

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

Brief Summary

The Interim Final Rule (IFR) from the Department of Health and Human Services (HHS) Office of the National Coordinator for HIT (ONC) implements the provisions of the American Recovery and Reinvestment Act of 2009 (ARRA) that authorize the development of certification standards/criteria for electronic health record (EHR) technology for the purposes of the Medicare/Medicaid “meaningful use” incentives programs.

The IFR was published in the January 13, 2010 *Federal Register*, and will go into effect 30 days after publication. A public comment period will be open for 60 days, after which ONC may (or may not) make modifications and readopt the rule.

Related Rulemakings

In addition to this IFR, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule in the January 13, 2010 *Federal Register* that defines “meaningful use” and implements the incentives programs for eligible professionals (EPs) and hospitals ([see the ACR summary here](#)). Thus, the criteria in the IFR establish the capabilities and related standards that certified EHR technology will need in order to support the achievement of CMS’ proposed Stage 1 of the meaningful use programs. The assumption is that ONC’s Stage 2 and 3 rulemakings on certification standards/criteria will coincide with CMS’s Stage 2 and 3 rulemakings on meaningful use.

In addition to ONC’s IFR and CMS’s proposed rule, ONC plans to release a proposed rule in early 2010 to establish an HHS certification process for EHR technology. The proposed rule will focus on how individual products may be able to achieve certification, and how certain organizations may become recognized certifiers/product-testers for the purposes of the meaningful use incentives programs.

Certified EHR Technology

Certified EHR Technology must be a “Complete EHR” or a combination of “EHR modules,” each of which meet the requirements of being an electronic record of health-related information on an individual that includes patient demographic and clinical health information (such as medical history and problem lists); provides clinical decision support and physician order entry; captures and queries information relevant to health care quality; and exchanges electronic health information with, and integrate such information from, other sources.

“Complete EHRs” vs. “EHR Modules”

Complete EHRs must meet all applicable certification criteria (see Table 1 below), and are typically considered traditional, comprehensive electronic medical records. On the other hand, *EHR Modules* can be any service, component, or combination thereof that fulfills the requirements of at least one certification criterion (see Table 1 below). Examples of EHR modules include, but are not limited to:

- Interface or other software program that provides the capability to exchange electronic health information;
- Open source software program that enables individuals online access to certain health information maintained by EHR technology;
- Clinical decision support rules engine;
- Software program used to submit public health information to public health authorities; and
- Quality measure reporting service or software program.

Note that each EHR module must be *individually* tested and certified—*combinations* of multiple certified modules are not. It will be the user’s responsibility to ensure their respective combination meets all applicable certification criteria necessary to meet the definition of “Certified EHR Technology.”

ONC notes that combining EHR modules requires diligence from the EP or hospital to ensure that the modules are able to communicate and work together to achieve meaningful use. As this requires a certain degree of knowledge and comfort with the technology, ONC anticipates that EHR modules will play an increasingly important role as the meaningful use incentives program evolves in Stage 2 and 3.

Certification Criteria

The certification criteria listed in Table 1 corresponds with the proposed Stage 1 meaningful use objectives in CMS's proposed rule. The objectives displayed below differ slightly from the objectives listed in ACR's summary of the proposed rule. This is because ACR's summary of the proposed rule focuses exclusively on objectives/measures for the Medicare incentives program for EPs, whereas the below table shows objectives/certification criteria for the hospital program as well as the EP program.

Table 1 - Certification Criteria

Proposed Meaningful Use Objectives for EPs (Stage 1)	Certification Criteria to Support the Achievement of Meaningful Use Stage 1 by Eligible Professionals
Use CPOE	<p><i>A Complete EHR or EHR Module must include to capability to:</i></p> <p>Enable a user to electronically record, store, retrieve, and manage, at a minimum, the following order types:</p> <ol style="list-style-type: none"> 1. Medications; 2. Laboratory; 3. Radiology/imaging; and 4. Provider referrals.
Implement drug-drug, drug-allergy, drug-formulary checks	<ol style="list-style-type: none"> 1. Automatically and electronically generate and indicate (e.g., pop-up message or sound) 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 CPOE. 2. Enable a user to electronically check if drugs are in a formulary or preferred drug list in accordance with the standard specified in Table 2A row 2. 3. Provide certain users with administrator rights to deactivate, modify, and add rules for drug-drug and drug-allergy checking. 4. Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.
Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT®	Enable a user to electronically record, modify, and retrieve a patient's problem list for longitudinal care (i.e., over multiple office visits) in accordance with the applicable standards% specified in Table 2A row 1.
Generate and transmit permissible prescriptions electronically (eRx)	Enable a user to electronically transmit medication orders (prescriptions) for patients in accordance with the standards specified in Table 2A row 3.
Maintain active medication list	Enable a user to electronically record, modify, and retrieve a patient's active medication list as well as medication history for longitudinal care (i.e., over multiple office visits) in accordance with the applicable standard specified in Table 2A row 1.
Maintain active medication allergy list	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 (i.e., over multiple office visits).
Record demographics: preferred language; insurance type; gender; race; ethnicity; date of birth	Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, insurance type, gender, race, ethnicity, and date of birth.
Record and chart changes in vital signs: height; weight; blood pressure; Calculate and display: BMI; Plot and display growth charts for children 2-20 years, including BMI.	<ol style="list-style-type: none"> 1. 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. Automatically calculate and display body mass index (BMI) based on a patient's height and weight. 3. Plot and electronically display, upon request, growth charts (height, weight, and BMI) for patients 2-20 years old.
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.

Incorporate clinical lab-test results into EHR as structured data	<ol style="list-style-type: none"> 1. Electronically receive clinical laboratory test results in a structured format and display such results in human readable format. 2. Electronically display in human readable format any clinical laboratory tests that have been received with LOINC® codes. 3. Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).6 4. Enable a user to electronically update a patient's record based upon received laboratory test results.
Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach	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.
Report ambulatory quality measures to CMS or the States	<ol style="list-style-type: none"> 1. Calculate and electronically display quality measure results as specified by CMS or states. 2. Enable a user to electronically submit calculated quality measures in accordance with the standard specified in Table 2A row 5.
Send reminders to patients per patient preference for preventive/ follow up care	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.
Implement 5 clinical decision support rules relevant to specialty or high clinical priority, including diagnostic test ordering, along with the ability to track compliance with those rules	<ol style="list-style-type: none"> 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. 2. Automatically and electronically generate and indicate (e.g., pop-up message or sound) in realtime, alerts and care suggestions based upon clinical decision support rules and evidence grade. 3. Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.
Check insurance Eligibility electronically from public and private payers	Enable a user to electronically record and display patients' insurance eligibility, and submit insurance eligibility queries to public or private payers and receive an eligibility response in accordance with the applicable standards specified in Table 2A row 4.
Submit claims electronically to public and private payers.	Enable a user to electronically submit claims to public or private payers in accordance with the applicable standards specified in Table 2A row 4.
Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies), upon request	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: 1) human readable format; and 2) accordance with the standards% specified in Table 2A row 1 to provide to a patient on electronic media, or through some other electronic means.
Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, allergies) within 96 hours of the information being available to the EP	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.
Provide clinical summaries for patients for each office visit	<ol style="list-style-type: none"> 1. Enable a user to provide clinical summaries to patients (in paper or electronic form) for each office visit that include, at a minimum, diagnostic test results, medication list, medication allergy list, procedures, problem list, and immunizations. 2. If the clinical summary is provided electronically (i.e., not printed), it must be provided in: 1) human readable format; and 2) accordance with the standards% specified in Table 2A row 1 to provide to a patient on

	electronic media, or through some other electronic means.
<p>Capability to exchange key clinical information (for example, problem list, medication list, allergies, diagnostic test results), among providers of care and patient authorized entities electronically</p> <p>Provide summary care record for each transition of care and referral</p>	<ol style="list-style-type: none"> 1. Electronically receive a patient summary record, from other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures and upon receipt of a patient summary record formatted in an alternative standard specified in Table 2A row 1, displaying it in human readable format. 2. 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 the standards% specified in Table 2A row 1.
Perform medication reconciliation at relevant encounters and each transition of care	Electronically complete medication reconciliation of two or more medication lists (compare and merge) into a single medication list that can be electronically displayed in real-time.
Capability to submit electronic data to immunization registries and actual submission where required and accepted	Electronically record, retrieve, and transmit immunization information to immunization registries in accordance with the standards% specified in Table 2A row 8 or in accordance with the applicable state-designated standard format.
Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice	Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	<ol style="list-style-type: none"> 1. 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. 2. Permit authorized users (who are authorized for emergency situations) to access electronic health information during an emergency. 3. Terminate an electronic session after a predetermined time of inactivity. 4. Encrypt and decrypt electronic health information according to user-defined preferences (e.g., backups, removable media, at log-on/off) in accordance with the standard specified in Table 2B row 1. 5. Encrypt and decrypt electronic health information when exchanged in accordance with the standard specified in Table 2B row 2. 6. Record actions (e.g., deletion) related to electronic health information in accordance with the standard specified in Table 2B row 3 (i.e., audit log), provide alerts based on userdefined events, and electronically display and print all or a specified set of recorded information upon request or at a set period of time. 7. Verify that electronic health information has not been altered in transit and detect the alteration and deletion of electronic health information and audit logs in accordance with the standard specified in Table 2B row 4. 8. Verify that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information. 9. 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 Table 2B row 5. 10. Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in Table 2B row 6.
<p>“%” indicates instances where the version of an adopted standard (specified in the regulation text) will be “at a minimum” the version to which a Complete EHR or EHR Module must be tested and certified in</p>	

order to be considered compliant with the adopted standard.

Certification Standards

ONC defines *standard* to mean: a technical, functional, or performance-based rule, condition, requirement, or specification that stipulates instructions, fields, codes, data, materials, characteristics, or actions. ONC divides the adopted standards into four separate categories:

1. *Vocabulary Standards* (i.e., standardized nomenclatures and code sets used to describe clinical problems and procedures, medications, and allergies); (*see Table 2A*)
2. *Content Exchange Standards* (i.e., standards used to share clinical information such as clinical summaries, prescriptions, and structured electronic documents); (*see Table 2A*)
3. *Transport Standards* (i.e., standards used to establish a common, predictable, secure communication protocol between systems); (*see Page 7*) 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. (*see Table 2B*)

Table 2A - Content Exchange and Vocabulary Standards

Table 2A shows content exchange and vocabulary tables for Stage 1, and also predicts which future standards may (or may not) support Stage 2 of meaningful use. *The Stage 2 column standards are not actually adopted by this IFR, and will be revisited in a future rulemaking—they were included simply to give vendors and users an understanding of where ONC might go in the future in terms of applicable standards.* The blue column below shows the actual *adopted* content exchange and vocabulary standards for Stage 1.

Row	Purpose	Category	Adopted Standards to Support Meaningful Use (Stage 1)	Potential Candidate Standard(s) to Support Meaningful Use (Stage 2)
1	Patient Summary Record	Content Exchange	HL7 CDA R2 CCD Level 2 or ASTM CCR	Alternatives expected to be narrowed based on HIT Standards Committee recommendations
	-Problem List	Vocabulary	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	Vocabulary	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	RxNorm
	-Medication Allergy List	Vocabulary	No standard adopted at this time.	UNII
	-Procedures	Vocabulary	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	Vocabulary	No standard adopted at this time.	CDA template
	-Units of Measure	Vocabulary	No standard adopted at this time.	UCUM
	-Lab Orders and Results	Vocabulary	LOINC® when LOINC® codes have been received from a laboratory	LOINC®
2	Drug Formulary Check	Content Exchange	Applicable Part D standard required by law (i.e., NCPDP Formulary &	Applicable Part D standard required by law

			Benefits Standard 1.0)	
3	Electronic Prescribing	Content Exchange	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
		Vocabulary	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	RxNorm
4	Administrative Transactions	Content Exchange	Applicable HIPAA transaction standards required by law	Applicable HIPAA transaction standards required by law
5	Quality Reporting	Content Exchange	CMS PQRI 2008 Registry XML Specification	Potentially newer version(s) or standards based on HIT Standards Committee Input
6	Submission of Lab Results to Public Health Agencies	Content Exchange	HL7 2.5.1	Potentially newer version(s) or standards based on HIT Standards Committee Recommendations
		Vocabulary	LOINC® when LOINC® codes have been received from a laboratory	LOINC®, UCUM, and SNOMED CT® or Applicable Public Health Agency Requirements
7	Submission to Public Health Agencies for Surveillance or Reporting (excluding adverse event reporting)	Content Exchange	HL7 2.3.1 or HL7 2.5.1	Potentially newer version(s) or standards based on HIT Standards Committee Input
		Vocabulary	According to Applicable Public Health Agency Requirements	GIPSE or According to Applicable Public Health Agency Requirements
8	Submission to Immunization Registries	Content Exchange	HL7 2.3.1 or HL7 2.5.1	Potentially newer version(s) or standards based on HIT Standards Committee Recommendations
		Vocabulary	CVX	CVX

Table 2B - Adopted Privacy and Security Standards

Row	Purpose	Adopted Standard
1	General Encryption and Decryption of Electronic Health Information	A symmetric 128 bit fixed-block cipher algorithm capable of using a 128, 192, or 256 bit encryption key must be used (e.g., FIPS 197 Advanced Encryption Standard, (AES), Nov 2001).+
2	Encryption and Decryption of Electronic Health Information for Exchange	An encrypted and integrity protected link must be implemented (e.g., TLS, IPv6, IPv4 with IPsec).+
3	Record Actions Related to Electronic Health Information (i.e., audit log)	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., modification).+
4	Verification that Electronic Health Information has not been	A secure hashing algorithm must be used to verify that electronic health information has not been altered in transit.

	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).+
5	Cross-Enterprise Authentication	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).+
6	Record Treatment, Payment, and Health Care Operations Disclosures	The date, time, patient identification (name or number), user identification (name or number), and a description of the disclosure must be recorded.+
“+” indicates those standards that are <u>not</u> voluntary consensus standards. ONC has adopted voluntary consensus standards wherever practical.		

Transport Standards

In terms of *transport standards*, the Organization for the Advancement of Structured Information Standards (OASIS) Simple Object Access Protocol (SOAP) Version 1.2 (incorporated by reference in §170.299); or, a stateless, client-server, cacheable communications protocol that adheres to the principles of Representational State Transfer (REST) must be used. SOAP was adopted because it is widely used and versatile enough to allow for the use of different transport protocols, is platform independent, and is language independent

ONC clarifies that *transport standards* are different from the aforementioned *content exchange standards* in that transport standards are not domain specific while content exchange standards are. That is, SOAP and REST can be used by other industries to exchange information while the content exchange standards are specifically designed for the exchange of health information.

Implementation Specifications

Implementation specifications provide specific configuration instructions and constraints for implementing a particular standard or set of standards. ONC indicated that very few implementation specifications are widely used or mature enough for adoption before Stage 2 of meaningful use. Implementation specifications ONC adopted for Stage 1 are:

- As Certified EHR Technology must be capable of using the CMS PQRI 2008 Registry XML Specification for quality reporting, ONC is adopting as the implementation specifications for this standard, the *Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry*.
- As Certified EHR Technology must be capable of using applicable HIPAA transaction standards for eligibility for health plan transactions and for health care claims or equivalent encounter information transactions, the specific HIPAA standards and “implementation specifications” associated with covered transactions have also been adopted.
- ONC has also adopted the requirements of Phase 1 of the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) as a supporting implementation specification for the standard regarding eligibility for a health plan transaction.

Comments and Questions

The American College of Radiology will continue to review CMS’ proposed rule and ONC’s Interim Final Rule, and will develop formal comments for both items in accordance with the notices in the January 13, 2010 *Federal Register*. ACR is interested in gathering input from our members. All feedback will be used to inform the ACR IT & Informatics Commission (ITIC) leaders and ACR staff as we work to develop draft comments over the next couple of months.

Please contact Michael Peters, Assistant Director of Regulatory and Legislative Portfolio, ACR Government Relations Department, at mpeters@acr-arrs.org or 703-716-7546.