Summary of 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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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. The interim final rule was published in the January 13, 2010 issue of the *Federal Register*, and although the interim final rule was effective February 12, 2010, provision was made for a 60-day comment period, which ended on March 15, 2010.

On July 13, 2010, the ONC for HIT put on public display a final rule specifying the initial set of standards, implementation specifications, and certification criteria for electronic health record (EHR) technology. The rule was published in the July 28, 2010 issue of the *Federal Register*. 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 (EPs) and eligible hospitals and critical access hospitals (CAHs) under the Medicare and Medicaid EHR Incentive Programs (see the separate summary of the final rule on EHR meaningful use for further details).

ONC reiterates that the purpose of the final rule is to adopt standards, implementation specifications, and certification criteria to test and certify that EHR technology provides certain capabilities, and that it is not intended to impose independent requirements on entities using that technology. ONC indicates that the specification of how a Complete EHR or EHR Module complies with adopted standards will be solely reflected in the certification criteria. ONC also anticipates adoption of additional standards, implementation specifications, and certification criteria, as well as revisions and updates to those initially adopted, for future stages of meaningful use which will require a framework to support harmonization across different meaningful use scenarios and that support real world testing.

ONC emphasizes that the final rule is part of an iterative process to enhance interoperability, functionality, utility, and security of HIT, and its belief that the final rule will be a catalyst for an innovative marketplace. The final rule is effective August 27, 2010. Please note that the 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 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." In declining to accept a suggestion from comments to the interim final rule that it add the phrase "developed through the use of an open, collaborative, consensus-based process" to the definition of a standard, ONC notes that it is already required to use, wherever practical, technical standards developed or adopted by voluntary consensus standards bodies and that the addition of that phrase would preclude currently authorized exceptions for inconsistency with applicable law or impracticality.

The final rule defines "implementation specifications" as "specific requirements or instructions for implementing a standard" (that is, the Health Insurance Portability and Accountability Act of 1996 (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 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 declines to adopt a recommendation from commenters to expand this definition to include additional functionality and indicates that any additional capabilities will be addressed in subsequent adoption of additional standards, implementation specifications, and certification criteria. ONC also declines to further define terms within the definition, such as clarity, query, other sources, etc., indicating that the meanings of those terms will vary on the context in which the terms are used and the associated capabilities of the certified EHR technology involved, as well as standards and implementation specifications.

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. In the final rule, ONC clarifies that an EHR Module may provide any amount of capabilities that is less than a Complete EHR. To qualify, it must have at least one capability that is tested and certified to the certification criterion at the present time, but may have additional functionalities that do not meet certification criteria for use as part of certified

EHR technology. On the issue of whether interfaces should be included in the definition of EHR Module, ONC indicates that the determining factor is the certification criterion. For example, if a certification criterion required a particular capability for exchanging electronic health information, the interface could then be tested and certified as an EHR Module. Or if the interface were an integral component of an EHR Module without which it could not be tested, the interface would be part of the EHR Module submitted for testing and certification.

The final rule also clarifies the definition of the term "Complete EHR" as meaning "EHR technology that has been developed to meet*, at a minimum,* all applicable certification criteria adopted by the Secretary." ONC explains that the definition is a floor to signify that, once tested and certified to all applicable certification criteria, a complete EHR meets the definition of certified EHR technology. A complete EHR may or may not include additional capabilities, but it must be certified to all certification criteria for the ambulatory or inpatient setting, as the case may be.

In response to confusion among commenters as to its interpretation, the final rule revises the definition of "certified EHR technology" to mean the following:

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.

ONC also clarifies that EPs, eligible hospitals and CAHs are not required to use EHR Modules to meet the definition of certified EHR technology, and that the HIT they employ may have additional capabilities beyond those tested and certified to demonstrate meaningful use. ONC reiterates 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.

The interim final rule restated the text used to define "disclosure" as written for purposes of HIPAA regulations: "the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information." Responding to confusion among commenters, ONC in the final rule substitutes a cross-reference to the HIPAA definition rather than restating the text.

In response to requests, ONC defines “human readable format” to mean a format that enables a human to read and easily comprehend the information presented to him or her regardless of the method of presentation (e.g. computer screen, handheld device, electronic document). ONC notes that the term may have different meanings for EPs and eligible hospitals as compared to patients. ONC also notes that its requirements apply to Complete EHRs or EHR Modules and indicates that these requirements do not obviate the need to comply with other provisions of law relating to human readable formats—for example, for persons with disabilities who require reasonable accommodation.

ONC also notes that the term “user” may have different meanings in different contexts, such as a health care professional, office staff, or software program, and indicates that this flexibility is required.

Flexibility and Innovation

ONC notes that administrative flexibility is limited by law and rulemaking requirements, and that publications incorporated by reference are limited to the edition of the publication specifically referred to and do not include updates, revisions, or amendments made to those publications after the date of incorporation by reference.

ONC identifies 4 ways in which it seeks to provide flexibility or encourage innovation: 1) alternative standards, 2) minimum code set standards, 3) optional standards, implementation specifications, and certification criteria, and 4) backwards compatibility.

In providing for alternative standards, ONC balances promotion of interoperability with the HIT industry’s ability to comply and its need for flexibility which, occasionally, may require additional non-native formatting. Minimum code set standards are a floor for testing and certification with respect to which the Secretary may accept newer versions for voluntary use. ONC notes that it has identified and deemed acceptable newer versions of Logical Observation Identifiers Names and Codes (LOINC) version 2.3 (released 2/26/2010) and CVX – Vaccines Administered (released 3/17/2010) and certified EHR technology may be upgraded at any time to comply with the newer versions without affecting its certification status. Optional standards, implementation specifications, and certification criteria are voluntary and are not required for testing and certifying a Complete EHR or EHR Module.

Backwards compatibility is a newer version of a standard that retains the full functionality of an older version previously adopted in regulation and that permits successful completion of the transaction with entities using the older version. The process for ONC review of adopting a backward compatible version of an older standard includes review of whether the newer version retains at a minimum the full functionality of the older version, whether a standard should be updated with

the newer version, whether use of either the older or newer version would be compliant, and whether use of the newer version would conflict with existing regulatory requirements. If ONC believed voluntary adoption of the newer version was appropriate, it would seek HIT Standards Committee evaluation as well as solicit input from the public. EPs and eligible hospitals would be permitted to voluntarily upgrade their certified EHR technology to include the newer version. ONC believes backward adoption would be limited to years between meaningful use stages.

Standards

Transport Standards. In response to comments, ONC removes the adopted standards SOAP and REST and will not require, at the present time, specific transport standards as a condition of certification. ONC notes it will closely monitor the impact of this decision on interoperability.

Content Exchange, Vocabulary, and Privacy and Security Standards

The final rule adopts standards in the following three categories which are described in more detail in an appendix to this summary:

1. Content Exchange Standards (i.e., standards used to share clinical information such as clinical summaries, prescriptions, structured electronic documents, and quality reporting) and Associated Implementation Specifications listed in 45 CFR 170.205.

2. Vocabulary Standards (i.e., standardized nomenclatures, terminology, and code sets used to describe clinical problems and procedures, lab test results, medications, immunizations, and race and ethnicity) listed in 45 CFR 170.207.

3. Privacy and Security Standards (e.g., encryption and decryption, access control, and transmission security) which relate to and span across all of the other types of standards listed in 45 CFR 170.210.

Accessibility Standards

ONC does not adopt specific accessibility standards as a condition of certification in this final rule. However, it believes adoption of such standards in future rulemaking would be beneficial and encourages developers to take the needs of users of assistive technology into account when designing their technology, and specifically encourages implementing WCAG 2.0 when providing web-oriented content. ONC also expects the HIT Standards Committee to identify accessibility standards for future rulemaking.

Certification Criteria and Associated Standards and Implementation Criteria

ONC revises its approach to specifying certification criteria to more clearly focus on the capabilities with which they are associated. ONC reiterates that the purpose of certification is to verify that a Complete EHR or EHR Module can perform the capabilities; ONC considers it outside the scope of the final rule to require when capabilities must be used or to whom data must be transmitted.

General Certification for Complete EHRs or EHR Modules

The final rule changes many general certification criteria and associated standards to support the achievement of meaningful use Stage 1. The following table lists the final certification criteria applicable for meaningful use Stage 1 objectives and measures and describes changes in these certification criteria as well as ONC clarification in response to comments. The appendix provides a detailed listing of the content exchange, vocabulary and privacy/security standards that are relevant to a particular certification criterion (these standards are only identified by regulatory section number in the table).

Final General Certification Criteria to Support the Achievement of Meaningful Use Stage 1	Changes / Observations
A Complete EHR or EHR Module must include the capability to:	
Implement Drug-drug and Drug-allergy Interaction Checks (1) Notifications. 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). (2) Adjustments. Provide certain users with the ability to adjust notifications provided for drug-drug and drug-allergy interaction checks.	• Replaces "alert" with "notification" because alert implies a particular implementation while notification is more neutral; applies globally across all criteria that used "alert" • Clarifies use of pop-up message or sound not a specified requirement • Removes alert statistics from criterion • Revises customization to be adjustments to indicate goal of permitting users to adjust severity level for which notifications are presented (removes "deactivate, modify or add rules") • Removes age as a required data element (ONC never intended to require the technology to be capable of performing checks on type or dosage of drugs to patient's age or drug-age checks) • Clarifies inclusion of CPOE in criterion meant notifications should occur based on new medication orders in addition to current medications and medication allergies, as they are entered; clarifies notifications occur during order-entry workflow • Clarifies technology is expected to perform checks based on medication and medication allergy list information included in technology as structured data but is not expected to read information in other formats, (e.g. scanned documents), for checks • Declines to add drug-test check to required capabilities for Stage 1
Implement Drug-formulary Checks	• Adopts a more general criterion for Formulary and Benefits standard (i.e. does not refer to any

Final General Certification Criteria to Support the Achievement of Meaningful Use Stage 1	Changes / Observations
Enable a user to electronically check if drugs are in a formulary or preferred drug list.	particular standard) that is applicable in both ambulatory and inpatient settings, but notes that those EPs who must meet Medicare Part D e-prescribing requirements must continue to use the applicable Formulary and Benefits standard • Emphasizes that Complete EHRs and EHR Modules must contain drug-formulary check in inpatient settings as a capability for purposes of demonstrating meaningful use—now separate from drug-drug and drug-allergy capabilities
Maintain an Up-to-date Problem List Enable a user to electronically record, modify, and retrieve a patient's problem list for longitudinal care in accordance with: (1) The [vocabulary] standard specified in §170.207(a)(1); or (2) At a minimum, the version of the [vocabulary] standard specified in §170.207(a)(2).	• Finds that adoption of both SNOMED-CT and ICD-9-CM should provide adequate coverage for patient diagnoses and conditions • Discourages use of free text to document problem lists • Reiterates that meaningful use requirements specify whether adopted standard must be used among components of a business organization or solely for electronic exchange with other legal entities • Requires entries to be recorded as structured data and the certification criterion specifies SNOMED-CT/ICD-9-CM as codes sets • Clarifies that longitudinal care means capability to include entries over extended period of time: in ambulatory setting, over multiple encounters; in inpatient setting, for entire duration of hospitalization
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.	• Clarifies that retrieve means retrieval of information directly stored and managed by certified EHR technology; it does not mean retrieval from external sources (unless explicitly otherwise stated) • Clarifies that medication history includes record of prior modifications to a patient's medications • Removes from certification criterion the requirement that it use the medication list standard described in §170.205(a)(2)(iv) of the interim final rule
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.	• Responses to comments for the measure Maintain Active Medication List above apply to this measure as well
Record and Chart Vital Signs (1) Vital signs. Enable a user to electronically record, modify, and retrieve a patient's vital signs including, at a minimum, height, weight, and blood pressure. (2) Calculate body mass index. Automatically calculate and display body mass index (BMI) based on a patient's height and weight. (3) Plot and display growth charts. Plot and electronically display, upon request, growth	• Removes temperature and pulse from vital signs certification criterion since they are not included under the applicable meaningful use objective • Declines to specify measurement units (e.g. metric) • Insists certified EHR technology should have capabilities, such as a growth chart component, regardless of the setting for which it is designed (i.e. will be required for inpatient setting) • Since objective addresses ages 2-20, not necessary to require capabilities for charting other ages

Final General Certification Criteria to Support the Achievement of Meaningful Use Stage 1	Changes / Observations
charts for patients 2-20 years old.	• Clarifies expectation that growth chart plots over time and as compared to national norms—while not specifically required in the regulation text, ONC encourages developers to include this feature • Declines as a condition of certification to specify how BMI should be coded
Smoking Status 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.	• Fields should mirror those expressed by the CDC, National Health Center for Statistics, National Health Interview Survey related to smoking codes • Broadens smoking statuses required to be recorded • Current every day / some day smoker has smoked at least 100 cigarettes and still smokes • Former smoker is a current nonsmoker who smoked at least 100 cigarettes • Never smoker has smoked fewer than 100 cigarettes in his/her lifetime
Incorporate Laboratory Test Results (1) Receive results. Electronically receive clinical laboratory test results in a structured format and display such results in human readable format. (2) Display test report information. Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7). (3) Incorporate results. Electronically attribute, associate, or link a laboratory test result to a laboratory order or patient record.	• Declines to specify standards for transmission or receipt—just capability • Removes criterion requirement for receipt and display of LOINC code, but does expect certified EHR technology to be able to reuse a LOINC code once received; does not expect crosswalk or mapping of internal codes to LOINC codes • States ONC cannot provide regulatory relief from CLIA requirements in the case of a modification to certified EHR technology that displayed test report information in violation of CLIA requirements • Clarifies update to mean that lab test result is incorporated in certified EHR technology with originating lab order or with a patient's record in any of the listed methods—thus would permit batches of lab test results to be electronically linked to lab orders or patient records without manual intervention; criterion requires support of electronic lab interfaces (which may not be helpful for small and medium size practices)
Generate Patient Lists 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.	• Declines to adopt Institute of Medicine 2009 recommendations for Race, Ethnicity and Language Data because public has not had ample opportunity to consider them • Removes "patient's clinical information" and "specific conditions" from criterion • Changes "output" to "generate" to align with meaningful use measure • Does not require a period of time to be associated with a patient list for purposes of certification
Medication Reconciliation Enable a user to electronically compare two or more medication lists.	• Clarifies that "electronically" means providing a user the ability to electronically compare two or more medication lists; did not intend to require automated medication reconciliation

Final General Certification Criteria to Support the Achievement of Meaningful Use Stage 1	Changes / Observations
	• Indicates a desire to make more use of this capability in future rounds of certification criteria • Directs readers to EHR meaningful use final rule for definitions of "medication reconciliation", "transitions of care", and "relevant encounter"
Submission to Immunization Registries Electronically record, modify, retrieve, and submit immunization information in accordance with: (1) The [content exchange] 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 [vocabulary] standard specified in §170.207(e).	• Focuses specifically on Federal requirements; drops requirement for State-designated standard format • Focuses on transmission—not designating recipient—thus drops reference "to immunization registries" in certification criterion • Permits use of HL7 2.3.1 or HL7 2.5.1 for certification; adopts two most common standards used for transmission of immunization information • Notes that CDC maintains a publicly available list of updated CVX codes as well as mapping of CVX codes to CPT codes on its website • Revises criterion to substitute "submit" for "transmit" • Adopts and encourages migration to the following implementation specifications for submission of information: for HL7 2.3.1, "Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol, Implementation Guide Version 2.2" and for HL7 2.5.1, "Implementation Guide for Immunization Messaging Release 1.0" • Adds "modify" to certification criterion
Public Health Surveillance Electronically record, modify, retrieve, and submit syndrome-based public health surveillance information in accordance with the [content exchange] standard (and applicable implementation specifications) specified in §170.205(d)(1) or §170.205(d)(2).	• Notes that while the final rule adopts two content exchange standards for electronic submission, it does not adopt a specific vocabulary standard • Removes reference to public health agencies as recipient; also revises criterion to substitute "submit" for "transmit" • Adopts the following implementation specification for HL7 2.5.1: "Public Health Information Network HL7 Version 2.5 Message Structure Specification for National Condition Reporting Final Version 1.0 and the Errata and Clarifications National Notification Message Structural Specification"; did not find suitable implementation specification for HL7 2.3.1 • Reiterates that the test for specification criteria is the capability of the certified EHR technology to transmit pursuant to standards adopted—not whether a recipient has the capability to receive it • Declines to modify criterion to explicitly refer to adverse events
Patient-Specific Education Resources Enable user to electronically identify and provide patient-specific education resources	• Applicable to Complete EHRs and EHR Modules designed for ambulatory and inpatient settings

Final General Certification Criteria to Support the Achievement of Meaningful Use Stage 1	Changes / Observations
according to, at a minimum, the data elements included in the patient's: problem list; medication lists; and lab test results; as well as provide such resources to the patient.	
Access Control 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	• No changes
Emergency Access Permit authorized users (who are authorized for emergency situations) to access electronic health information during an emergency.	• No change in criterion • Criterion not intended to specify what constitutes an emergency or who would be authorized to access the information in an emergency—those are fact-specific determinations and subject to state and federal law, organizational policies and procedures, and relevant standards of care • Access controls still apply in emergency situation—they are just different from those that apply under non-emergency circumstances • Does not believe automated notification of system administrator when emergency access invoked is required at this time
Automatic Log-off Terminate an electronic session after a predetermined time of inactivity.	• No changes
Audit Log (1) Record actions. Record actions related to electronic health information in accordance with the [privacy/security] standard specified in §170.210(b). (2) Generate audit log. 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 [privacy/security] standard at 170.210(b).	• Removes "printed" from the standard because of the many ways to circumvent the function—difficult to design product to capture it all • Adds "accessed" to the standard, which includes reading/viewing/export • Specifies actions recorded are associated with recorded user id • Notes that ensuring EP/eligible hospital access to a portion or all of audit log is essential • Notes that what a HIPAA covered entity must do to comply with HIPAA security rule is separate from Complete EHR/EHR Module capability certification, and thus ONC may require more than HIPAA • Believes capabilities specified in criterion and standard are common industry practice • Defers adoption of Audit Trail and Node Authentication (ATNA) standard due to multiple possible configurations
Integrity (1) Message Digest. Create a message digest in accordance with the [privacy/security] standard specified in 170.210(c).	• Requires criterion to support, at a minimum, HIPAA Security Rule (i.e. implement security measures to ensure electronically transmitted electronic protected health information is not improperly modified without detection until disposed of) • Clarifies certified EHR technology must have

Final General Certification Criteria to Support the Achievement of Meaningful Use Stage 1	Changes / Observations
(2) Verification. Verify in accordance with the [privacy/security] standard specified in §170.210(c) upon receipt of electronically exchanged health information that such information has not been altered. (3) Detection. Detect the alteration of audit logs.	capability to check integrity of health information received through electronic exchange; to create a message digest, and to use message digest to verify contents have not been altered • Clarifies integrity standard to read "A hashing algorithm with a security strength equal to or greater than SHA-1 must be used to verify that electronic health information has not been altered." • Revises standard to require that alterations to audit logs be detected—removed reference to detection of deleted electronic health information • For hashing, certified EHR technology must be capable of generating a hash of electronic health information and verifying it has not been altered when electronically exchanged
Authentication Verify that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information.	• Removes requirement for cross-network authentication • Declines to specify types of factors that users may utilize to authenticate themselves
Encryption (1) General encryption. Encrypt and decrypt electronic health information in accordance with the [privacy/security] 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. (2) Encryption when exchanging electronic health information. Encrypt and decrypt electronic health information when exchanged in accordance with the [privacy/security] standard specified in §170.210(a)(2).	• Certified EHR technology must include capability to encrypt/decrypt information regardless of transmission method • Clarifies that the standard for "encrypted and integrity protected link" is any encrypted and integrity protected link • Revises general encryption standard to be "Any encryption algorithm identified by the NIST as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2" which identifies symmetric and asymmetric key encryption algorithms per FIPS 140-2—subject to revision if a listed encryption algorithm poses a significant security risk in which case ONC-ACTBs would not test/certify EHRs that use that algorithm • Removes "user-defined preferences" from the requirement for capability to encrypt / decrypt
Accounting of Disclosures Record disclosures made for treatment, payment, and health care operations in accordance with the [privacy/security] standard specified in §170.210(e)	• Indicates certification criterion is optional • Will likely update for future rulemaking • Had anticipated that "description of the disclosure" would be a free text field for information that could be readily and electronically associated with disclosure

The final rule removes requirements for Complete EHRs/EHR Modules to include capabilities for Check Insurance Eligibility and Submit Claims (§170.302(j) and §170.302(k) in the interim final rule) because CMS removed the objectives from

meaningful use Stage 1 requirements. ONC notes that CMS explained in the final rule on EHR meaningful use that inclusion of administrative simplification requirements as part of Stage 2 is an important long-term policy goal, and ONC announces its intention to include for adoption administrative transactions standards and certification criteria to support meaningful use Stage 2 rulemaking and expects providers and Complete EHRs/EHR Modules developers to take this into account for 2013. ONC also notes that it is removing the CORE Phase 1 implementation specification.

Specific Certification for Complete EHRs or EHR Modules for Ambulatory and Inpatient Settings

The final rule also changes many certification criteria and associated standards specific to the ambulatory and inpatient settings to support the achievement of meaningful use Stage 1. The following table lists the final certification criteria applicable for meaningful use Stage 1 objectives and measures and describes changes in these certification criteria as well as ONC clarification in response to comments. Again, applicable content exchange, vocabulary, and privacy/security standards are referenced only by regulatory section numbers, with the appendix providing a more detailed listing of these standards.

Final Certification Criteria to Support the Achievement of Meaningful Use Stage 1 Specific to Ambulatory / Inpatient Setting	**Changes / Observations**
A Complete EHR or EHR Module must include the capability to:	
Use Computerized Provider Order Entry (CPOE) *Ambulatory and Inpatient Settings* 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	• Omits many order types included in interim final rule • Replaces "manage" with "modify" as a capability • For labs, technology must be capable of electronically attributing, associating, or linking a lab test result to a lab order / patient record; notes that bidirectional exchange (including electronic transmission of lab orders) is not a meaningful use Stage 1 requirement • Declines to specify the persons who would need to use CPOE • Clarifies that criteria for CPOE pertain only to ordering—not delivery of results (reports/images) • Identical criteria for ambulatory and inpatient settings; but anticipates criteria requirements could differ for ambulatory v. inpatient settings in the future
Electronic Prescribing *Ambulatory Setting* Enable a user to electronically generate and transmit prescriptions and prescription-related information in accordance with: (1) The [content exchange] standard specified in §170.205(b)(1) or	• Modifies criterion to specify that Complete EHR/EHR Module would be compliant if it can generate and transmit prescription and prescription-related information according to NCPDP SCRIPT 8.1 or NCPDP SCRIPT 10.6, while also using the respective adopted vocabulary standard • Revises vocabulary standard as a functional standard that enables the use of any source

Final Certification Criteria to Support the Achievement of Meaningful Use Stage 1 Specific to Ambulatory / Inpatient Setting	Changes / Observations
§170.205(b)(2); and (2) The [vocabulary] standard specified in 170.207(d).	vocabulary included within RxNorm (goal is for Complete EHR/EHR Modules to be capable of classifying and categorizing medications for clinical quality measurement and clinical decision support) • Ignores interim final rule issued by the Drug Enforcement Administration in March 2010, which authorizes e-prescribing of controlled substances provided that certain requirements are met
Record Demographics *Ambulatory and Inpatient Settings* Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, gender, race, ethnicity, and date of birth, and, for inpatient setting only, also the date and preliminary cause of death Enable race and ethnicity to be recorded in accordance with the [vocabulary] standard specified at §170.207(f).	• Adopts OMB race and ethnicity codes • Removes capability to record insurance type • For eligible hospitals and CAHs, criterion includes date and preliminary cause of death
Generate Patient Reminder List *Ambulatory Setting* Patient reminders. 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: (1) Problem list; (2) Medication list; (3) Medication allergy list; (4) Demographics; and (5) Laboratory test results.	• Removes "upon request" • Stated goal is that technology should be able to leverage structured data to generate list • For purposes of certification, the requirement refers to list creation for EP/staff internal purposes; the final rule on EHR meaningful use establishes the standard for required EP action
Clinical Decision Support *Ambulatory and Inpatient Settings* (1) Implement rules. 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. (2) Notifications. Automatically and	• Identical criteria for ambulatory and inpatient settings • Changes "alerts" to "notifications" • Clarifies that for notifications, real-time means at the point of clinical decisionmaking • Drops requirement for alert statistics • Drops "evidence grade" from criterion • Drops "high priority hospital condition" from criterion

Final Certification Criteria to Support the Achievement of Meaningful Use Stage 1 Specific to Ambulatory / Inpatient Setting	Changes / Observations
electronically generate and indicate in real-time, notifications and care suggestions based upon clinical decision support rules.	
Electronic Copy of Health Information *Ambulatory and Inpatient Settings* 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: (1) Human readable format; and (2) On electronic media or through some other electronic means in accordance with: (i) The [content exchange] 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) Problems. The [vocabulary] standard specified in §170.207(a)(1) or, at a minimum, the version of the [vocabulary] standard specified in §170.207(a)(2); (B) *(For inpatient setting only)* Procedures. The [vocabulary] standard specified in §170.207(b)(1) or §170.207(b)(2). (C) Laboratory test results. At a minimum, the version of the [vocabulary] standard specified in §170.207(c); (D) Medications. The [vocabulary] standard specified in §170.207(d); and *Also, for inpatient setting only:* (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.	• Declines to add durable medical equipment for Stage 1 • Declines to specify timeframe of information required, but indicates it should have most current information and more than just the information available at the end of an encounter • For EPs, removes reference to "immunizations" and "procedures" from criterion • Declines to specify the form in which electronic copy is generated but encourages developers to ensure EP compliance with HIPAA Privacy and Security Rules • Clarifies that to meet requirement, technology must be capable of generating an electronic copy in human readable format AND as a Continuity of Care Document (CCD) or Continuity of Care Record (CCR) • Disagrees that the requirement presents problems for HIPAA Privacy and Security Rules; clarifies that eligible hospitals and CAHs will be able to determine which electronic media is permissible—ONC does not require thumb drives, etc.—and where to distribute it (patient portal is acceptable) • Declines to limit requirement to readable human format only • For eligible hospitals and CAHs, revises criterion to specify that for discharge summary ONC does not require use of any standard (such as CCD or CCR), but notes that the technology must be able to provide an electronic copy of a discharge summary like a patient record summary in human readable format and on electronic media (e.g. a PDF) • For eligible hospitals and CAHs, clarifies that the adopted standard applies to the vocabulary used to express procedures—regardless of how selected • Clarifies that diagnoses included in patient summary record are meant to convey clinically relevant conditions rather than billing diagnoses • Adopts SNOMED-CT as an alternative standard to CPT-4
Electronic copy of discharge information *Ambulatory and Inpatient Settings* 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	• Removes "procedures" from criterion (consistent with final rule on EHR meaningful use) • Time of discharge clarified in final rule on EHR meaningful use

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some other electronic means.	
Timely Access *Ambulatory Setting* 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.	• Declines to replace "online" with "electronic" citing goal of patient access at a time of their choosing • Removes "procedures" and "immunizations" from criterion
Clinical Summaries *Ambulatory Setting* 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 [content exchange] 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 [vocabulary] standard must be used: (A) Problems. The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2); (B) Laboratory test results. At a minimum, the version of the standard specified in §170.207(c); and (C) Medications. The standard specified in §170.207(d).	• Notes that certification criterion is not the manner in which to address concerns about patient/family literacy • Also notes it is outside scope of ONC final rule to require EPs to affirmatively offer summaries to the patient or to limit provider responsibility for completeness and accuracy
Exchange Clinical Information and Summary Record *Ambulatory and Inpatient Settings* (1) Electronically receive and display. 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, for inpatient settings procedures, in accordance with the content exchange	• Clarifies that compliance with criterion means that a Complete EHR/EHR Module is capable of (1) receiving and displaying, in human readable format, patient summary records that comply with either CCR and CCD patient summary record standards, and (2) generating and transmitting patient summary record according to those patient summary record standards and applicable standards • Adopts both CCR and CCD patient summary record standards • For CCD adoption, removes requirement for generating a level 2 CCD and adopts

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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) Electronically transmit. 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, for inpatient settings procedures, in accordance with: (i) The content exchange 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) Problems. The vocabulary standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2); (B) (For inpatient settings) Procedures. The vocabulary standard specified in §170.207(b)(1) or §170.207(b)(2); (C) Laboratory test results. At a minimum, the version of the vocabulary standard specified in §170.207(c); and (D) Medications. The vocabulary standard specified in §170.207(d).	implementation specification HITSP C32 (version 2.5) • Clarifies that a compliant CCD implemented according to HITSP C32 must include the information for those entries required by HITSP C32; also notes that it should include data specified in the criterion to populate "optional" entries for which ONC adopts vocabulary standards • The above would also be used to test and certify Complete EHR/EHR Module's ability to populate a CCR • Removes "immunizations" (and only for EPs "procedures") from criterion • Clarifies that data from paper records are not relevant factor for testing and certification • Expects patient summary record to include health information that is coded in accordance with adopted vocabulary standards AND permits an EP or eligible hospital/CAH to map or crosswalk local or proprietary codes to adopted vocabulary standards before transmitting the record • Does not adopt standards for radiology reports or images; notes that CCR and CCD can convey narrative texts and objects (e.g. scanned documents) • For eligible hospitals and CAHs, excludes discharge summary from this criterion
Reportable Lab Results *Inpatient Setting* Electronically record, modify, retrieve, and submit reportable clinical lab results in accordance with the [content exchange] standard (and applicable implementation specifications) specified in §170.205(c) and, at a minimum, the version of the [vocabulary] standard specified in §170.207(c).	• Clarifies that criterion is not intended to specify how or how often reports are triggered • Adopts HL7 2.5.1: Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) to constrain how HL7 2.5.1 is formatted for submitting lab test results to public health • Includes "modify" in certification criterion • Does not believe industry and public health departments ready for SNOMED-CT and Unified Code for Units of Measure (UCUM) on a widespread basis
Advance Directives *Inpatient Setting* Enable a user to electronically record whether a patient has an advance directive.	• Applicable to Complete EHRs/EHR Modules designed for inpatient settings • Assumes developers have already built in this functionality

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Report Quality Measures *Ambulatory and Inpatient Settings* *For Ambulatory Setting* (1) Calculate. (i) Electronically calculate all of the core clinical measures specified by CMS for EPs. (ii) Electronically calculate, at a minimum, three clinical quality measures specified by CMS for EPs, in addition to those clinical quality measures specified in paragraph (1)(i). (2) Submission. Enable a user to electronically submit calculated clinical quality measures in accordance with the content exchange standard and implementation specifications specified in §170.205(f). *For Inpatient Setting* (1) Calculate. Electronically calculate all of the clinical quality measures specified by CMS. (2) Submission. Enable a user to electronically submit calculated clinical quality measures in accordance with the content exchange standard and implementation specifications specified in §170.205(f).	• Adopts Physician Quality Reporting Initiative (PQRI) 2009 Registry XML specification as the standard for electronic submission of quality reporting data • Notes that CMS requires data to be submitted on aggregated summary level—not patient specific • Does not believe specific implementation of standard required for hospital setting • Revised certification to align with meaningful use requirements and explicitly focuses certification criterion on Federal requirements—removes reference to States • Creates specific certification criterion for each setting (ambulatory v. inpatient), but does NOT require separate criterion for calculation and submission of data • Complete EHR/EHR Modules required to be tested and certified for all 6 EP core set requirements and at least 3 additional quality measures; requires disclosure by EHR developers and ONC-Authorized Testing and Certification Bodies of which additional measures have been tested • Complete EHR/EHR Modules required to be tested and certified for all clinical quality measures specified by CMS for eligible hospitals • Declines to automatically deem PQRI registries as Certified EHR Module • Agrees that Complete EHR/EHR Modules should only be required to be tested and certified to developed electronic measure specifications

ONC adopts certification criteria for the following meaningful use Stage 1 objectives (which are noted in the applicable table above):

Record Advance Directives for Patients 65 Years Old and Older. The certification criterion is to enable a user to electronically record whether the patient has an advance directive. ONC notes that it is applicable to Complete EHRs and EHR Modules designed for inpatient settings, and assumes developers have already built in this functionality.

Patient-Specific Education Resources. The certification criterion is to enable user to electronically identify and provide patient-specific education resources according to, at a minimum, the data elements included in the patient's problem and medication lists, and lab test results; and to provide those resources to the patient. This is applicable to Complete EHRs and EHR Modules designed for ambulatory and inpatient settings.

Automated Calculation of Percentage-based Meaningful Use Measures

ONC clarifies that for each meaningful use objective with a percentage-based measure, the certification criterion requires the technology to have the capability to electronically record the numerator and denominator and generate a report including numerator, denominator, and resulting percentage associated with each meaningful-use measure. ONC clarifies that certified EHR technology must be capable of calculating all denominators for those meaningful use measures that are percentage-based and for which CMS requires the submission of results at the end of an EHR reporting period. EPs and eligible hospitals and CAHs must verify that the denominator is complete and are responsible for correct entry of data and for entry of all applicable patient records. ONC does not require as a certification condition that a Complete EHR or EHR Module provide results for meaningful use measures that require only a yes/no attestation.

Regulatory Impact Analysis

ONC finalizes its assumptions and cost estimates identified in the interim final rule and believes the additional clarity and specificity for certification criteria provided under the final rule as well as removal of some required capabilities lowers the cost estimates for compliance. In the interim final rule, ONC believed it was 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) in 2007 or 2008 will only incur moderate costs to prepare for certification, and ONC expects that of those, 65 ambulatory and 15 inpatient, will be submitted for certification. ONC estimated 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. In the final rule, ONC assumes that Complete EHRs previously certified by CCHIT in 2007/2008 will meet approximately 75 percent of the adopted certification criteria, and that average low and high per certification cost for testing and certification for these products will be $50,000 and $200,000. In the case of never CCHIT-Certified-EHRs and of out-of-date CCHIT-certified-EHRs, ONC expects that there will be 8 Complete EHRs for EPs and 5 for eligible hospitals and CAHs prepared to be tested and certified to all of the applicable certification criteria, and ONC believes comprehensive adjustments will be required as those EHRs will meet only approximately 40 percent of the adopted certification criteria.

ONC also believed 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 assumed 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 estimated 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 clarifies that it assumes EHR Modules are developed by those interested in commercially marketing them.

ONC further assumed 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%).

Appendix
Standards and Implementation Specifications for Health Information Technology Reproduced from Final Rule

§170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

(a) Patient summary record.

(1) Standard. Health Level Seven (HL7) Clinical Document Architecture (CDA) Release 2, Continuity of Care Document (CCD).

- Implementation specifications. The Healthcare Information Technology Standards Panel (HITSP) Summary Documents Using HL7 CCD Component HITSP/C32.

(2) Standard. ASTM E2369 Standard Specification for Continuity of Care Record (CCR) and Adjunct to ASTM E2369.

(b) Electronic prescribing.

(1) Standard. 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.

(2) Standard. NCPDP SCRIPT Standard, Implementation Guide, Version 10.6.

(c) Electronic submission of lab results to public health agencies.

Standard. HL7 2.5.1.

- Implementation specifications. HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm).

(d) Electronic submission to public health agencies for surveillance or reporting.

(1) Standard. HL7 2.3.1.

(2) Standard. HL7 2.5.1.

- Implementation specifications. 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.

(e) Electronic submission to immunization registries.

(1) Standard. HL7 2.3.1.

- Implementation specifications. Implementation Guide for Immunization Data Transactions using Version 2.3.1 of HL7 Standard Protocol Implementation Guide Version 2.2.

(2) Standard. HL7 2.5.1.

- Implementation specifications. HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0.

(f) Quality reporting.

Standard. The CMS Physician Quality Reporting Initiative (PQRI) 2009 Registry XML Specification.

- Implementation specifications. PQRI Measure Specifications Manual for Claims and Registry.

§170.207 Vocabulary standards for representing electronic health information.

(a) Problems.

(1) Standard. The code set specified at 45 CFR 162.1002(a)(1) (relating to ICD-9-CM Volumes 1 and 2) for the indicated conditions.

(2) Standard. International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED-CT®) July 2009 version.

(b) Procedures.

(1) Standard. The code set specified at 45 CFR 162.1002(a)(2) (relating to ICD-9-CM Volume 3 procedures).

(2) Standard. The code set specified at 45 CFR 162.1002(a)(5) (relating to combination of HCPCS and CPT-4).

(c) Laboratory test results.

Standard. Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, when such codes were received within an electronic transaction from a laboratory.

(d) Medications.

Standard. Any source vocabulary that is included in RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine.

(e) Immunizations.

Standard. HL7 Standard Code Set CVX - Vaccines Administered, July 30, 2009 version.

(f) Race and Ethnicity.

Standard. The OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, October 30, 1997 (available at http://www.whitehouse.gov/omb/rewrite/fedreg/ombdir15.html).

§170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.

(a) Encryption and decryption of electronic health information

(1) 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.

(2) Exchange. Any encrypted and integrity protected link.

(b) Record actions related to electronic health information. 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.

(c) Verification that electronic health information has not been altered in transit.

Standard. 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.

(d) Record treatment, payment, and health care operations disclosures. 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.