

**Summary of Interim Final Rule  
Health Information Technology: Initial Set of Standards,  
Implementation Specifications, and Certification Criteria for  
Electronic Health Record Technology**

[RIN 0991-AB58]

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# Summary of Interim Final Rule Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology

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## Introduction

On December 30, 2009, the Office of the National Coordinator (ONC) for Health Information Technology (HIT) put on public display an interim final rule specifying the initial set of standards, implementation specifications, and certification criteria for electronic health record (EHR) technology. This action was required to take place by December 31, 2009 under section 3004(b)(1) of the Public Health Service Act. The certification criteria adopted in this initial set establish the capabilities and related standards that certified EHR technology will need to include in order to, at a minimum, support the achievement of the proposed meaningful use Stage 1 by eligible professionals and eligible hospitals under the Medicare and Medicaid EHR Incentive Programs (see the separate summary of the relevant proposed rule for further details). ONC emphasizes that the initial set of standards, implementation specifications, and certification criteria adopted in the interim final rule is only “the beginning” of what is expected to be “an iterative approach to enhancing the interoperability, functionality, utility, and security of HIT.”

The interim final rule is scheduled to be published in the January 13, 2010 issue of the *Federal Register*. Although the interim final rule is effective February 12, 2010, provision is made for a 60-day comment period, which will end at 5:00 P.M. on March 15, 2010. The ONC anticipates publishing a final rule in 2010. Early in 2010, the ONC also plans to issue a notice of proposed rulemaking to establish the policies for the certification of HIT and the process a certification body will need to follow to become an authorized certification body. That document will also be summarized separately once it becomes available.

Please note that the interim final rule deals with very technical issues and will be of special interest to EHR vendors, HIT experts, and any organization hoping to play a role in the certification of EHR products.

## Definitions

The interim final rule defines “standard” to mean “a technical, functional, or performance-based rule, condition, requirement, or specification that stipulates instructions, fields, codes, data, materials, or actions.” It defines “implementation specifications” as “specific requirements or instructions for implementing a standard” (that is, the HIPAA regulatory definition of this term). And “certification

criteria” is defined as “criteria: 1) to establish that health information technology meets applicable standards and implementation specifications adopted by the Secretary; or 2) that are used to test and certify that health information technology includes required capabilities.”

The interim final rule adopts the statutory definition of “Qualified EHR” at section 3000(13) of the Public Health Service Act without modification. It defines “EHR Module” as “any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary.”

ONC warns health care providers that elect to adopt and implement certified EHR Modules to “ensure that the certified EHR Modules they select are interoperable and can properly perform in their expected operational environment” but goes on to say that it believes that it will be common in the near future for Certified EHR Technology to be assembled from several replaceable and swappable EHR Modules. The term “complete EHR” is defined to mean “EHR technology that has been developed to meet all applicable certification criteria adopted by the Secretary.”

The interim final rule defines “Certified EHR Technology” as 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 notes that it has adopted specific certification criteria that are only applicable to complete EHRs and EHR modules designed for use in an ambulatory setting or an inpatient setting. Finally, the interim final rule defines the term “disclosure” as “the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information.”

### **Certification Criteria**

The ONC has used the proposed objectives in the Medicare and Medicaid EHR Incentive Programs proposed rule to identify the initial set of certification criteria adopted in the interim final rule and has linked the certification criteria to these objectives. This presumably means that any changes in the objectives contained in the proposed rule would subsequently be mirrored by adjustments in the interim final rule. All certification criteria are prefaced with the statement “A Complete EHR or EHR Module must include the capability to:” in order to create uniformity in the way each certification criterion is read. ONC also notes that certain types of standards in the interim final rule are considered a floor for certification. Table 1 of the interim final rule lists 27 proposed Stage 1 meaningful use objectives and the detailed certification criteria to support achievement of these objectives by eligible professionals (EPs) and eligible hospitals (in some cases, the certification criteria for a single objective vary for eligible professionals and eligible hospitals and in other cases they are identical, and some objectives apply only to eligible professionals or eligible hospitals).

The objectives and the certification criteria are very closely linked as demonstrated by the following examples taken from Table 1.

<b>Proposed Meaningful Use Stage 1 Objective</b>	<b>Certification Criteria to Support the Achievement of Meaningful Use Stage 1 by Eligible Professionals</b>	<b>Certification Criteria to Support the Achievement of Meaningful Use Stage 1 by Eligible Hospitals</b>
	<u>A Complete EHR or EHR Module must include the capability to:</u>	
Use Computerized Provider Order Entry (CPOE)	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	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.
Record smoking status for patients 13 years old or older.	Enable a user to electronically record, modify, and retrieve the smoking status of a patient to: current smoker, former smoker, or never smoked.	
Implement 5 clinical decision support rules.	<ol style="list-style-type: none"> <li>1. 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 test results and/or patient medication list.</li> <li>2. Automatically and electronically generate and indicate (e.g., pop-up message or sound) in real-time, alerts and care suggestions based upon clinical decision support rules and evidence grade.</li> <li>3. Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.</li> </ol>	<ol style="list-style-type: none"> <li>1. 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.</li> <li>2. Automatically and electronically generate and indicate (e.g., pop-up message or sound) in real-time, alerts and care suggestions based upon clinical decision support rules and evidence grade.</li> <li>3. Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.</li> </ol>

CMS requests public comment on whether any of the adopted certification criteria are insufficiently specific to be used to test and certify Complete EHRs or

EHR Modules with reasonable assurance that the technology will effectively support the delivery of health care as well as the achievement of meaningful use Stage1, once finalized.

### **Standards**

The interim final rule adopts standards in four categories:

1. Vocabulary Standards (i.e., standardized nomenclatures and code sets used to describe clinical problems and procedures, medications, and allergies);
2. Content Exchange Standards (i.e., standards used to share clinical information such as clinical summaries, prescriptions, and structured electronic documents);
3. Transport Standards (i.e., standards used to establish a common, predictable, secure communication protocol between systems); and
4. Privacy and Security Standards (e.g., authentication, access control, transmission security) which relate to and span across all of the other types of standards.

Table 2A of the interim final rule lists the adopted Content Exchange (Cx) and Vocabulary (V) Standards to support meaningful use Stage 1 (for various purposes), and identifies candidate standards that ONC believes should be adopted and required in certification criteria to support meaningful use Stage 2. An edited version of Table 2A is shown below (acronyms in the table are explained and relevant material found elsewhere in the interim final rule has been added to the table).

<b>Purpose</b>	<b>Category</b>	<b>Adopted Standard for Stage 1</b>	<b>Candidate Standard for Stage 2</b>
<b><i>Patient Summary Record</i></b>	Cx	Health Level Seven (HL7) Clinical Document Architecture (CDA) Release 2 (R2) Continuity of Care Document (CCD) Level 2 or ASTM Continuity of Care Record (CCR)	Alternatives expected to be narrowed based on HIT Standards Committee recommendations
• Problem List	V	Applicable HIPAA code set required by law (i.e., ICD-9-CM); or SNOMED CT®	Applicable HIPAA code set required by law (e.g., ICD-10-CM) or SNOMED CT®
• Medication List	V	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

Purpose	Category	Adopted Standard for Stage 1	Candidate Standard for Stage 2
		RxNorm <sup>+</sup>	
• Medication Allergy List	V	No standard adopted at this time.	Unique Ingredient Identifier (UNII)
• Procedures	V	Applicable HIPAA code sets required by law (i.e., ICD-9-CM or CPT-4®)	Applicable HIPAA code sets required by law (i.e., ICD-10-PCS or CPT-4®)
• Vital Signs	V	No standard adopted at this time.	CDA template
• Units of Measure	V	No standard adopted at this time.	Unified Code for Units of Measure (UCUM)
• Lab Orders and Results	V	Logical Observation Identifiers Names and Codes (LOINC®) when LOINC® codes have been received from a laboratory	LOINC®
<b>Drug Formulary Check</b>	Cx	Applicable Part D standard required by law (i.e., National Council for Prescription Drug Programs (NCPDP) Formulary & Benefits Standard 1.0)	Applicable Part D standard required by law
<b>Electronic Prescribing</b>	Cx	Applicable Part D standard required by law (e.g., NCPDP SCRIPT 8.1) or NCPDP SCRIPT 8.1 and NCPDP SCRIPT 10.6	NCPDP SCRIPT 10.6
	V	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 <sup>+</sup>	RxNorm
<b>Administrative Transactions</b>	Cx	Applicable HIPAA transaction standards required by law. <i>Since the 5010 and D.0 HIPAA transaction standards are required to be used in the second year of meaningful use Stage 1, Certified EHR Technology will need to be capable of using both Versions 4010/4010A and 5010 and Versions 5.1 and D.0, respectively.</i>	Applicable HIPAA transaction standards required by law
<b>Quality Reporting</b>	Cx	CMS PQRI 2008 Registry XML Specification <sup>#,†</sup> <i>ONC seeks comment on whether HL7 Quality Reporting Document Architecture (QRDA) Implementation Guide based on HL7 CDA Release 2 is mature enough</i>	Potentially newer version(s) or standards based on HIT Standards Committee input

Purpose	Category	Adopted Standard for Stage 1	Candidate Standard for Stage 2
		<i>to be used as a standard during meaningful use Stage 1.</i>	
<b>Submission of Lab Results to Public Health Agencies</b>	Cx	HL7 2.5.1	Potentially newer version(s) or standards based on HIT Standards Committee recommendations
	V	LOINC® when LOINC® codes have been received from a laboratory	LOINC®, UCUM, and SNOMED CT® or applicable public health agency requirements
<b>Submission to Public Health Agencies for Surveillance or Reporting (excluding adverse events)</b>	Cx	HL7 2.3.1 or HL7 2.5.1	Potentially newer version(s) or standards based on HIT Standards Committee input
	V	According to applicable public health agency requirements	Geocoded Interoperable Population Summary Exchange (GIPSE) or according to applicable public health agency requirements
<b>Submission to Immunization Registries</b>	Cx	HL7 2.3.1 or HL7 2.5.1	Potentially newer version(s) or standards based on HIT Standards Committee recommendations
	V	The standard code set CVX – Vaccines Administered (CVX), maintained by the National Center of Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention <sup>†</sup>	CVX

# HIT Standards Committee recommended this standard to the National Coordinator but it was not part of the prior ONC process.

\* Standard was neither recommended by the HIT Standards Committee nor part of the prior ONC process.

+ Standard is not a voluntary consensus standard.

In the case of Transport Standards, ONC adopts the Simple Object Access Protocol (SOAP) version 1.2 and Representational state transfer (REST) to provide standard ways for systems to interact with each other. SOAP, which relies on Extensible Markup Language (XML) as its message format, is a protocol for exchanging structural information in the implementation of Web Services in computer networks. The SOAP architecture consists of several layers of specifications for message format, message exchange patterns, underlying transport protocol bindings, message processing models, and protocol extensibility. REST is a style of software architecture for distributed hypermedia systems such as the Internet.

Table 2B of the interim final rule lists the adopted privacy and security standards for various purposes. An edited version of Table 2B is shown below (once again, acronyms in the table are explained).

<b>Purpose</b>	<b>Adopted Standard</b>
<b><i>General Encryption and Decryption of Electronic Health Information</i></b>	A symmetric 128 bit fixed-block cipher algorithm capable of using a 128, 192, or 256 bit encryption key must be used (e.g., Federal Information Processing Standards (FIPS) 197 Advanced Encryption Standard (AES), Nov 2001). <sup>+</sup>
<b><i>Encryption and Decryption of Electronic Health Information for Exchange</i></b>	An encrypted and integrity protected link must be implemented (e.g., TLS, IPv6, IPv4 with IPsec). <sup>+</sup>
<b><i>Record Actions Related to Electronic Health Information (i.e., audit log)</i></b>	The date, time, patient identification (name or number), and user identification (name or number) must be recorded when electronic health information is created, modified, deleted, or printed. An indication of which action(s) occurred must also be recorded (e.g., modifications). <sup>+</sup>
<b><i>Verification that Electronic Health Information has not been Altered in Transit</i></b>	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., FIPS Publication (PUB) Secure Hash Standard (SHS) FIPS PUB 180-3). <sup>+</sup>
<b><i>Cross-Enterprise Authentication</i></b>	Use of a cross-enterprise secure transaction that contains sufficient identity information such that the receiver can make access control decisions and produce detailed and accurate security audit trails (e.g., IHE Cross Enterprise User Assertion (XUA) with SAML identity assertions). <sup>+</sup>
<b><i>Record Treatment, Payment, and Health Care Operations Disclosures</i></b>	The date, time, patient identification (name or number), user identification (name or number), and a description of the disclosure must be recorded. <sup>+</sup>

+ Standard is not a voluntary consensus standard.

ONC notes that it intends to work with the HIT Policy Committee and the HIT Standards Committee to explore capabilities beyond those explicitly specified in the HIPAA Security Rule and, in the future, adopt, where possible, new certification criteria and standards to improve the capabilities Certified EHR Technology can provide to protect health information. ONC also emphasizes the following:

- The interim final rule does not change existing HIPAA Privacy Rule or Security Rule requirements, guarantee compliance with those requirements, or absolve an eligible professional, eligible hospital, or other health care provider from having to comply with any applicable provision of the HIPAA Privacy or Security Rules.
- The use of Certified EHR Technology alone does not equate to compliance with the HIPAA Privacy or Security Rules.

## **Implementation Specifications**

ONC notes that very few implementation specifications are widely used and most are immature or too architecturally specific for adoption by large segments of the HIT industry before meaningful use Stage 2. ONC invites public comment on whether there are implementation specifications that are industry-tested and would not present a significant burden if adopted, and says it will consider adopting implementation specifications for any or all adopted standards “provided that there is convincing evidence submitted in public comment of the specifications’ maturity and widespread usage.” The above notwithstanding, the interim final rule adopts the following implementation specifications:

1. The Physician Quality Reporting Initiative (PQRI) Measure Specifications Manual for Claims and Registry (for the standard CMS PQRI 2008 Registry XML Specification);
2. The implementation specifications for the HIPAA standards for eligibility for health plan transactions and for health care claims or equivalent encounter information transactions; and
3. Phase 1 of the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE).

## **Additional Considerations, Clarifications, and Requests for Public Comments**

ONC invites public comment regarding industry readiness if it were to adopt certification criteria requiring the use of additional vocabularies and code sets in parallel with meaningful use Stage 2. ONC goes on to note that such certification criteria could include not only that Certified EHR Technology be capable of presenting information in human readable format (that is, a format that enables a human to read and easily comprehend the information presented regardless of the method of presentation, such as computer screen, handheld device, or electronic document), but also that it be capable of automatically incorporating certain vocabulary or code sets (i.e., machine readable information).

As noted above, the interim final rule adopts a certification criterion that requires the capability to record disclosures made for treatment, payment, and health care operations (but not other types of disclosures), and a requirement that a “description of the disclosure” be recorded (without specifying what should be included in such a description). ONC invites comments regarding the technical feasibility of recording the purpose or reason for a disclosure, to whom the disclosure was made (i.e., the recipient), and any other elements that may be beneficial for a patient to know about with respect to their health information. ONC also acknowledges that the Secretary has 6 months following the interim final rule’s adoption of standards on accounting for disclosures related to treatment, payment, and health care operations made through an EHR to modify the HIPAA Privacy Rule to require that HIPAA covered entities account for such

disclosures, and that the Secretary has the discretion to modify the compliance date for the revised accounting-for-disclosure regulations to as late as 2013 for HIPAA covered entities that acquire EHRs after January 1, 2009. The interim final rule states that the Secretary will address this compliance date in a later rulemaking.

Finally, ONC requests public comment:

- To inform future deliberations on whether specific certification criteria could be adopted to further promote the capabilities Certified EHR Technology should provide with respect to meeting the accessibility needs of individuals with disabilities, and with respect to the prevention and detection of potential fraud, waste and abuse; and
- Regarding the candidate standards to support meaningful use Stage 2 listed in Table 2A, especially feedback on implementation feasibility, maturity, and prevalence in the industry.

### **Regulatory Impact Analysis**

ONC believes it is reasonable to assume that a few hundred unique Complete EHRs and EHR Modules make up the available universe of HIT for health care providers, and that there will be very little growth in the market. ONC also believes that a significant number of EHRs previously certified by the Certification Commission for HIT (CCHIT) will only incur moderate costs to prepare for certification. ONC estimates that it will cost \$10,000 to \$250,000 per certification criterion to prepare a Complete EHR or EHR Module for testing and certification, or a one-time cost per EHR ranging from a low of \$500,000 to a high of \$2 million in the case of EHRs certified by CCHIT in 2008, and ranging from a low of \$1.2 million to a high of \$4.8 million in the case of other products.

ONC also believes that EHR Modules will play an increasingly important role and that they are most likely for the following 7 types of capabilities: electronic prescribing; administrative transactions; core clinical capabilities; computerized provider order entry; quality reporting; online patient portals; and interfacing with a health information organization to enable the electronic exchange of health information. During meaningful use Stage 1, ONC assumes there will be on average 7 EHR Modules prepared to be tested and certified for each of these 7 types or about 50 EHR Modules. ONC estimates the one-time costs to prepare such Modules for certification to applicable adopted certification criteria would range from a low of \$100,000 to a high of \$500,000 per module.

ONC further assumes that it will generally take 6 to 18 months for commercial vendors and open source developers of Complete EHRs and EHR Modules to prepare for testing and certification, and that more such vendors and developers will prepare their products for testing and certification in 2010 (45%) and 2011 (40%) rather than 2012 (15%).