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Date: July 26, 2010

Subject: Final Rule on Standards, Implementation Specifications, and Certification Criteria for EHR Technology

On July 13, 2010 the Office of the National Coordinator for Health Information Technology (“ONC”) released its final regulation (“Final Rule”) establishing an initial set of standards, implementation specifications and certification criteria for electronic health record technology (“EHR”). This memorandum provides a summary of the Final Rule and an analysis of the policies adopted therein.

I. Overview

In the Interim Final Rule with Comment (“IFR”) issued in December 2009, ONC adopted an initial set of standards, implementation specifications, and certification criteria for EHR technology that were fundamentally linked to the Medicare and Medicaid EHR incentive programs through their specification of the capabilities and related standards required of Certified EHR Technology to support Eligible Professionals (“EPs”) and Eligible Hospitals (“EHs”) achievement of Stage 1 meaningful use objectives and measures. The EHR incentive programs allow EPs and EHs to earn incentive payments if, among other requirements, they are able to demonstrate meaningful use of Certified EHR Technology. To be deemed Certified EHR Technology, EHR products must be tested and certified against the certification criteria and associated standards and implementation specifications specified by ONC via the rulemaking process.

While the Final Rule completes the adoption of the initial set of standards and certification criteria and more closely aligns the set with the final meaningful use Stage 1 objectives and measures established by the Medicare and Medicaid EHR incentive programs Final Rule (the “Incentive Program Final Rule”), it in large part does not significantly differ from the IFR. Instead, the Final Rule primarily clarifies and revises certification criteria in response to public comment, enhances the specificity and implementation specifications of adopted standards, and harmonizes the rule with final meaningful use requirements. Specifically, the Final Rule:

- Clarifies and provides additional specificity for a number of certification criteria.
- Harmonizes certification criteria to final meaningful use Stage 1 requirements including 1) the removal of certification criteria dealing with administrative transactions and related standards and implementation specifications, and 2) the addition of three new certification criteria.
- Removes transport standards from the initial standard set.
- Removes one content exchange standard (NCPDP Formulary and Benefits Standard 1.0 for drug formulary check) from the initial standard set.
- Removes the vocabulary standard (RxNorm) from the medication lists criterion.
- Adopts new implementation specifications.
- Adopts one new vocabulary standard (The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity).
- Makes optional the certification criterion requiring that an EHR have the ability to record disclosures made for treatment, payment and health care operations.

Like the IFR, and despite a significant amount of public comment urging for additional guidance with regard to future EHR technology certification requirements, the Final Rule defines certification requirements for only Stage 1 meaningful use and provides details on potential future requirements in only a limited number of instances. ONC reiterates that it expects to adopt new and/or modified certification criteria every two years, concurrently and in support of a transition to Stage 2 and Stage 3 meaningful use requirements.

The initial set of certification criteria adopted through the Final Rule will be used to test and certify EHR technology under the process established by the Temporary Certification Program Final Rule that was issued by ONC in June 2010.

II. Summary and Analysis

A. Key Definitions

ONC adopts the following baseline definitions in the Final Rule:

- Certified EHR Technology:
 - 1) A Complete EHR that meets the requirements included in the definition of a Qualified EHR and has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the secretary; or
 - 2) A combination of EHR Modules in which each constituent EHR Module of the combination has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary, and the resultant combination also meets the requirements included in the definition of a Qualified EHR.

Though ONC does not make any substantive changes to the definition of Certified EHR Technology specified in the IFR, the agency modifies the wording of this definition in the Final Rule to make clear that the definition of Certified EHR Technology can be met in either of these two ways.¹

- Qualified EHR. “An electronic record of health-related information on an individual that:
 - 1) Includes patient demographic and clinical health information, such as medical history and problem lists; and
 - 2) Has the capacity
 - i) to provide clinical decision support;
 - ii) to support physician order entry;
 - iii) to capture and query information relevant to health care quality; and
 - iv) to exchange electronic health information with, and integrate such information from, other sources.”

As ONC employs the statutory definition of Qualified EHR put forth in the legislation that established the incentive programs, this definition is the same as that which was included in the IFR. ONC notes that this definition sets only the floor for the capabilities that Certified EHR Technology must include, as ONC adopts certification criteria that require capabilities beyond those specified in this definition and that EHR systems must additionally meet to be considered Certified EHR Technology.

- EHR Module. Any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by ONC.

ONC makes no changes to the definition of EHR Module included in the IFR.

- Complete EHR. EHR technology that has been developed to meet, at minimum, all applicable certification criteria adopted by the Secretary.

¹ In the IFR, ONC specified the following definition of Certified EHR Technology: “A Complete EHR or a combination of EHR Modules, each of which: 1) meets the requirements included in the definition of a Qualified EHR; and 2) has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary.”

ONC slightly revised this definition from the IFR to include the language “at minimum” to clarify that it does not intend for the term Complete EHR to limit the capabilities included in such a system, but rather to signify EHR technology that can perform all of the applicable capabilities required by certification criteria. ONC expects that some Complete EHRs will have capabilities beyond those addressed by certification criteria.

- Human Readable Format. A format that enables a human to read and easily comprehend the information presented to him or her regardless of the method of presentation.

This definition was not included in the IFR. It was added to the Final Rule in response to a significant number of comments across several certification criteria requesting clarification of the meaning of the term “human readable format.”

B. Adopted Standards, Certification Criteria and Implementation Specifications

As in the IFR, certification criteria define the capabilities that an EHR technology must have in order to be certified for meaningful use. In some, but not all, instances, certification criteria include requirements for the use of specific standards and implementation specifications.

1. Overall Approach
 - a. Flexibility and Innovation

ONC received a large number of comments requesting that the agency provide more flexibility in the Final Rule to accommodate new and ongoing developments in health information technology (“health IT”) and to facilitate innovation within the health IT industry. ONC expressed agreement with the need to accommodate flexibility and innovation to the greatest extent possible in this and future rulemakings through at least one of four means:

Alternative Standards

- In the IFR and the Final Rule, ONC has adopted “alternative” standards (and applicable implementation specifications) for several certification criteria.
- As a general rule, when an adopted certification criterion refers to two or more standards as alternatives, use of at least one of the alternative standards will be considered compliant with the certification criterion.
- ONC notes that in these instances, it has tried to balance the need for flexibility with the goal of advancing interoperability, while also taking into account that the health IT industry has not yet migrated to a single specific standard for certain purposes, such as its adoption of both the Continuity of Care Document (“CCD”) and Continuity of Care Record (“CCR”) standards as alternatives with respect to patient summary records.

Minimum Code Set Standards

- As outlined in the IFR, ONC adopted several minimum code set standards and specifies that these code sets standards represent the floor, not the ceiling, for testing and certification.
- If and/or when the Secretary accepts a newer version of an adopted minimum standard code set, the Secretary will, in effect, raise the ceiling for what is permitted for testing and certification as well as allow for Certified EHR Technology to be upgraded to that newer version without adversely affecting the Certified EHR Technology’s certified status.
- Compliance by Certified EHR Technology developers and vendors to the new version of the adopted minimum standard code set will be voluntary unless or until the certification criteria is officially revised and the new version adopted through future rulemaking.

Optional Standards, Implementation Specifications, and Certification Criteria

- ONC suggests that the adoption and designation of “optional” standards, implementation specifications and certification criteria will facilitate additional flexibility and specificity into this and future rulemaking and may help better prepare the health IT industry for future mandatory certification requirements.
- ONC specifies that optional standards, implementation specifications and certification criteria would be entirely voluntary and would not be required for testing and certifying a Complete EHR or EHR Module.
- In the Final Rule, ONC has designated one certification criterion as optional (the requirement that systems be able to record disclosures made for treatment, payment and health care operations in accordance with the specified standard).

Standards and Backwards Compatibility

- The Final Rule references a definition of backwards compatibility from a previous HHS rulemaking related to the adoption of electronic prescribing for the Medicare Part D prescription drug program. Backwards compatibility is described as meaning that a newer version of a standard retains at a minimum the full functionality of the version previously adopted in regulation, and that the newer version would permit the successful completion of the applicable transaction(s) with entities that continue to use the older version(s). If a newer version of a standard were backward compatible with an adopted standard, it would be possible to pursue a more expedited approach to permit the utilization of the newer version while still remaining in compliance with the law.
- ONC endorses this concept with the caveat that the approach could be implemented only when a newer version of a standard is technically capable of fully functioning with the adopted version of the standard to conduct the specified transaction.
- ONC anticipates that, much like a minimum code set standard, there will be cases where an EHR technology would be permitted to be certified according to the adopted backward compatible version.
- ONC expects that it would only allow backward compatibility in the intermediate years between final rules related to meaningful use stages.

2. Certification Criteria

The Final Rule primarily clarifies and provides additional specificity for a number of certification criteria. In response to public comments, ONC reiterates in the Final Rule that certification criteria define only capabilities that Certified EHR Technology must have to be certified for meaningful use and do not dictate which of those functionalities EPs and EHs should use. ONC also reiterates that certification criteria are meant to serve only as a “floor,” and that the agency expects that some vendors will choose to offer additional functionality which exceeds Stage 1 certification requirements.

The Final Rule includes a set of general certification criteria for Complete EHRs or EHR Modules, as well as specific certification criteria for Complete EHRs or EHR Modules designed for an ambulatory setting and those designed for an inpatient setting.

A complete table showing all adopted general certification criteria for Complete EHRs or EHR Modules is attached as Appendix A.

A complete table showing all specific certification criteria for Complete EHRs or EHR Modules designed for an ambulatory setting is attached as Appendix B.

A complete table showing all specific certification criteria for Complete EHRs or EHR Modules designed for an inpatient setting is attached as Appendix C.

a. New Certification Criteria

In order to align with final Stage 1 meaningful use requirements, ONC added three new certification criteria.

Record Advance Directives (Inpatient)

In the Medicare and Medicaid EHR incentive program Notice of Proposed Rulemaking (“NPRM”), CMS explained that the health IT Policy Committee had recommended that EHRs “record advance directives” but that the agency found the recommendation ambiguous and so did not include it as a proposed requirement for Stage 1. However, in the Incentive Program Final Rule, CMS reversed its position, citing numerous public comments and resolution of some of the ambiguity associated with the measure, and included it as a Stage 1 requirement.

- ONC will require that Certified EHR Technology for an inpatient setting enable users to electronically record whether a patient has an advance directive, which in turn, it says, will help ensure that a patient’s wishes are known and can be followed.
- ONC further suggests that it does not believe the capability will be a significant burden for Certified EHR Technology developers and assumes that some already have this or a similar capability built into their systems.

Patient-Specific Education Resources (Ambulatory and Inpatient)

While discussed but not proposed in the NPRM, the Incentive Program Final Rule expressly requires that more than 10 percent of all unique patients seen by an EP or admitted to an EHR’s or CAH’s inpatient or emergency department (POS 21 or 23) during the EHR reporting period be provided patient-specific education resources in order to meet the related new meaningful use Stage 1 objective.

- To support the achievement of this objective and measure, ONC will require that Certified EHR Technology for an inpatient setting have the capability of enabling a user to electronically identify and provide patient-specific education resources based on particular types of data elements such as medications.
- ONC clarified that it will not specify how Certified EHR Technology must be used to provide such resources to a patient (for example, such resources could be printed out, faxed, or emailed by the end user but ONC will not require any specific methods of disseminating the information).

Automated Calculation of Percentage-Based Meaningful Use Measures (Ambulatory and Inpatient)

In the Final Rule, ONC clarifies that the ability to calculate meaningful use Stage 1 measures where calculation is required (numerator and denominator and resulting percentage) is included in Certified EHR Technology, and defines certification criterion regarding the automated calculation of percentage-based meaningful use measures.

- Certified EHR Technology must be capable of calculating all denominators for those meaningful use measures which are percentage-based and for which CMS requires an EP or EHR to submit the results at the end of an EHR reporting period.
- An EP or EHR will be responsible for verifying that the denominator produced by Certified EHR Technology is complete.
- The EP or EHR would be expected to know whether the data had been incorrectly entered into Certified EHR Technology or whether all patient records were included in the EHR.
- For meaningful use Stage 1, the CMS Final Rule identifies these measures as “Measures with a Denominator of Unique Patients Regardless of Whether the Patient’s Records are Maintained Using Certified EHR Technology” and “Measures with a Denominator Based on Counting Actions for Patients whose Records are Maintained Using a Certified EHR Technology.”
- ONC will not require, as a condition of certification, that a Complete EHR or EHR Module provide results for meaningful use Stage 1 measures that require only a “yes/no” attestation.

b. Removal of Administrative Transaction Certification Criteria

To align with the Incentive Program Final Rule, ONC removed the two administrative transaction certification criteria and the related administrative transport standards and implementation specifications from Stage 1 requirements. ONC states, however, that as described by CMS in the Incentive Program Final Rule, the inclusion of administrative simplification requirements as part of Stage 2 meaningful use is an important long-term policy goal. Accordingly, ONC states that the agency intends to include administrative transactions standards and certification criteria to support meaningful use Stage 2 rulemaking, and that it expects health care providers and EHR Technology developers to take this into consideration leading up to 2013.

c. Optional Certification Criteria

In line with the “flexible” approach ONC describes, the Final Rule makes one certification criterion optional (the requirement that systems be able to record disclosures made for treatment, payment and health care operations in accordance with the specified standard).

3. Standards

a. Content Exchange, Vocabulary, and Privacy and Security Standards

ONC adopts several content exchange, vocabulary and privacy and security standards, most of which were included in the IFR. As mentioned, administrative transaction standards were not adopted, in order to align the Final Rule with final Stage 1 meaningful use requirements. Additionally, based on public comment, the following two standards also were not adopted for drug formulary checks and the creation of medication lists:

NCPDP Formulary and Benefits Standard 1.0 for Drug Formulary Checks:

- Several commenters noted that the NCPDP Formulary and Benefits Standard 1.0 is not used in an inpatient setting.
- ONC agrees with the inconsistency and determined that it would be appropriate to adopt a more general certification criterion that would be applicable to Certified EHR Technology designed for both ambulatory and inpatient settings.
- ONC removes any reference to a particular standard, noting that an EP or EH would be able to satisfy this meaningful use measure by checking an internally managed drug formulary.
- ONC also notes, however, that EPs who seek to comply with the Medicare Part D e-prescribing requirements are required to use the standard for that program.

RxNorm for Creation of Medication Lists:

- Several commenters stated that more clarification was needed with respect to whether RxNorm identifiers needed to be stored internally within Certified EHR Technology or only needed to be used upon the electronic exchange of health information. A number of additional commenters expressly suggested that the mapping of the vocabulary be limited to instances where the electronic exchange of health information would take place.
- ONC agrees that it would be premature to require the use of RxNorm in this context and that continuing to associate the standard with the certification criterion could potentially impose a significant unintentional burden on the industry.
- Accordingly, ONC removes any reference to a particular standard for this criterion.

Finally, though not included in the IFR, ONC adopts a new vocabulary standard related to codifying race/ethnicity information (The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, October 30, 1997).

A complete table showing all adopted standards and related implementation specifications (which compares Final Rule requirements to those listed in the IFR) is attached at Appendix D.

b. Transport Standards

ONC received extensive comments on its proposal in the IFR to require transport standards as part of the certification criteria. Comments ranged from urging for the complete removal of SOAP and REST to requests for detailed implementation specifications for SOAP and REST to the need for very specific, detailed guidance around which transactions required the transport standards.

- In consideration of the public comments, ONC decided to remove the adopted standards SOAP and REST from the Final Rule completely, citing the significant potential conflicts with other adopted standards identified through comments.
- ONC will not require specific transport standards as a condition of certification at the present time.
- However, ONC notes that it plans to monitor the impact of this decision and its effect on interoperability, and expressly encourages Certified EHR Technology developers to utilize transport standards that will help the industry coalesce around common methods of health information exchange.

4. Implementation Specifications

ONC in the Final Rule adopts one of the implementation specifications included in the IFR (PQRI Measure Specifications Manual for Claims and Registry) and, in accordance with changes to final meaningful use requirements, does not adopt the other implementation specification included in the IFR (CAQH CORE Phase I).

ONC also adopts a number of new implementation specifications, including:

- The Healthcare Information Technology Standards Panel (HITSP) Summary Documents Using HL7 CCD Component HITSP/C32
- HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1
- Public Health Information Network HL7 Version 2.5 Message Structure Specification for National Conditioning Reporting Final Version 1.0 and Errata and Clarifications National Notification Message Structural Specification
- Implementation Guide for Immunization Data Transactions Using Version 2.3.1 of the HL7 Standard Protocol Implementation Guide Version 2.2
- HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0

A complete table showing all adopted standards and related implementation specifications is attached at Appendix D.

C. Key Issues

In addressing the significant number of comments submitted by the public, the Final Rule provides clarification on a number of key issues.

1. Electronic Prescribing

NCPDP SCRIPT 10.6 as an Alternate Standard

- Many commenters supported the adoption of NCPDP SCRIPT 8.1 and the adoption of NCPDP SCRIPT 10.6 for the e-prescribing requirements. Commenters also urged the exclusive adoption of NCPDP SCRIPT 10.6 for Stage 2 meaningful use requirements.
- ONC agrees that NCPDP SCRIPT 10.6 is backward compatible to NCPDP SCRIPT 8.1 and modifies this certification criterion to specify that Complete EHR and EHR Module developers may seek to have their technology tested and certified to either solely NCPDP SCRIPT 8.1 or 10.6.
- ONC further clarifies that a Certified EHR Technology would be compliant with this certification criterion if it has the capability of generating and transmitting prescription and prescription –related information according to NCPDP SCRIPT 8.1 or NCPDP SCRIPT 10.6 while also using the adopted vocabulary standard.
- ONC does not address comments related to Stage 2 meaningful use requirements.

RxNorm as a Vocabulary Standard

- Several commenters supported the adoption of RxNorm and the use of RxNorm code sets as a vocabulary standard for the e-prescribing requirements. However, other commenters suggested that more testing is needed before RxNorm could be adopted in full and that Stage 1 would be too aggressive of a timeline for broader industry implementation.
- ONC reiterates that, as it had outlined in the IFR, it believes the health IT industry would benefit from a certain degree of flexibility with respect to coding of medications. To provide such flexibility while also establishing what it calls a “glide path to full adoption of RxNorm,” ONC elects to adopt a standard that permits the use of many different vocabulary standards.
- ONC clarifies that the standard adopted in the Final Rule is a functional standard that enables the use of any source vocabulary that is included within RxNorm. Consequently, any code set by an RxNorm drug data source provider that is identified by the United States National Library of Medicine (NLM) as being a complete data set integrated within RxNorm may be used, or any other source vocabulary successfully included within RxNorm.

Drug Enforcement Agency (DEA) Interim Final Rule on Electronic Prescribing of Controlled Substances

- Some commenters raised concerns about the e-prescribing criterion causing two different workflows because of the restrictions placed on the electronic prescribing of controlled substances.
- Since the publication of the IFR, the DEA published an interim final rule related to the electronic prescribing of controlled substances (75 FR 16236).
- ONC specifies that, at the present time, it will not require as a condition of certification that EHRs be capable of enabling compliance with the current DEA provisions for e-prescribing of controlled substances.

Pharmacies Not Capable of Receiving Electronic Prescriptions

- A few commenters expressed concerns about some pharmacies not being capable of receiving electronic prescriptions and one commenter suggested the criterion be amended to include the language “where possible.”

- ONC responds that while it recognizes that some pharmacies are not currently able to receive electronic prescriptions, the agency does not believe this limitation should affect the capability that Certified EHR Technology must provide.

Inpatient Electronic Prescribing Requirements

- Many commenters suggested that the drug-formulary requirements should not apply to Certified EHR Technology designed for an inpatient setting because there was no proposed requirement in Stage 1 of meaningful use for EHRs to electronically prescribe.
- ONC disagrees with these comments, clarifying that the capability will be required to be enabled in all Certified EHR Technology, inpatient or ambulatory, seeking certification for Stage 1 meaningful use but that the extent to which health care providers must use those capabilities falls outside the scope of this rule.

2. SNOMED CT and ICD-9-CM

As has long been debated on the national stage, many commenters expressed concerns about the use of ICD-9-CM for clinical transactions because the coding classification system is used primarily for billing and administrative purposes and therefore may not accurately represent the true clinical meaning of a problem or condition when it is documented at the point of care.

- Several commenters recommended that only SNOMED-CT be adopted. Some commenters also suggested ONC expressly indicate an intention to move away from ICD-9-CM and ICD-1 in the future.
- ONC outlines its conceptual support that a single standard for clinical information would be desirable in the long term. However, ONC acknowledges that both systems are presently being used by EHR Technologies to code clinical information and reiterates its desire to provide flexibility in the Final Rule.
- ONC confirms its decision to allow both ICD-9-CM and SNOMED-CT as alternative standards, believing that with adoption of both coding classification systems, health care providers should have adequate coverage for patient diagnoses and conditions.
- ONC discourages the use of free text for documenting problem lists, citing the limitations free text places on the usefulness of other tools such as clinical reminders, decision support and other patient safety and quality reporting.

3. Laboratory Tests

The certification criteria and standards related to laboratory tests generated a notable amount of public comment. Accordingly, ONC extensively addressed the issue in the Final Rule.

Requirements for Laboratories

- In response to many commenters, ONC clarifies that the agency does not believe it falls within the scope of the Final Rule to dictate the standard by which laboratories transmit test results. ONC describes the scope of the Final Rule as solely focused on the adoption of certification criteria that specify required capabilities of Certified EHR Technology (in this case, receiving the laboratory information in a structured format) and not, in this instance, specifying the standard by which laboratories must transmit test results.
- ONC clarifies that for purposes of demonstrating compliance with this certification criterion, when laboratory results are received in a structured format by Certified EHR Technology, the technology must be capable of incorporating the results.

LOINC

- Commenters requested clarification regarding what needed to be displayed in the context of LOINC codes.
- ONC clarifies that it does not expect Certified EHR Technology to natively (or internally) support LOINC in its entirety, which is why the agency has chosen not to specify a subset of common LOINC codes.
- ONC agrees with commenters that the certification criterion should not require a received LOINC code to subsequently be displayed. However, ONC does expect a Certified EHR Technology to be able to reuse a LOINC code once it has been received and is accessible to the EHR. ONC does not expect that Certified EHR Technology will have to crosswalk or map internal or local codes to LOINC codes.

CLIA

- Some commenters expressed concern that modifications to Certified EHR Technology could potentially result in the failure of the EHR to display the test report information as required by regulations and thereby put the laboratory in technical violation of the CLIA regulations.
- These commenters suggested that because a Complete EHR or EHR Module must be tested and certified to be in compliance with 42 CFR 493.1291(c)(1) through (7), that certification should replace any requirements for the laboratory to confirm that the information has been properly transmitted and meets the CLIA requirements.
- Further, the commenters asserted that a laboratory should be relieved of any further regulatory responsibility for the display of the required report information to the physician or subsequent viewers of the information if the Certified EHR Technology has been implemented by an EP or EH.
- ONC expresses understanding for the concern expressed by commenters but reiterates that the scope of the Final Rule applies only to the required capabilities of Certified EHR Technology and does not provide the agency with the authority to grant the regulatory relief requested by commenters.

4. Continuity of Care Document (CCD) v. Continuity of Care Record (CCR)

The inclusion of both CCD and CCR as acceptable standards for patient summary records generated extensive public comment.

Use of Both CCD and CCR as Acceptable Standards

- While a few commenters expressed support for ONC's adoption of the CCR standard, many were opposed to its inclusion as an alternate standard and did not believe it was an appropriate selection. Several commenters did not comment on the merits of CCR versus CCD but expressed a general concern that adopting two standards would be wasteful, counter-productive, confusing and time-consuming, and would reduce interoperability.
- ONC reaffirms its decision to include both standards, CCD and CCR, as patient summary record standards and believes that at the present time, each standard could be equally used to satisfy the requirements for Stage 1 meaningful use. ONC disagrees with commenters who suggested the CCR was not widely used and instead states the belief that a significant segment of the health IT industry currently uses the CCR standard and that some providers prefer the use of CCR over CCD.
- ONC states that it did not want to mandate at such an early stage that all early adopters adopt a different summary record standard for the purposes of Stage 1 meaningful use given that electronic health information exchange is not required.

- ONC further suggests that in some circumstances, CCR is easier, faster and requires fewer resources to implement than the CCD.

Certification Criteria Related to CCD

- ONC received numerous comments questioning why the agency did not adopt the HITSP C32 implementation specification for the CCD. Commenters also requested additional clarification regarding ONC's adoption of a "level 2" CCD as part of this standard.
- ONC considered public comment and makes two changes in the Final Rule related to the adoption of the CCD standard.
 - ONC agrees with commenters that the HITSP C32 (version 2.5) implementation specification would be appropriate to adopt.
 - In the Final Rule, ONC removes reference to level 2 within the standard.

Clarification of Receiving and Display Requirements

- ONC clarifies that compliance with this certification criterion can be achieved by demonstrating the Certified EHR Technology is capable of receiving and displaying patient summary records that comply with either the CCR or CCD standard (and if the alternative standard is used, displaying the non-natively implemented patient summary record in human readable format) and generating and transmitting a patient summary record according to one of the patient summary record standards populated with the specific data types and their applicable standard(s).

Discharge Summaries

- Commenters noted that neither the CCD nor CCR standard contain an applicable section for discharge summary.
- ONC agrees with commenters' concerns and revises associated certification criterion to reflect that while other data elements can be conveyed using the patient summary records (CCR or CCD), the agency will not require the use of any standards for discharge summaries.

5. Security

ONC received a variety of comments on various components of the certification criteria related to the Meaningful Use Stage 1 measure requiring EPs and EHRs to conduct or review a security risk analysis and to implement security updates as necessary. The Final Rule clarifies the requirements for audit logs, data integrity, authentication, encryption and accounting of disclosures (see Appendix A).

APPENDIX A

GENERAL CERTIFICATION CRITERIA FOR COMPLETE EHRs or EHR MODULES

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Implement drug-drug and drug-allergy interaction checks	The EP/eligible hospital/CAH has enabled this functionality for the entire EHR reporting period	<p>Interim Final Rule Text:</p> <p>(1) <u>Alerts</u>. Automatically and electronically generate and indicate in real-time, alerts at the point of care for drug-drug and drug-allergy contraindications based on medication list, medication allergy list, age, and computerized provider order entry (CPOE).</p> <p>(3) <u>Customization</u>. Provide certain users with administrator rights to deactivate, modify, and add rules for drug-drug and drug-allergy checking.</p> <p>(4) <u>Alert statistics</u>. Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.</p>
		<p>Final Rule Text:</p> <p>§170.302(a)</p> <p>(1) <u>Notifications</u>. Automatically and electronically generate and indicate in real-time, notifications at the point of care for drug-drug and drug-allergy contraindications based on medication list, medication allergy list, and computerized provider order entry (CPOE).</p> <p>(2) <u>Adjustments</u>. Provide certain users with the ability to adjust notifications provided for drug-drug and drug-allergy interaction checks.</p>
Implement drug-formulary checks	The EP/eligible hospital/CAH has enabled this functionality and has access to at least one internal or external drug formulary for the entire EHR reporting period.	<p>Interim Final Rule Text:</p> <p>(2) <u>Formulary checks</u>. Enable a user to electronically check if drugs are in a formulary or preferred drug list in accordance with the standard specified in §170.205(b).</p>
		<p>Final Rule Text:</p> <p>§170.302(b)</p> <p><u>Drug-formulary checks</u>. Enable a user to electronically check if drugs are in a formulary or preferred drug list.</p>
Maintain an up-to-date problem list of current and active diagnoses	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital's	<p>Interim Final Rule Text:</p> <p><u>Maintain up-to-date problem list</u>. Enable a user to electronically record, modify and retrieve a patient's problem list for longitudinal care in accordance with:</p>

GENERAL CERTIFICATION CRITERIA FOR COMPLETE EHRs or EHR MODULES

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
	or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry or an indication that no problems are known for the patient recorded as structured data	<p>(1) The standard specified in §170.205(a)(2)(i)(A); or (2) At a minimum, the version of the standard specified in §170.205(a)(2)(i)(B).</p> <p>Final Rule Text: §170.302(c) Final rule text remains the same as Interim Final Rule text, except for references to adopted standards, which have been changed.</p>
Maintain active medication list	More than 80% of unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry (or an indication that the patient is not currently prescribed any medication) recorded as structured data.	<p>Interim Final Rule Text: <u>Maintain active medication list.</u> Enable a user to electronically record, modify, and retrieve a patient's active medication list as well as medication history for longitudinal care in accordance with the standard specified in §170.205(a)(2)(iv).</p> <p>Final Rule Text: §170.302(d) <u>Maintain active medication list.</u> Enable a user to electronically record, modify, and retrieve a patient's active medication list as well as medication history for longitudinal care.</p>
Maintain active medication allergy list	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry (or an indication that the patient has no known medication allergies) recorded as structured data.	<p>Interim Final Rule Text: <u>Maintain active medication allergy list.</u> Enable a user to electronically record, modify, and retrieve a patient's active medication allergy list as well as medication allergy history for longitudinal care.</p> <p>Final Rule Text: Unchanged. Now §170.302(e)</p>
Record and chart changes in vital signs: • Height • Weight	For more than 50% of all unique patients age 2 and over seen by the EP or admitted to eligible hospital's	<p>Interim Final Rule Text: (1)<u>Vital signs.</u> Enable a user to electronically record, modify, and retrieve a patient's vital signs including, at a minimum, the height, weight, blood pressure, temperature, and pulse. (2)<u>Calculate body mass index.</u> Automatically calculate and display body mass index (BMI)</p>

GENERAL CERTIFICATION CRITERIA FOR COMPLETE EHRs or EHR MODULES

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
<ul style="list-style-type: none"> • Blood pressure • Calculate and display BMI • Plot and display growth charts for children 2-20 years, including BMI 	or CAH’s inpatient or emergency department (POS 21 or 23), height, weight and blood pressure are recorded as structured data	<p>based on a patient’s height and weight. (3) <u>Plot and display growth charts</u>. Plot and electronically display, upon request, growth charts for patients 2-20 years old.</p> <hr/> <p>Final Rule Text: §170.302(f) (1) <u>Vital signs</u>. Enable a user to electronically record, modify, and retrieve a patient’s vital signs including, at a minimum, height, weight, and blood pressure. (2) Unchanged (3) Unchanged</p>
Record smoking status for patients 13 years old or older	More than 50% of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital’s or CAH’s inpatient or emergency department (POS 21 or 23) have smoking status recorded as structured data	<p>Interim Final Rule Text: <u>Smoking status</u>. Enable a user to electronically record, modify, and retrieve the smoking status of a patient. Smoking status types must include: current smoker, former smoker, or never smoked.</p> <hr/> <p>Final Rule Text: §170.302(g) <u>Smoking status</u>. Enable a user to electronically record, modify, and retrieve the smoking status of a patient. Smoking status types must include: current every day smoker; current some day smoker; former smoker; never smoker; smoker, current status unknown; and unknown if ever smoked.</p>
Incorporate clinical lab-test results into certified EHR technology as structured data	More than 40% of all clinical lab tests results ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period	<p>Interim Final Rule Text: (1) <u>Receive results</u>. Electronically receive clinical laboratory test results in a structured format and display such results in human readable format. (2) <u>Display codes in readable format</u>. Electronically display in human readable format any clinical laboratory tests that have been received with LOINC® codes. (3) <u>Display test report information</u>. Electronically display all the information for a test report specified at 42 CFR</p>

GENERAL CERTIFICATION CRITERIA FOR COMPLETE EHRs or EHR MODULES

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
	whose results are either in a positive/negative or numerical format are incorporated in certified EHR technology as structured data	<p>Final Rule Text: §170.302(h) (1) Unchanged (2) <u>Display test report information</u>. Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7). (3) <u>Incorporate results</u>. Electronically attribute, associate, or link a laboratory test result to a laboratory order or patient record.</p>
Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research or outreach	Generate at least one report listing patients of the EP, eligible hospital or CAH with a specific condition	<p>Interim Final Rule Text: <u>Generate patient lists</u>. Enable a user to electronically select, sort, retrieve, and output a list of patients and patients’ clinical information, based on user-defined demographic data, medication list, and specific conditions.</p>
		<p>Final Rule Text: §170.302(i) <u>Generate patient lists</u>. Enable a user to electronically select, sort, retrieve, and generate lists of patients according to, at a minimum, the data elements included in: (1) Problem list; (2) Medication list; (3) Demographics; and (4) Laboratory test results.</p>
Eligible Professionals: Report ambulatory clinical quality measures to CMS or the States Eligible Hospitals and CAHs: Report hospital clinical quality	For 2011, provide aggregate numerator, denominator, and exclusions through attestation as discussed in section II(A)(3) of [the Medicare and Medicaid EHR Incentive Programs final rule]	<p>Interim Final Rule Text: (1) <u>Display</u>. Calculate and electronically display quality measures as specified by CMS or states. (2) <u>Submission</u>. Enable a user to electronically submit calculated quality measures in accordance with the standard and implementation specifications specified in §170.205(e).</p>
		<p>Final Rule Text: §170.304(j)</p>

GENERAL CERTIFICATION CRITERIA FOR COMPLETE EHRs or EHR MODULES

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
measures to CMS or the States	For 2012, electronically submit the clinical quality measures as discussed in section II(A)(3) of [the Medicare and Medicaid EHR Incentive Programs final rule]	<p>(1) <u>Calculate</u>.</p> <p>(i) Electronically calculate all of the core clinical measures specified by CMS for eligible professionals.</p> <p>(ii) Electronically calculate, at a minimum, three clinical quality measures specified by CMS for eligible professionals, in addition to those clinical quality measures specified in paragraph (1)(i).</p> <p>(2) <u>Submission</u>. Enable a user to electronically submit calculated clinical quality measures in accordance with the standard and implementation specifications specified in §170.205(f).</p> <p>§170.306(i)</p> <p>(1) <u>Calculate</u>. Electronically calculate all of the clinical quality measures specified by CMS for eligible hospitals and critical access hospitals.</p> <p>(2) <u>Submission</u>. Enable a user to electronically submit calculated clinical quality measures in accordance with the standard and implementation specifications specified in §170.205(f).</p>
Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate	More than 10% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient-specific education resources	<p>Interim Final Rule Text: N/A</p>
		<p>Final Rule Text: §170.302(m) Patient-specific education resources. Enable a user to electronically identify and provide patient-specific education resources according to, at a minimum, the data elements included in the patient's: problem list; medication list; and laboratory test results; as well as provide such resources to the patient.</p>
The EP, eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication	The EP, eligible hospital or CAH performs medication reconciliation for more than 50% of transitions of care in which the patient is transitioned into the care of the EP or admitted to	<p>Interim Final Rule Text: <u>Medication reconciliation</u>. Electronically complete medication reconciliation of two or more medication lists by comparing and merging into a single medication list that can be electronically displayed in real-time.</p> <p>Final Rule Text:</p>

GENERAL CERTIFICATION CRITERIA FOR COMPLETE EHRs or EHR MODULES

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
reconciliation	the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23)	§170.302(j) <u>Medication reconciliation</u> . Enable a user to electronically compare two or more medication lists.
Capability to submit electronic data to immunization registries or Immunization Information Systems and actual submission in accordance with applicable law and practice	Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries and follow up submission if the test is successful (unless none of the immunization registries to which the EP, eligible hospital or CAH submits such information have the capacity to receive the information electronically)	<p>Interim Final Rule Text: <u>Submission to immunization registries</u>. Electronically record, retrieve, and transmit immunization information to immunization registries in accordance with: (1) One of the standards specified in §170.205(h)(1) and, at a minimum, the version of the standard specified in §170.205(h)(2); or (2) The applicable state-designated standard format.</p> <p>Final Rule Text: §170.302(k) <u>Submission to immunization registries</u>. Electronically record, modify, retrieve, and submit immunization information in accordance with: (1) The standard (and applicable implementation specifications) specified in §170.205(e)(1) or §170.205(e)(2); and (2) At a minimum, the version of the standard specified in §170.207(e).</p>
Capability to submit electronic syndromic surveillance data to public health agencies and actual submission in accordance with applicable law and practice	Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies and follow-up submission if the test is successful (unless none of the public health agencies to which an EP, eligible hospital or CAH submits such information have the capacity to receive the information electronically)	<p>Interim Final Rule Text: <u>Public health surveillance</u>. Electronically record, retrieve, and transmit syndrome-based public health surveillance information to public health agencies in accordance with one of the standards specified in §170.205(g).</p> <p>Final Rule Text: §170.302(l) <u>Public health surveillance</u>. Electronically record, modify, retrieve, and submit syndrome-based public health surveillance information in accordance with the standard (and applicable implementation specifications) specified in §170.205(d)(1) or §170.205(d)(2).</p>

GENERAL CERTIFICATION CRITERIA FOR COMPLETE EHRs or EHR MODULES

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process	Interim Final Rule Text: <u>Access control.</u> Assign a unique name and/or number for identifying and tracking user identity and establish controls that permit only authorized users to access electronic health information.
		Final Rule Text: §170.302(o) Unchanged
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process	Interim Final Rule Text: <u>Emergency access.</u> Permit authorized users (who are authorized for emergency situations) to access electronic health information during an emergency.
		Final Rule Text: §170.302(p) Unchanged
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process	Interim Final Rule Text: <u>Automatic log-off.</u> Terminate an electronic session after a predetermined time of inactivity
		Final Rule Text: §170.302(q) Unchanged
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process	Interim Final Rule Text: (1) <u>Record actions.</u> Record actions related to electronic health information in accordance with the standard specified in §170.210(b). (2) <u>Alerts.</u> Provide alerts based on user-defined events. (3) <u>Display and print.</u> Electronically display and print all or a specified set of recorded

GENERAL CERTIFICATION CRITERIA FOR COMPLETE EHRs or EHR MODULES

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
	process	<p>information upon request or at a set period of time.</p> <p>Final Rule Text: §170.302(r) (1) <u>Record actions</u>. Record actions related to electronic health information in accordance with the standard specified in §170.210(b). (2) <u>Generate audit log</u>. Enable a user to generate an audit log for a specific time period and to sort entries in the audit log according to any of the elements specified in the standard at 170.210(b).</p>
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process	<p>Interim Final Rule Text: (1) <u>In transit</u>. Verify that electronic health information has not been altered in transit in accordance with the standard specified in §170.210(c). (2) <u>Detection</u>. Detect the alteration and deletion of electronic health information and audit logs, in accordance with the standard specified in §170.210(c).</p> <p>Final Rule Text: §170.302(s) (1) Create a message digest in accordance with the standard specified in 170.210(c). (2) Verify in accordance with the standard specified in 170.210(c) upon receipt of electronically exchanged health information that such information has not been altered. (3) <u>Detection</u>. Detect the alteration of audit logs.</p>
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process	<p>Interim Final Rule Text: (1) <u>Local</u>. Verify that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information. (2) <u>Cross network</u>. Verify that a person or entity seeking access to electronic health information across a network is the one claimed and is authorized to access such information in accordance with the standard specified in §170.210(d).</p>

GENERAL CERTIFICATION CRITERIA FOR COMPLETE EHRs or EHR MODULES

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
		<p>Final Rule Text: §170.302(t) <u>Authentication.</u> Verify that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information.</p>
<p>Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities</p>	<p>Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process</p>	<p>Interim Final Rule Text: (1) <u>General.</u> Encrypt and decrypt electronic health information according to user-defined preferences in accordance with the standard specified in §170.210(a)(1). (2) <u>Exchange.</u> Encrypt and decrypt electronic health information when exchanged in accordance with the standard specified in §170.210(a)(2).</p>
		<p>Final Rule Text: §170.302(u) <u>General encryption.</u> Encrypt and decrypt electronic health information in accordance with the standard specified in §170.210(a)(1), unless the Secretary determines that the use of such algorithm would pose a significant security risk for Certified EHR Technology. §170.302(v) <u>Encryption when exchanging electronic health information.</u> Encrypt and decrypt electronic health information when exchanged in accordance with the standard specified in §170.210(a)(2).</p>
<p>Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities</p>	<p>Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process</p>	<p>Interim Final Rule Text: Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in §170.210(e).</p>
		<p>Final Rule Text: §170.302(w) Certification criterion made optional, while the text of this certification criterion remains unchanged.</p>

GENERAL CERTIFICATION CRITERIA FOR COMPLETE EHRs or EHR MODULES

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
N/A	N/A	<p>Interim Final Rule Text: N/A</p> <hr/> <p>Final Rule Text: §170.302(n) <u>Automated measure calculation.</u> For each meaningful use objective with a percentage-based measure, electronically record the numerator and denominator and generate a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.</p>

APPENDIX B

SPECIFIC CERTIFICATION CRITERIA FOR COMPLETE EHRs or EHR MODULES DESIGNED FOR AN AMBULATORY SETTING

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
<p>Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines</p>	<p>More than 30% of unique patients with at least one medication in their medication list seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one medication order entered using CPOE</p>	<p>Interim Final Rule Text: Enable a user to electronically record, store, retrieve, and manage, at a minimum, the following order types: (1) Medications; (2) Laboratory; (3) Radiology/imaging; and (4) Provider referrals.</p>
		<p>Final Rule Text: §170.304(a) <u>Computerized provider order entry.</u> Enable a user to electronically record, store, retrieve, and modify, at a minimum, the following order types: (1) Medications; (2) Laboratory; and (3) Radiology/imaging.</p>
<p>Generate and transmit permissible prescriptions electronically (eRx)</p>	<p>More than 40% of all permissible Prescriptions written by the EP are transmitted electronically using certified EHR technology</p>	<p>Interim Final Rule Text: Enable a user to electronically transmit medication orders (prescriptions) for patients in accordance with the standards specified in §170.205(c).</p>
		<p>Final Rule Text: §170.304(b) <u>Electronic prescribing.</u> Enable a user to electronically generate and transmit prescriptions and prescription-related information in accordance with: (1) The standard specified in §170.205(b)(1) or §170.205(b)(2); and (2) The standard specified in 170.207(d).</p>

SPECIFIC CERTIFICATION CRITERIA FOR COMPLETE EHRs or EHR MODULES DESIGNED FOR AN AMBULATORY SETTING

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Record demographics <ul style="list-style-type: none"> • preferred language • gender • race • ethnicity • date of birth 	More than 50% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have demographics recorded as structured data	<p>Interim Final Rule Text: Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, insurance type, gender, race, ethnicity, and date of birth.</p> <p>Final Rule Text: §170.304(c) <u>Record demographics.</u> Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, gender, race, ethnicity, and date of birth. Enable race and ethnicity to be recorded in accordance with the standard specified at 170.207(f).</p>
Send reminders to patients per patient preference for preventive/follow-up care	More than 20% of all unique patients 65 years or older or 5 years old or younger were sent an appropriate reminder during the EHR reporting period	<p>Interim Final Rule Text: Electronically generate, upon request, a patient reminder list for preventive or follow-up care according to patient preferences based on demographic data, specific conditions, and/or medication list.</p> <p>Final Rule Text: §170.304(d) <u>Patient reminders.</u> Enable a user to electronically generate a patient reminder list for preventive or follow-up care according to patient preferences based on, at a minimum, the data elements included in:</p> <ol style="list-style-type: none"> (1) Problem list; (2) Medication list; (3) Medication allergy list; (4) Demographics; and (5) Laboratory test results.
Implement one clinical decision support rule relevant to specialty or high clinical priority along with the ability to track	Implement one clinical decision support rule	<p>Interim Final Rule Text: (1) <u>Implement rules.</u> Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) according to specialty or clinical priorities that use demographic data, specific patient diagnoses, conditions, diagnostic</p>

SPECIFIC CERTIFICATION CRITERIA FOR COMPLETE EHRs or EHR MODULES DESIGNED FOR AN AMBULATORY SETTING

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
compliance that rule		<p>test results and/or patient medication list.</p> <p>(2) <u>Alerts</u>. Automatically and electronically generate and indicate in real-time, alerts and care suggestions based upon clinical decision support rules and evidence grade.</p> <p>(3) <u>Alert statistics</u>. Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.</p>
		<p>Final Rule Text: §170.304(e)</p> <p>(1) <u>Implement rules</u>. Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in: problem list; medication list; demographics; and laboratory test results.</p> <p>(2) <u>Notifications</u>. Automatically and electronically generate and indicate in real-time, notifications and care suggestions based upon clinical decision support rules.</p>
Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies), upon request	More than 50% of all patients of the EP or the inpatient or emergency departments of the eligible hospital or CAH (POS 21 or 23) who request an electronic copy of their health information are provided it within 3 business days	<p>Interim Final Rule Text: Enable a user to create an electronic copy of a patient’s clinical information, including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures in:</p> <p>(1) Human readable format; and</p> <p>(2) On electronic media or through some other electronic means in accordance with:</p> <p>(i) One of the standards specified in §170.205(a)(1);</p> <p>(ii) The standard specified in §170.205(a)(2)(i)(A), or, at a minimum, the version of the standard specified in §170.205(a)(2)(i)(B);</p> <p>(iii) One of the standards specified in §170.205(a)(2)(ii);</p> <p>(iv) At a minimum, the version of the standard specified in §170.205(a)(2)(iii); and</p> <p>(v) The standard specified in §170.205(a)(2)(iv).</p> <p>Final Rule Text: §170.304(f)</p> <p><u>Electronic copy of health information</u>. Enable a user to create an electronic copy of a patient’s clinical information, including, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list in:</p>

SPECIFIC CERTIFICATION CRITERIA FOR COMPLETE EHRs or EHR MODULES DESIGNED FOR AN AMBULATORY SETTING

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
		(1) Human readable format; and (2) On electronic media or through some other electronic means in accordance with: (i) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and (ii) For the following data elements the applicable standard must be used: (A) <u>Problems</u> . The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2); (B) <u>Laboratory test results</u> . At a minimum, the version of the standard specified in §170.207(c); and (C) <u>Medications</u> . The standard specified in §170.207(d).
Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, medication allergies) within four business days of the information being available to the EP	More than 10% of all unique patients seen by the EP are provided timely (available to the patient within four business days of being updated in the certified EHR technology) electronic access to their health information subject to the EP's discretion to withhold certain information	Interim Final Rule Text: Enable a user to provide patients with online access to their clinical information, including, at a minimum, lab test results, problem list, medication list, medication allergy list, immunizations, and procedures.
		Final Rule Text: §170.304(g) <u>Timely access</u> . Enable a user to provide patients with online access to their clinical information, including, at a minimum, lab test results, problem list, medication list, and medication allergy list.
Provide clinical summaries for patients for each office visit	Clinical summaries provided to patients for more than 50% of all office visits within 3 business days	Interim Final Rule Text: (1) <u>Provision</u> . Enable a user to provide clinical summaries to patients for each office visit that include, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations and procedures. (2) <u>Provided electronically</u> . If the clinical summary is provided electronically it must be: (i) Provided in human readable format; and (ii) On electronic media or through some other electronic means in accordance with: (A) One of the standards specified in §170.205(a)(1); (B) The standard specified in §170.205(a)(2)(i)(A), or, at a minimum, the version of the

SPECIFIC CERTIFICATION CRITERIA FOR COMPLETE EHRs or EHR MODULES DESIGNED FOR AN AMBULATORY SETTING

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
		<p>standard specified in §170.205(a)(2)(i)(B); (C) One of the standards specified in §170.205(a)(2)(ii); (D) At a minimum, the version of the standard specified in §170.205(a)(2)(iii); and (E) The standard specified in §170.205(a)(2)(iv).</p> <p>Final Rule Text: §170.304(h) <u>Clinical summaries.</u> Enable a user to provide clinical summaries to patients for each office visit that include, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list. If the clinical summary is provided electronically it must be: (1) Provided in human readable format; and (2) Provided on electronic media or through some other electronic means in accordance with: (i) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and (ii) For the following data elements the applicable standard must be used: (A) <u>Problems.</u> The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2); (B) <u>Laboratory test results.</u> At a minimum, the version of the standard specified in §170.207(c); and (C) <u>Medications.</u> The standard specified in §170.207(d).</p>
<p>Capability to exchange key clinical information (for example, problem list, medication list, medication allergies, diagnostic test results), among providers of care and patient authorized entities electronically ----- The EP, eligible hospital or CAH who transitions their</p>	<p>Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information ----- The EP, eligible hospital or CAH who transitions or refers their patient to another setting of care or provider of care provides a</p>	<p>Interim Final Rule Text: (1) <u>Electronically receive and display.</u> Electronically receive a patient's summary record, from other providers and organizations including, at a minimum, diagnostic tests results, problem list, medication list, medication allergy list, immunizations, and procedures in accordance with §170.205(a) and upon receipt of a patient summary record formatted in an alternate standard specified in §170.205(a)(1), display it in human readable format. (2) <u>Electronically transmit.</u> Enable a user to electronically transmit a patient summary record to other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures in accordance with: (i) One of the standards specified in §170.205(a)(1); (ii) The standard specified in §170.205(a)(2)(i)(A), or, at a minimum, the version of the standard</p>

SPECIFIC CERTIFICATION CRITERIA FOR COMPLETE EHRs or EHR MODULES DESIGNED FOR AN AMBULATORY SETTING

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
<p>patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary of care record for</p>	<p>summary of care record for more than 50% of transitions of care and referrals</p>	<p>specified in §170.205(a)(2)(i)(B); (iii) One of the standards specified in §170.205(a)(2)(ii); (iv) At a minimum, the version of the standard specified in §170.205(a)(2)(iii); and (v) The standard specified in §170.205(a)(2)(iv).</p> <p>Final Rule Text: §170.304(i) (1) <u>Electronically receive and display</u>. Electronically receive and display a patient’s summary record, from other providers and organizations including, at a minimum, diagnostic tests results, problem list, medication list, and medication allergy list in accordance with the standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2). Upon receipt of a patient summary record formatted according to the alternative standard, display it in human readable format. (2) <u>Electronically transmit</u>. Enable a user to electronically transmit a patient summary record to other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list in accordance with: (i) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and (ii) For the following data elements the applicable standard must be used: (A) <u>Problems</u>. The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2); (B) <u>Laboratory test results</u>. At a minimum, the version of the standard specified in 170.207(c); and (C) <u>Medications</u>. The standard specified in §170.207(d).</p>

APPENDIX C

SPECIFIC CERTIFICATION CRITERIA FOR COMPLETE EHRs or EHR MODULES DESIGNED FOR AN INPATIENT SETTING

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
<p>Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines</p>	<p>More than 30% of unique patients with at least one medication in their medication list seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one medication order entered using CPOE</p>	<p>Interim Final Rule Text: Enable a user to electronically record, store, retrieve, and manage, at a minimum, the following order types: (1) Medications; (2) Laboratory; (3) Radiology/imaging; (4) Blood bank; (5) Physical therapy; (6) Occupational therapy; (7) Respiratory therapy; (8) Rehabilitation therapy; (9) Dialysis; (10) Provider consults; and (11) Discharge and transfer.</p> <p>Final Rule Text: §170.306(a) <u>Computerized provider order entry.</u> Enable a user to electronically record, store, retrieve, and modify, at a minimum, the following order types: (1) Medications; (2) Laboratory; and (3) Radiology/imaging.</p>
<p>Record demographics</p> <ul style="list-style-type: none"> • preferred language • gender • race • ethnicity • date of birth • date and preliminary cause of 	<p>More than 50% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have demographics recorded as structured data</p>	<p>Interim Final Rule Text: Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, insurance type, gender, race, ethnicity, date of birth, and date and cause of death in the event of mortality.</p> <p>Final Rule Text: §170.306(b)</p>

SPECIFIC CERTIFICATION CRITERIA FOR COMPLETE EHRs or EHR MODULES DESIGNED FOR AN INPATIENT SETTING

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
death in the event of mortality in the eligible hospital or CAH		<u>Record demographics.</u> Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, gender, race, ethnicity, date of birth, and date and preliminary cause of death in the event of mortality. Enable race and ethnicity to be recorded in accordance with the standard specified at §170.207(f).
Record advance directives for patients 65 years old or older	More than 50% of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) have an indication of an advance directive status recorded	<p>Interim Final Rule Text: N/A</p> <p>Final Rule Text: §170.306(h) <u>Advance directives.</u> Enable a user to electronically record whether a patient has an advance directive.</p>
Implement one clinical decision support rule related to a high priority hospital condition along with the ability to track compliance with that rule	Implement one clinical decision support rule	<p>Interim Final Rule Text:</p> <p>(1) <u>Implement rules.</u> Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy/contraindication checking) according to a high priority hospital condition that use demographic data, specific patient diagnoses, conditions, diagnostic test results and/or patient medication list.</p> <p>(2) <u>Alerts.</u> Automatically and electronically generate and indicate in real-time, alerts and care suggestions based upon clinical decision support rules and evidence grade.</p> <p>(3) <u>Alert statistics.</u> Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.</p> <p>Final Rule Text: §170.306(c)</p> <p>(1) <u>Implement rules.</u> Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in: problem list; medication list; demographics; and laboratory test results.</p> <p>(2) <u>Notifications.</u> Automatically and electronically generate and indicate in real-time, notifications and care suggestions based upon clinical decision support rules.</p>

SPECIFIC CERTIFICATION CRITERIA FOR COMPLETE EHRs or EHR MODULES DESIGNED FOR AN INPATIENT SETTING

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
<p>Provide patients with an electronic copy of their health Information (including diagnostic test results, problem list, medication lists, medication allergies, discharge summary, procedures), upon request</p>	<p>More than 50% of all patients of the EP or the inpatient or emergency departments of the eligible hospital or CAH (POS 21 or 23) who request an electronic copy of their health information are provided it within 3 business days</p>	<p>Interim Final Rule Text: Enable a user to create an electronic copy of a patient’s clinical information, including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, procedures, and discharge summary in: (1) Human readable format; and (2) On electronic media or through some other electronic means in accordance with: (i) One of the standards specified in §170.205(a)(1); (ii) The standard specified in §170.205(a)(2)(i)(A), or, at a minimum, the version of the standard specified in §170.205(a)(2)(i)(B); (iii) One of the standards specified in §170.205(a)(2)(ii); (iv) At a minimum, the version of the standard specified in §170.205(a)(2)(iii); and (v) The standard specified in §170.205(a)(2)(iv).</p> <p>Final Rule Text: §170.306(d) (1) Enable a user to create an electronic copy of a patient’s clinical information, including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, and procedures: (i) In human readable format; and (ii) On electronic media or through some other electronic means in accordance with: (A) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and (B) For the following data elements the applicable standard must be used: (1) <u>Problems</u>. The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2); (2) <u>Procedures</u>. The standard specified in §170.207(b)(1) or §170.207(b)(2); (3) <u>Laboratory test results</u>. At a minimum, the version of the standard specified in §170.207(c); and (4) <u>Medications</u>. The standard specified in §170.207(d). (2) Enable a user to create an electronic copy of a patient’s discharge summary in human readable format and on electronic media or through some other electronic means.</p>

SPECIFIC CERTIFICATION CRITERIA FOR COMPLETE EHRs or EHR MODULES DESIGNED FOR AN INPATIENT SETTING

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
<p>Provide patients with an electronic copy of their discharge instructions at time of discharge, upon request</p>	<p>More than 50% of all patients who are discharged from an eligible hospital or CAH's inpatient department or emergency department (POS 21 or 23) and who request an electronic copy of their discharge instructions are provided it</p>	<p>Interim Final Rule Text: Enable a user to create an electronic copy of the discharge instructions and procedures for a patient, in human readable format, at the time of discharge on electronic media or through some other electronic means.</p> <p>Final Rule Text: §170.306(e) <u>Electronic copy of discharge instructions.</u> Enable a user to create an electronic copy of the discharge instructions for a patient, in human readable format, at the time of discharge on electronic media or through some other electronic means.</p>
<p>Capability to exchange key clinical information (for example, discharge summary, procedures, problem list, medication list, medication allergies, diagnostic test results), among providers of care and patient authorized entities electronically</p> <p>-----</p> <p>The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary of care record for each transition of care or referral</p>	<p>Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information</p> <p>-----</p> <p>The EP, eligible hospital or CAH who transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50% of transitions of care and referrals</p>	<p>Interim Final Rule Text: (1) <u>Electronically receive and display.</u> Electronically receive a patient's summary record from other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, procedures, and discharge summary in accordance with §170.205(a) and upon receipt of a patient summary record formatted in an alternate standard specified in §170.205(a)(1), display it in human readable <u>format.</u> (2) <u>Electronically transmit.</u> Enable a user to electronically transmit a patient's summary record to other providers and organizations including, at a minimum, diagnostic results, problem list, medication list, medication allergy list, immunizations, procedures, and discharge summary in accordance with: (i) One of the standards specified in §170.205(a)(1); (ii) The standard specified in §170.205(a)(2)(i)(A), or, at a minimum, the version of the standard specified in §170.205(a)(2)(i)(B); (iii) One of the standards specified in §170.205(a)(2)(ii); (iv) At a minimum, the version of the standard specified in §170.205(a)(2)(iii); and (v) The standard specified in §170.205(a)(2)(iv).</p> <p>Final Rule Text: §170.306(f)</p>

SPECIFIC CERTIFICATION CRITERIA FOR COMPLETE EHRs or EHR MODULES DESIGNED FOR AN INPATIENT SETTING

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
		<p>(1) <u>Electronically receive and display</u>. Electronically receive and display a patient’s summary record from other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, and procedures in accordance with the standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2). Upon receipt of a patient summary record formatted according to the alternative standard, display it in human readable format.</p> <p>(2) <u>Electronically transmit</u>. Enable a user to electronically transmit a patient’s summary record to other providers and organizations including, at a minimum, diagnostic results, problem list, medication list, medication allergy list, and procedures in accordance with:</p> <p>(i) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and</p> <p>(ii) For the following data elements the applicable standard must be used:</p> <p>(A) <u>Problems</u>. The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2);</p> <p>(B) <u>Procedures</u>. The standard specified in §170.207(b)(1) or §170.207(b)(2);</p> <p>(C) <u>Laboratory test results</u>. At a minimum, the version of the standard specified in §170.207(c); and</p> <p>(D) <u>Medications</u>. The standard specified in §170.207(d).</p>
<p>Capability to submit electronic data on reportable (as required by state or local law) lab results to public health agencies and actual submission in accordance with applicable law and practice</p>	<p>Performed at least one test of certified EHR technology’s capacity to provide electronic submission of reportable lab results to public health agencies and follow-up submission if the test is successful (unless none of the public health agencies to which eligible hospital or CAH submits such information have the capacity to receive the information electronically)</p>	<p>Interim Final Rule Text: Electronically record, retrieve, and transmit reportable clinical lab results to public health agencies in accordance with the standard specified in §170.205(f)(1) and, at a minimum, the version of the standard specified in §170.205(f)(2).</p> <p>Final Rule Text: §170.306(g) <u>Reportable lab results</u>. Electronically record, modify, retrieve, and submit reportable clinical lab results in accordance with the standard (and applicable implementation specifications) specified in §170.205(c) and, at a minimum, the version of the standard specified in §170.207(c).</p>

APPENDIX D

ADOPTED STANDARDS and IMPLEMENTATION SPECIFICATIONS

Purpose	Interim Final Rule Standards/Implementation Specifications	Final Rule Standards/Implementation Specifications
Content Exchange Standards		
Patient Summary Record	<p><u>Standards:</u></p> <ul style="list-style-type: none"> HL7 Clinical Document Architecture (CDA) Release 2, Continuity of Care Document (CCD) - OR - ASTM E2369 Standard Specification for Continuity of Care Record and Adjunct to ASTM E2369 <p><u>Implementation Specifications:</u></p> <ul style="list-style-type: none"> None adopted. 	<p><u>Standards:</u></p> <ul style="list-style-type: none"> HL7 Clinical Document Architecture (CDA) Release 2, Continuity of Care Document (CCD) - OR - ASTM E2369 Standard Specification for Continuity of Care Record and Adjunct to ASTM E2369 <p><u>Implementation Specifications:</u></p> <ul style="list-style-type: none"> The Healthcare Information Technology Standards Panel (HITSP) Summary Documents Using HL7 CCD Component HITSP/C32
Electronic Prescribing	<p><u>Standards:</u></p> <ul style="list-style-type: none"> The National Council for the Prescription Drug Programs (NCPDP) Prescriber/Pharmacist Interface SCRIPT standard, Implementation Guide Version 8, Release 1 (Version 8.1) October 2005 - OR - NCPDP SCRIPT 8.1 and NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 	<p><u>Standards:</u></p> <ul style="list-style-type: none"> The National Council for the Prescription Drug Programs (NCPDP) Prescriber/Pharmacist Interface SCRIPT standard, Implementation Guide Version 8, Release 1 (Version 8.1) October 2005 - OR - NCPDP SCRIPT Standard, Implementation Guide, Version 10.6
Drug Formulary	<p><u>Standard:</u></p> <ul style="list-style-type: none"> NCPDP Formulary & Benefits Standard1.0 	<p><u>Standards:</u></p> <ul style="list-style-type: none"> None adopted.

ADOPTED STANDARDS and IMPLEMENTATION SPECIFICATIONS

Purpose	Interim Final Rule Standards/Implementation Specifications	Final Rule Standards/Implementation Specifications
Administrative Transactions	<p><u>Standards:</u></p> <ul style="list-style-type: none"> • X12 4010A1 and NCPDP 5.1 <p><u>Implementation Specifications:</u></p> <ul style="list-style-type: none"> • Phase I of the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) 	<p><u>Standards:</u></p> <ul style="list-style-type: none"> • None adopted. <p><u>Implementation Specifications:</u></p> <ul style="list-style-type: none"> • None adopted.
Submission of Lab Results to Public Health Agencies	<p><u>Standard:</u></p> <ul style="list-style-type: none"> • HL7 2.5.1 <p><u>Implementation Specifications:</u></p> <ul style="list-style-type: none"> • None adopted. 	<p><u>Standard:</u></p> <ul style="list-style-type: none"> • HL7 2.5.1 <p><u>Implementation specifications:</u></p> <ul style="list-style-type: none"> • HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1
Public Health Surveillance and Reporting	<p><u>Standards:</u></p> <ul style="list-style-type: none"> • HL7 2.3.1 - OR - • HL7 2.5.1 <p><u>Implementation Specifications:</u></p> <ul style="list-style-type: none"> • None adopted. 	<p><u>Standards:</u></p> <ul style="list-style-type: none"> • HL7 2.3.1 - OR - • HL7 2.5.1 <p><u>Implementation specifications:</u></p> <ul style="list-style-type: none"> • Public Health Information Network HL7 Version 2.5 Message Structure Specification for National Condition Reporting Final Version 1.0 and Errata and Clarifications National Notification Message Structural Specification
Immunization Reporting to Registries	<p><u>Standards:</u></p> <ul style="list-style-type: none"> • HL7 2.3.1 - OR - • HL7 2.5.1 	<p><u>Standards:</u></p> <ul style="list-style-type: none"> • HL7 2.3.1 - OR - • HL7 2.5.1

ADOPTED STANDARDS and IMPLEMENTATION SPECIFICATIONS

Purpose	Interim Final Rule Standards/Implementation Specifications	Final Rule Standards/Implementation Specifications
	<p><u>Implementation Specifications:</u></p> <ul style="list-style-type: none"> • None adopted. 	<p><u>Implementation specifications:</u></p> <ul style="list-style-type: none"> • Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol Implementation Guide Version 2.2 • HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0
Quality Reporting	<p><u>Standard:</u></p> <ul style="list-style-type: none"> • The CMS Physician Quality Reporting Initiative (PQRI) 2008 Registry XML Specification <p><u>Implementation specifications:</u></p> <ul style="list-style-type: none"> • Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry 	<p><u>Standard:</u></p> <ul style="list-style-type: none"> • The CMS Physician Quality Reporting Initiative (PQRI) 2009 Registry XML Specification <p><u>Implementation specifications:</u></p> <ul style="list-style-type: none"> • Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry
Vocabulary Standards		
Problem List	<p><u>Standard:</u></p> <ul style="list-style-type: none"> • The code set specified at 45 CFR 162.1002(a)(1) for the indicated conditions (i.e. ICD9-CM) <li style="text-align: center;">- OR - • International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) July 2009 version 	<p><u>Standard:</u></p> <ul style="list-style-type: none"> • The code set specified at 45 CFR 162.1002(a)(1) for the indicated conditions (i.e. ICD9-CM) <li style="text-align: center;">- OR - • International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) July 2009 version

ADOPTED STANDARDS and IMPLEMENTATION SPECIFICATIONS

Purpose	Interim Final Rule Standards/Implementation Specifications	Final Rule Standards/Implementation Specifications
Procedures	<p>Standard:</p> <ul style="list-style-type: none"> The code set specified at 45 CFR 162.1002(a)(2). (i.e. ICD-9) <p style="text-align: center;">- OR -</p> <ul style="list-style-type: none"> The code set specified at 45 CFR 162.1002(a)(5) (i.e. CPT-4) 	<p>Standard:</p> <ul style="list-style-type: none"> The code set specified at 45 CFR 162.1002(a)(2). (i.e. ICD-9) <p style="text-align: center;">- OR -</p> <ul style="list-style-type: none"> The code set specified at 45 CFR 162.1002(a)(5) (i.e. CPT-4)
Vital signs	<p>Standard:</p> <ul style="list-style-type: none"> None adopted. 	<p>Standard:</p> <ul style="list-style-type: none"> None adopted.
Units of Measure	<p>Standard:</p> <ul style="list-style-type: none"> None adopted. 	<p>Standard:</p> <ul style="list-style-type: none"> None adopted.
Medication Allergies	<p>Standard:</p> <ul style="list-style-type: none"> None adopted. 	<p>Standard:</p> <ul style="list-style-type: none"> None adopted.
Medication Lists	<p>Standard:</p> <ul style="list-style-type: none"> Any source vocabulary that is included in RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine. 	<p>Standard:</p> <ul style="list-style-type: none"> None adopted.
Lab Orders and Results	<p>Standard:</p> <ul style="list-style-type: none"> Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, when such codes were received within an electronic transmission from a laboratory 	<p>Standard:</p> <ul style="list-style-type: none"> Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, when such codes were received within an electronic transmission from a laboratory

ADOPTED STANDARDS and IMPLEMENTATION SPECIFICATIONS

Purpose	Interim Final Rule Standards/Implementation Specifications	Final Rule Standards/Implementation Specifications
Electronic Prescribing	<p>Standard:</p> <ul style="list-style-type: none"> Any code set by an RxNorm drug data source provider that is identified by the United States National Library of Medicine as being a complete data set integrated within RxNorm. 	<p>Standard:</p> <ul style="list-style-type: none"> Any source vocabulary that is included in RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine.
Submission of Lab Results to Public Health Agencies	<p>Standard:</p> <ul style="list-style-type: none"> Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, when such codes were received within an electronic transmission from a laboratory 	<p>Standard:</p> <ul style="list-style-type: none"> Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, , when such codes were received within an electronic transmission from a laboratory
Public Health Surveillance or Reporting	<p>Standard:</p> <ul style="list-style-type: none"> According to applicable Public Health Agency requirements. 	<p>Standard:</p> <ul style="list-style-type: none"> None adopted.
Immunizations	<p>Standard:</p> <ul style="list-style-type: none"> HL7 Standard Code Set CVX - Vaccines Administered, July 30, 2009 version 	<p>Standard:</p> <ul style="list-style-type: none"> HL7 Standard Code Set CVX - Vaccines Administered, July 30, 2009 version
Race/Ethnicity	<p>Standard:</p> <ul style="list-style-type: none"> None adopted. 	<p>Standard:</p> <ul style="list-style-type: none"> The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, October 30, 1997

ADOPTED STANDARDS and IMPLEMENTATION SPECIFICATIONS

Purpose	Interim Final Rule Standards/Implementation Specifications	Final Rule Standards/Implementation Specifications
Privacy Standards		
Encryption and Decryption of Electronic Health Information	<p><u>Standards:</u></p> <ul style="list-style-type: none"> • In general - Any symmetric 128 bit fixed-block cipher algorithm capable of using a 128, 192, or 256 bit encryption key must be used.+ • For data exchange - An encrypted and integrity protected link must be implemented (e.g., TLS, IPv6, IPv4 with IPsec). 	<p><u>Standards:</u></p> <ul style="list-style-type: none"> • In general - Any encryption algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2. • For data exchange - Any encrypted and integrity protected link.
Record Actions Related to Electronic Health Information (Audit Log)	<p><u>Standard:</u></p> <ul style="list-style-type: none"> • The date, time, patient identification, and user identification must be recorded when electronic health information is created, modified, accessed, or deleted; and an indication of which action(s) occurred and by whom must also be recorded (e.g., modification). 	<p><u>Standard:</u></p> <ul style="list-style-type: none"> • The date, time, patient identification, and user identification must be recorded when electronic health information is created, modified, accessed, or deleted; and an indication of which action(s) occurred and by whom must also be recorded.
Verification that Electronic Health Information Has Not Been Altered in Transit	<p><u>Standard:</u></p> <ul style="list-style-type: none"> • A secure hashing algorithm must be used to verify that electronic health information has not been altered in transit. The secure hash algorithm used must be SHA-1 or higher (e.g., Federal Information Processing Standards (FIPS) Publication (PUB) Secure Hash Standard (SHS) FIPS PUB 180-3). 	<p><u>Standard:</u></p> <ul style="list-style-type: none"> • A hashing algorithm with a security strength equal to or greater than SHA-1 (Secure Hash Algorithm (SHA-1) as specified by the National Institute of Standards and Technology (NIST) in FIPS PUB 180-3 (October, 2008)) must be used to verify that electronic health information has not been altered.
Authentication	<p><u>Standard:</u></p> <ul style="list-style-type: none"> • Use of a cross-enterprise secure transaction that contains sufficient identity information such that the receiver can make access control decisions 	<p><u>Standard:</u></p> <ul style="list-style-type: none"> • None adopted.

ADOPTED STANDARDS and IMPLEMENTATION SPECIFICATIONS

Purpose	Interim Final Rule Standards/Implementation Specifications	Final Rule Standards/Implementation Specifications
	and produce detailed and accurate security audit trails (e.g., IHE Cross Enterprise User Assertion (XUA) with SAML identity assertions).	
Record Treatment, Payment, and Health Care Operations Disclosures	<p><u>Standard:</u></p> <ul style="list-style-type: none"> The date, time, patient identification, user identification, and a description of the disclosure must be recorded. 	<p><u>Standard:</u></p> <ul style="list-style-type: none"> The date, time, patient identification, user identification, and a description of the disclosure must be recorded for disclosures for treatment, payment, and health care operations, as these terms are defined at 45 CFR 164.501.