Summary of Public Health Objectives in Stage 2 Meaningful Use ONC and CMS Final Rules Version 1.1 (Updated on April 1, 2014)

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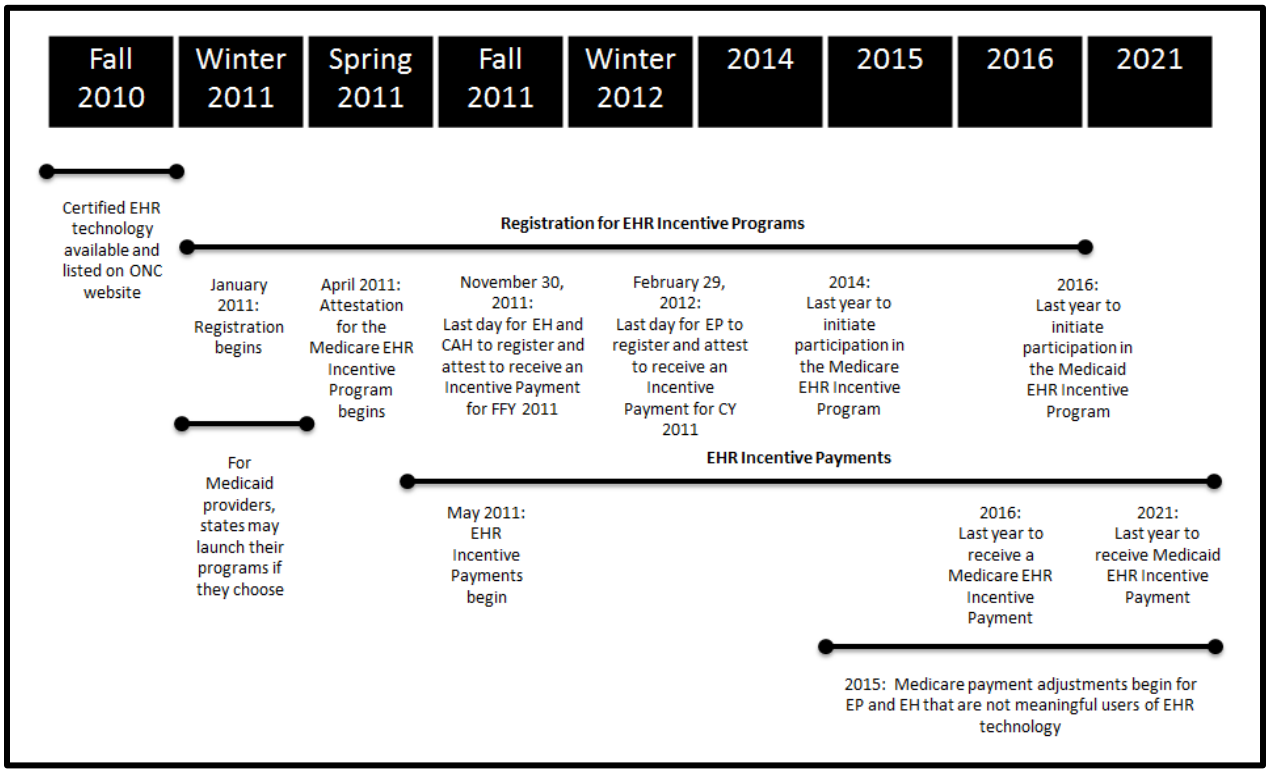
i. Introduction

The Stage 2 Meaningful Use (MU) final rules were published in the Federal Register on September 4th, 2012. In Stage 2 MU, the Eligible Professionals (EPs) must meet (or qualify for an exclusion to) 17 core objectives and 3 of 6 menu set objectives. Similarly, the Eligible Hospitals (EHs) and Critical Access Hospitals (CAHs) must meet (or qualify for an exclusion) to 16 core objectives and 3 of 6 menu objectives. The core objectives are part of mandatory requirements, while menu objectives can be selected from a total of 6 available options, for demonstrating meaningful use. In addition, starting in 2014, Clinical Quality Measures (CQMs) reporting has been incorporated into the definition of a "meaningful user" rather than being a core set requirement. This final rule delays the onset of Stage 2 MU criteria until 2014; the start date for EHs will be October 1st, 2013 and for EPs it will be January 1st, 2014. Specific to the Stage 2 MU Public Health objectives, the capability to submit electronic data for Immunizations is in the core set for EPs, and the capability to submit electronic data for Immunizations, Reportable Laboratory Results and Syndromic Surveillance are all in the core set for EHs. In addition, two new public health objectives for EPs have been added to the menu set, and include the capability to identify and report 1) cancer cases to a cancer registry and 2) specific cases to a specialized registry (other than a cancer registry).

Original MU Timeline



Stage 2 Timeline Delayed to 2014

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

HHS had announced in a November 2011 under the "We Can't Wait" announcement, that the Stage 1 has been extended an additional year for providers who attested in 2011 – meaning that these providers will have to attest to Stage 2 in 2014, instead of in 2013.

The onset of Stage 2 criteria has been delayed. The earliest that the Stage 2 criteria will be effective is in fiscal year 2014 for EHs and CAHs or calendar year 2014 for EPs. Note that providers who were early demonstrators of meaningful use in 2011 will meet three consecutive years of meaningful use under the Stage 1 criteria before advancing to the Stage 2 criteria in 2014. All other providers would meet two years of meaningful use under the Stage 1 criteria before advancing to the Stage 2 criteria in their third year.

For 2014 Only

All providers regardless of their stage of meaningful use are only required to demonstrate meaningful use for a three-month Electronic Health Record (EHR) reporting period.

Medicare Providers: eligible to receive Medicare EHR incentives, however the 3-month reporting period is fixed to the quarter of either the fiscal (for eligible hospitals and CAHs) or calendar (for EPs) year to align with existing Center for Medicare & Medicaid Services (CMS) quality measurement programs.

Medicaid Providers: eligible to receive Medicaid EHR incentives, however the 3-month reporting period is NOT fixed since Medicaid providers do not have the same alignment needs as Medicare Providers.

CMS is permitting this one-time three-month reporting period in 2014 only so that providers who must upgrade to 2014 Certified EHR Technology will have adequate time to implement their new Certified EHR systems.

STAGE 2	EH & CAHs	EPs
2014	90-day EHR Reporting	90-day EHR Reporting
2015	Full Fiscal Year EHR Reporting	Full Calendar Year EHR Reporting

Certified Electronic Health Record Technology (CEHRT) Transparency

To increase clarity for purchasers in the Health Information Technology (HIT) market, Office of the National Coordinator (ONC) has established methods for representing certified Complete EHRs and certified EHR Modules, including when Complete EHRs and EHR Modules meet the Base EHR definition. They also require that test results used for EHR technology certification to be made publicly available in an effort to increase transparency and provide EPs, EHs, and CAHs a potential starting point from which to assess any implementation issues associated with certified Complete EHRs and certified EHR Modules. Finally, as another means of increasing transparency and mitigating any potential confusion in the market, ONC requires that ONC – Authorized Certifying Bodies (ONC-ACBs) ensure that EHR technology developers include in their marketing materials and communications notification to potential purchasers any additional types of costs that an EP, EH, or CAH has to or may elect to pay to implement their certified Complete EHR or certified EHR Module in order to attempt to meet MU objectives and measures.

National Institute of Standards & Technology (NIST) Testing

Health Information Technology for Economic and Clinical Health (HITECH) Act requires that with respect to the development of standards and implementation specifications, the Director of NIST in coordination with the HIT Standards Committee (HITSC), "shall support the establishment of a conformance testing infrastructure, including the development of technical test beds. The HITECH Act also indicates that "the development of this conformance testing infrastructure may include a program to accredit independent, non-Federal laboratories to perform testing**.**

ii. Common MU Data Set

ONC has created term **"Common MU Data Set,"** which includes the following data from the ONC Stage 2 Meaningful Use Final Rule:

1. Patient name.

2. Sex.
3. Date of birth.
4. Race.
5. Ethnicity.
6. Preferred language.
7. Smoking status.
8. Problems.
9. Medications.
10. Medication allergies.
11. Laboratory test(s).
12. Laboratory value(s)/result(s).
13. Vital signs – height, weight, blood pressure, BMI.
14. Care plan field(s), including goals and instructions.
15. Procedures.
16. Care team member(s).

iii. Stage 2 MU Public Health Objectives

Objective	Eligible Professionals (EPs) Measure	Eligible Hospitals (EHs) and CAHs Measure
Immunization Registries	**Core Set – Successful ongoing submission of electronic immunization data from certified EHR Technology (CEHRT) to an immunization registry or immunization information system for the entire EHR reporting period (unless no registries are capable)**	**Core Set - Successful ongoing submission of electronic immunization data from certified EHR Technology (CEHRT) to an immunization registry or immunization information system for the entire EHR reporting period (unless no registries are capable)**
Reportable Lab Results (ELR)	**N/A**	**Core Set - Successful ongoing submission of electronic reportable laboratory results from CEHRT to a public health agency for the entire EHR reporting period (unless no PH agency is capable)**
Syndromic Surveillance	**Menu Set - Successful ongoing submission of electronic syndromic surveillance data from CEHRT to a public health agency for the entire EHR reporting period (unless no PH agency is capable)**	**Core Set - Successful ongoing submission of electronic syndromic surveillance data from CEHRT to a public health agency for the entire EHR reporting period (unless no PH agency is capable)**
Cancer Reporting	**Menu Set - Successful ongoing submission of cancer case information from CEHRT to a cancer registry for the entire EHR reporting period (unless no PH agency is capable)**	**N/A**

Reporting to Specialized Disease Registry	**Menu Set - Successful ongoing submission of specific case information from CEHRT to a specialized registry for the entire EHR reporting period (unless no PH agency is capable)**	**N/A**

iv. Meaningful Use Exchange Standards

Stage 2 MU Public Health Objectives	2014 Edition EHR Certification Criteria for Stage 2 MU	
	Exchange Standards	**Vocabulary Standards**
Immunization Registries (IIS)	**Standard – HL7 2.5.1** • **HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4**	• **HL7 Standard Code Set CVX -- Vaccines Administered, updates through July 11, 2012**
Reportable Lab Results (ELR)	**Standard – HL7 2.5.1** • **Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with Errata and Clarifications**	• **IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release** • **Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40**
Syndromic Surveillance	**Standard – HL7 2.5.1** • **PHIN Messaging Guide for Syndromic Surveillance and Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, Addendum to PHIN Messaging Guide for Syndromic Surveillance** *Note: The above implementation guide is required for inpatient settings, but optional for ambulatory settings.*	*None*
Cancer Reporting	**Standard - HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition** • **Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA)**	• **IHTSDO SNOMED CT® International Release July 2012 (incorporated by reference in § 170.299) and US Extension to SNOMED CT® March 2012 Release** • **Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40**
Reporting to Specialized Registry	*None*	*None*

Single Standard for PH Transactions:

In Stage 2 MU, all public health transactions (except cancer reporting) will be expected to use the HL7 2.5.1 standard. For Cancer, the mandated standard will be HL7 Clinical Document Architecture (CDA) Release 2, with Systematized Nomenclature of Medicine--Clinical Terms (SNOMED-CT) and Logical Observation Identifiers Names and Codes (LOINC) as the required vocabularies.

Transport Standards for PH Transactions:

ONC has made it clear that we do not require EHR technology to be certified to any transport standard, including Direct, to meet the 2014 certification criterion. Since there is no consensus transport standard that states and public health agencies use for the reporting. Therefore, ONC believes that it is appropriate for EHR technology developers to have the flexibility to include in their EHR technology and implement the transport standards that permit EPs, EHs, and CAHs to report in their states and to local public health agencies (PHAs). As per the Stage 2 final rule, an eligible provider is required to utilize the transport method or methods supported by the PHA in order to achieve meaningful use. Further, ONC clarified that this is independent of the EHR certification criteria as EHR certification does not address transport for public health objectives.

PHA Capacity Declaration:

PHA must officially declare if it has the capacity to accept electronic data using the specification prescribed by ONC for MU objectives by the deadline set by CMS. If the PHA does not have the capacity to accept reporting (including situations when the PHA accepts electronic data but lacks the capacity to enroll the EP, EH or CAH during that reporting period), the EP or EH can claim an exclusion for this measure.

Centralized PH Repository:

In determining whether the PHA has the capacity, CMS anticipates developing a centralized repository for this information, including a deadline for the PHA to submit information. If the PHA fails to provide information to this centralized repository by the deadline, the provider could claim the exclusion. In the event, that we are unable to develop a centralized repository, providers will make the determination of PHA capacity by working directly with the PHA as is the case for Stage 1 of meaningful use.

Ongoing Data Submission to PHA:

If the PHA does have the capacity, the measure may be satisfied through any of the following general public health criteria:

- Ongoing submission was already achieved for an EHR reporting period in a prior year and continues throughout the current EHR reporting period using either the 2014 standard or the standards included in the 2011 Edition EHR certification criteria adopted by ONC during the prior EHR reporting period when ongoing submission was achieved.

- Registration with the PHA or other body to whom the information is being submitted intend to initiate ongoing submission by the deadline (within 60 days of the start of the EHR reporting period) and ongoing submission was achieved.
- Registration of intent to initiate ongoing submission was made by the deadline and the EP or hospital is still engaged in testing and validation of ongoing electronic submission.
- Registration of intent to initiate ongoing submission was made by the deadline and the EP or hospital is awaiting invitation to begin testing and validation.

The measure will not be met in the following situations:

- Provider fails to register their intent by the deadline; or
- Provider fails to participate in the onboarding process as demonstrated by their failure to respond to the PHA written requests for action within 30 days on two separate occasions.

*Actual patient data is required for the meaningful use measures that include ongoing submission of patient data to PHAs.

v. PH Objectives: From CMS and ONC Stage 2 Final Rules

Please note in the table below, the numbers within brackets point to the page number in Final Rule's documents published in the Federal Register.

IMMUNIZATION
CMS Stage 2 Final Rule • Term Immunization Registries Retained : Some commenters suggested that the term immunization information systems was all encompassing making the inclusion of immunization registries redundant; Response: We agree that an information system could include registries; however, we do not believe that modifying the objective serves a distinct purpose and could confuse those accustomed to the term immunization registries. [54022] • Public Health Agency (PHA) Readiness Issue: Commenters, although supportive of moving immunization registry reporting from menu to core, expressed concern that PHAs did not have the capacity to accept electronic data from additional providers. [54022] Response: We agree that not all PHAs will have the resources to onboard providers for immunization registry reporting. The final rule allows for an EP or hospital to be excluded from the measure if they operate in a jurisdiction for which no immunization registry is capable of accepting data. We further clarify that this exception applies not only if the technical capacity to receive the data does not exist, but also if the resources are not available within the public health authority to initiate ongoing submission with the EP or hospital. We also permit (as earlier stated) an EP or hospital to meet the measure so long as they have registered to submit and are either still in the process of testing and validation (within the time limits established earlier), or are still awaiting an invitation to begin submission. [54023] • Bidirectional Exchange: Numerous commenters encouraged the inclusion of bidirectional

exchange of data with immunization registries. Many commenters noted that the EP or eligible hospital cannot take advantage of rich data and clinical decision support contained within an immunization registry without bidirectional exchange.

Response: While we agree that the need for bidirectional data exchange is clear, this measure aligns more with the goals of Stage 3 meaningful use stated in the proposed rule. Additionally, the standards and mechanisms for bidirectional data exchange need to be more standardized across public health authorities. After consideration of the public comments received, we are finalizing this objective for EPs at §495.6 (j)(15)(i) and for eligible hospitals and CAHs at §495.6(l)(12)(i) as proposed. [54023]

- HL7 2.3.1 Grandfathering Issue: We agree that during the implementation of Stage 1 reporting of immunization data, the need for a more harmonized standard for immunization reporting was highlighted. To address this issue, the option of using version HL7 2.3.1 versus 2.5.1 for certification was removed and now only an HL7 2.5.1 message can be used for Stage 2 reporting of immunization data. The implementation guide for HL7 2.5.1 has been updated to remove much of the variability across states for immunization registry reporting. However, if EPs prior to CY 2014 and eligible hospitals and CAHs prior to FY2014 have achieved successful ongoing submission using EHR technology certified to the 2011 Edition EHR certification criteria (HL7 2.3.1 only) it is acceptable to continue this ongoing submission and meet the Stage 2 measure for as long as HL7 2.3.1 continues to be accepted by the immunizations information system or immunization registry. EPs and eligible hospitals and CAHs conducting submissions using HL7 2.5.1 will be able to get their arrangement certified to the 2014 Edition EHR certification criteria; After consideration of the public comments received, we are finalizing this measure at for EPs at 495.6 (j)(15)(ii) and for eligible hospitals and CAHs at 495.6(l)(12)(ii) as proposed; Exclusions: (1) the EP, eligible hospital or CAH does not administer any of the 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) the EP, eligible hospital or CAH operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required for CEHRT at the start of their EHR reporting period (3) the EP, eligible hospital or CAH operates in a jurisdiction where no immunization registry or immunization information system provides information timely on capability to receive immunization data; or (4) the EP, eligible hospital or CAH operates in a jurisdiction for which no immunization registry or immunization information system that is capable of accepting the specific standards required by CEHRT at the start of their EHR reporting period can enroll additional EPs, eligible hospitals or CAHs. The second exclusion will not apply if an entity designated by the immunization registry or immunization information system can receive electronic immunization data submissions. [54023]
- Immunization in Core Set for EPs , EHs/CAHs: Stage 2 Objective for Eligible Professionals, Eligible Hospitals and CAHs: Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice [54047]
- Stage 2 Measures: Successful ongoing submission of electronic immunization data from Certified EHR Technology to an immunization registry or immunization information system for the entire EHR reporting period. [54047]

ONC Stage 2 Final Rule

- Certification Criteria Change: Comment: Commenters supported our proposed "two certification criteria approach." One commenter noted strong support for ONC's change in terminology from "retrieve and modify" to "access and change" and the clarification that this criterion does not include in scope the retrieval of immunization data from an external source to the EHR; Response: We appreciate the support for the proposed certification criteria and the change in terminology. We are adopting these certification criteria as proposed, but with the inclusion of an updated implementation guide as discussed below. [54239]
- Single HL7 Standard: We appreciate the support for the moving solely to HL7 2.5.1. We do not believe that permitting EHR technology to continue to be certified to HL7 2.3.1 as a means of meeting this certification criterion promotes improved exchanged and interoperability. Therefore, we are adopting only HL7 2.5.1 for the "transmission to immunization registries" certification criterion. [54240]
- Immunization Implementation Guide (Release 1.4): The CDC has worked to clarify ambiguities in Release 1.3 of the implementation guide and has published a new version of the implementation guide, Release 1.4, which reflects these clarifications. In particular, Release 1.4 clarifies the separate usage responsibilities for senders and receivers, provides conformance statements identifying core data elements that must be supported based on the National Vaccine Advisory Committee (NVAC) core data elements, adds support for messaging Vaccine Information Statement (VIS) data based on a 3D barcode, and provides HL7 version 2.7.1 usage guidance that improves clarity for conformance criteria and the requirements for HL7 message elements. Overall, these revisions do not establish additional substantive requirements in comparison to Release 1.3. Rather, the revisions improve the ability to test and certify EHR technology to the implementation guide and make it easier for EHR technology developers to implement the guide's requirements based on the corrections and clarifications. Accordingly, in lieu of adopting Release 1.3 of the implementation guide as we had proposed, we have adopted Release 1.4 for the "transmission to immunization registries" certification criterion. For the reasons stated above, we are not adopting HL7 2.3.1. [54240]
- Transport Standards Comments (please see ONC's response below): An expert panel convened by CDC and American Immunization Registry Association (AIRA) has recommended a SOAP-based standard for transport of immunization data. [54240]
- CVX Vocabulary Standard: As we required for the 2011 Edition EHR certification criterion for immunization reporting, we continue to believe that the adoption of CVX is appropriate and that no other vocabulary standard need to be expressly adopted for the purposes of certification. [54240]
- Scope of Certification: Any EHR technology that meets the certification requirements can be utilized to submit data to an Immunization Registry. Again, to meet this certification criterion, EHR technology must be able to properly create immunization information for electronic transmission according to the adopted standard and implementation specification. How this standardized data created by CEHRT gets to public health is not within the scope of certification. Additionally, we are aware that some states are considering modular certification of the state immunization registry to accomplish this function. [54241]
- HL7 2.5.2 Batch Reporting: It is our understanding that most state immunization registries can accept batch reporting via the HL7 2.5.1 message standard and we previously indicated this approach was acceptable in FAQ 9-10-002-1. [54241]
- Transport Standards Response: We want to make clear that we do not require EHR technology to be certified to any transport standard, including Direct, to meet this certification criterion.

There is no consensus transport standard that states and public health agencies use for the reporting of immunization information. Therefore, we believe that it is appropriate for EHR technology developers to have the flexibility to include in their EHR technology and implement the transport standards that permit EPs, EHs, and CAHs to report in their states and to local public health agencies. [54241]

We note that while no proposal for a single interface to all immunization registry exists, an expert panel convened by CDC and AIRA recommended standards for transport that include a standard WSDL which should help reduce the financial burden on EHRs to interface with immunization registries. [54242]

SYNDROMIC SURVEILLANCE

CMS Stage 2 Final Rule

- SS in Menu Set for EPs: Although not all public health authorities are able to accept syndromic surveillance data from Eligible Professionals, since many EPs already report this measure and some public health authorities have the ability to accept this data, the measure will remain as a menu set option. [54025]
- SS in Core Set for EHs Since many hospitals already report this measure and many public health authorities have the ability to accept this data, the measure will remain as core. If there are no public health authorities for the hospitals to report syndromic surveillance data to, the hospital can claim an exemption [54025]
- While a single national implementation guide exists for syndromic surveillance data of emergency department data from hospitals, currently an implementation guide does not exist for syndromic surveillance reporting from the eligible professional. The Centers for Disease Control and Prevention is working in conjunction with the International Society for Disease Surveillance and draft guidance is currently available for the reporting of ambulatory based syndromic surveillance. [54025]
- Currently public health departments that collect syndromic surveillance data streamline the data collection process and collect data at an organization or facility level depending on the provider. Syndromic surveillance data is not collected at the provider level, although attestation would be at the provider level where reporting by a single organization or facility could count for multiple providers. [54025]
- Successful ongoing submission of electronic syndromic surveillance data from CEHRT to a public health agency for the entire EHR reporting period. [54025]
- Exclusions: Any EP, eligible hospital or CAH that meets one or more of the following criteria may be excluded from this objective: (1) the EP is not in a category of providers that collect ambulatory syndromic surveillance information on their patients during the EHR reporting period; (2) the eligible hospital or CAH does not have an emergency or urgent care department; (3) the EP, eligible hospital, or CAH operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required by CEHRT at the start of their EHR reporting period; (4) the EP, eligible hospital or CAH operates in a jurisdiction where no public health agency provides information timely on capability to receive syndromic surveillance data; or (5) the EP, eligible hospital or CAH operates in a jurisdiction for which no public health agency that is capable of accepting the specific standards required by CEHRT at the start of their EHR reporting period can enroll additional EPs, eligible hospitals or CAHs. [54026]
- Stage 2 objective for eligible hospitals and CAHs: Capability to submit electronic syndromic

surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice [54048]

- Stage 2 Measures: Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period. [54048]

ONC Stage 2 Final Rule

- SS Certification Criteria: We are adopting as part of the 2014 Edition EHR certification criteria the certification criterion focused on the capability to create syndrome-based public health surveillance in accordance with the standards we have specified (§ 170.314(f)(3)). We are not, however, adopting the certification criterion we proposed that focused on data capture. We have chosen to drop this proposed certification criterion because we do not believe that it is essential to focus on from a testing and certification perspective. It is our understanding that EPs, EHs, and CAHs will not necessarily be recording, accessing, and capturing separate kinds of "syndromic surveillance" information to facilitate the transmission of syndrome-based public health surveillance information to public health agencies. Rather, they will simply be "passing on" or reporting the information that already exists in their CEHRT to public health agencies. Thus, upon further reflection, this "data capture" certification criterion is unnecessary for certification. [54242]
- SS Certification Criteria (Modular Certification): Our approach to the public health certification criteria could enable additional EHR technologies (likely in the form of EHR Modules) to be certified and provides additional pathways and flexibility to EPs, EHs, and CAHs to have EHR technology that can be used to satisfy the proposed revised definition of CEHRT. [54242]
- Single HL7 Standard: We have now adopted the HL 2.5.1 standard as the sole standard for this certification criterion. We are adopting only the 2.5.1 standard because, as noted above and in the Proposed Rule, public health agencies are rapidly moving to this standard and all stakeholders would benefit from focusing on a single standard for public health surveillance. [54242]
- Syndromic Surveillance Implementation Guide (Release 1.1): The CDC has recently published Release 1.1 of the implementation guide. Release 1.1 reflects the work of the CDC to correct errors and clarify ambiguities that were present in Release 1.0 as well as provide information that was missing in Release 1.0. The CDC also recently published an addendum to the implementation guide, titled "Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance." The addendum consolidates Release 1.1 information and clarifies existing conformance requirements of the implementation guide. Therefore, we believe the adoption of Release 1.1 and the addendum is appropriate as they will improve the ability to test and certify EHR technology to the implementation guide, as well as make it easier for EHR technology developers to implement the guide's requirements. [54243]
- Inpatient versus Ambulatory Settings: The designation "inpatient" is a general designation that we use to distinguish certification criteria and capabilities that apply to a particular setting for certification. We currently designate only two settings for certification, the inpatient setting and the ambulatory setting without variation. EHs use "inpatient-certified" EHR technology for their inpatient department and emergency departments. For urgent care settings that are not the emergency department, the providers would be non-hospital-based EPs and would require "ambulatory-certified" EHR technology. Therefore, we are retaining the "inpatient" designation.

[54243]

- Transport Standards Guidance: We want to make clear that we do not require EHR technology to be certified to any transport standard, including Direct, to meet this certification criterion. There is no consensus transport standard that states and public health agencies use for the reporting of syndrome-based public health surveillance information. Therefore, we believe that it is appropriate for EHR technology developers to have the flexibility to include in their EHR technology and implement the transport standards that permit EPs, EHs, and CAHs to report in their states and to local public health agencies. [54243]
- SS Certification Criteria: We do not believe that it is appropriate to modify the certification criterion to explicitly reference adverse drug events or any other specific syndrome-based surveillance information for the purposes of EHR technology certification. [54243]
- SS Certification Criteria: EHR technology must be able to electronically create syndrome-based public health surveillance information for electronic transmission in accordance with: (i) Ambulatory setting only, (ii) Inpatient setting only [54291]

REPORTABLE LAB RESULTS

CMS Stage 2 Final Rule

- Public Health Agencies Onboarding Issue Guidance: We agree that not all PHAs will have the resources to onboard providers for electronic laboratory reporting. The final rule allows for an EP, eligible hospital or CAH to be excluded from the measure if they operate in a jurisdiction for which no public health authority is capable of accepting electronic laboratory data. We further clarify that this exception applies not only if the technical capacity to receive the data does not exist, but also if the resources are not available within the public health authority to initiate ongoing submission with the EP, eligible hospital or CAH. We also permit (as earlier stated) an EP, eligible hospital or CAH to meet the measure so long as they have registered to submit and are either still in the process of testing and validation, or are still awaiting an invitation to begin submission. [54024]
- Reportable Lab Results (RLR) Implementation Guide: ONC has adopted an updated implementation guide for electronic laboratory reporting from EHR technology in its 2014 Edition EHR certification criteria. Additionally, the Centers for Disease Control and Prevention in coordination with the Council of State and Territorial Epidemiologists have created the national Reporting Condition Mapping Table that provides further guidance on appropriate vocabularies usable for reportable conditions across the country for reporting of ELR data. [54024]
- RLR Certification Criteria (Modular Certification): Eligible Hospitals can choose to report data directly from any kind of EHR technology that has been certified to the certification criteria adopted by ONC. This could include EHR technology from a single EHR technology developer, a separate modularly certified component such as a LIMS certified as an EHR Module, or the technical capability offered by an HIE that is certified as an EHR Module for electronic laboratory reporting. After consideration of the public comments, we are finalizing this objective for eligible hospitals and CAHs at 495.6(l)(13)(i)as proposed. [54024]
- Ongoing Data Submission to PHA: We are modifying this measure for eligible hospitals and CAHs at §495.6(l)(13)(ii) to successful ongoing submission of electronic reportable laboratory results from CEHRT to a public health agency for the entire EHR reporting period". We further specify that in order to meet this objective and measure, an eligible hospital or CAH must use

the capabilities and standards of CEHRT at 45 CFR 170.314(f)(4); Exclusions: The eligible hospital or CAH that meets one or more of the following criteria may be excluded from this objective: (1) operates in a jurisdiction for which no public health agency is capable of receiving electronic reportable laboratory results in the specific standards required for Certified EHR Technology at the start of the EHR reporting period; (2) operates in a jurisdiction where no public health agency provides information timely on capability to receive electronic reportable laboratory results or (3) the eligible hospital or CAH operates in a jurisdiction for which no public health agency that is capable of accepting the specific standards required by CEHRT at the start of their EHR reporting period can enroll additional eligible hospitals or CAHs. [54024]

- Stage 2 CORE objective for Eligible Hospitals and CAHs: Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice [54048]
- Stage 2 Menu objective for Eligible Professionals: Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities [54048]
- Stage 2 Measures: Successful ongoing submission of electronic reportable laboratory results from Certified EHR Technology to public health agencies for the entire EHR reporting period. [54048]

ONC Stage 2 Final Rule

- Reportable Lab Results (RLR) Certification Criteria: We are adopting as part of the 2014 Edition EHR certification criteria the certification criterion focused on the capability to electronically create reportable laboratory rests and values/results for electronic transmission in accordance with the standards we have specified (§ 170.314(f)(4)). We are not, however, adopting the certification criterion we proposed that focused on data capture. For similar reasons as expressed in the syndromic surveillance certification criterion, we have dropped this requirement because we believe it is not necessary to focus on for the purposes of EHR technology certification. [54247]
- RLR Implementation Guide: We have adopted the proposed certification criterion [the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with errata, as well as the latest versions of SNOMED CT® and LOINC®.], including the proposed standards and implementation guide with errata and clarifications and a recently published supplement to the implementation guide, titled ""ELR 2.5.1 Clarification Document for EHR Technology Certification." Accordingly, we are adopting the Supplement and the proposed Release 1 with errata and clarifications. [54247]
- RLR Vocabulary Standards: We have established a process for adopting certain vocabulary standards, including SNOMED CT® and LOINC®, which permits the use of newer versions of those standards than the one adopted in regulation. [54247]
- Transport Standards Guidance: We want to make clear that we do not require EHR technology to be certified to any transport standard, including Direct, to meet this certification criterion. There is no consensus transport standard that states and public health agencies use for the reporting of laboratory test and values/results. Therefore, we believe that it is appropriate for EHR technology developers to have the flexibility to include in their EHR technology and implement the transport standards that permit EPs, EHs, and CAHs to report in their states and to local public health agencies. [54247]

- Reportable Lab Results (RLR) Certification Criteria: EHR technology must be able to electronically create reportable laboratory tests and values/results for electronic transmission in accordance with: (i) The standard (and applicable implementation specifications) specified in § 170.205(g); and (ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2). [54291]

CANCER REPORTING

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- Cancer Reporting Guidance: For those EPs who do not meet the proposed exclusion of not diagnosing or directly treating cancer, yet are not already under a requirement to report to cancer registries, we note that this is a menu objective and can be deferred. Between the proposed exclusions and the option to defer, we do not believe the measure imposes a reporting burden on providers who would not normally report to cancer registries. [54029]
- Public Health Central Cancer Registry reporting: We agree that the term public health central cancer registry is better than just cancer registries and more inclusive than just state cancer registries as used in the proposed objective, but not the proposed measure. After consideration of the public comments received, we are modifying this objective for EPs at §495.6 (k)(4)(i) to "Capability to identify and report cancer cases to a public health central cancer registry, except where prohibited, and in accordance with applicable law and practice." [54029]
- Cancer Reporting from EPs (Menu Set Stage 2 MU Objective): After consideration of the public comments received, we are modifying this measure for EPs at §495.6 (k)(4)(ii) to "Successful ongoing submission of cancer case information from CEHRT to a public health central cancer registry for the entire EHR reporting period" and modify the exclusions to conform with the general criteria for public health objectives; Exclusions: Any EP that meets at least 1 of the following criteria may be excluded from this objective: (1) The EP does not diagnose or directly treat cancer; (2) the EP operates in a jurisdiction for which no public health agency is capable of receiving electronic cancer case information in the specific standards required for CEHRT at the beginning of their EHR reporting period; (3) the EP operates in a jurisdiction where no PHA provides information [54029]
- Stage 2 objectives for Eligible Professionals: Capability to identify and report cancer cases to a public health central cancer registry, except where prohibited, and in accordance with applicable law and practice. [54029]
- Stage 2 measures: Successful ongoing submission of cancer case information from CEHRT to a public health central cancer registry for the entire EHR reporting period [54029]

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- Cancer Reporting Certification Guidance: While many commenters supported the proposed certification criteria, many also requested that the certification criteria be designated “optional” for Complete EHR certification. By designating the certification criteria as optional, EHR technology would not need to be certified to these certification criteria in order to satisfy the Complete EHR definition. The optional designation will permit EHR technology developers that support EPs intending to report on the associated MU menu objective and measure to still get certified to these certification criteria, but will alleviate the requirement that all Complete EHRs be certified to these certification criteria. Designating these certification criteria as optional will mitigate any perceived unnecessary costs and burden mentioned by commenters. [54195]

- Cancer Reporting Implementation Guide: We have adopted Release 1 of the implementation guide for the "transmission to cancer registries" certification criterion. [54196]

SPECIALIZED DISEASE REGISTRY

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- Specialized Disease Registry Reporting Guidance: We are purposefully general in our description of specialized registry because we do not wish to exclude certain registries in an attempt to be more specific. The only limitation we place on our description of specialized registries is that the specialized registry cannot be duplicative of any of the other registries included in other meaningful use objectives and measures. This means that an EP cannot meet the immunization, syndromic surveillance or cancer objectives and this objective by reporting to the same registry. EPs who either do not wish to participate with a specialized registry or cannot overcome the barriers to doing so can defer or exclude this measure as their situation warrants. [54030]
- Stage 2 objectives for Eligible Professionals: Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice. The purpose of this objective and measure is to give meaningful use credit to those EPs who are engaged in ongoing submission with specialized registries. It is not expected that every EP will select this objective and measure from the menu nor even that every EP will have the capability to submit to a specialized registry. We are purposefully general in our description of specialized registry because we do not wish to exclude certain registries in an attempt to be more specific. The only limitation we place on our description of specialized registries is that the specialized registry cannot be duplicative of any of the other registries included in other meaningful use objectives and measures. This means that an EP cannot meet the immunization, syndromic surveillance or cancer objectives and this objective by reporting to the same registry. EPs who either do not wish to participate with a specialized registry or cannot overcome the barriers to doing so can defer or exclude this measure as their situation warrants. [54030]
- Specialized Disease Registry Reporting Guidance: A registry that is focused on healthcare associated infections could certainly be considered a specialized registry. [54030]
- For purposes of the exclusion only, we limit it to registries sponsored by national specialty societies and specialized registries maintained by PHAs. We believe this provides needed limitations on the exclusions. This limitation does not apply to the specialized registries that can be used to satisfy the measure as the benefits are not limited only to reporting to registries operated by Public Health Agencies or national medical specialty organizations. Specialized registries operated by patient safety organizations and quality improvement organizations also enable knowledge generation or process improvement regarding the diagnosis, therapy and prevention of various conditions that affect a population; Exclusions: Any EP that meets at least 1 of the following criteria may be excluded from this objective: (1) The EP does not diagnose or directly treat any disease associated with a specialized registry sponsored by a national specialty society for which the EP is eligible, or the public health agencies in their jurisdiction; (2) the EP operates in a jurisdiction for which no specialized registry sponsored by a public health agency or by a national specialty society for which the EP is eligible is capable of receiving electronic specific case information in the specific standards required by CEHRT at the beginning of their EHR reporting period; (3) the EP operates in a jurisdiction where no public health agency or national specialty society for which the EP is eligible provides information

timely on capability to receive information into their specialized registries ; or (4) the EP operates in a jurisdiction for which no specialized registry sponsored by a public health agency or by a national specialty society for which the EP is eligible that is capable of receiving electronic specific case information in the specific standards required by CEHRT at the beginning of their EHR reporting period can enroll additional EPs. [54030]

- Stage 2 objectives for Eligible Professionals: Stage 2 objective: Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice. [54030]
- Stage 2 measures: Successful ongoing submission of specific case information from Certified EHR Technology to a specialized registry for the entire EHR reporting period. [54030]

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- N/A