaningful use when the receiving public health agency or clinical data registry moves the provider into a production phase**. We recognize that live data may be sent during the Testing and Validation phase of Option 2, but the data received in Option 2 is not sufficient for purposes of meeting Option 3 unless the public health agency and clinical data registry is actively accepting the production data from the provider for purpose of reporting. We agree with commenters who noted that issues may arise that require provider action. In such a case, **we require providers to respond to issues in the same manner as described in Option 2. For example, a provider in the production phase would not be able to successfully attest to Option 3 if there were issues in production where the provider fails to respond to an issue within 30 days on two occasions.**

Active Engagement (page 429-30)

- As we have noted in the proposed rule, under the active engagement requirement, **providers would only need to register once** with a public health agency or a clinical data registry and could register before the reporting period begins. In addition, we note that **previous registrations with a public health agency or clinical data registry that occurred in a previous stage of meaningful use could count toward option 1** of the active engagement requirement for purposes of attesting to Stage 3. We clarify that providers **must register with a public health agency or clinical data registry for each measure** they intend to use to meet meaningful use. Further, we also clarify that to meet option 1 of the active engagement requirement, registration with the applicable public health agency or clinical data registry is required where a provider seeks to meet meaningful use using a measure they have not successfully attested to in a previous EHR reporting period.

Active Engagement (page 430-31)

- The EHR Incentive Programs are based on individual providers meeting the objectives and measures of meaningful use. Therefore an individual provider can only meet an objective or measure if they are engaged in the activity which is used to meet the measure. This means a provider can demonstrate meaningful use by using communications and information provided by a public health agency or clinical data registry to the provider directly for individual reporting. Or, **a provider also may demonstrate meaningful use by using communications and information provided by a public health agency or clinical data registry to the practice or organization of the provider if the organization reports at the group level as long as the provider is contributing to the data reported by the group**. If the provider does not contribute to the data, they must claim the exclusion if applicable and/or meet another public health reporting measure. For example, a provider who does not administer immunizations should claim the exclusion even if their organization submits immunization reporting at the group level.

NPRM: PH Readiness: Centralized Repository

- We also propose to provide support to providers seeking to meet the requirements of this objective by creating a centralized repository of national, state, and local PHA and CDR readiness. In the Stage 2 final rule (77 FR 54021), we noted the benefits of developing a centralized repository where a PHA could post readiness updates regarding their ability to accept electronic data using specifications prescribed by ONC for the public health objectives. We also published, pursuant to the Paperwork Reduction Act of 1995, a notice in the Federal Register on February 7, 2014 soliciting public comment on the proposed information collection required to develop the centralized repository on public health readiness (79 FR 7461). We considered the comments and we now propose moving forward with the development of the centralized repository. The centralized repository is integral to meaningful use and is expected to be available by the start of CY 2017. We expect that the centralized repository will include readiness updates for PHAs and CDRs at the state, local, and national level. We welcome your comments on the use and structure of the centralized repository.

Stage 3 Rule: PH Readiness: Centralized Repository

- In response to comments received and the concern that providers need advance readiness notification from public health agencies and clinical data registries to prepare and plan before the EHR reporting period begins, we are broadening the exclusions that could apply to providers seeking to meet the objective. The exclusion will allow providers more time to prepare their processes to align with what data public health jurisdictions are ready to accept. Specifically, we will not finalize the proposed requirement that public health agency and clinical data registries declare readiness on the first day of the EHR reporting period. We are instead **finalizing a modified exclusion that if public health agencies have not declared 6 months before the start of the EHR reporting period whether the registry they are offering will be ready on January 1 of the upcoming year for use by providers seeking to meet EHR reporting periods in that upcoming year, a provider can claim an exclusion.** We believe that modifying the exclusion to request public health agency or clinical data registry to declare their readiness 6 months ahead of the first day of the EHR reporting period would allow providers adequate notice of public health agency and clinical data registry plans to accept data at the beginning of an EHR reporting period.

NPRM: 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).

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.

Mod Rule: Immunization Registry Reporting:

- We appreciate commenters' concerns regarding the addition of a bi-directionality requirement for the EHR reporting periods covered by the modified Stage 2 requirements. We agree with commenters that additional time may be needed for both public health agencies and providers to adopt the necessary technology to support bi-directional functionality. **Therefore, we are not finalizing the bi-directionality proposal in the EHR Incentive Programs for 2015 through 2017**.

Stage 3 Rule:– Immunization Registry Reporting:

- For clarification, we note that the provider's technology certified in accordance with the ONC Health IT Certification Program may layer additional information and recommendations on top of the forecast received from the immunization registry. The requirements of CEHRT serve only as a baseline upon which additional capabilities may be built.

- …we are finalizing this measure, with the modification that a **provider's health IT system may layer additional information on the immunization history, forecast, and still successfully meet this measure**

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

2015 Edition Final Rule: § 170.315(f)(1) (Transmission to immunization registries)

HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5 (October 2014)

- …have adopted **HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5 (October 1, 2014) and HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5, Addendum (July 2015)** for the transmission to immunization requirement. We clarify that to meet this criterion, health IT must comply with all mandatory requirements of Release 1.5 and its addendum, which would include the coding for race and ethnicity. The 2015 Edition "demographics" criterion and Common Clinical Data Set requirements related to race and ethnicity are not implicated by this criterion.

2015 Edition Final Rule: § 170.315(f)(1) (Transmission to immunization registries)

Require NDC Codes for recording administered vaccines, require CVX codes for historical vaccines

- we finalize a criterion that supports one set of codes to be used for administered vaccines at all times and another set of codes to be used for historical vaccines at other times.
- …we have adopted the **August 17, 2015 version of the CVX code set as the minimum standards code set for historical vaccines.**
- For purposes of **administered vaccines, we have adopted the National Drug Codes (NDC) –Vaccine NDC Linker**, updates through August 17, 2015 as the minimum standards code set.

2015 Edition Final Rule: § 170.315(f)(1) (Transmission to immunization registries)

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

- We have adopted the requirement for a Health IT Module to enable a user to request, access, and display a patient's immunization history and forecast from an immunization registry in accordance with the Release 1.5 IG.
- However, we note that this criterion **does not prescribe a particular workflow or reconciliation requirements**. Providers and health IT developers may reconcile forecast and history information in a manner that best meets their needs for workflow and patient safety.

CEHRT – Immunization Registries

- CEHRT under Mod Rule Years, 2015-2017:
  - HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.4 (August 2012)
- CEHRT under Stage 3 Option Year 2017:
  - HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5 (October 2014) and HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5, Addendum (July 2015)
- CEHRT under MU Stage 3 2018 and beyond:
  - HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5 (October 2014) and HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5, Addendum (July 2015)

2015 Edition Test Procedures - Immunization

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- Companion Guides
  - https://www.healthit.gov/policy-researchers-implementers/2015-edition-test-method

- Test Procedures for Comment
  - http://confluence.oncprojectracking.org/display/ONCCERT2015/ONC+Health+IT+Certification+Program+2015+Edition+Test+Methods+Home

NPRM: Measure 2—Syndromic Surveillance Reporting

- The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care ambulatory setting for EPs, or an emergency or urgent care department for eligible hospitals and CAHs. This measure remains a policy priority for Stage 3 because electronic syndromic surveillance is valuable for early detection of outbreaks, as well as monitoring disease and condition trends.

NPRM: Measure 2—Syndromic Surveillance Reporting

- We are distinguishing between EPs and eligible hospital or CAHs reporting locations because, as discussed in the Stage 2 final rule, few PHAs appeared to have the ability to accept non-emergency or non-urgent care ambulatory syndromic surveillance data electronically. We continue to observe differences in the infrastructure and current environments for supporting electronic syndromic surveillance data submission to PHAs between eligible hospitals or CAHs and EPs. Because eligible hospitals and CAHs send syndromic surveillance data using different methods as compared to EPs, we are defining slightly different exclusions for each setting as described later in this section.

Mod Rule: Measure 2—Syndromic Surveillance Reporting

- We disagree with commenters who suggest that the syndromic surveillance measure should be removed from the EHR Incentive Programs for 2015 through 2017
- we are adopting a modification that allows all eligible professionals to submit syndromic surveillance data for an EHR reporting period in 2015 through 2017.

Stage 3: Measure 2—Syndromic Surveillance Reporting

- Because syndromic surveillance reporting is more appropriate for urgent care settings and eligible hospitals/CAHs, we remove this measure for eligible professionals for Stage 3 with the exception of providers who are practicing in urgent care settings. For CAHs and eligible hospitals, we adopt this measure as proposed

- **New Measure Language for EP- Syndromic surveillance reporting: The EP is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting**

NPRM: Exclusion for Measure 2 (EPs) – Syndromic Surveillance

Exclusion for EPs for Measure 2: Any EP meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the EP: (1) Does not treat or diagnose or directly treat any disease or condition associated with a syndromic surveillance system in their jurisdiction; (2) operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from EPs 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 syndromic surveillance data from EPs at the start of the EHR reporting period.

NPRM: Exclusion for Measure 2 (EHs, CAHs) – Syndromic Surveillance

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Exclusion for eligible hospitals/CAHs for Measure 2: Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the eligible hospital or CAH: (1) Does not have an emergency or urgent care department; (2) operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from eligible hospitals or CAHs 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 syndromic surveillance data from eligible hospitals or CAHs at the start of the EHR reporting period.

Mod Rule: Exclusion for Measure 2 (EPs) – Syndromic Surveillance

We are modifying the proposed EP exclusion which states “does not treat or diagnose or directly treat any disease or condition associated with a syndromic surveillance system in his or her jurisdiction” to better indicate that the registry may or may not allow the EP to report based on their category rather than on whether they treat or diagnose specific diseases or condition for syndromic surveillance reporting.”

- (i) Is not in a category of providers from which ambulatory syndromic surveillance data is collected by their jurisdiction's syndromic surveillance system;
- (ii) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from EPs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.
- (iii) Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from EPs at the start of the EHR reporting period.

NPRM: § 170.315(f)(2) Transmission to public health agencies—syndromic surveillance

Emergency Department, Urgent Care, and Inpatient Settings

- We propose to adopt the PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent, Ambulatory Care, and Inpatient Settings, Release 2.0, September 2014 ("Release 2.0").
- Given the improvements included in Release 2.0 of the IG, we propose to adopt it at § 170.205(d)(4) and include it in the 2015 Edition "transmission to public health agencies—syndromic surveillance" certification criterion for emergency department, urgent care, and inpatient settings.

2015 Edition Final Rule: § 170.315(f)(2) Transmission to public health agencies—syndromic surveillance

Emergency Department, Urgent Care, and Inpatient Settings

- Overall, the April 21, 2015, updated version and the addendum do not create additional substantive requirements in comparison to Release 2.0. Rather, through the corrections, clarifications, and additional information the IG will improve testing, certification, implementation, and interoperability. **Therefore, we have adopted this criterion with both the April 21, 2015, updated version and addendum**.
- We also note that any IG instructions regarding the frequency of submission are outside the scope of certification as certification focuses on the technical capabilities of the Health IT Module presented for certification.

NPRM: § 170.315(f)(2) Transmission to public health agencies—syndromic surveillance

Ambulatory Syndromic Surveillance

- We propose to permit, for ambulatory setting certification, the use of any electronic means for sending syndromic surveillance data to public health agencies as well as optional certification to certain syndromic surveillance data elements. In the 2014 Edition Release 2 final rule, we adopted a certification criterion for ambulatory syndromic surveillance at § 170.314(f)(7) that permits use of any electronic means of sending syndromic surveillance data to public health agencies for ambulatory settings (79 FR 54440-01). We adopted this criterion to provide EPs under the EHR Incentive Programs to meet the Stage 2 syndromic surveillance objective with the use of CEHRT. Because there were no IGs to support HL7 2.5.1 messaging or query-based syndromic surveillance for ambulatory settings, we expanded our policy to provide more flexibility to EPs to meet the syndromic surveillance objective.

2015 Edition Final Rule: § 170.315(f)(2) Transmission to public health agencies—syndromic surveillance

Ambulatory Syndromic Surveillance

- With consideration of public comments, comments received on a prior rulemaking (79 FR 54439-54441), and stakeholder feedback through public health outreach, we have determined **to not adopt certification requirements for the ambulatory setting**. Without mature standards and the widespread acceptance of ambulatory syndromic surveillance data across public health jurisdictions, sufficient reason does not exist to justify certification to the proposed functionality. To clarify, **the PHIN 2.0 IG does support the urgent care ambulatory setting and would be appropriate for use in that particular setting.**

CEHRT – Syndromic Surveillance for Eligible Hospital and CAH

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- CEHRT under Mod Rule Years, 2015-2017:
  - PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data, Release 1.1 (August 2012) and PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data, Addendum Release 1.1 (August 2012)
  - www.cdc.gov/nssp/documents/guides/phin_msg_guide_for_ss_ed_and_uc_data_v1_1.pdf and www.cdc.gov/nssp/documents/guides/ss-addendum_v1_1.pdf
- CEHRT under Stage 3 Option Year 2017:
  - Either option
- CEHRT under MU Stage 3 2018 and beyond:
  - PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0 (April 21, 2015) and Erratum to the CDC PHIN 2.0 Implementation Guide, August 2015; Erratum to the CDC PHIN 2.0 Messaging Guide, April 2015 Release for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings
  - www.cdc.gov/nssp/documents/guides/syndrsurvmessagguide2_messagingguide_phn.pdf and www.cdc.gov/nssp/documents/guides/erratum-to-the-cdc-phin-2.0-implementation-guide-august-2015.pdf

CEHRT – Syndromic Surveillance for EPs

- CEHRT under Mod Rule Years, 2015-2017:
  - Data elements only § 107.314(f)(3)

    or
  - (for urgent care settings only) PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data, Release 1.1 (August 2012) and PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data, Addendum Release 1.1 (August 2012)
- CEHRT under Stage 3 Option Year 2017:
  - Either
- CEHRT under MU Stage 3 2018 and beyond:
  - (for urgent care setting only) PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0 (April 21, 2015) and Erratum to the CDC PHIN 2.0 Implementation Guide, August 2015; Erratum to the CDC PHIN 2.0 Messaging Guide, April 2015 Release for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings

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.

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.

Mod Rule: Measure 3—Case Reporting:

- We continue to believe that case reporting is a core component of public health reporting and to health improvement around the country and, as noted elsewhere, are maintaining this measure for Stage 3. However, for purposes of the EHR Incentive Program for 2015 through 2017, we believe additional time is needed across the HIT landscape to develop the technology and infrastructure to support case reporting and **we are not finalizing this measure as proposed**. If a provider chooses to participate in Stage 3 in 2017, they must meet the requirements defined for the Stage 3 Public Health and Clinical Data Registry Reporting objective which may include the case reporting measure defined for the Stage 3 objectives discussed in section II.B.2.b.viii of this final rule with comment period.

Stage 3: Measure 3—Electronic Case Reporting:

However, to allow EPs, EHR vendors, and other entities adequate time to prepare for this new measure in Stage 3, this measure **will not begin requiring electronic case reporting until 2018**.By the 2018 year of Stage 3, we believe that the standards will be mature and that jurisdictions will be able to accept these types of data. Therefore, we finalize this measure as proposed to begin in 2018.

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.

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.

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.

2015 Edition Final Rule: § 170.315(f)(5) Transmission to public health agencies—electronic case reporting

- We understand commenters' concerns with the current state of standards available and the continual evolution of standards. We also agree with commenters' suggestions that an appropriate approach for this criterion would be to permit flexibility for case reporting by not referencing a specific content exchange standard for certification at this time.
- We understand the industry is moving towards RESTful approaches and considering FHIR for different exchange patterns, including case reporting. To accommodate this evolution, **we have not adopted the proposed IHE profile as part of this certification criterion or another exchange standard.**

2015 Edition Final Rule: § 170.315(f)(5) Transmission to public health agencies—electronic case reporting

Specifically, a Health IT Module would need to support the ability to electronically:

(1) consume and maintain a table of trigger codes to determine which encounters should initiate an initial case report being sent to public health;

(2) when a trigger is matched, create and send an initial case report to public health;

(3) receive and display additional information, such as a "notice of reportability" and data fields to be completed; and

(4) submit a completed form.

2015 Edition Final Rule: § 170.315(f)(5) Transmission to public health agencies—electronic case reporting

Given the priority to receive the initial case report form, we have adopted the following functionality that supports the first two identified steps above. To meet this certification criterion, a Health IT Module must be able to

- (1) consume and maintain a table of trigger codes to determine which encounters should initiate an initial case report being sent to public health to determine reportability; and
- (2) when a trigger is matched, create an initial case report that includes specific data (Common Clinical Data Set; encounter diagnoses; provider name, office contact information, and reason for visit, and an identifier representing the row and version of the trigger table that triggered the case report).

2015 Edition Final Rule: § 170.315(f)(5) Transmission to public health agencies—electronic case reporting

The CCD template of the C-CDA Release 2.1 is currently the most viable approach for achieving step (2) above. We note, however, that the CDC and CSTE, with the HL7 Public Health and Emergency Response Working Group, are currently developing C-CDA and FHIR IGs to specify the data needed in the initial case report form and the data that would be provided in the information returned to the provider. As standards evolve, additional/supplemental data would likely be requested electronically about cases for which public health has received an initial case report that is deemed reportable. To support this additional data reporting, the future might include a FHIR-based approach that could utilize the FHIR Structured Data Capture (SDC) IG

2015 Edition Final Rule: § 170.315(f)(5) Transmission to public health agencies—electronic case reporting

We agree with commenters that a common public health interface or intermediary would reduce the burden on health IT developers and state and local public health agencies. The CDC and the public health community have made an investment in a centralized approach for receipt of electronic case reports. The CDC will identify a test harness and tool for all the functional requirements described above. Additionally, as the CDC and public health approach matures to include other interfaces, the CDC will continue to monitor the development of standards to support these functional requirements. **As noted above, this may lead to future rulemaking for the certification of electronic case reporting.**

CEHRT – Electronic Case Reporting

- CEHRT under Mod Rule Years, 2015-2017:
  - n/a
- CEHRT under Stage 3 Option Year 2017:
  - n/a
- CEHRT under MU Stage 3 2018 and beyond:
  - Consume and maintain a table of trigger codes to determine which encounters may be reportable
  - Case report creation. Create a case report for electronic transmission based on a matched trigger that contains at a minimum
    - The Common Clinical Data Set
    - Encounter diagnoses
    - The provider's name, office contact information, and reason for visit
    - An identifier representing the row and version of the trigger table that triggered the case report

Measure 4—Public Health Registry Reporting
Measure 5—Clinical Data Registry Reporting

- The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit data to public health registries.
- The EP, eligible hospital, or CAH is in active engagement to submit data to a clinical data registry.

NPRM: Measure 4—Public Health Registry Reporting

In the Stage 2 final rule, we were purposefully general in our use of the term "specialized registry" (other than a cancer registry) to encompass both registry reporting to public health agencies and clinical data registries in order to prevent inadvertent exclusion of certain registries through an attempt to be more specific (77 FR 54030). In response to insight gained from the industry through listening sessions, public forums, and reponses to the February 2014 Public Health Reporting RFI; we propose to carry forward the concept behind this broad category from Stage 2, but also propose to split public health registry reporting from clinical data registry reporting into two separate measures which better define the potential types of registries available for reporting. We propose to define a "public health registry" as a registry that is administered by, or on behalf of, a local, state, territorial, or national PHA and which collects data for public health purposes. While immunization registries are a type of public health registry, we propose to keep immunization registry reporting separate from the public health registry reporting measure to retain continuity from Stage 1 and 2 policy in which immunization registry reporting was a distinct and separate objective (77 FR 54023).

NPRM: Measure 5—Clinical Data Registry Reporting

For the purposes of meaningful use, “public health registries” are those administered by, or on behalf of, a local, state, territorial, or national public health agencies; and “clinical data registries” are administered by, or on behalf of, other non-public health agency entities. We believe that clinical data registries are important for providing information that can inform patients and their providers on the best course of treatment and for care improvements, and can support specialty reporting by developing reporting for areas not usually covered by PHAs but that are important to a specialist's provision of care. Clinical data registries can also be used to monitor health care quality and resource use.

Mod Rule: Measure 4/Measure 5 now Specialized Registries

…we agree that our proposal to split the Specialized Registry Reporting objective into two measures may inadvertently cause some providers to no longer use their current reporting option to meet the measure. We are therefore not finalizing our proposal to split specialized registry reporting into two measures as proposed. Instead, we will maintain for 2015 through 2017 a unified specialized registry reporting measure which adopts the change from "ongoing submission" to "active engagement". We believe that this will allow providers flexibility to continue in the direction they may have already planned for reporting while still allowing for a wide range of reporting options in the future.

Mod Rule: Measure 4/Measure 5 now Specialized Registries

As noted previously, we are not adopting this policy for the public health reporting measure, and we are also therefore not adopting the policy for a separate clinical data registry reporting measure

Mod Rule: Measure 4/5 now Specialized Registries

We further note that we have previously supported the inclusion of a variety of registries under the specialized registry measure, including Prescription Drug Monitoring Program reporting and electronic case reporting. We agree that a variety of registries may be considered specialized registries, which allows providers the flexibility to report using a registry that is most helpful to their patients. **Therefore, we will continue to allow these registries to be considered specialized registries for purposes of reporting the EHR Reporting period in 2015, 2016, and 2017**. However, **we will modify the exclusion not only to reflect the change from public health registry to specialized registry but also to allow an exclusion if the provider does not collect the data relevant to a specialized registry within their jurisdiction**.

Mod Rule: Measure 4/5 now Specialized Registries

We are also finalizing our proposed policy to incorporate cancer case reporting into the measure for EPs only. Therefore, EPs who were previously planning to attest to the cancer case reporting objective, may count that action toward the Specialized Registry Reporting measure.

Stage 3: Measure 4 Public Health Registry Reporting

…public health jurisdictions began to accept electronic case reporting and prescription drug monitoring during previous stages of meaningful use and these reporting options were considered specialized registries.

…we will allow such specialized registries to be counted for purposes of reporting to this objective in Stage 3 under the public health registry reporting measure for Stage 3 in 2017, 2018 and subsequent years in the following manner: **A provider may count a specialized registry if the provider achieved the phase of active engagement defined under Active Engagement Option 3: Production, including production data submission with the specialized registry in a prior year under the applicable requirements of the EHR Incentive Programs in 2015 through 2017**. We do note that reporting to specialized registries does not require certification under the ONC Health IT Certification Program or adherence to specific implementation guides for reporting in 2015 through 2017, and we direct readers to section aII.B.2.b.x for further information on the Specialized Registry Reporting measure for 2015 through 2017

Stage 3: Measure 4 Public Health Registry Reporting

However we note that providers would not be able to count production reporting to a specialized registry under the Public Health Reporting Objective for 2015 through 2017, **if there are standards and requirements referenced in the ONC 2015 Edition regulations for Public Health and Clinical Data Registry Stage 3 Measures**

Stage 3: Measure 5 Clinical Data Registry

Our definition of jurisdiction here is general, and the scope may be local, state, regional or at the national level. The definition will be dependent on the type of registry to which the provider is reporting. A registry that is "borderless" would be considered a registry at the national level and would be included for purposes of this measure.

Exclusions for Measure 4 Public Health Registry Reporting

Any EP, eligible hospital, or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure if the EP, eligible hospital, or CAH: (1) Does not diagnose or directly treat any disease or condition associated with a public health registry in their jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions 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 registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

Exclusions for Measure 5 Clinical Data Registry Reporting

Any EP, eligible hospital, or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure if the EP, eligible hospital, or CAH: (1) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions 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 clinical data registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

Stage 3 Measure 4/5 Exclusions

We believe that the measure and associated exclusions that we have proposed provide a variety of options for providers to successfully attest or as appropriate be excluded from the measure.

(Mod rule changes noted to reflect Specialized Registries)

NPRM: § 170.315(f)(4) Transmission to cancer registries

- HL7 Implementation Guide for CDA© Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers Release 1 or "HL7 IG Release 1"
- We propose to include the September 2014 Release of the U.S. Edition of SNOMED CT® and LOINC® version 2.50 in this criterion. We refer readers to section III.A.2.d ("Minimum Standards" Code Sets) for further discussion of our adoption of SNOMED CT® and LOINC® as minimum standards code sets and our proposals to adopt the versions cited above, or potentially newer versions if released before a subsequent final rule, as the baselines for certification to the 2015 Edition.

NPRM: § 170.315(f)(4) Transmission to cancer registries

- Aligns with C-CDA Release 2.0 templates, where possible;
- Adds new data elements, including grade, pathologic TNM stage,[165] family history of illness, height and weight, discrete radiation oncology items, planned medications, and planned procedures;Show citation box
- Changes optionality for some data elements in response to cancer community input and to align with C-CDA Release 2.0 templates;
- Improves documentation and aligns conformance statements with table constraints;
- Adds some new vocabulary links and a new reportability list for ICD-10-CM;
- Fixes some within-document references;
- Fixes some LOINC® codes;
- Fixes some Code System and Value Set Object Identifiers;
- Fixes some conformance verbs;
- Improves sample XML snippets;
- Fixes some conformance verbs and data element names in Appendix B “Ambulatory Healthcare Provider Cancer Event Report—Data Elements”; and
- Fixes a value in the value set.

2015 Edition Final Rule: § 170.315(f)(4) Transmission to cancer registries

Putting the I in HealthIT
www.HealthIT.gov

We appreciate the overall support for this criterion and the HL7 Release 1 IG. The CDC recently published and updated version of the IG (HL7 CDA® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1, U.S. Realm)113 ("Release 1.1."). Release 1.1 involves technical corrections to Release 1. No new content has been included. The templates in the IG were versioned due to the versioning of included templates (see the detailed section "Changes from Previous Version" in Volume 2 of for a detailed view of these changes).

We have adopted this criterion with the updated IG, Release 1.1 (both Volumes 1 and 2). Commenters were supportive of our overall proposed approach and the proposed IG. As detailed above, Release 1.1 addresses errors, ambiguities, implementation issues, and commenters' concerns. Therefore, the adoption of Release 1.1 will lead to improved implementation and interoperability.

2015 Edition Final Rule: § 170.315(f)(4) Transmission to cancer registries

Putting the I in HealthIT
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Mapping to the NAACCR format is not included in the IG because the mapping rules are complex, and can change over time based on continued input and refinement by the cancer registry community

NPRM: § 170.315(f)(6) Transmission to public health agencies—antimicrobial use and resistance reporting

HL7 Implementation Guide for CDA ® Release 2—Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm (August 2013)

We propose to test and certify a Health IT Module for conformance with the following sections of the IG:

- HAI Antimicrobial Use and Resistance (AUR) Antimicrobial Resistance Option (ARO) Report (Numerator) specific document template in Section 2.1.2.1 (pages 69-72);
- Antimicrobial Resistance Option (ARO) Summary Report (Denominator) specific document template in Section 2.1.1.1 (pages 54-56); and
- Antimicrobial Use (AUP) Summary Report (Numerator and Denominator) specific document template in Section 2.1.1.2 (pages 56-58).

2015 Edition Final: § 170.315(f)(6) Transmission to public health agencies—antimicrobial use and resistance reporting

(No changes) We appreciate the overall support for this criterion and the IG. We have adopted this criterion as proposed (with both Volumes 1 and 2 of the HAI IG). We intend to work with federal partners, such as the CDC, to eliminate or reduce any negative impacts on health IT developers resulting from the frequency of reporting changes or the manner in which changes are implemented in the associated program. We note that certification to the adopted version of the standard is what is necessary to meet the CEHRT definition under the EHR Incentive Programs. In regard to the concern about state variations, this data will only be collected by the CDC at the national level. The CDC is the only public health agency that needs to be able to receive these surveys electronically, which it is capable of doing. The use of a national interface for receipt avoids the problems associated with jurisdictional variation

NPRM: § 170.315(f)(7) Transmission to public health agencies—health care surveys

HL7 Implementation Guide for CDA ® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, Draft Standard for Trial Use (December 2014),[171] which we propose to adopt at § 170.205(s)(1).

- Automating the survey process using the CDA standard streamlines the collection of data and increases the sample pool by allowing all providers who want to participate in the surveys to do so. The HL7 Implementation Guide defines the electronic submission of the data to the CDC. We clarify that the IG is intended for the transmission of survey data for both the NAMCS (*e.g.,* for ambulatory medical care settings) and NHAMCS (*e.g.,* for hospital ambulatory settings including emergency departments and outpatient departments).

2015 Final Edition: § 170.315(f)(7) Transmission to public health agencies—health care surveys

We clarify that, as proposed, certification would cover the entire NHCS IG. The NHCS IG consists of the National Hospital Care Survey, NHAMCS, and NAMCS. In the Proposed Rule, we focused on clarifying that the NHAMCS and NAMCS were included in the IG and the changes in the surveys as compared to past versions. **However, all three surveys are covered by the NHCS IG and will be covered as part of testing and certification.**

All public health agencies may not be able to receive this data electronically and that variability across jurisdictions could be problematic. However, this data will only be collected by the CDC at the national level. The CDC is the only public health agency that needs to be able to receive these surveys electronically, which it is capable of doing. The use of a national interface for receipt avoids the problems associated with jurisdictional variation.

CEHRT – Public Health Registries

- CEHRT under Mod Rule Years, 2015-2017 (now Measure 3 - Specialized Registries):
  - Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries (August 2012) (EP Only)
- CEHRT under Stage 3 Option Year 2017:
  - Either
- CEHRT under MU Stage 3 2018 and beyond
  - HL7 CDA® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1, U.S. Realm) (EP Only)
  - HL7 Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm (August 2013) (Eligible Hospital/CAH only)
  - HL7 Implementation Guide for CDA ® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, Draft Standard for Trial Use (December 2014)

CEHRT – Clinical Data Registries

- CEHRT under Mod Rule Years, 2015-2017 (now Measure 3 - Specialized Registries):
  - None
- CEHRT under Stage 3 Option Year 2017:
  - None
- CEHRT under MU Stage 3 2018 and beyond:
  - None

NPRM: Measure 6—Electronic Reportable Laboratory Result Reporting

The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results. This measure is available to eligible hospitals and CAHs only.

Mod Rule/Stage 3: Measure 6—Electronic Reportable Laboratory Result Reporting

(No changes) We thank commenters for their support of this measure. However, we do not agree that this measure should be extended to EPs. We note that in-house laboratories of EPs do not perform the types of tests that are reportable to public health jurisdictions. For example, many in-house laboratories focus on tests such as rapid strep tests that test for strep throat. The rapid strep tests are not reportable to public health agencies.

Exclusion for Measure 6 – Electronic Reportable Laboratory Result Reporting

Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result reporting measure if the eligible hospital or CAH: (1) Does not perform or order laboratory tests that are reportable in their jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no public health agency is capable of accepting the specific ELR 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 reportable laboratory results from an eligible hospital or CAH at the start of the EHR reporting period.

NPRM: § 170.315(f)(3) Transmission to public health agencies—reportable laboratory tests and values/results

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"

- Corrects errata;
- Updates Objective Identifiers;
- Applies conformance statements from the LRI DSTU;
- Provides technical corrections; and
- Updates usage for consistent treatment of modifier fields.

NPRM: § 170.315(f)(3) Transmission to public health agencies—reportable laboratory tests and values/results

We propose to include the September 2014 Release of the U.S. Edition of SNOMED CT® and LOINC® version 2.50 in this criterion. We refer readers to section III.A.2.d ("Minimum Standards" Code Sets) for further discussion of our adoption of SNOMED CT® and LOINC® as minimum standards code sets and our proposals to adopt the versions cited above, or potentially newer versions if released before a subsequent final rule, as the baselines for certification to the 2015 Edition.

We appreciate the expression of support for this criterion and the proposed standards. We note, however, that the HL7 Public Health and Emergency Response Workgroup is currently working on a newer version of the proposed IG that harmonizes with the HL7 Laboratory Results Interface (LRI) profiles. Harmonization with LRI will address the noted concerns as well as ensure alignment across laboratory IGs, including the LRI IG and the Laboratory Orders Interface (LOI) IG. This updated IG is not yet complete and cannot be adopted at this time. With these considerations, we do not believe it would be appropriate to adopt the proposed IG as health IT developer and provider efforts to meet and implement the requirements of the proposed IG would shortly be superseded by the updated IG**. Therefore, we have not adopted the proposed IG. We have also not adopted the updated vocabulary standards because without a newer IG, there is little benefit from having health IT developers be tested and certified to updated vocabulary standards for this particular use case.**

We have adopted a 2015 Edition "transmission to public health agencies – reportable laboratory tests and values/results" certification criterion that requires adherence to the same standards as we referenced in the 2014 Edition "transmission of reportable laboratory tests and values/results" criterion. Data from CDC and CMS indicates that over 80% of hospitals are already in the process of submitting electronic laboratory results using the previously adopted standards (**HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 with Errata and Clarifications, ELR 2.5.1 Clarification Document for EHR Technology Certification, and versions of SNOMED CT®and LOINC®**). Our decision to adopt these same standards for the 2015 Edition criterion will ensure continuity in reporting and reduce burden for providers as well as health IT developers as this criterion is eligible for gap certification.

CEHRT – Electronic Reportable Laboratory Result Reporting

- CEHRT under Mod Rule Years, 2015-2017:
  - HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (February 2010) and Errata (October 2011 and July 2013)
- CEHRT under Stage 3 Option Year 2017:
  - Same as above
- CEHRT under MU Stage 3 2018 and beyond:
  - Same as above

Questions

meaningfuluse@cdc.gov

Comment period

- Can you clarify that the only comments requested as part of the CMS FR is related to MACRA/MIPS and this is not an open call for comments on any topic in the Final Rule?
  - The Stage 3 provisions of the rule are affected by MACRA, including the EHR reporting periods themselves for Medicare EPs beginning in 2017. Therefore, we are accepting comments on the Stage 3 provisions of the rule only. The policies are still final and effective as of the effective date of the rule (December 15, 2015). Any comments received will be considered in rule-writing for the provisions of MACRA.

Reporting Period

- Most of our eligible hospitals (EHs) and critical access hospitals (CAHs) attesting for Stage 2 (electronic lab reporting or ELR) registered with state public health agency for the fiscal period 10/1/2014 to 9/30/2015 (which has ended). Does this satisfy the "90-day period from 10/1/2014 to 12/31/2015" now specified, yes?
  - For episodic measures, we define the concept of being during the EHR reporting period to mean during the same year as the EHR reporting period when that period is less than a full year. We allow the reporting period to be any time from 10/1/2014 through 12/31/2015 for eligible hospitals and CAHs in 2015. So that is the scope of the EH/CAH "year" in which the reporting period, and the action, must occur.

Reporting Period

- What is meant by this? - "Despite the change to a 90-day EHR reporting period in 2015, providers will not be able to attest to meaningful use for an EHR reporting period in 2015 prior to January 4, 2016." Why can't they attest prior to 1/4/2016? (Is this only for payment reasons?)
  - No, it is not for payment reasons, as stated in the Final Rule, we have to update systems to be able to accept the provider attestations based on the changes to the program. All providers will be able to attest to an EHR reporting period for 2015 at the close of the 2015 calendar year.

Reporting Period

- If an EH or CAH is brand new to Stage 2 for ELR, it's okay if they register to attest 10/1/2015 to 12/31/2015? (90 day period?) But they can also choose a 90-day period in 2016, if they don't attest the last 3 months of 2015, correct? (If they do attest the last three months of this year, they have to register for a full year next year, right?)
  - Has this provider demonstrated meaningful use before? If the provider has demonstrated meaningful use before, they can do 90 days for 2015. Then a new year starts in January of 2016 and for 2016 the EHR reporting period for return participants is one full year. There is no allowance that a reporting period in 2016 could count for 2015 participation in any way.

Registration of Intent

- If our Organization would like to begin submitting data to the Cancer Registry, do we need to register as an organization or as individual providers?

Active Engagement

- Recall that earlier this year we were discussing that a public health test for stage 1 providers could be conducted anytime during 2014 to meet 2014 attestation requirements. Could this same rule apply for 2015?
  - New requirement is active engagement for all providers –
    - Option 1 – Completed Registration to Submit Data:
    - Option 2 - Testing and Validation
    - Option 3 – Production

Active Engagement

- Is a “registration of intent” required for all hospitals (stage 1 and stage 2), or just hospitals attesting at a stage 2 level? This looks to be a requirement for all measure on p 247. We need to clarify whether hospitals that were planning to submit stage 1 in 2015 will need to secure this documentation for the current year.
  - Everyone should follow the rules for active engagement; registrations of intent from previous years can count
    - Option 1 – Completed Registration to Submit Data:
    - Option 2 - Testing and Validation
    - Option 3 – Production

NEW CMS FAQ

- **For 2015, how should a provider report on the public health reporting objective if they had not planned to attest to certain public health measures? Is there an alternate exclusion available to accommodate the changes to how the measures are counted?**

NEW CMS FAQ

We do not intend to inadvertently penalize providers for their inability to meet measures that were not required under the previous stages of meaningful use. Nor did we intend to require providers to engage in new activities during 2015, which may not be feasible after the publication of the final rule in order to successfully demonstrate meaningful use in 2015.

In the final rule at 80 FR 62788, we discuss our final policy to allow for alternate exclusions and specifications for certain objectives and measures where there is not a Stage 1 measure equivalent to the Modified Stage 2 (2015 through 2017) measure or where a menu measure is now a requirement. This includes the public health reporting objective as follows.

First, EPs scheduled to be in Stage 1 may attest to only 1 public health measure instead of 2 and eligible hospitals or CAHs may attest to only 2 public health measures instead of 3.

Second, we will allow providers to claim an alternate exclusion for a measure if they did not intend to attest to the equivalent prior menu objective consistent with our policy for other objectives and measures as described at 80 FR 62788.

We will allow Alternate Exclusions for the Public Health Reporting Objective in 2015 as follows:

EPs scheduled to be in Stage 1: Must attest to at least 1 measure from the Public Health Reporting Objective Measures 1-3

• May claim an Alternate Exclusion for Measure 1, Measure 2 or Measure 3.

• An Alternate Exclusion may only be claimed for up to two measures, then the provider must either attest to or meet the exclusion requirements for the remaining measure described in 495.22 (e)(10)(i)(C).

EPs scheduled to be in Stage 2: Must attest to at least 2 measures from the Public Health Reporting Objective Measures 1-3

• May claim an Alternate Exclusion for Measure 2 or Measure 3 (Syndromic Surveillance Measure or Specialized Registry Reporting Measure)

Eligible hospitals/CAHs scheduled to be in Stage 1: Must attest to at least 2 measures from the Public Health Reporting Objective Measures 1-4

• May claim an Alternate Exclusion for Measure 1, Measure 2, Measure 3 or Measure 4

• An Alternate Exclusion may only be claimed for up to three measures, then the provider must either attest to or meet the exclusion requirements for the remaining measure described in 495.22 (e)(10)(ii)(C).

Eligible hospitals/CAHs scheduled to be in Stage 2: Must attest to at least 3 measures from the Public Health Reporting Objective Measures 1-4

• May claim an Alternate Exclusion for Measure 3 (Specialized Registry Reporting Measure)

Specialized Registries

- Upon the release of the CMS MU 2015-2017 Final Rules we realized that we have a number of physicians that have encountered a public health reporting barrier that may not allow them to attest to MU this year.

- The scenario: A pulmonologist is in Stage 2 this year. He was claiming an exclusion to the Immunization Submission Registry measure since he administers no immunizations. The three menu measures he was going to attest to were: 1) Imaging Results 2) Electronic Progress Notes 3) Family History. Now that the final rules were released, they will not need to attest to those three menu measures but they will need a second public health measure.

- The problem is that they had not anticipated needing that additional public health measure and as a result, are not interfaced with any registries. Since the rule was released in October there was no time to set that interface up so they could be submitting data for the “entire reporting period.”

- Have you encountered this issue yet? Any guidance for physicians in this situation? In Texas, we do not have the ability to choose Syndromic Surveillance as a measure because our public health departments are not accepting electronic data. We could have chosen that measure and claimed the immunization and syndromic exclusions but recently, CMS made is so that providers had to move to another measure if they could before claiming an exclusion and this pulmonologist does diagnosis the occasional lung cancer.

Specialized Registries -

- The Modified Stage 2 Final Rule is asking to meet 2 or 3 (eligible professional or eligible hospital, respectively) public health measures. Our clients are struggling with another entity to whom to report data electronically to meet this measure. I saw your agency suggested by ONC in the proposed rule as a possible agency to report data electronically. Iowa is not listed as a state required to submit HAI data to your agency, but would you be able to accept electronic data submitted by the EHR with an interface?
  - See alternate exclusions; CDC will accept NHSN AU/AR and Health Care Surveys in the future

Specialized Registries

- We are a specialty, gastroenterology practice with 14 providers and 2 NPs. We do perform some hepatitis immunizations/vaccinations, but not all of our providers always do this. (Much of the hepatitis vaccines are handled by one of the gastro physicians who is a liver disease specialist, not all of the gastro docs working here will perform hepatitis immunizations.) The same is true about the cancer reporting -- although we do diagnose cancer (esp. colorectal), we are not oncologists and treating/staging the cancer is part of the requirement for using this measure, which we do not do. We do not handle syndromic surveillance measures, either.
  - Alternate Exclusions

Specialized Registries

- In response to the modified MU rule for 2015 through 2017, we are needing to initiate a new public health measure in California. This is to address an exclusion for syndromic in several jurisdictions. We have found the option for Newborn Screening Results. This is a two-phase project. The first phase is an ORU inbound message to the hospital (HL7 2.5.1 format) with the newborn genetic screening results. The second phase of this project (looks to be in development) involves the hospital staff updating the demographic information and to the state. I have included basic information about this project. Would this be an acceptable option for Measure 3 Specialized Registry – to meet the new requirements for 2015?
  - Specialized Registries must declare their readiness to accept data and support the registration/onboarding and production processes

Specialized Registries

- We are a multispecialty group of providers who are primary care, pediatrics, OB/GYN, neurosciences, gastroenterology, etc. Most of our providers are in Stage 2. The state of Tennessee only participates in the immunization registry and the cancer registry. We are already engaged in immunization registry. Can you help me understand what we need to do concerning the public health reporting measure for 2015?
- Just for clarification, if an EP claims an exclusion for options #1 and #2 (immunization and syndromic surveillance), are they REQUIRED to submit to TWO (2) specialized registries? Therefore, must they engage with two registries to meet the two measures?
  - Yes, but alternate exclusions may apply

Specialized Registries

- For measure #3 under the Public Health Reporting Objective "Specialized Registry": Is this measure only referring to public health registries that are maintained by a government agency and operating in the jurisdiction of the EP/EH/CAH? For example, in the state of Missouri, there is a state Cancer Registry, but this is the only specialized public health registry available to EPs. If the EP is eligible (because they either diagnose and/or directly treat cancer cases), it is required that they report to this registry to meet the 2/3 MU requirement, or if they weren't intending to report to the cancer registry, can they take an exclusion? If the EP is not eligible for the cancer registry (because they neither diagnose nor directly treat cancer cases), should they take the exclusion for this measure?
- Vendors are telling providers that they must participate in other registries that are not public health registries—for example, the American College of Cardiology "Pinnacle" registry, or one of the registries that are used for PQRS reporting (such as a Qualified Clinical Data Registry)—to meet the specialized registry measure. Is this accurate? If so, this is a requirement that is above and beyond the previous Stage 2 requirements for those providers that were not intending to select this as a menu item.
  - CMS FAQ addresses this with alternate exclusions

Specialized Registries

- We are a single solo Primary Care Physician office doing the 90 day reporting in 2015 for Stage 2 Meaningful Use.

- We have for the past few years met the Immunization registry requirement but have never done any specialized registry reporting. Can you please provide some assistance as to how we can meet Stage 2 specialized registry reporting requirement for 2015? If all else fails, we may file for an exclusion.
  - Alternate exclusions

Specialized Registries

- I wanted to reach out to you to see if you could provide me some information on how states are handling the scenario of eligible providers wanting to participate in MU stage 2 cancer reporting but they do not actually diagnose or treat cancer. For example, we have a family medicine practice in the state that wants us to write an exclusion letter for them because they are not one of the specialties we are interested in working with but we have not gotten the approval to do so and from what they are saying based off the new proposed CMS rules they have to choose two and they are doing immunizations and will be getting an exclusion letter from the department of health for syndromic surveillance and possibly ELR so that just leaves cancer reporting as their only other option to choose
  - It is not the public health agency's responsibility to "grant" an exclusion or provide a letter indicating an exclusion.

Specialized Registries

- One of our providers contacted me and mentioned that with the release of the MU2 revised temporary final rule providers now have to report to the national registry and not to the local state registry. Do you have any information about this
  - National registries can be an option, but there are alternate exclusions that can apply

Specialized Registries

- Public Health reporting requirements. Specifically: Better clarification of what meets the requirements for specialty registry. Examples would be great .Does QCDR reporting count as specialty registry? Pennsylvania, there are significant costs from the state for the syndromic surveillance registry. Is this a justifiable exclusion, especially for those specialties that do not administer immunizations?
  - All registries must declare readiness and be able to support documentation for providers; cannot double dip to count for other measures
  - Remember the alternate exclusions

Specialized Registries

- For EPs in our state, there is no electronic Immunization Registry, Syndromic Surveillance System or Cancer Registry. Are EPs expected to look to report to other registries? Even if those registries are not necessarily relevant to their practice?
  - Should not report to registries that are not relevant; alternate exclusions may apply

Specialized Registries

- How far does an EP have to go to confidently exclude? CA Example for all counties that report to CAIR: Iz – Can attest Yes, Syndromic Surveillance – nearly throughout the state, must exclude- Specialized – In this scenario, the EPs do not diagnose or treat cancer (envision FQHCs, the EP might suspect cancer, but they refer out and another provider does the actual diagnosis). So, while we have a Cancer Registry up and running (or nearly), many EPs should exclude for not being EPs that diagnose or treat. The only other registry post thru CAIR (see snippet below) is Blood Lead, but it is not up and running, therefore the EPs would have to exclude Blood Lead. So, to my question. How many lists or national resources does an EP have to go to either find a "specialized registry" or to be able to say that they exhausted all registries and can exclude?
  - State Public Health and the specialist sites that apply to them
  - Alternate exclusions

Specialized Registries - FAQ

- North Carolina's Syndromic and Immunization registries do not accept connections from eligible professionals thus there are two exclusions. In this case, must a provider show active engagement or connection to a specialized registry other than Syndromic and Immunization to meet Meaningful Use?
  - Yes, but alternate exclusions may apply

Specialized Registries/NHSN

- We have a few questions regarding the new CMS Modified Stage 2 Rule (2015-2017), specifically for the new Specialized Registry reporting requirements for eligible hospitals (see CMS screenshot below). As an Eligible Hospital (EH), we can meet the Public Health Reporting measure by being in Active Engagement with Specialized Registry (CDC/NHSN) for 2015?
  - This should be electronic submission and not meeting another requirement by reporting to NHSN
  - Manual data entry does not count

Centralized Repository

- I am writing in regards to the new modification rules for meaningful use for 2015. With the final rule released last week, one of the public health measure requirements is going to be to submit to a specialized registry of any sort. As an EHR vendor, we are hoping to assist our clients with this by guiding them to the correct specialized registries. We are hoping that the CDC can be of assistance by helping us obtain a list of qualified specialized registries nationwide.
- I have read that CMS is or has developed a centralized repository that physicians can contact to see if a public health agency is accepting electronic submissions. I am wondering if this has developed and if so how do I access it?
- For hospitals: Measure #3 Specialized Registry: The final rules state hospitals are not eligible to report to cancer registries, so they would need to be reporting to another specialized public health registry. Where do hospitals find a list of such registries? For example, does this include the CDC's NHSN (National Health Safety Network), or the National Hospital Care Survey? What other "specialized" registries are they talking about—could it include voluntary registries? MUST they report to a voluntary registry to meet three of the four measures?
- Our compliance team here is hoping you can assist us in finding specialized registries for providers in your state to be able to meet this measure.
  - We will keep everyone updated on this development

Centralized Repository

- How many CDRs does he have to document an exclusion in order (satisfy MU)? Would it be two, because this is the number of times a submitter can select the Specialized Registry measure? Or does it have to be every potential CDR on the MU list (i.e. the CDR list that CMS will be providing in the future)?
  - State Public Health and the specialist sites that apply to them; alternate exclusions may apply

Centralized Repository

- I represent a group of Pain Management Doctors located in New York/Long Island, New York/Manhattan, Virginia, Maryland and Connecticut. I am trying to understand the Public Health Measures for Meaningful Use. To my current understanding, we are to claim an exclusion for all three measures. We do not administer or collect immunization data. Also, I do not believe we collect any data that would meet the criteria for a specialized registry or surveillance data. I am having trouble finding that specific criteria. I was able to find that in Virginia, surveillance data is related to influenza-like illness during flu season, illnesses and injuries associated with major storms and natural disasters, health problems associated with mass gatherings, and emerging outbreaks and issues of public health concern in the community. Could you provide me with information regarding specialized registry and surveillance requirements for each state? I want to be sure we are excluded from this measure.
  - State Public Health and the specialist sites that apply to them; alternate exclusions may apply

Centralized Repository

- What is CDC currently accepting? We would like to be able to send hospitals your way if they are looking for an additional measure and you have one that applies to them
  - NHSN AU/AR or Health Care Surveys will be possible in the future

Syndromic

- Are urgent care sites participating in Meaningful Use at the facility-level rather than the provider-level? I interpreted urgent care sites, previously, as a MU participating site based on the EPs that work there, so at the provider level. The MU Stage 3 rules seems to group them with EHs. Are urgent cares likely to register their intent for a facility rather than a provider (s). Do they receive incentive payments like an EH rather than an EP?
  - For EPs, only those in urgent care settings should report on syndromic starting in Stage 3

Syndromic

- I just want to be clear on this because I think somewhere I accepted what might be a misunderstanding. Is there truly no frequency of reporting standard for how often syndromic data relative to the time of the actual encounters? I just need to know that for sure, because that's what I believe I heard. But today I heard that that some commenters wanted to eliminate the syndromic reporting requirement all together but the value of this information was recognized. I'd argue that, without timely reporting, much of the value of syndromic surveillance is negated. I'll also share that the impact on system performance from the incorporation of huge batched files is not negligible. Is my original underlined statement correct and, if it is, is this something that is open for comment to change?
  - The ONC rule only states that frequency will not be tested as part of CEHRT and is not incorporated into the standards; states are still welcome to work with providers to meet their business needs for frequency

Immunization Standards

- I work with an EHR vendor who is MU certified and has an immunization module as part of its EHR. We maintain a list of possible substances to be administered. How can i make sure this list of possible immunizations to be administered by a department of health or other provider stays updated?
  - …we have adopted the **August 17, 2015 version of the CVX code set as the minimum standards code set for historical vaccines.**
  - For purposes of **administered vaccines, we have adopted the National Drug Codes (NDC) –Vaccine NDC Linker**, updates through August 17, 2015 as the minimum standards code set.

ELR Standards

- In regards to MSH-2: Per the HL7 v2.5.1 Standard for ELR, the MSH-2 field can only be 4 characters. Per the HL7 v2.5.1 Implementation Guide for ELR, there are only 4 characters specified as valid within Chapter 2 (Section 2.1.1) page 9 and page 10 of the guide (page 21 in the PDF). In Section 2.1.3, the guide says, "The transmission of the truncation character in message data is not being pre-adopted.". Further, in Section 5.1, MSH-2 has a length of "4..5" (see screenshot below). If the messages are coded as four characters '^~\&' in MSH-2, NIST validation throws an error (MSH.2 SHALL contain the constant value '^~\&#' – which has five characters).
- Can you please clarify if the MSH-2 is required to be 5 characters because we are not able to find that requirement? I would greatly appreciate your input. Thanks for your time!
  - Please refer to the addendum and errata for clarification

Cancer

- I am hoping you can clarify the requirement for selecting cancer as the specialized registry measure. We have already had several inquiries from providers wanting to select the cancer measure for specialized registry but their EHR is not certified for cancer reporting. Do we allow them to submit cancer cases in any format? How are you interpreting the following statements in the final rule as it relates to cancer reporting? Certified EHR technology is not required for specialized registry reporting for 2015-2017, but EHR Technology certified to the 2014 Edition or 2015 Edition may be used. Other nonnamed specialized registries unsupported by certification requirements
  - CEHRT is still required for Cancer Reporting under Specialized Registries for 2015-2017 and under Public Health Registries for 2018

Cancer

- It is clear that cancer registries fall under the definition of "public health registries" (and not "clinical registries"). However, we received some questions about the term "specialized registries". Are cancer registries included in the definition of "specialized registries"? I understand that these definitions may also be specific to MU Stage.
  - For Mod rule they are included in specialized; Stage 3 included in PH registries

Cancer

- Since EPs are not able to select from a menu of mixed PH and non-PH items anymore, there is more interest in the cancer registry; however, some vendors have chosen not to support cancer reporting and are not certified for it. These people have 3 options: find a non-PH specialized registry, find a cancer module to purchase, or fail because the PHA is accepting cancer but they don't have the certified module (we have seen some not realize this and think registration with the PHA was enough). Should we advise them to find another specialized registry? If so, see question 2. How feasible is it for an EP to buy a cancer module and implement in a short time frame
  - Really up to provider to determine what is best for them; they can take alternate exclusions for 2015