DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 170

RIN 0991-AB58

Health Information Technology: Initial Set of Standards, Implementation

Specifications, and Certification Criteria for Electronic Health Record Technology

AGENCY: Office of the National Coordinator for Health Information Technology

(ONC), Department of Health and Human Services.

ACTION: Final Rule.

SUMMARY: The Department of Health and Human Services (HHS) is issuing this final

rule to complete the adoption of an initial set of standards, implementation specifications,

and certification criteria, and to more closely align such standards, implementation

specifications, and certification criteria with final meaningful use Stage 1 objectives and

measures. Adopted certification criteria establish the required capabilities and specify the

related standards and implementation specifications that certified electronic health record

(EHR) technology will need to include to, at a minimum, support the achievement of

meaningful use Stage 1 by eligible professionals, eligible hospitals, and/or critical access

hospitals (hereafter, references to "eligible hospitals" in this final rule shall mean

"eligible hospitals and/or critical access hospitals") under the Medicare and Medicaid

EHR Incentive Programs. Complete EHRs and EHR Modules will be tested and certified

according to adopted certification criteria to ensure that they have properly implemented

adopted standards and implementation specifications and otherwise comply with the

adopted certification criteria.

DATES: <u>Effective Date</u>: This final rule is effective [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Steven Posnack, Director, Federal Policy Division, Office of Policy and Planning, Office of the National Coordinator for Health Information Technology, 202-690-7151

SUPPLEMENTARY INFORMATION:

Acronyms

ANSI	American National Standards Institute
CAH	Critical Access Hospital
CCD	Continuity of Care Document
CCHIT	Certification Commission for Health Information Technology
CCR	Continuity of Care Record
CDA	Clinical Document Architecture
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CGD	Certification Guidance Document
CMS	Centers for Medicare & Medicaid Services
CPOE	Computerized Provider Order Entry
EHR	Electronic Health Record
FIPS	Federal Information Processing Standards

HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HIT	Health Information Technology
HITECH	Health Information Technology for Economic and Clinical Health
HITSP	Healthcare Information Technology Standards Panel
HL7	Health Level Seven
ICD	International Classification of Diseases
ICD-9-CM	International Classification of Diseases, 9th Revision, Clinical Modification
ICD-10-PCS	International Classification of Diseases, 10th Revision, Procedure Coding System
ICD–10–CM	International Classification of Diseases, 10th Revision, Clinical Modification
IHS	Indian Health Service
LOINC	Logical Observation Identifiers Names and Codes
NCPDP	National Council for Prescription Drug Programs
NLM	National Library of Medicine
OCR	Office for Civil Rights
OMB	Office of Management and Budget
ONC	Office of the National Coordinator for Health Information Technology
PHSA	Public Health Service Act
PQRI	Physician Quality Reporting Initiative
REST	Representational state transfer

RFA   Regulatory Flexibility Act

SNOMED-CT Systematized Nomenclature of Medicine Clinical Terms

SOAP   Simple Object Access Protocol

UCUM   Unified Code for Units of Measure

UMLS   Unified Medical Language System

XML   eXtensible Markup Language

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I. Background

A. Legislative History

The Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5), was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act (PHSA) and established "Title XXX – Health Information Technology and Quality" to improve health care quality, safety, and efficiency through the promotion of health information technology (HIT) and the electronic exchange of health information. Section 3004(b)(1) of the PHSA requires the Secretary of Health and Human Services (the Secretary) to adopt an initial set of standards, implementation specifications, and certification criteria by December 31, 2009 to enhance the interoperability, functionality, utility, and security of health information

technology. Section 3004(b)(1) of the PHSA also permits the Secretary to adopt the initial set of standards, implementation specifications, and certification criteria on an interim, final basis.

B. Regulatory History

1. Initial Set of Standards, Implementation Specifications, and Certification Criteria for EHR Technology Interim Final Rule

On December 30, 2009, the Federal Register made available for public inspection, an interim final rule (the Interim Final Rule) with a request for comments, which adopted an initial set of standards, implementation specifications, and certification criteria. As noted in this rulemaking (75 FR 2014), we described how Congress fundamentally tied the adopted standards, implementation specifications, and certification criteria to the incentives available under the Medicare and Medicaid EHR Incentive Programs by requiring the meaningful use of Certified EHR Technology. Congress outlined several goals for meaningful use, one of which included the "use of certified EHR technology in a meaningful manner." This means that to qualify for incentives, an eligible professional or eligible hospital must both adopt Certified EHR Technology and demonstrate meaningful use of this technology.

The initial set of standards, implementation specifications, and certification criteria adopted in the Interim Final Rule established the capabilities that Certified EHR Technology would need to include to, at a minimum, support eligible professionals' and eligible hospitals' efforts to achieve what had been proposed for meaningful use Stage 1 under the Medicare and Medicaid EHR Incentive Programs proposed rule.

2. Interdependencies with Other HITECH Provisions and Relationship to Other Regulatory Requirements

In addition to our discussion of how the standards, implementation specifications, and certification criteria adopted in the Interim Final Rule correlated with the Medicare and Medicaid EHR Incentive Programs proposed rule, we also discussed our approach to align adopted standards, implementation specifications, and certification criteria with new and pending HITECH Act regulatory actions and with other already established regulatory requirements. We also explained our approach for aligning these standards, implementation specifications, and certification criteria with: the adopted standard and certification criterion related to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule Accounting of Disclosures Regulation under the HITECH Act; alignment with the HIPAA Privacy and Security Regulations; the Medicare Part D Electronic Prescribing Regulations; and the HIPAA Transactions and Code Sets Standards Regulations.

II. Overview of the Final Rule

We are amending part 170 of title 45 of the Code of Federal Regulations (CFR) to complete the adoption of the initial set of standards, implementation specifications, and certification criteria as required by section 3004(b)(1) of the PHSA and realign them with the final objectives and measures established for meaningful use Stage 1. After reviewing and considering public comments on our adopted standards, implementation specifications, and certification criteria, we have made several revisions to support the final meaningful use objectives and measures, clarify certain certification criteria to

resolve identified technical challenges related to some of the standards and

implementation specifications we adopted, and to provide for additional flexibility.

III. Section-by-Section Discussion of the Final Rule and Response to Comments

A. Introduction

This section summarizes the nearly 400 timely comments received by ONC

related to the Interim Final Rule. In some cases, due to the simultaneous publication and

topical similarity of the notice of proposed rulemaking for meaningful use Stage 1,

commenters inadvertently submitted comments to our regulation docket on

regulations.gov instead of the Centers for Medicare & Medicaid Services (CMS)

regulation docket, and vice versa. Recognizing this oversight, CMS and ONC shared

misplaced comments between the offices and we included within our review all

comments that could be reasonably identified as comments on the Interim Final Rule.

We have organized the preamble of this final rule along the following lines. First,

we respond to general comments, including those related to the scope and applicability of

the final rule that we believe are necessary to clarify upfront. Next, we respond to

comments regarding the definitions of certain defined terms. We then respond to public

comments on each certification criterion, and where an adopted certification criterion also

references standards and implementation specifications, we include our response to

public comments on the related standards and implementation specifications. These

concepts were separately discussed in the Interim Final Rule and we believe that

discussing the certification criteria together with associated standards and implementation

specifications will improve the clarity of the final rule and will allow us to more fully

address public comments in a broader context. We include the following table at the

beginning of the discussion of each certification criterion section to illustrate the final

meaningful use Stage 1 objectives for eligible professionals and eligible hospitals and to

show how we have revised adopted certification criteria in response to the revised

meaningful use objectives and measures and public comments.

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Eligible Professional and/or Eligible Hospital & Critical Access Hospital Objective	Eligible Professional and/or Eligible Hospital & Critical Access Hospital Measure	**Interim Final Rule Text:** Certification Criterion
		Final Rule Text: Certification Criterion

Finally, in considering public comments on the Interim Final Rule, we analyzed

whether we had structured the regulation text in an optimal and understandable manner.

For several provisions, we received comments requesting additional clarification and we

felt that the original regulatory structure contributed to the commenters' confusion.

Because of those comments and in an effort to better structure the regulation text for

future revisions, we have revised the structure conceptually to group content exchange

standards and associated implementation specifications and vocabulary standards, and

separated them into different sections. In line with this "conceptual" restructuring, we

have determined that specifying how a Complete EHR or EHR Module must comply

with an adopted standard should be solely reflected in the certification criteria. As a

result, several certification criteria have been revised to more clearly reflect how a

Complete EHR or EHR Module must comply with adopted standards and, where

applicable, the relevant adopted implementation specifications.

B. General Comments

Some commenters appear to have misinterpreted or misunderstood the scope of the Interim Final Rule and the applicability of the adopted standards, implementation specifications, and certification criteria. We would therefore like to clarify these concepts at the beginning of this final rule and are providing the following responses to the relevant comments.

Comments. Some commenters seem to have construed the adoption of standards, implementation specifications, and certification criteria as including requirements that apply to the health care providers that will use the Certified EHR Technology, rather than as required capabilities of the Certified EHR Technology itself. These commenters, for instance, questioned whether entities using Certified EHR Technology must comply with adopted standards and implementation specifications when electronically using or transmitting health information within or among components of the legal entity or alternatively whether the standards apply solely to transmissions between legal entities. Other commenters specifically requested clarification regarding the adopted standards that are required to be used internally within each provider's office, institution, or closed system and which standards are required for purposes of electronically exchanging health information among such entities. Some comments implied that the Interim Final Rule should have specified when an eligible professional or eligible hospital would be required to use adopted standards. One commenter specifically requested that the adopted standards apply only to the electronic exchange of health information between legal entities.

Response. As stated in §170.101, we specify that "[t]he standards, implementation specifications, and certification criteria adopted in this part apply to

Complete EHRs and EHR Modules and the testing and certification of such Complete EHRs and EHR Modules." In §§170.200 and 170.300, we further specify that "[t]he standards and implementation specifications adopted in this part apply with respect to Complete EHRs and EHR Modules" and that "[t]he certification criteria adopted in this subpart apply to the testing and certification of Complete EHRs and EHR Modules."

The purpose of this final rule, therefore, is to adopt standards, implementation specifications, and certification criteria to test and certify that a Complete EHR or EHR Module provides certain capabilities, and where applicable, to require that those capabilities be implemented in accordance with adopted standards and implementation specifications. The adopted standards, implementation specifications, and certification criteria were not intended to impose independent requirements on the entities using Certified EHR Technology. Unlike certain other regulatory requirements to which eligible professionals or eligible hospitals may be subject, it is not within the intended scope of this final rule to specify the requirements for entities using Certified EHR Technology.

We understand the commenters' point though that an adopted standard and implementation specification could apply equally to electronic transactions between legal entities as well as to transmissions within an entity. This final rule, however, is not intended to specify the conditions under which adopted standards and implementation specifications must be used, only that a Complete EHR or EHR Module, in order to be certified, must include specified capabilities that are implemented in accordance with those standards, implementation specifications, and certification criteria. We anticipate that other regulations, as well as the clinical and business needs of HIT users, anticipated

efficiencies and desired quality improvements, and technical, architectural, and enterprise limitations will determine when entities will utilize the capabilities required of Certified EHR Technology. Additionally, we would note that Complete EHRs and EHR Modules will, in many cases, be tested and certified independent of the environment within which they will be implemented. Consequently, specifying when an entity that implements Certified EHR Technology must utilize a particular capability in its operating environment exceeds the scope of this rule.

To further demonstrate this point, Certified EHR Technology implemented by an eligible professional will need to possess the capability to generate an electronic prescription according to one of the standards we have adopted. To specify the contexts in which an electronic prescription (generated according to the adopted standard) must be transmitted would go beyond the scope of certification. Moreover, it would raise a more serious and practical consideration. Attempting to specify when entities must utilize the capabilities of Certified EHR Technology would add an unnecessary level of complexity to this rule and create the potential for conflicts with other regulations promulgated by the HHS. For instance, HHS has already promulgated at least two sets of regulations identifying when health care providers need to use specific standards and the contexts in which those standards must be used. Under the HIPAA Transactions and Code Sets Standards regulations, HHS specifies at 45 CFR 162.923(a) that "[e]xcept as otherwise provided in this part, if a covered entity conducts with another covered entity (or within the same covered entity), using electronic media, a transaction for which the Secretary has adopted a standard under this part, the covered entity must conduct the transaction as a standard transaction." (Emphasis added.) Consequently, in the HIPAA context,

covered entities must use adopted transaction standards for covered transactions both within the covered entities and with outside entities. The Medicare Part D electronic-prescribing (e-prescribing) regulations implement a different approach for certain e-prescribing transactions. Health care providers that electronically prescribe Part D drugs for Part D eligible individuals under 42 CFR 423.160(a)(3)(iii), "may use either HL7 messages or the NCPDP SCRIPT Standard to transmit prescriptions or prescription-related information internally when the sender and the recipient are part of the same legal entity. If an entity sends prescriptions outside the entity (for example, from an HMO to a non-HMO pharmacy), it must use the adopted NCPDP SCRIPT Standard or other applicable adopted standards." Therefore, we believe that it is unnecessary and outside of the intended scope of this rule to specify the contexts or circumstances under which adopted standards and implementation specifications must be utilized.

Moreover, we anticipate that future meaningful use objectives and measures will specify, as necessary and appropriate, the conditions under which certain health care providers will need to use adopted standards and implementation specifications. The context, for instance, governing when a standard must be used will, in some cases, be directly related to whether and how an eligible professional or eligible hospital must meaningfully use Certified EHR Technology. For example, a final meaningful use Stage 1 objective requires that eligible professionals and eligible hospitals use Certified EHR Technology to record demographics including, among other fields, race and ethnicity. While we have adopted the race and ethnicity codes published by the Office of Management and Budget (OMB), in the context Medicare and Medicaid EHR incentive programs, the meaningful use of Certified EHR Technology will dictate whether such

codes must be used "inside" an organization. Another example of when a meaningful use objective establishes the context in which a standard must be used is the objective that requires eligible professionals and eligible hospitals to use Certified EHR Technology to maintain an up-to-date problem list of current and active diagnoses. The measure associated with this objective requires that entries be recorded in "structured data" and in this context we adopted ICD-9 or SNOMED-CT® to provide that structure. As a result, Certified EHR Technology must be capable of using ICD-9 or SNOMED-CT® when an eligible professional or eligible hospital seeks to maintain an up-to-date problem list.

In other instances, the Department does not specify explicitly in regulation the context for certain meaningful use objectives and whether meaningful use of Certified EHR Technology would require the use of a standard for electronic transactions solely between two different legal entities, or for all transactions, or for most transactions with certain exemptions.

Comments. Several commenters requested that we provide more information about the standards we expect the Secretary to adopt in order to support future stages of meaningful use. These commenters noted, along with referencing the timelines for making changes to HIT, that it would benefit the HIT industry if we could provide a roadmap, framework, or more descriptive "glide path" for future standards adoption activities.

Response. We anticipate that future stages of meaningful use will require us to adopt additional standards, implementation specifications, and certification criteria. We also expect that standards we have adopted will continue to be revised and updated over time, to reflect current technology, changing medical practice and regulatory

requirements. We will therefore need to continue to harmonize those adopted standards

with other standards to support interoperability. We anticipate that the standards required

to support future stages of meaningful use will need a framework that supports

harmonization across different meaningful use scenarios and that supports early real

world testing. We plan to work closely with the HIT Standards Committee to develop a

forward looking agenda and to make known in advance the types of standards,

implementation specifications, and certification criteria on which we will seek

recommendations from the HIT Standards Committee. We believe this will benefit the

HIT industry by providing greater transparency of the standards adoption activities and

will serve as an early indication for the public of candidate standards that are being

identified for possible adoption.

C. Definitions – §170.102

In this section, we respond to public comment on the definitions adopted in the

Interim Final Rule. We address the definition of Certified EHR Technology last after we

provide clarifications related to the definitions of Complete EHR and EHR Module.

1. Definition of Disclosure

Comments. A few commenters noted that the definition of disclosure was too

broad or asked that we refine the adopted definition to be more limited and to only apply

in certain circumstances.   One commenter noted that this was a new definition.

Response. As we explained in the preamble of the Interim Final Rule, this

definition repeated the text specified at 45 CFR 160.103 (the General Provisions section

for the HIPAA regulations). Because the Interim Final Rule created a new part in Title

45 of the CFR, the definition of disclosure as it is used in the HIPAA regulations would

not necessarily have applied to our use of the term in this rule. Therefore, to prevent unnecessary ambiguity for the regulated community, we adopted the definition of the term as it is defined at 45 CFR 160.103.

In light of public comment and to prevent any future regulatory inconsistency that would require rulemaking to correct, we have revisited our approach of repeating the text of the definition of disclosure from 45 CFR 160.103 and have decided to cross reference 45 CFR 160.103 in the definition of disclosure. The final definition will read: disclosure is defined as it is in 45 CFR 160.103.

2. Definition of Standard

Comment. A commenter stated that our definition of standard was comprehensive from a technical perspective, but believed the definition was incomplete from a policy perspective. The commenter argued that for interoperability to be successful, it was essential that standards be created through collaborative, consensus-based processes that take into consideration the needs and concerns of all interested stakeholders. For that reason, the commenter suggested, in order for the definition to be whole from both a technical and policy perspective, we should add to the definition the phrase "developed through the use of open, collaborative, consensus-based processes."

Response. While we appreciate the commenter's point, we believe that the proposed language is unnecessary and potentially problematic. Federal agencies are already required under the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 3701 et seq.) and OMB Circular A-119[1] to use, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. In drafting the

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[1] http://www.whitehouse.gov/omb/circulars_a119

Interim Final Rule, we briefly discussed relevant provisions of the NTTAA and OMB Circular A-119, our compliance with the statute and the Circular, and we requested comments on our approach to the selection of standards. We also explained that both the NTTAA and OMB Circular A-119 provide for certain exceptions to selecting only standards developed or adopted by voluntary consensus standards bodies, namely when doing so would be "inconsistent with applicable law or otherwise impractical." In the Interim Final Rule, we identified those instances in which we had and had not adopted voluntary consensus standards. In the instances in which we had not adopted voluntary consensus standards, we provided two principal reasons: first, that in most cases a voluntary consensus standard that could meet the requisite technical goals was simply unavailable; and second, that to the extent a potentially equivalent voluntary consensus standard was available, the standard was too limiting and did not meet our policy goals, including allowing for greater innovation by the industry. In this final rule, we have adopted only voluntary consensus standards, except for two government-unique standards (CMS Physician Quality Reporting Initiative (PQRI) 2009 Registry XML Specification and the Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity), a functional standard relating to vocabularies included in RxNorm, and the specified standards to protect electronic health information. We are aware of no voluntary consensus standards that would serve as alternatives to these standards for the purposes that we have identified. We encourage the HIT Standards Committee to obtain public input, hold hearings on, and recommend to the National Coordinator standards that have been developed or adopted by voluntary consensus standards bodies.

3. Definition of Implementation Specification

We did not receive any comments applicable to the definition of implementation specification and consequently did not make any changes to the definition.

4. Definition of Certification Criteria

Comments. One commenter expressly stated its support for our definition of certification criteria.

Response. We appreciate the commenter's support for our definition of certification criteria and have not made any changes to the definition in this final rule.

5. Definition of Qualified EHR

Comments. A couple of commenters asserted that there is uncertainty in the industry with respect to what constitutes an EHR due both to the seemingly inconsistent definitions of terms in the HITECH Act and to the alternative definitions published by different organizations and associations. The commenters made specific reference to the definition of "Qualified Electronic Health Record" ("Qualified EHR") at section 3000 of the PHSA and to the term "EHR" found in the HITECH Act at section 13400 of Subtitle D. The latter defines EHR as "an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized clinicians and staff." The former defines Qualified EHR as "an electronic record of health-related information on an individual that: (1) includes patient demographic and clinical health information, such as medical history and problem lists; and (2) has the capacity: (i) to provide clinical decision support; (ii) to support physician order entry; (iii) to capture and query information relevant to health care quality; and (iv) to exchange electronic health information with, and integrate such information from other sources." Both commenters

recommended that the definition of Qualified EHR be clarified with one commenter

suggesting that the definition should follow the definition of EHR as it relates to health

care providers.

Response. We appreciate these comments and recognize that the existence of

multiple terms that include the word "EHR" can be confusing. However, we believe that

Congress intended for HHS to apply the definition of a Qualified EHR found in section

3000 of the PHSA to this regulation for specific reasons that cannot be overlooked. As a

result, we have decided not to adopt the recommendation to follow the definition of the

term EHR that is found in Subtitle D of the HITECH Act. We discuss additional

responses to comments on the definition of Qualified EHR below.

Comments. A few commenters requested that we expand the definition of

Qualified EHR to include a variety of additional functionality and that a Qualified EHR

be able to comply with business or legal requirements. These comments requested that

we add required elements for an EHR to constitute a Qualified EHR, including that the

EHR: have a record-keeping capability for legal purposes; include certain requirements

for usability; enable health care providers to perform several other actions not specified

in the definition; and that certain elements of patient demographic information be

specified.

Response. We understand the rationale behind these commenters' suggestions,

but we do not believe that it is necessary to add more prerequisite capabilities to the

definition of Qualified EHR. We believe Congress defined Qualified EHR to include a

minimum level of capabilities. Furthermore, to meet the definition of Certified EHR

Technology, a Qualified EHR must be certified in accordance with a certification

program established by the National Coordinator. As a result, we believe that any additional capabilities a Qualified EHR would need to possess to allow an eligible professional or eligible hospital to be in a position to qualify for incentive payments under the Medicare and Medicaid EHR incentive programs will be more appropriately addressed through the Secretary's adoption of additional standards, implementation specifications, and certification criteria.

Comments. Some commenters requested that we clarify some of the terms in the definition of Qualified EHR such as "capture," "query," "other sources," and "relevant to health care quality" with respect to how they related to Certified EHR Technology. Another commenter expressly stated that if we only intended to repeat the statutory definition of Qualified EHR without modification, we should at least clarify the meaning of demographic information.

Response. We do not believe that additional clarity is needed or desirable for such terms because the meanings are context specific. The intended meanings of these terms will depend significantly on the contexts in which the terms are used and the associated capabilities of the Certified EHR Technology. The terms' meanings may also be affected by any standards and implementation specifications that are associated with those capabilities and adopted. In certain circumstances, for instance, the meaning of the phrase "other sources" as used in the definition of Qualified EHR will depend on the specific context in which electronic health information is being integrated or exchanged, and perhaps on whether the source is external to or internal within the Complete EHR or the EHR Module. Similarly, the meanings of the terms or phrases "capture," "query," "relevant to health care quality" and "demographic" information may vary according the

context of the required capabilities of the EHR technology.   In each of these instances,

we believe that the adopted certification criteria and meaningful use objectives and

measures will provide these contexts, identify the associated required capabilities, and

consequently clarify the intended meanings of these terms.

6. Definition of Complete EHR

Comments. Some commenters supported our definition of Complete EHR and

believed that it was understandable, sufficient, and reasonable. Other commenters,

however, suggested that the definition of Complete EHR was too narrow, because the

term is tied to only those certification criteria adopted by the Secretary. These

commenters argued that the Complete EHR and the adopted certification criteria should

be more comprehensive and should include functionality that is not presently required for

a Complete EHR to achieve certification. Many of these commenters referenced the

Health Level Seven (HL7) EHR System Functional Model (EHR-S FM) and contended

that what we had defined as a Complete EHR did not align with or include all of the

functionality specified in the EHR-S FM. One commenter requested that we clarify what

we meant by "we fully expect some EHRs to have capabilities beyond those addressed by

certification criteria" when we made this point during our discussion of the definition of

Complete EHR in the preamble of the Interim Final Rule. Other commenters

recommended specific wording changes to the definition.

Response. In the Interim Final Rule we defined Complete EHR to mean "EHR

technology that has been developed to meet all applicable certification criteria adopted by

the Secretary." We clarified that the term Complete EHR is "meant to encompass EHR

technology that can perform all of the applicable capabilities required by certification

criteria adopted by the Secretary and distinguish it from EHR technology that cannot perform those capabilities." We believe that commenters misunderstood the scope and purpose of the regulatory definition and believe that the definition effectively fulfills its regulatory purpose. We intend for the definition of Complete EHR to be used to clearly identify EHR technology as being able to perform, at a minimum, all of the applicable capabilities required by certification criteria adopted by the Secretary, and thereby, as providing eligible professionals or eligible hospitals with the technical capabilities they need to support their achievement of meaningful use of Certified EHR Technology. It is in this context that we view such EHR technology as "complete."

We recognize that many commenters recommended a definition of "Complete EHR" that would be more comprehensive than the definition we provided. Many commenters contended that HIT exists and is available for eligible professionals and eligible hospitals to implement, and much of it includes a myriad of capabilities far surpassing the capabilities required to meet the definition of Complete EHR. We do not dispute that point. We also understand that the capabilities included in a Complete EHR, as defined for the purposes of this regulation, may not encompass all of the capabilities a specific eligible professional or eligible hospital or for that matter any health care provider, may deem essential to meet their unique business needs and use cases.

This definition, however, does not in any way preclude any additional capabilities from being included in a Complete EHR or implemented in a complementary fashion. The definition sets forth a floor, not a ceiling, and serves to signify that once tested and certified to all applicable certification criteria, a Complete EHR meets the definition of Certified EHR Technology. For this reason, we did not seek to craft this definition in a

way that signified that a Complete EHR would be able to provide all of the capabilities a health care provider desired or deemed necessary, or that the entity's EHR could only include the capabilities for which the Secretary has adopted certification criteria. Nor did we define Complete EHR according to a particular functional model, because doing so would have been inconsistent with the regulatory purpose of the definition.

In light of public comment and to further clarify the regulatory purpose of the definition of Complete EHR as well as make clear that a Complete EHR should not be misinterpreted to mean EHR technology that is any more comprehensive than the certification criteria to which it was tested and certified, we have added the phrase "at a minimum" to the definition. The final definition of Complete EHR will therefore read "EHR technology that has been developed to meet, at a minimum, all applicable certification criteria adopted by the Secretary."

As a related point, we would also note that an eligible professional or eligible hospital would need to use a capability that is included among the adopted certification criteria to meet the associated meaningful use objective or measure. The eligible professional or eligible hospital therefore could not attempt to use a capability that is superfluous to certification to demonstrate the meaningful use of "Certified EHR Technology." We understand that the Medicare and Medicaid EHR Incentive Programs final rule discusses this issue more fully in several places, and we defer to those discussions concerning the requirements for achieving meaningful use of Certified EHR Technology.

Comment. In the context of the definition of Complete EHR, one commenter asked for clarification regarding how many certification criteria a Complete EHR must be developed to meet.

Response. For the purposes of meeting the definition of Complete EHR, EHR technology designed for an ambulatory setting (to be used by eligible professionals) must be certified to all of the certification criteria adopted at 45 CFR 170.302 and 45 CFR 170.304, and EHR technology designed for an inpatient setting (to be used by eligible hospitals) must be certified to all of the certification criteria adopted at 45 CFR 170.302 and 45 CFR 170.306.

7. Definition of EHR Module

Comments. Numerous commenters strongly supported our inclusion of a modular approach to meet the definition of Certified EHR Technology. Many of these commenters saw this approach as a way to spur greater innovation in the HIT marketplace, provide more choices for health care providers, and generally broaden the appeal of HIT and expedite its adoption. Some commenters noted, however, that they believed the definition needed further clarification with respect to what would constitute an EHR Module. In most cases, these commenters provided examples of technologies that they believed should meet the definition of EHR Module and they sought confirmation that these technologies would meet the definition. Included among these technologies were radiology information systems (RIS), picture archiving and communication systems (PACS), PHRs, speech recognition software, electrocardiogram systems, remote patient monitoring (RPM) devices, and other electronic devices including non-health care devices.

Response. In the Interim Final Rule, we defined an EHR Module to mean "any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary." Consequently, EHR Modules, by definition, must provide a capability that can be tested and certified in accordance with at least one certification criterion adopted by the Secretary. Therefore, if an EHR Module does not provide a capability that can be tested and certified at the present time, it is **not** HIT that would meet the definition of EHR Module. We stress "at the present time," because as new certification criteria are adopted by the Secretary, other HIT could be developed and then tested and certified in accordance with the new certification criteria as EHR Modules.

We encourage eligible professionals and eligible hospitals to use any and all HIT they believe will help make the health care they deliver more effective and efficient. However, unless the HIT is tested and certified to at least one certification criterion for use as part of Certified EHR Technology, it does not constitute an EHR Module for the purposes of this regulation. Eligible professionals and eligible hospitals are not prohibited from using or implementing this HIT, but again, at the present time, such HIT cannot constitute an EHR Module and serve as a necessary component of Certified EHR Technology for eligible professionals or eligible hospitals to use when seeking to achieve meaningful use as defined in the Medicare and Medicaid EHR Incentive Programs final rule.

In response to these comments, we would also like to clarify our conceptualization of an EHR Module. An EHR Module could provide a single capability required by one certification criterion or it could provide all capabilities but one, required

by the certification criteria for a Complete EHR. In other words, we would call HIT tested and certified to one certification criterion an "EHR Module" and HIT tested and certified to nine certification criteria an "EHR Module," where ten certification criteria are required for a Complete EHR. We have not made any changes to the definition of EHR Module as a result of these comments or the comments addressed below.

Comment. One commenter asked whether we meant to include in the definition of EHR Module "interfaces" that perform data mapping or transformation. The commenter raised this question while noting that some organizations use multiple interfaces to interconnect their HIT systems and that it would be an arduous task for these organizations to ensure that all individual interfaces are certified. Another commenter sought clarification regarding what we meant when we stated as an example in the Interim Final Rule that EHR Modules could be "an interface or other software program that provides the capability to exchange electronic health information."

Response. As discussed above, to meet the definition of EHR Module, HIT would need to provide a capability that could be tested and certified to at least one certification criterion. If a certification criterion has therefore been adopted that requires a particular capability for exchanging electronic health information, an interface or other software program that provides that capability could be tested and certified as an EHR Module. In many circumstances, an interface or program may provide valuable functionality, but not a capability for which a certification criterion has been adopted. For example, software implemented by an eligible professional that performs data translation or mapping between two databases or data sets may provide critical functionality, yet that software would not constitute an EHR Module. Similarly,

interfaces between "HIT systems" may be critical to the functionality of the separate systems, but they themselves would not be EHR Modules.

In those circumstances in which an interface or other software program is an integral component of an EHR Module without which it would not be able to be tested and certified, then such interface or other software program, though not itself an EHR Module, would function as a critical piece of the overall EHR Module presented for testing and certification. For example, a software program that would permit an eligible professional or eligible hospital to electronically exchange health information with other eligible professionals or eligible hospitals could be tested and certified as an EHR Module, if it provides the capability to electronically exchange health information according to standards adopted by the Secretary. In this example, whatever comprises the software program would be considered part of the EHR Module that is tested and certified.

Finally, in situations where an eligible professional or eligible hospital believes that it has multiple HIT systems that would each meet the definition of EHR Module, we suggest that the eligible professional or eligible hospital evaluate whether these systems could be combined with other systems to constitute a Complete EHR. If they are capable of being combined to form a Complete EHR, it may be more expeditious and beneficial for an eligible professional or eligible hospital to simply seek Complete EHR testing and certification.

Comments. A few commenters requested that we clarify how EHR Modules would be tested and certified to adopted privacy and security certification criteria. Other

commenters asked whether we meant to allow for there to be EHR Modules that provided only privacy and security capabilities.

Response. These comments pertain to the certification programs rule, and are outside of the scope of this rule. We therefore respond to these comments in the Temporary Certification Program final rule (75 FR 36158).

8. Definition of Certified EHR Technology

Comments. Multiple commenters commended ONC for recognizing the need to certify EHR Modules and enabling certified EHR Modules to be used in combination to meet the definition of Certified EHR Technology. These commenters noted that this approach makes it clear that eligible professionals and eligible hospitals will have the flexibility to select certified EHR modules that are the most useful to them, and can achieve meaningful use either with combinations of certified HIT or a single EHR system. However, some commenters mentioned that the definition is unnecessarily ambiguous, and subject to possible alternative interpretations. Some commenters also commented on certain statements in the preamble regarding EHR Modules and queried how a proper combination of EHR Modules could be used to meet the definition of Certified EHR Technology. Other commenters, while acknowledging that adopted certification criteria will determine in part what constitutes Certified EHR Technology, urged ONC to revise the definition to include only patient care functionality. Finally, a few commenters offered specific word changes for the definition to improve its clarity.

Response. In the Interim Final Rule, we defined Certified EHR Technology to mean "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."

With respect to a combination of EHR Modules, we clarified in the preamble of the

Interim Final Rule that:

> "As long as each EHR Module has been separately tested and certified in accordance with the certification program established by the National Coordinator…to all of the applicable certification criteria adopted by the Secretary, a proper combination of certified EHR Modules could meet the definition of Certified EHR Technology. To clarify, we are not requiring the certification of combinations of certified EHR Modules, just that the individual EHR Modules combined have each been certified to all applicable certification criteria in order for such a "combination" to meet the definition of Certified EHR Technology."

Many commenters appeared to be confused by the inclusion of "each of which" in

the definition of Certified EHR Technology. Other commenters also stated that "each of

which" was awkwardly placed, making it difficult to interpret how the combination of

EHR Modules must satisfy the subsequent requirements of the definition. This confusion

also made it difficult to understand the clarifying remarks reiterated above regarding our

intention to avoid implying that a combination of certified EHR Modules had to be

certified a second time when a proper combination had been created. We generally agree

with these comments and are revising the definition slightly to avoid this ambiguity and

to clarify that the definition of Certified EHR Technology can be met in either of two

ways.

The first way that the definition of Certified EHR Technology can be met is for a

Complete EHR to: 1) meet the requirements included in the definition of a Qualified

EHR, and 2) be 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. The second way that the definition of Certified EHR

Technology can be met is if each constituent EHR Module of a combination of EHR

Modules 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.

As previously written, it was unclear to many commenters that the comma

preceding "each of which" was meant to separately apply a Complete EHR and

"combination of EHR Modules" to the subsequent requirements. Our intention was that a

combination of EHR Modules would have to provide the capabilities necessary to meet

the definition of a Qualified EHR and that the EHR Modules combined would have each

been tested and certified in accordance with the certification criteria applicable to each

EHR Module.

In response to commenters, we have decided to revise the definition of Certified

EHR Technology to state explicitly the two distinct ways the definition can be met. The

revised definition will read as follows. Certified EHR Technology means:

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.

As discussed in the Temporary Certification Program final rule, a pre-coordinated integrated bundle of EHR Modules would fall under the second definition of Certified EHR Technology, although each EHR Module of the bundle would be tested and certified at the same time rather than separately. Therefore, provided that a proper combination of EHR Modules has been created, combinations of EHR Modules could be tested and certified either at the same time or at separate times, to meet the definition of Certified EHR Technology.

Finally, we believe that commenter suggestions to revise the definition of Certified EHR Technology to reference specific certification criteria are misguided. The definition, regardless of the certification criteria that must be included in a Complete EHR or combination of EHR Modules, must be able to accommodate changes in certification criteria over time. Accordingly we believe that the final definition meets this intended goal and conveys a clear meaning.

Comments. Some commenters appeared to interpret our definition as providing that EHR Modules must be used to meet the definition of Certified EHR Technology. Of these commenters, some requested that we clarify whether health care providers would be required to obtain certification of EHR Modules that no vendors support. Other commenters asked whether non-certified "EHR modules" could be used in combination with a Complete EHR or in combination with EHR Modules that are used to meet the definition of Certified EHR Technology.

Response. We would like to make clear that eligible professionals and eligible

hospitals are not required to use EHR Modules in order to meet the definition of Certified

EHR Technology. The use of EHR Modules is completely voluntary and provides an

alternate avenue for eligible professionals and eligible hospitals who seek to implement

more customized HIT solutions while still meeting the definition of Certified EHR

Technology. Commenters who expressed concerns about their responsibility for seeking

certification for EHR Modules for which no vendor supports did not provide specific

examples, and we are uncertain as to the basis for their concerns. Regardless, we

reiterate that the use of EHR Modules is voluntary and we believe that most eligible

professionals and eligible hospitals that are adopting HIT for the first time will have a

variety of Complete EHRs available from which to choose.

We also clarify that only those EHR Modules that provide capabilities necessary

to meet the definition of Certified EHR Technology will need to be tested and certified.

That being said, eligible professionals and eligible hospitals are free to utilize any other

type of HIT to complement or in combination with Certified EHR Technology, including

HIT that provides capabilities for other purposes not related to meaningful use.

Comments. Some commenters suggested that our definition was too broad.

Most of these commenters argued that we should permit eligible professionals to adopt

only Complete EHRs and EHR Modules that were certified as including only those

capabilities applicable to their specialty or practice. In other words, these commenters

sought for the definition of Certified EHR Technology to be interpreted in such a way as

to permit different specialty-oriented variations of Certified EHR Technology to exist.

Response. At the present time, we believe that the definition of Certified EHR Technology already includes some of the flexibility these commenters request. We permit, for example, a Complete EHR designed for an ambulatory setting and a Complete EHR designed for an inpatient setting both to meet the definition of Certified EHR Technology, even though each is compliant with a slightly different set of applicable certification criteria. In that regard, we believe we have integrated a balanced and appropriate amount of flexibility into the definition of Certified EHR Technology, which will also allow us to make additional refinements over time. We believe that it is possible based on industry need for us to specify in a future rulemaking sets of applicable certification criteria for Complete EHRs and EHR Modules designed for particular clinical settings.

9. Definition of Human Readable Format

Comments. A number of commenters across several certification criteria requested that we clarify the meaning of "human readable format." These commenters questioned what human readable format meant when it was used in the certification criteria and offered examples of what they thought would constitute human readable format such as, style sheets and PDFs. A couple of commenters suggested that human readable format should consider patients' linguistic needs. A commenter requested we discuss the compliance requirements associated with the Americans with Disabilities Act and the relevant sections of the Rehabilitation Act of 1973 to ensure human readable format was meant to include an obligation to provide people with disabilities alternative formats such as large print or Braille.

Response. In the Interim Final Rule, we discussed the meaning of human readable format and provided examples of what we believe would constitute human readable format. We reiterate that discussion below.

> We believe that in order to recognize the enormous potential of HIT, greater standardization in future years is necessary. In that regard, we recognize that more advanced interoperability requires health information to be represented by specific vocabularies and code sets that can be interpreted by EHR technology as well as converted and presented in a readable format to the users of such technology. At the present time we recognize that implementing certain vocabularies and code sets in EHR technology is a difficult, technical undertaking. For that reason, we have not adopted specific vocabularies and code sets for a number of the exchange purposes … We have, however, as a transitional step, adopted certification criteria that require Certified EHR Technology to be capable of presenting health information received in human readable format. By human readable format, we mean a format that enables a human to read and easily comprehend the information presented to them regardless of the method of presentation (e.g., computer screen, handheld device, electronic document). This would likely require information in coded or machine readable format to be converted to, for example, its narrative English language description. In an effort to further the transition to, and prevalence of, more specific vocabularies and code sets, we are interested in public comment regarding industry readiness if we were to adopt certification criteria requiring the use of additional vocabularies and code sets in parallel with meaningful use Stage 2. Such certification criteria could include not only that Certified EHR Technology be capable of presenting information in human readable format but also that it be capable of automatically incorporating certain vocabulary or code sets (i.e., machine readable information).

The term human readable format is used in two contexts, when coded health information should be displayed to an eligible professional or (to a health care professional within) an eligible hospital using Certified EHR Technology and in the circumstances where Certified EHR Technology must be capable of generating an electronic copy of health information for individuals. Each context may dictate a different human readable format. For example, the use of a style sheet may be appropriate for both health care professionals that are interacting with Certified EHR Technology as well as individuals who receive an electronic copy of their health

information to access at a later time. In other circumstances it may be more appropriate

for a health care professional to view health information in human readable format on

their handheld device while an individual may seek an electronic document, such as a

PDF. Given the requests for additional clarity regarding the meaning of human readable

format, we have decided to define the term in this final rule as follows: Human readable

format means 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).

We noted in the Interim Final Rule that the standards, implementation

specifications, and certification criteria adopted by the Secretary applied to Complete

EHRs and EHR Modules, not to persons or entities. We also stated that nothing required

by the Interim Final Rule should be construed as affecting existing legal requirements

under other Federal laws. Accordingly, this final rule does not affect an eligible

professional or eligible hospital's requirements to comply with other Federal laws in the

event health information is provided in human readable format and persons with

disabilities require reasonable accommodations.

10. Definition of User

Comments. A number of commenters commenting on several certification

criteria requested that we clarify the meaning of the term "user."

Response. We recognize that the term user is referenced in the certification

criteria and at times could be interpreted differently. We believe this flexibility is

necessary because a user may be different depending on the certification criterion and the

context within which the capability it specifies is used. Accordingly, we believe a user

could be a health care professional or office staff, someone who might interact directly

with Certified EHR Technology or that it could also be software program or service.

D. Final Rule Amendments to Adopted Standards, Implementation Specifications, and

Certification Criteria §§170.202, 170.205, 170.207, 170.210, 170.302, 170.304, 170.306

1. Flexibility and Innovation

Comments. Many commenters requested that we provide more flexibility in the

final rule to accommodate new developments in HIT. These commenters agreed with our

approach to identify minimum standards for certain code sets and they recommended a

similar approach for other standards. Some commenters suggested alternative

approaches to adopting standards, such as adopting standards at a higher level of

abstraction (e.g., HL7 2.x, where "x" could be any version within the version 2 family)

and accompanying the adopted standards with detailed implementation specifications or

guidance outside of the rulemaking process.

Response. We appreciate commenters' support for the "minimum standard"

approach that we established in the Interim Final Rule. We believe that code sets are an

appropriate type of standard to set as a "minimum." In the Temporary Certification

Program final rule, we discuss the approaches available to the Secretary to identify and

accept newer versions of adopted minimum code set standards. Below, we discuss how

we have added flexibility into this final rule and how we can add flexibility in future

rulemakings.

In many cases, however, our flexibility may be limited due to legal requirements

to adopt substantive requirements through following the procedures of the Administrative

Procedure Act (APA). Depending upon the circumstances and subject matter, we may

not be able to alter the substantive standards that apply to Certified EHR Technology solely through guidance. In addition, a real and practical need to ensure consistency among various standards regulations constrains the amount of flexibility we can incorporate into the standards we adopt.

In addition, in accordance with Office of the Federal Register regulations related to "incorporation by reference," which we follow for this final rule, the publications we reference are "limited to the edition of the publication that is approved" and do not include "[f]uture amendments or revisions of the publication." Consequently, we do not include regulatory language that refers, for instance, to "Version 1.X" when "X" remains a variable.

We do believe, however, that additional flexibility can be added into this and future rulemakings through at least one of four currently identified means.

- Alternative Standards. In the Interim Final Rule and in this final rule, we have adopted "alternative" standards (and applicable implementation specifications) for several certification criteria. As a general rule, when an adopted certification criterion refers to two or more standards as alternatives, use of at least one of the alternative standards will be considered compliant with the certification criterion. For the certification criterion at §170.302(k)(1), for instance, we have adopted HL7 2.3.1 and HL7 2.5.1 as alternatives, and the use of either standard (and the applicable implementation specifications) would be sufficient to comply with the certification criterion. In each of these instances, we have tried to balance the need for flexibility with the goal of advancing interoperability, while also taking into account that the HIT industry has not yet migrated to a single specific

standard for certain purposes. In some cases, this balancing has required the adoption of certification criteria that requires certain EHR technology to be capable of receiving electronic health information formatted according to a standard that it is not natively capable of generating. For example, with respect to patient summary records, we have adopted the Continuity of Care Document and Continuity of Care Record standards as alternatives. As a condition of certification, section 170.304(i)(1) provides as an additional requirement that upon receipt of a patient summary record formatted in the alternative standard, the EHR technology must be capable of displaying the patient summary record in human readable format. We believe this final rule correctly balances at this stage of EHR adoption our goal of promoting interoperability with the HIT industry's ability to comply with the certification criteria and its need for flexibility. Consistent with our long-term goals for interoperability, we anticipate that this balance will need to change as the HIT industry migrates to single specific standards for particular purposes.

- Minimum Code Set Standards. As previously discussed in the Interim Final Rule, we adopted several minimum code set standards. It is important to note that these code set standards set the floor, not the ceiling, for testing and certification. If, and when, the Secretary accepts a newer version of an adopted minimum standard code set, the Secretary will, in effect, raise the ceiling for what is permitted for testing and certification as well as whether Certified EHR Technology can be upgraded to that newer version without adversely affecting the Certified EHR Technology's certified status. For context purposes we repeat a portion of the

Interim Final Rule's preamble that discussed our approach to minimum code set standards.

"We have implemented this approach by preceding references to specific adopted standards with the phrase, 'at a minimum.' In those instances, the certification criterion requires compliance with the version of the code set that has been adopted through incorporation by reference, or any subsequently released version of the code set. This approach will permit Complete EHRs and EHR Modules to be tested and certified, to, 'at a minimum,' the version of the standard that has been adopted or a more current or subsequently released version."

We would note that consistent with this approach the Secretary has proactively identified and deemed acceptable newer versions of the following adopted "minimum standard" code sets:

1) LOINC version 2.3, released on February 26, 2010; and

2) CVX – Vaccines Administered, March 17, 2010.

We are consequently using this opportunity to inform Complete EHR and EHR Module developers, prospective ONC-Authorized Testing and Certification Bodies, and the rest of the public of the Secretary's recognition of these newer versions of certain adopted "minimum standard" code sets. We reiterate that use of these newer versions is voluntary. We also note in accordance with 45 CFR 170.455(b)(2) that Certified EHR Technology may be upgraded to comply with these newer versions at any time without adversely affecting the certification status of the Certified EHR Technology.

- <u>Optional Standards, Implementation Specifications, and Certification Criteria.</u> We believe that additional flexibility and specificity can be introduced into this and future cycles of rulemaking through the adoption and designation of "optional" standards, implementation specifications, and certification criteria. Optional standards, implementation specifications, and certification criteria would

be voluntary and would not be required for testing and certifying a Complete

EHR or EHR Module. We believe that optional standards, implementation

specifications, and certification criteria will also help better prepare the HIT

industry for future mandatory certification requirements.

- Standards and Backwards Compatibility. In previous rulemakings, specifically

  the Secretary's adoption of electronic prescribing (e-prescribing) standards (70

  FR 67579) related to the Medicare Part D prescription drug program, HHS

  discussed a process to improve flexibility in regulatory requirements which

  involves "backwards compatibility." HHS described backwards compatibility as

  meaning that a newer version of a standard retains at a minimum the full

  functionality of the version previously adopted in regulation, and that the newer

  version would permit the successful completion of the applicable transaction(s)

  with entities that continue to use the older version(s). HHS discussed that if a

  newer version of a standard were backward compatible with an adopted standard,

  it would be possible to pursue a more expedited approach to permit the utilization

  of the newer version while still remaining in compliance with the law. We

  believe that the approach established in the e-prescribing rulemaking could be

  leveraged in many situations for the standards and implementation specifications

  adopted for HIT certification. However, we note that this approach can only be

  implemented when a newer version of a standard is technically capable of fully

  functioning with the adopted version of the standard to conduct the specified

  transaction.

Much like minimum code set standards, we could foresee possibly adopting a backward compatible version of a previously adopted standard and allowing entities to voluntarily use the newer version for a period of time. In such cases, much like a minimum code set standard, Complete EHR and EHR Module developers would be permitted to have their Complete EHR or EHR Module certified according to the adopted backward compatible version, and eligible professionals and eligible hospitals in possession of Certified EHR Technology would be permitted to upgrade voluntarily their Certified EHR Technology to include the adopted backwards compatible version. Given that we anticipate adopting new or modified standards, implementation specifications, and certification criteria every two years in sync with the initiation of a new meaningful use stage, we believe that the Secretary's adoption of backward compatible versions of standards would generally be limited to intermediate years (i.e., 2012 and 2014). To accomplish the adoption of a backwards compatible version, we would take an approach very similar to the approach described in the final e-prescribing regulation.

We would first review whether the new version of an adopted standard retains at a minimum the full functionality of the adopted version of the standard as well as whether it enables the successful completion of the applicable transaction(s) with entities that continue to use the older version(s). We would then review whether a standard should be updated with a new version and whether use of either the new version or the older version would be considered compliant as well as whether use of the new version would conflict with any

already existing regulatory requirements. If we believe that the Secretary's

adoption of a newer version of a standard on a voluntary basis would be

appropriate, we would then seek the advice of the HIT Standards Committee to

evaluate the newer version of the standard and to solicit relevant public input.

The Secretary would then recognize or adopt for voluntary use the new version of

the standard in a Federal Register publication. At that point, use of either the new

or old version would be considered compliant. Entities that would voluntarily

adopt the later backward compatible version of the standard would remain

obligated to accommodate the earlier adopted version without modification. Prior

to the Department formally retiring the older version of the standard and

mandating the use of the later version, the Department would engage in notice and

comment rulemaking.

2. Transport Standards

Comments. Generally, commenters echoed one of two responses: some urged for

the complete removal of SOAP and REST and others requested that we provide detailed

implementation specifications for SOAP and REST along with the identification of the

transactions to which SOAP and REST were applicable. Some commenters also stated

that neither standard was sufficiently specified in order to ensure interoperability, while

others pointed out that it appeared that we had globally applied the usage of SOAP or

REST to all adopted standards, which, if true, would cause conflicts with several adopted

standards (e.g., it was noted that the HL7 standards we adopted utilize Minimum Lower

Layer Protocol (MLLP) as the transport standard and not SOAP or REST).

Response. We have considered the public comments received on this matter and we are convinced that it is prudent to remove the adopted standards, SOAP and REST. We did not intend for the significant potential conflicts identified by commenters to occur as a result of our adoption of SOAP and REST. We have determined that it would be more appropriate and reasonable for us not to require at the present time specific transport standards as a condition of certification. We hope that this will reduce some of the burden on Complete EHR and EHR Module developers and provide greater opportunities for innovation. With that said, we plan to carefully watch the impact of this decision and its affect on interoperability. We encourage Complete EHR and EHR Module developers to utilize transport standards that will help the industry coalesce around common methods for electronic health information exchange, and we plan to examine this decision in future rulemakings.

3. Certification Criteria and Associated Standards and Implementation Specifications

We have organized our discussion of the final certification criteria according to the order in which they are currently specified at 45 CFR 170 subpart C. We note that the final regulatory citations will have changed for many certification criteria and encourage the public to review, in full, the final regulatory text specified in subpart C of part 170 in the regulation text of this final rule. We begin with the certification criteria at 45 CFR 170.302 (general certification criteria for Complete EHRs and EHR Modules), move on to 45 CFR 170.304 (specific certification criteria for Complete EHRs and EHR Modules designed for an ambulatory setting) and end with 45 CFR 170.306 (specific certification criteria for Complete EHRs or EHR Modules designed for an inpatient

setting). We also include, where appropriate, a discussion of the adopted standard(s) and

implementation specifications associated with each certification criterion. For each final

certification criterion, we start with an overview of the final version and then discuss and

respond to public comments.

a. General Certification for Complete EHRs or EHR Modules - §170.302

§170.302(a) - Drug-drug, drug-allergy, drug-formulary checks

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Implement drug-drug and drug-allergy interaction checks	The EP/eligible hospital/CAH has enabled this functionality for the entire EHR reporting period	**Interim Final Rule Text:** (1)Alerts. Automatically and electronically generate and indicate in real-time, alerts at the point of care for drug-drug and drug-allergy contraindications based on medication list, medication allergy list, age, and computerized provider order entry (CPOE). (3)Customization. Provide certain users with administrator rights to deactivate, modify, and add rules for drug-drug and drug-allergy checking. (4)Alert statistics. Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.
		Final Rule Text: §170.302(a) (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.

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Implement drug-formulary checks	The EP/eligible hospital/CAH has enabled this functionality and has access to at least one internal or external drug formulary for the entire EHR reporting period	**Interim Final Rule Text:** (2)Formulary checks. Enable a user to electronically check if drugs are in a formulary or preferred drug list in accordance with the standard specified in §170.205(b).
		Final Rule Text: §170.302(b) Drug-formulary checks. Enable a user to electronically check if drugs are in a formulary or preferred drug list.

Comments. Based on the example given in the preamble of the Interim Final Rule, several commenters believed that we required real-time alerts to utilize a pop-up message or sound. Commenters stated that the method of delivering real-time alerts should not be included in the regulation as it would restrain innovation. One commenter expressed concern that the requirements of this certification criterion were overly specific with respect to how the Certified EHR Technology needed to perform the tasks rather than focusing on the desired result. The commenter recommended the certification criterion be modified to ensure that such alerts are clearly visible to the physicians at the point-of-care. Some commenters recommended that the term "notification" should replace the term "alert" for this and other certification criterion because the term alert implied a particular implementation whereas notification was more neutral.

Response. Unfortunately, many of the commenters who reacted to our example also believed that it was a requirement. We simply added the example of a pop-up message or sound in the preamble of the Interim Final Rule to make the requirement clear. The use of a pop-up message or sound was not a specified requirement in the regulation text. We agree with the commenters who explained that there may be better ways to provide alerts. For the purposes of testing and certification, we leave it entirely up to Complete EHR and EHR Module developers to innovate in this area and provide capabilities that are both easy to use and prevent medical errors. Additionally, we agree with the commenters who suggested that we replace "alert" with "notification," and we have made that change globally across all certification criteria that used the term alert.

Comments. A few commenters requested clarification of the requirement to track and report on the number of alerts responded to by a user. A commenter requested

clarification on why the number of alerts is captured but not what the user did with the alert and if this data is going to be used to rate providers based upon the number of alerts they received. Two commenters requested that "responded to by a user" be clarified and asked whether it meant that a user had taken a different action as a result of the alert. One commenter recommended removing the alert requirement unless it is more clearly specified. One commenter recommended deleting the requirement on alert statistics because it could lead to alert fatigue. A few commenters expressed concern about the ability to deactivate, modify, and add rules for drug-drug and drug-allergy checking. These commenters recommended that this capability be removed because of the risk to patient safety. A commenter noted that treating physicians should have the ability to ignore alerts in light of other clinical facts about the patient and felt that providing the ability to delete or modify alerts in a way that would be inconsistent with current medical standards would be irresponsible and contrary to the meaningful use goal of preserving the health and safety of patients. Other commenters requested clarification as to whether the ability to "deactivate" rules implied the ability to remove specific rules or drug pairs as they exist in commercially-available clinical decision support (CDS) databases; the ability to "modify" rules implied that an administrator would be able to change the rules as they exist in these commercially-available CDS databases; and the ability to "add" new rules implied that the administrator could create new rules in commercially-available CDS databases. The commenters interpreted "modify" to mean, for example, the ability to override or change severity setting; and "add" to mean activating a category of CDS, such as drug-drug interactions, but not individual rules; and "deactivate" as the ability to "turn off" specific types of rules. Another commenter requested clarification as to

whether the requirement for customization would be met if a system administrator were to set the selected severity level to reflect the collective decision of a practice or if alerts must be tailored on an EP-by-EP basis. A commenter requested clarification on what qualifies as a "response" to an alert. One commenter recommended that the rule clarify that "responded to by a user" means in a way which meaningfully addresses the alerts. A couple of commenters stated that centrally hosted services would have problems complying with the customization requirements because the hosting vendor takes responsibility for the administration, maintenance and updating of the clinical decision support rules including alerts for drug interactions alerts, including drug-drug, drug-allergy and drug-problem. These commenters were concerned that allowing each of their clients to create local drug-interaction rules would slow their ability to provide important updates to their client base, since this would require navigation of a complex hierarchy of preferred local rules. These local rules would also introduce clinical risk if old local rules could create a conflict with a clinically appropriate global, updated rule.

Response. Based on the significant number of comments presenting diverse interpretations of these provisions, we determined that this certification criterion needed further clarification and have revised it accordingly. Our intention related to the alert statistics capability had been to mirror the clinical decision support capability. With respect to customization, we sought to provide users of Certified EHR Technology with a way to adjust the severity level for which alerts are presented. In response to public comment, and to clarify what we believe Certified EHR Technology must include as a condition of certification, we have removed the "alert statistics" part of the certification criterion altogether and revised the "customization" part of the certification criterion to

more clearly specify this capability. Our revisions focus on Certified EHR Technology's capability to allow certain users (e.g., those with administrator rights) with the ability to adjust notifications provided for drug-drug and drug-allergy checks (e.g., set the level of severity for which notifications are presented).

Comment. A commenter stated that use of age as a required data element in this certification criterion is a problem because drug databases handle age in non-standard ways. It was also stated that for geriatric patients weight is also considered along with age.

Response. We agree with this commenter. After considering this comment, particularly in light of the potentially divergent interpretations of this certification criterion we noted above, we have removed "age" from the certification criterion. It was never our intention, as could have been anticipated, to require that Certified EHR Technology be capable of performing checks that relate type or dosage of drugs to the patient's age, or "drug-age checks."

Comment. A commenter encouraged ONC to add adverse drug events to the certification criterion and to identify candidate standards for its inclusion to support meaningful use Stage 2.

Response. We appreciate the suggestion and believe that identifying adverse drug events is important. Because the final meaningful use Stage 1 requirements under the Medicare and Medicaid EHR incentive programs do not include such a requirement, though, we do not believe that it would be appropriate at the present time to add such a requirement as a condition of certification. This does not preclude Complete EHR or EHR Module developers from including such functionality.

Comment. A couple of commenters requested clarification on what CPOE means in the certification criterion. A commenter requested that ONC clarify that this certification criterion applies only to the order-entry workflow and is not applicable to other office processes or work flows which might involve the same clinical data but which would not necessarily generate these alerts.

Response. We clarify for commenters that our inclusion of CPOE in the certification criterion is meant to indicate that notifications should occur based on new medication orders, in addition to a patient's current medications and medication allergies, as they are being entered. In response to the other commenter's request for clarification, we believe that notifications will occur during the order-entry workflow.

Comment. A commenter requested that the rule be clarified to explicitly require that drug-drug, drug-allergy, and drug formulary checks occur based on information and medication lists in an individual's complete medical record derived from all relevant providers, not only the drug list of the specific provider.

Response. We clarify that we expect Certified EHR Technology to perform drug-drug and drug-allergy checks based on medication list and medication allergy list information included within Certified EHR Technology as structured data. We recognize that Certified EHR Technology may also store health information in scanned documents, images, and other non-interoperable non-computable formats and, consequently, do not expect Certified EHR Technology to be capable of reading or accessing the information in these other formats for the purposes of performing drug-drug and drug-allergy checks.

Comment. A commenter requested that ONC clarify that EHR vendors will not be required to remove the option to disable drug-drug and drug-allergy checks.

Response. While we do not require that the option to disable drug-drug and drug-allergy checks be removed as a condition of certification, we note that in order for an eligible professional or eligible hospital to become a meaningful user of Certified EHR Technology this capability must be enabled.

Comments. Several commenters noted that the NCPDP Formulary and Benefits standard is not used in an inpatient setting. The commenters consequently requested clarification as to how the standard can be used in an inpatient setting. Some of the commenters noted that for inpatient settings, hospitals typically relied on their own formularies for performing the types of checks specified. Another commenter requested clarification whether the correct content exchange standard was National Council for Prescription Drug Programs (NCPDP) Formulary and Benefits Standard version 1.0 and that if it was, the commenter recommended its adoption. Another commenter noted that some State Medicaid formularies are not yet available via nationwide e-prescribing networks and recommended that ONC encourage the implementation of State Medicaid formularies within the NCPDP Formulary and Benefits Standard via a nationwide e-prescribing network.

Response. We agree with those commenters who identified the inconsistency of applying the Formulary and Benefits standard to the inpatient setting. Because the CMS proposed meaningful use objectives applied to both eligible professionals and eligible hospitals, we did not make the distinction as to when a Complete EHR or EHR Module would need to include the Formulary and Benefits standard. However, in light of these comments and to support the final meaningful use measure, we have determined that it would be appropriate to adopt a more general certification criterion that would be

applicable to both Complete EHRs and EHR Modules designed for ambulatory and inpatient settings. Accordingly, we have removed any reference to a particular standard because an eligible professional or eligible hospital that does not have external access to a drug formulary would be able to satisfy this meaningful use measure by checking an internally managed drug formulary. Although the Formulary and Benefits standard is no longer required as a condition of certification, we note that eligible professionals who seek to comply with the electronic prescribing requirements associated with Medicare Part D eligible individuals will need to use this standard as they do today. Additionally, we do not agree that it is within the scope of this rulemaking to address State Medicaid Agencies' participation in nationwide e-prescribing networks.

Comments. Many commenters noted that the drug-formulary requirement should not apply to Complete EHRs and EHR Modules designed for an inpatient setting because there was no proposed requirement for meaningful use Stage 1 for eligible hospitals to electronically prescribe. Many of the commenters recommended removing this as a requirement for eligible hospitals while retaining it with the criteria for eligible professionals. A few commenters specifically recommended adding it to the criterion for electronic prescribing. Several commenters recommended that if the requirement were kept for hospitals it should be written as a separate criterion to address the query of a hospital's drug formulary during the order entry process and not the NCPDP Formulary and Benefits standard. A commenter stated that current industry practice among vendors of EHR technology is to provide a "generic" national formulary rather than the formulary for a particular plan. The commenter recommended that the functionality require that a user actually perform an eligibility check before access is provided and, in response to

that check, the functionality show the correct formulary and benefits information, rather than just generic data.

Response. We believe that our discussion above regarding the removal of the standard associated with this certification criterion addresses many of the concerns raised by commenters. However, we disagree with the suggestion that Complete EHRs and EHR Modules designed for an inpatient setting should not be required to include this capability. This capability is required to be enabled for the purposes of meeting the meaningful use Stage 1 measure. Consistent with the final meaningful use Stage 1 objectives which separated drug-drug and drug-allergy checks from drug-formulary checks, we have separated out these capabilities into two different certification criteria.

Comments. A commenter stated a concern that this criterion, combined with future meaningful use requirements, will shift providers' focus from prescribing the best drug for the patient to prescribing what is covered by the patient's insurance plan or generic brands. Another commenter stated that adding formulary checks to the workload of physicians will decrease physicians' efficiency and increase their costs.

Response. In this rule, the Secretary is completing the adoption of the initial set of standards, implementation specifications, and certification criteria for the certification of Complete EHRs and EHR modules. The certification criteria ensure that Certified EHR Technology includes certain capabilities. The extent to which health care providers must use those capabilities and how they integrate EHR technology into their practice falls outside the scope of this rule. We therefore do not believe that these concerns are within the scope of this rulemaking.

Comment. A commenter recommended that "drug-test checks" should be added. The commenter stated that many drugs require some form of laboratory testing to ensure that drugs are prescribed appropriately. The commenter stated, for example, that an anticoagulant medication should not be prescribed unless there is a test result on record that shows that giving this drug would not cause harm.

Response. Presently, drug-test checking is not a required capability for eligible professionals and eligible hospitals to use in order to successfully meet the requirements of meaningful use Stage 1. Accordingly, we do not believe that it would be appropriate to require Certified EHR Technology to be capable of performing drug-test checks as a condition of certification at the present time.

§170.302(b) - Maintain up-to-date problem list

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Maintain an up-to-date problem list of current and active diagnoses	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry or an indication that no problems are known for the patient recorded as structured data	**Interim Final Rule Text:** Maintain 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 standard specified in §170.205(a)(2)(i)(A); or (2) At a minimum, the version of the standard specified in §170.205(a)(2)(i)(B).
		Final Rule Text: §170.302(c) Final rule text remains the same as Interim Final Rule text, except for references to adopted standards, which have been changed.

Comments. Several commenters expressed concerns about the use of ICD-9-CM because it is primarily used for billing and administrative purposes and may not accurately represent the true clinical meaning of a problem or condition when it is documented at the point of care. One commenter stated a concern that the problem list standards do not allow for capturing of free text that health care providers use when an appropriate code is in neither SNOMED-CT® nor ICD-9-CM.

Response. The comments are correct in that ICD-9-CM is primarily used for billing and administrative purposes. SNOMED-CT® is offered as an alternative standard that will support more clinical descriptions of patient problems or conditions. We believe that with the adoption of both SNOMED-CT® and ICD-9-CM, healthcare providers should have adequate coverage for patient diagnoses and conditions. We are discouraging the use of free text for documenting problem lists since this will limit the usefulness of problem lists for clinical reminders, decision support and other patient safety and quality reporting.

Comments. Several commenters recommended that only SNOMED-CT® be adopted, or alternatively, that we expressly indicate an intention to move away from ICD-9CM and ICD-10 in the future. Another commenter recommended against the adoption of SNOMED-CT® because the commenter felt that our adoption of SNOMED-CT® would require eligible professionals and eligible hospitals to use both ICD-9-CM and SNOMED-CT®. One commenter recommended that a publicly vetted and HHS approved standard mapping between ICD-9-CM and SNOMED CT® should be made available at the public's expense.

Response. We agree conceptually that a single standard for clinical information would be desirable in the long term. However, presently both ICD-9-CM and SNOMED-CT® are used by EHR technology to code clinical information, and adopting both would provide users with additional flexibility. Moreover, we anticipate that as meaningful use objectives and measures evolve over time, we will receive additional public input and experience related to these standards and may eventually be able to adopt only one standard.

Comments. A few commenters asked for clarification as to whether SNOMED-CT® or ICD-9CM codes needed to be included within Certified EHR Technology or if these standards were only necessary when electronic health information is exchanged. Some of these commenters also requested that we permit any coding system to be used as long as it can be mapped to the appropriate format when electronic health information is to be exchanged.

Response. As previously discussed, meaningful use requirements will typically specify whether an adopted standard will have to be used among components of a business organization or solely for the electronic exchange of health information with other legal entities. The measure for this final meaningful use objective provides that entries be recorded as structured data. The certification criterion specifies that ICD-9CM or SNOMED-CT® are the code sets which must be included in Certified EHR Technology, and are therefore the code sets that would be used to record entries as structured data.

Comments. A few commenters recommended the removal of "longitudinal care" in the certification criterion. These commenters cited our clarification in the preamble that by longitudinal care we meant "over multiple office visits." These commenters questioned how this language would be applicable to an inpatient setting since patients are typically treated for acute episodes and not over multiple office visits.

Response. The reference to longitudinal care is intended to convey that the problem list must be comprehensive in the sense that it must be capable of including entries provided over an extended period of time. Consequently, for Complete EHRs and EHR Modules to be certified for an ambulatory setting, they will need to be designed to

enable the user to electronically record, modify, and retrieve a patient's problem list over multiple encounters. For an inpatient setting, they will need to enable the user to electronically record, modify, and retrieve a patient's problem list for the duration of an entire hospitalization. This clarification was also requested in relation to the medication list and medication allergy list certification criteria and we have not repeated our response. As a result, we have retained "longitudinal care" in each certification criterion where the term is referenced and only make this clarification once.

Comment. A commenter suggested that we include a reasonable expectation of what constitutes "up-to-date" in the reference to "up-to-date" problem list.

Response. We referred this comment to CMS, and it is addressed in the final rule on the Medicare and Medicaid EHR Incentive Programs.

§170.302(c) - Maintain active medication list

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Maintain active medication list	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry (or an indication that the patient is not currently prescribed any medication) recorded as structured data	**Interim Final Rule Text:** 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 in accordance with the standard specified in §170.205(a)(2)(iv). **Final Rule Text:** §170.302(d) 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.

Comments. A few commenters agreed with the certification criterion. One commenter requested that we provide more clarity on the use of term "retrieve." The commenter questioned whether we intended to use the word "retrieve" in the certification criterion to mean solely the retrieval of information available to Certified EHR Technology or if we intended for it to also include the interactive retrieval of medication

list information from external sources. The commenter suggested we clarify that

"retrieve" meant retrieval of only information internally available to Certified EHR

Technology. Other commenters, similar to their comments on the problem list

certification criterion, stated that there needed to be more clarity with respect to how the

reference to "longitudinal care" applied to a Complete EHR or EHR Module used by an

eligible hospital.

Response. We clarify that for this certification criterion, and all other certification

criteria, the term "retrieve" means the retrieval of information directly stored and

managed by Certified EHR Technology and that it does not mean the retrieval of

information from external sources, unless explicitly stated otherwise. We also take this

opportunity, in the context of our response regarding "longitudinal care" above, to clarify

that "medication history" is intended to include a record of prior modifications to a

patient's medications.

Comment. A commenter stated that there needs to be more clarity with respect to

whether an EHR Module must maintain a list of all active medications or if a specialty

system, such as a cardiology system, could maintain a list of medications specific to its

specialty use and provide the list to the enterprise EHR.

Response. If an EHR Module developer seeks to have its "medication list EHR

Module" certified, the EHR Module must provide the capabilities specified by the

certification criterion. We do not intend to limit how the EHR Module could

appropriately provide these capabilities (i.e., whether the EHR Module must itself enable

the user to electronically record, modify, and retrieve a patient's active medication list for

longitudinal care, or whether the EHR Module could be designed to provide those capabilities through its interaction with a device or devices at the enterprise level).

Comment. One comment stated that this criterion should include a provision to include the ability to transmit this information to public health entities as required by law.

Response. Nothing we adopt in this final rule precludes such a capability from being included in a Complete EHR or EHR Module. That is not, however, currently a necessary requirement for certification.

Comments. One commenter stated that it would need to perform extensive reprogramming to accommodate the standard we adopted if it meant modifying underlying medication databases. This commenter suggested that this standard as it applied to the maintenance of medication lists be deferred. Along those lines, a couple of commenters stated that more clarification was needed with respect to whether RxNorm identifiers needed to be stored internally within Certified EHR Technology or only needed to be used upon the electronic exchange of health information. Other commenters expressly stated that the mapping of the vocabulary be limited to instances where the electronic exchange of health information would take place.

Response. We understand these commenters' concerns and agree that it would be premature to require the use of the adopted standard in this context. In that regard, we seek to clarify for commenters our intention, which was solely to associate this adopted standard (as some commenters suggested) with the certification criteria that require the capability to electronically exchange health information. We recognize that continuing to associate this standard with the adopted certification criterion could potentially impose a significant burden on the industry, which we did not intend. Accordingly, we have

removed from this certification criterion the requirement to use this standard. We discuss

our response to comments on the standard itself in the context of the patient summary

record certification criterion.

§170.302(d) - Maintain active medication allergy list

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Maintain active medication allergy list	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry (or an indication that the patient has no known medication allergies) recorded as structured data	**Interim Final Rule Text:** 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.
		Final Rule Text: Unchanged Now §170.302(e)

Comments. Much like the prior certification criterion, many commenters signaled

their support for this certification criterion. Other commenters raised the same points

related to this certification criterion as they did for the medication list certification

criterion.

Response. We believe our responses to the problem list and medication list

certification criteria are applicable to these repeated comments.

Comments. Many commenters suggested that non-medication allergies be added

to this certification criterion. A few commenters stated that it could jeopardize patient

safety if not all allergens were included in Certified EHR Technology.

Response. Patient safety is one of HHS's top priorities. At the present time, the

final meaningful use objective and measure focus on medication allergies. Accordingly,

we have adopted a certification criterion to support this objective and measure. We

would like to reiterate, however, that a certification criterion sets the floor not the ceiling

for the capabilities Certified EHR Technology must include. We encourage Complete

EHR and EHR Module developers to provide more comprehensive capabilities than those currently required for achieving certification.

§170.302(e) - Record and chart vital signs

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
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	For more than 50% of all unique patients age 2 and over seen by the EP or admitted to eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23), height, weight and blood pressure are recorded as structured data	**Interim Final Rule Text:** (1)Vital signs. 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)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 charts for patients 2-20 years old.
		Final Rule Text: §170.302(f) (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) Unchanged (3) Unchanged

Comment. One commenter noted that the units of measurement should be specified in the EHR with regards to vital signs. For example that height should be specified in inches or centimeters.

Response. We do not believe that this level of specificity is necessary. We expect that Complete EHR and EHR Module developers will include the units of measure that their customers believe are necessary to meet their needs, which in many cases will include those that patients routinely request. We also expect that many Complete EHR and EHR Module developers will offer both metric units and U.S. units of measurement, as a standard business practice.

Comments. In what appeared to be a reaction to the proposed meaningful use objective and measure, some commenters requested that we remove BMI as part of the

certification criterion for Complete EHR or EHR Modules designed for an inpatient setting. The rationale provided was that acute care providers would not be required to track BMI.

Response. While we can understand these commenters' concern, we believe that BMI is a simple mathematical calculation that Certified EHR Technology should be capable of performing regardless of the setting for which it is designed.

Comment. One commenter recommended that BMI and age components should be used to create an alert when an unhealthy BMI is indicated for a patient and that Certified EHR Technology should record whether the patient was informed of the unhealthy BMI status.

Response. We believe that this recommendation is overly specific, is more germane to meaningful use, and exceeds the type of capability we believe should be specified as a condition of certification.

Comments. A few commenters noted this certification criterion applies more directly to specialties that predominantly treat children. For other specialties, this criterion would add unnecessary cost and complexity to many HIT products that they would use. Many commenters suggested that a growth chart component should not be required for EHR technology designed for an inpatient setting, as it is not feasible to track this data in a meaningful way over a long enough period of time in an inpatient setting (which is typically of a short and infrequent duration). A couple of commenters suggested that non-traditional forms of growth charts should be accepted. One commenter suggested that the certification criterion establish a baseline, but should not limit the expansion of this capability to other ages. Other commenters made specific

suggestions for different age ranges, such as including children under the age of two and lowering the upper age to ages less than 20 years old (e.g., 18).

Response. As we stated above with respect to the calculation of BMI, we believe that Certified EHR Technology should be capable of performing this capability regardless of the setting for which it is designed. Moreover, with respect to whether growth charts should be applicable to Complete EHRs and EHR Modules designed for an inpatient setting, we remind commenters that children's hospitals qualify as eligible hospitals under the Medicaid EHR incentive program and will also need to demonstrate meaningful use of Certified EHR Technology. We do not preclude Complete EHR and EHR Module developers from designing novel approaches to displaying growth charts. Finally, we concur with the commenter that suggested this certification criterion should be a baseline. We reiterate that this certification criterion establishes a floor, not a ceiling, and we encourage Complete EHR and EHR Module developers to include additional functionality where it will enhance the quality of care that eligible professionals and eligible hospitals can provide.

Comments. Similar to the comments above, many commenters suggested the growth chart requirement should include children under age 2. The charting would then include: weight, length, pulse oximetry, head circumference, and blood pressure (with percentiles based on age and weight).

Response. For Stage 1, the related meaningful use objective addresses ages 2-20. In order to remain consistent with and support this objective, we do not believe that it is necessary at this time to require a capability for charting any additional ages as a condition of certification.

Comment. One commenter requested that we clarify whether "plot and electronically display" means to plot height, weight, and BMI over time or against national norms.

Response. We clarify that we expect a growth chart to plot the height, weight, and BMI over time, as compared to national norms. While the regulation text does not specifically require comparison to national norms, we understand that this type of information is typically provided along with the growth chart itself to provide greater relevance and meaning for the growth charts. We encourage Complete EHR and EHR Module developers to include this feature.

Comment. A commenter suggested that SNOMED-CT® be used for designation of BMI.

Response. Although we agree that SNOMED-CT® could be used to code BMI, we only require that Certified EHR Technology be capable of calculating BMI. We do not believe that it is necessary, as a condition of certification, to specify how BMI should be coded. That being said, we do not preclude the use of SNOMED-CT® to code BMI.

Comment. One commenter suggested that the certification criterion should be better aligned with the final meaningful use objective and measure. The commenter noted that the criterion includes temperature and pulse, which is not included in the meaningful use objective and measure.

Response. We agree with the comment and have removed temperature and pulse from the certification criterion.

§170.302(f) - Smoking status

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion

Record smoking status for patients 13 years old or older	More than 50% of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have smoking status recorded as structured data	**Interim Final Rule Text:** Smoking status. Enable a user to electronically record, modify, and retrieve the smoking status of a patient. Smoking status types must include: current smoker, former smoker, or never smoked.
		Final Rule Text: §170.302(g) 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.

Comments. Several commenters stated that the smoking status certification criterion was overly prescriptive because it specified certain status variables. These commenters agreed that recording smoking status is crucial to health improvement efforts, but contended that mandating certain fields was the wrong approach. Many of these commenters stated that they were unaware of defined industry standard value set for smoking terminology and other suggested that our reference to specific types of smokers be removed. Others asked whether these variables were examples or the only responses allowed. A few commenters agreed with this certification criterion as reasonable and appropriate because it would provide value for both clinical care and public health. Commenters recommended that besides what we had specified, the certification criterion should also reference packs per day history information, secondhand smoke exposure, and alcohol consumption information. Other commenters recommended that the certification criterion be changed to reflect tobacco use rather than smoking.

Response. We have adopted this certification criterion to fully support the final meaningful use objective and measure, which in response to comments has been revised to further clarify the purpose of the objective and measure. We therefore disagree with those commenters who stated that this certification criterion is too prescriptive.

Concurring with CMS, we believe that the fields associated with this measure should mirror those expressed in the Centers for Disease Control and Prevention, National Center for Health Statistics, National Health Interview Survey related to smoking status recodes.[2] Accordingly, the final certification criterion further specifies and slightly broadens the smoking statuses we expect Certified EHR Technology to be capable of recording. Generally speaking, we understand that a "current every day smoker" or "current some day smoker" is an individual who has smoked at least 100 cigarettes during his/her lifetime and still regularly smokes everyday or periodically, yet consistently; a "former smoker" would be an individual who has smoked at least 100 cigarettes during his/her lifetime but does not currently smoke; and a "never smoker" would be an individual who has not smoked 100 or more cigarettes during his/her lifetime.[3] The other two statuses (smoker, current status unknown; and unknown if ever smoked) would be available if an individual's smoking status is ambiguous. The status "smoker, current status unknown" would apply to individuals who were known to have smoked at least 100 cigarettes in the past, but their whether they currently still smoke is unknown. The last status of "unknown if ever smoked" is self-explanatory.

§170.302(g) - Incorporate laboratory test results

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Incorporate clinical lab-test results into certified EHR technology as structured data	More than 40% of all clinical lab tests results ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or	**Interim Final Rule Text:** (1) Receive results. Electronically receive clinical laboratory test results in a structured format and display such results in human readable format. (2) Display codes in readable format. Electronically display in human readable format any clinical laboratory tests that have been received with LOINC® codes. (3) Display test report information. Electronically display all the information for a test report specified at 42 CFR

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[2] Smoking status recodes: http://www.cdc.gov/nchs/nhis/tobacco/tobacco_recodes.htm
[3] ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/datasets/DATA2010/Focusarea27/O2701a.pdf

	23) during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in certified EHR technology as structured data	493.1291(c)(1) through (7). (4) Update. Enable a user to electronically update a patient's record based upon received laboratory test results.
		Final Rule Text: §170.302(h) (1) Unchanged (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.

Comments on 170.302(g)(1)

Comments. A few commenters suggested that we specify in the regulation that

the reference to receiving clinical laboratory test results in a "structured format" means in

HL7 version 2.3.1 format. These commenters further recommended that we refer to HL7

version 2.3.1 within the certification criterion.   These commenters stated that many

Complete EHR and EHR Module developers already use HL7 2.3.1 and that adopting it

as a standard would spur industry-wide adoption and also set the stage for driving

adoption of future HL7 standards, like HL7 2.5.1, in the later stages of meaningful use.

A commenter in support of including HL7 2.3.1 stated that it was concerned that if we

did not specify a standard for this requirement that there could be confusion regarding

which version of the standard should be used, and that laboratories would have to

continue to support multiple standards. Another commenter also noted that we did not

specify a standard format for the laboratory results that Certified EHR Technology must

be capable of receiving. This commenter, however, stated that many EHRs are compliant

with HL7 2.5.1 for the purposes of receiving laboratory results. The commenter also

recommended that we apply this certification criterion differently for ambulatory and

inpatient settings by requiring that Complete EHRs and EHR Modules designed for an

ambulatory setting be required to receive HL7 2.5.1 formatted laboratory test results and those designed for an inpatient setting be required to receive HL7 2.3.1 formatted laboratory test results. One commenter suggested that our objectives could be better supported if we stated that in this certification criterion a requirement that laboratory results must be received electronically using HL7 transactions with implementation guidance.

Response. While we understand the intent of these commenters' suggestions, we do not believe that it is within the scope of this rule to dictate the standard by which laboratories transmit test results. The scope of this rule is the adoption of certification criteria that specify required capabilities of Certified EHR Technology (in this case, receiving laboratory information in structured format) and not, in this instance, specifying the standard by which laboratories must transmit test results.

Comment. A commenter requested that we clarify how this certification criterion is applicable to hospital settings. The commenter asked whether we intended for the capability of receiving laboratory test results to include results obtained during a patient's stay at the hospital or if we meant to also include the receipt of laboratory test results from other time periods. They suggested requiring only those laboratory test results obtained during the patient stay.

Response. For the purposes of demonstrating compliance with this certification criterion, we do not specify the contexts (e.g., a patient stay) under which laboratory test results are received. Rather, consistent with the meaningful use objective and measure and the capabilities required by this certification criterion, we specify that when

laboratory test results are received in structured format by Certified EHR Technology, that the results can be incorporated.

Comment. One commenter requested that we clarify whether the structured data requirement applies to all laboratories (including reference labs, hospital labs, physician office labs, and physicians performing their own lab tests).

Response. This certification criterion requires Complete EHRs and EHR Modules to provide the capability to receive clinical laboratory test results in a structured format as a condition of certification. It does not speak to how laboratories must send the test results.

Comments on 170.302(g)(2)

Comments. Some commenters requested clarification on this specific capability within the certification criterion regarding what needed to be displayed in the context of LOINC codes. These commenters suggested that we not require the display of the actual LOINC code, but the description associated with the LOINC code. A commenter suggested that we identify a subset of common LOINC codes instead of requiring that tens of thousands of LOINC codes be supported for the purposes of certification. Other commenters suggested that we offer guidance in the form of a "starter set" of LOINC codes to encourage the use of the standard. One commenter requested that we confirm its understanding of this specific part of the certification criterion, which is that Certified EHR Technology must demonstrate the capability to import LOINC coded results from an external source. Finally, one commenter noted that the heading for the standard at §170.205(a)(2)(iii) should just refer to "laboratory test results" and not "laboratory orders and results."

Response. We clarify that we do not expect Certified EHR Technology to natively (or internally) support LOINC in its entirety, which is why we do not believe that it is necessary to specify a subset of common LOINC codes. Given the diverse comments and requests for clarification on this specific aspect of the certification criterion, we agree with commenters that we should not require a LOINC code that has been received, to then be displayed. Accordingly, we have decided to remove this requirement from the certification criterion. We do, however, wish to further clarify our current approach to Certified EHR Technology's use of LOINC codes. Presently, we expect Certified EHR Technology to be able to reuse a LOINC code once it has been received and is accessible to Certified EHR Technology. We do not expect, as we mention above, that Certified EHR Technology will have to crosswalk or map internal or local codes to LOINC codes. This clarification is applicable to the standard that we have adopted regarding LOINC codes now specified at §170.207. This response is applicable to similar comments we received on other certification criteria that also referenced the use of LOINC codes. Finally, we agree with the commenter who suggested that we revise the heading of the standard at §170.205(a)(2)(iii). We have done this as part of the overall restructuring of the regulation text.

Comments on 170.302(g)(3)

Comments. Some commenters agreed with the capability specified in 170.302(g)(3). One noted a concern that modifications to either a certified Complete EHR or certified EHR Module could potentially result in the failure of Certified EHR Technology to display the test report information as required by the regulations and, thereby, put the laboratory in technical violation of the CLIA regulations. These

commenters reasoned that because a Complete EHR or EHR Module must be tested and certified to be in compliance with 42 CFR 493.1291(c)(1) through (7) that certification should replace any requirement for the laboratory to confirm that the information has been properly transmitted and meets the CLIA requirements. These commenters also asserted that a laboratory should be relieved of any further regulatory responsibility under 42 CFR 493.1291(c)(1) through (7) for the display of the required report information to the physician or subsequent viewers of the information if the Certified EHR Technology has been implemented by an eligible professional or eligible hospital. One commenter reiterated the point by stating that because Certified EHR Technology would be required to display the required CLIA report elements, laboratories should not be unfairly held accountable for any elements that may be removed or altered by other parties from the test report before received by the physician.

Response. While we can understand the concern expressed by these commenters, we reiterate that the scope of our authority under this final rule only applies to capabilities that Certified EHR Technology must include. As a result, we cannot provide the regulatory relief that these commenters seek.

Comments on 170.302(g)(4)

Comments. A couple of commenters questioned whether we intended for the "updates" to be manual updates of electronic records. If that were true, some commenters were concerned that would create workflow problems and reduce the availability of results. Other commenters suggested that either the user be able to create an additional record, rather than be permitted to change the "official" record or that an adequate audit trail be preserved of the existing data and any updates, since an update

may result in disparities with the official record of test results. These commenters

wanted to ensure that the laboratory's record would be the same as the record maintained

in the EHR. One commenter stated that paragraph (g)(4) could imply process and system

behavior that we did not intend to require. The commenter stated that it is common

practice in a hospital setting for lab results to be transmitted in high volume from a lab

system to an EHR and made available for review to the clinician through the EHR,

without a need for a user to review each transaction before updating the EHR to make the

results available. Another commenter made a similar point and questioned whether an

"update" meant manual intervention, which they stated would be impracticable in a

hospital setting. One commenter stated that most EHR technology already links orders to

lab results in an established way. The commenter also indicated that the certification

criterion we adopted requires changes to a process that most EHR developers have

already implemented and introduces inefficiencies for both EHR developers and health

care providers.

Response. We appreciate the issues raised by commenters on this specific

capability and have revised this part of the certification criterion to more clearly express

our expectation for Certified EHR Technology and to be responsive to and consistent

with commenters' suggestions. We intended for an update to mean, as indicated by the

meaningful use objective and measures, that a laboratory test result would be

incorporated in Certified EHR Technology with the originating laboratory order or with a

patient's record in any one of the methods specified. Accordingly we have revised this

specific capability to more clearly reflect our intent. We believe this addresses

commenters' concerns and requests for clarification and would permit batches of

laboratory test results to be electronically linked to laboratory orders or patient records without manual intervention.

Comments. Some commenters noted that small and medium size practices have had a difficult time working with commercial laboratory vendors to provide interfaces from which they can receive lab test results. These commenters noted that laboratory vendors typically charge too much for their services and do not prioritize establishing connections with small and medium size practices because they do not have the same volume of laboratory referrals as large practices.

Response. This certification criterion requires as a condition of certification that Certified EHR Technology be capable of supporting electronic laboratory interfaces. We understand the concerns raised by commenters pertaining to the difficulty of certain practices being able to obtain laboratory interfaces and note that the meaningful use Stage 1 measure associated with this certification criterion is included in the "menu set" specified by CMS which we believe should help assuage some commenters' concerns. We do not believe that the ability of a practice (regardless of size) to obtain an interface or other type of connection is an issue that is within the scope of this final rule to address.

Comment. One commenter recommended that we revise this certification criterion to require that laboratory domain expertise be exhibited when laboratory information is displayed. The commenter further elaborated by stating that laboratory results are not homogeneous, and that specific laboratory domain expertise is necessary to design the ways in which the data associated with certain laboratory results (e.g., microbiology, molecular pathology) are displayed in EHR systems to ensure appropriate presentation and interpretation.

Response. With the exception of displaying the required elements specified at 42 CFR 493.1291(c)(1) through (7), we do not require as a condition of certification any additional display requirements. Accordingly, we do not preclude Complete EHR and EHR Module developers from designing more specific displays of laboratory results that may need to be displayed in a more complex fashion.

Comment. One commenter requested that we clarify that Certified EHR Technology did not need to enable the EHR Technology user to receive voluminous raw or pre-final-report lab data, and further, that not providing this capability would not disqualify a Complete EHR or EHR Module from becoming certified.

Response. Enabling a Complete EHR or EHR Module to receive "raw or pre-final-report lab data" is not required under this or any other adopted certification criterion.

Comment. One commenter suggested that we modify this certification criterion to require transmission of cancer related lab tests and results to cancer registries as required by law.

Response. Because this certification criterion is about incorporating lab test results in Complete EHRs and EHR Modules and does not require any electronic transmissions, we do not believe that this is an appropriate requirement to consider.

§170.302(h) - Generate patient lists

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research	Generate at least one report listing patients of the EP, eligible hospital or CAH with a specific condition	**Interim Final Rule Text:** Generate patient lists. 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. **Final Rule Text:** §170.302(i)

or outreach		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.

Comments. Several commenters requested clarification regarding the set of variables that should be included in the demographic information for the patient lists. Some of these commenters suggested that the gender, race, ethnicity and preferred language of the patient should be included in this data set. One commenter suggested that the final rule should explicitly adopt and incorporate the recommendations of a report published by the Institute of Medicine in mid-2009 entitled, "Race, Ethnicity and Language Data: Standardization for Health Care Quality Improvement."

Response. We appreciate the commenters' suggestions, and we have used them to clarify this certification criterion. It was our intention that Certified EHR Technology would be able to leverage the information, specifically the structured data it has available to it, to assist eligible professionals and eligible hospitals to generate patient lists. We have clarified this certification criterion to express this intent. Accordingly, we expect that Certified EHR Technology will be able to generate patient lists according to certain data elements for which structured data will be available: medical problems; medications; demographics; and laboratory test results. While we respect the work completed by the Institute of Medicine, we do not believe that the public has had an adequate opportunity to consider its recommendations related to demographics in the context of certification, and we are therefore not including them as a condition of certification at this time. We encourage the HIT Standards Committee to consider this report as it recommends standards to the National Coordinator.

Comments. Several commenters requested further clarification regarding the meaning of "patient's clinical information." Other commenters stated that this phrase was too vague and was not included as part of the proposed meaningful use objective or measure and should therefore be removed. Some commenters requested further definition of the term "specific conditions," particularly to clarify whether this term refers to problems and diagnoses. Clarification was also requested regarding whether this information includes: a patient summary; the patient's entire medical history; and patient encounter notes. One commenter recommended that we clarify how the lists must be structured and suggested that we specify time periods for patient histories. One commenter requested clarification of the term "output," and suggested that it should mean to produce a list for internal use and that it does not refer to exporting the patient list to a system or destination external to the office of an eligible professional.

Response. We appreciate the concerns raised by these commenters and after further consideration agree that the terms referenced by commenters could be interpreted in multiple ways. Accordingly we have removed "patient's clinical information" and "specific conditions" from the certification criterion, and have reframed the certification criterion to more directly align with the meaningful use measure by changing "output" to "generate." We sought to clarify that we intended that Certified EHR technology would be capable of electronically producing or "generating" patient lists for an eligible professional or eligible hospital's subsequent use. We do not require as a condition of certification that time periods be associated with a patient list, but presumably time (i.e., the age of the information) could be one factor an eligible professional or eligible hospital could also use to sort their lists (e.g., patients with XYZ problem recorded in the past 3

months). We believe that these revisions make this certification criterion clearer while addressing these commenters' concerns.

§170.302(i) - Report quality measures

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Eligible Professionals: Report ambulatory clinical quality measures to CMS or the States Eligible Hospitals and CAHs: Report hospital clinical quality measures to CMS or the States	For 2011, provide aggregate numerator, denominator, and exclusions through attestation as discussed in section II(A)(3) of [the Medicare and Medicaid EHR Incentive Programs final rule] For 2012, electronically submit the clinical quality measures as discussed in section II(A)(3) of [the Medicare and Medicaid EHR Incentive Programs final rule]	**Interim Final Rule Text:** (1) <u>Display.</u> Calculate and electronically display quality measures as specified by CMS or states. (2) <u>Submission.</u> Enable a user to electronically submit calculated quality measures in accordance with the standard and implementation specifications specified in §170.205(e). **Final Rule Text:** §170.304(j) (1) <u>Calculate.</u> (i) Electronically calculate all of the core clinical measures specified by CMS for eligible professionals. (ii) Electronically calculate, at a minimum, three clinical quality measures specified by CMS for eligible professionals, in addition to those clinical quality measures specified in paragraph (1)(i). (2) <u>Submission.</u> Enable a user to electronically submit calculated clinical quality measures in accordance with the standard and implementation specifications specified in §170.205(f). §170.306(i) (1) <u>Calculate.</u> Electronically calculate all of the clinical quality measures specified by CMS for eligible hospitals and critical access hospitals. (2) <u>Submission.</u> Enable a user to electronically submit calculated clinical quality measures in accordance with the standard and implementation specifications specified in §170.205(f).

Comments. Many commenters stated that the Physician Quality Reporting Initiative (PQRI) 2008 Registry XML specifications apply only in the context of eligible professionals. Some of these commenters went on to state that hospitals are not familiar with PQRI and have been submitting quality measurement data to CMS under a separate program. A few commenters recommended that this standard requirement be removed while several others stated we should adopt both Quality Reporting Document

Architecture (QRDA) and the PQRI XML Registry specification in this rulemaking and move to a single standard in the next rulemaking. Other commenters recommended that QRDA not be adopted in this rulemaking. Several commenters suggested that an implementation specification for eligible hospitals be created if we intend to continue to require that quality measure be reported in the PQRI Registry XML format. One commenter expressed a concern that if the PQRI 2008 Registry XML standard is maintained as the adopted standard that there is a danger that the certification Complete EHR and EHR Module developers obtain may become obsolete before Stage 1 has run its course. Finally, a couple of commenters suggested that ONC consider deferring the naming of a standard for submission of clinical quality measures until Stage 2 and instead only require what is necessary to support clinical quality measure submission in Stage 1.

Response. Many commenters misinterpreted our intent with respect to the adoption of the PQRI 2008 Registry XML specification as the standard for electronically submitting quality reporting data to CMS. Presently, CMS requires the submission of aggregate, summary level data for the purposes of meaningful use and not data at the patient-specific level. It is our understanding that the PQRI 2008 Registry XML specification is capable of serving as the "envelope" for aggregate, summary level data. Accordingly, we do not believe that, as some commenters suggested, an eligible hospital's familiarity with the PQRI program is relevant to the adoption of this standard for this specified purpose. Nor do we believe that a specific implementation of this standard is necessary for hospital settings as the standard's purpose and the type of data it will transmit to CMS will be the same – aggregate, summary level data. Through recent discussions with CMS since the publication of the Interim Final Rule we have determined

that the PQRI 2009 Registry XML specification, a more recent version of the standards

we adopted in the Interim Final Rule is a suitable replacement for 2008 version, and

accordingly, we have adopted the 2009 version in its place. We believe this revision

should assuage some commenters' concerns about the obsolescence of the adopted

standard and reduce concerns that a wholly different standard would be adopted in the

near future. If adopting a different standard for Certified EHR Technology becomes

necessary, we would do so only after engaging in subsequent rulemaking.

Comments. A few commenters stated that many of the clinical quality measures

proposed by CMS do not have electronic specifications and contended that it would be

difficult for any vendor to have embedded these measures in their EHR products in a

timely manner. But, these same commenters stated that when the specifications become

available, that HHS should ensure through the certification process that the products are

capable of generating accurate data. Many commenters expressed concerns that the

certification criterion was too vague or too broad (because it implicitly referenced all of

the quality measures CMS had proposed). Some of the commenters recommended that

this certification criterion be removed, while others recommended that it focus on a

subset of measures in order to constrain the amount of electronic measure specifications a

Complete EHR or EHR Module developer would need to address in order to be certified.

At least one of these latter commenters indicated that our adopted certification criteria

created uncertainty for Complete EHR and EHR Module Developers. This commenter

asked that we clarify what clinical quality measures would need to be tested in order to

satisfy this certification criterion and if there would be a baseline for eligible hospital

measures as well as some identified core set of measures for eligible professionals.

Along these same lines, another commenter recommended that EHR technology should be tested and certified only to the clinical quality measures applicable to the medical specialties of the eligible professionals that the EHR technology is intended to support and to whom it is marketed. Other commenters expressed concerns about timing and that a significant amount of effort would be required to reprogram Complete EHRs and EHR Modules to capture, calculate, and report the final meaningful use Stage 1 measures. Many commenters also stated that the proposed quality measures are not yet ready for automated reporting, that a significant amount of work is still required by the measure developer community, and that the value sets for these quality measures have not been validated. Several commenters objected to the reference to "States" in the certification criterion and recommended that it be removed. These commenters contended that the certification criterion should be limited to the "federal requirements" and further that it was unrealistic to expect Complete EHR and EHR Module developers to also comply with 50 separate State requirements as a condition of certification.

Response. We understand that CMS has worked to significantly increase the availability of a number of electronic measure specifications that are associated with specific clinical quality measures. In light of the final approach CMS has taken with respect to clinical quality measures for meaningful use Stage 1, we have revised this certification to better align it with the Medicare and Medicaid EHR Incentive Programs final rule requirements. We also agree with those commenters that requested we explicitly focus the report of clinical quality measures certification criterion, and the certification criteria in general, on Federal requirements and have removed the reference to "or States" in this certification criterion.

To better align this certification criterion with the final approach to clinical quality measures in the Medicare and Medicaid EHR Incentive Programs final rule, we have determined that it is no longer sufficient to specify one general certification criterion for both Complete EHRs and EHR Modules designed for either an ambulatory or inpatient setting. Accordingly, the final rule in §§170.304 and 170.306 will include a specific certification criterion for each setting. Complete EHRs and EHR Modules designed for an ambulatory setting will be required to be tested and certified as being compliant with all 6 of the core (3 core and 3 alternate core) clinical quality measures specified by CMS for eligible professionals (Section II(A)(3) of the Medicare and Medicaid EHR Incentive Programs final rule). Complete EHRs and EHR Modules designed for an ambulatory setting will also be required to be tested and certified as being compliant with, at a minimum, 3 of the additional clinical quality measures CMS has identified for eligible professionals (Section II(A)(3)of the Medicare and Medicaid EHR Incentive Programs final rule). We believe this revision provides clarity and flexibility and reduces the potential burden for Complete EHR and EHR Module developers (who may have been unfamiliar with certain clinical quality measures because of the type of eligible professional they serve) to become compliant with this certification criterion. As a result, Complete EHR and EHR Module developers for the ambulatory setting may provide Certified EHR Technology with a certain level of variability in terms of clinical quality measure capabilities. To provide further transparency for potential eligible professionals regarding the clinical quality measures to which a Complete EHR or EHR Module has been tested and certified, we specified that an ONC-Authorized Testing and Certification Body would need to report such information to the National Coordinator,

and further, that the Complete EHR or EHR Module developer would need to make sure this information is available and communicated to prospective purchasers as part of the Complete EHR or EHR Module's certification.

Complete EHRs and EHR Modules designed for an inpatient setting will be required to be tested and certified as being compliant with all of the clinical quality measures specified by CMS (Section II(A)(3) of the Medicare and Medicaid EHR Incentive Programs final rule) for eligible hospitals. Again, we believe this revision provides greater clarity and reduces the potential burden for Complete EHR and EHR Module developers.

Comments. One commenter suggested that we separate the calculation and the submission parts of this certification criterion into two separate certification criteria.

Response. We disagree. We see no basis for separating these two parts of this certification criterion into two separate certification criteria. However, we believe that it is necessary to specify two different certification criteria to account for the different clinical quality measures that eligible professionals and eligible hospitals will need to report. Accordingly, we have adopted separate certification criteria for Complete EHRs and EHR Modules designed for ambulatory and inpatient settings and referenced the respective quality measures for each in the appropriate certification criterion.

Comments. One commenter suggested that all approved PQRI registries be automatically certified as an EHR Module.

Response. We do not believe that it is prudent or appropriate to automatically deem certain HIT as certified. That being said, if a PQRI registry can adequately perform

the capability specified by the certification criterion, it could be certified as an EHR Module.

Comments. Several commenters stated that Certified EHR Technology should be capable of collecting quality measurement data and calculating results for reporting to avoid having eligible professionals and eligible hospitals perform these processes manually. These commenters also stated that Certified EHR Technology should be capable of accurately and reliably reporting quality measurement data. Some commenters recommended that a Complete EHR or EHR Module only be required to be certified to existing e-measure specifications.

Response. We agree that the collection of clinical quality measurement data and the calculation of results for submission to CMS should be performed by Certified EHR Technology. We also agree that Complete EHRs or EHR Modules should only be required to be tested and certified to developed electronic measure specifications. This is why CMS has only specified clinical quality measures for eligible professionals and eligible hospitals in the Medicare and Medicaid EHR Incentive Programs final rule for which electronic measure specifications have been developed. Complete EHR and EHR Module developers should follow these electronic measure specifications in order to accurately calculate clinical quality measures.

Comments. Several commenters recommended that the certification criterion should be revised to include the word "accurately."

Response. We expect that clinical quality measures would be accurately calculated and do not see a need to specifically include the word in the certification criterion.

§170.302(j) - Check insurance eligibility and §170.302(k) - Submit claims

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Removed from final rule	Removed from final rule	**Interim Final Rule Text:** 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 and implementation specifications specified in §170.205(d)(1) or (2).
		Final Rule Text: Removed

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Removed from final rule	Removed from final rule	**Interim Final Rule Text:** Enable a user to electronically submit claims to public or private payers in accordance with the standard and implementation specifications specified in §170.205(d)(3).
		Final Rule Text: Removed

Comments. Many commenters recommended that the certification criteria for administrative transactions be removed because they considered the administrative capabilities that we required to be outside of the scope of an electronic health record and stated further that their inclusion did not align with the HIT industry's common view of what constituted EHR technology. A large number of commenters conveyed specific challenges including: these functions are usually handled by practice management systems which generally are separate from an EHR, although on occasion some vendors include these functionalities in their EHRs; practice management systems adoption is already very high and requiring certification for these products would be unnecessary and burdensome, given the wide variety and number of vendors and significant potential for increasing costs for providers; providers interested in achieving meaningful use would have to abandon a working practice management system if their practice management

vendors were unwilling or unable to get certified; and many providers currently use clearinghouses to convert paper claims into electronic claims to submit to CMS and other payers. Several commenters recommended retaining the administrative transactions certification criteria because it would eventually reduce administrative costs across the health care system. Many commenters requested that we clarify several aspects of these certification criteria while some other commenters noted that significant progress has been made in using electronic eligibility inquires and claims transactions outside of an EHR context. Those commenters expressed concern that the inclusion of administrative transaction capability in this rule would create confusion, ambiguity, and potentially duplicate efforts. A couple of commenters noted that some payers do not accept electronic claims and eligibility checks. One commenter expressly noted that including the administrative functionalities would decrease innovation by creating a large barrier to entry for EHR innovators. Finally, a couple of commenters noted that health care providers would face significant challenges in the transition to ASC X12N 5010 and ICD-10 and lost productivity.

Response. In concert with CMS, we have considered commenters' rationale for and against the inclusion of these certification criteria. We have tried to summarize above several technical and programmatic challenges commenters identified if administrative transaction capability were included within the certification requirements. Due to the removal of these objectives from the meaningful use Stage 1 requirements, we do not believe that it would be appropriate to continue to require, as a condition of certification, that Complete EHRs and EHR Modules include these capabilities.

Accordingly, we have removed the adopted standards, implementation specifications, and certification criteria related to these administrative transactions from this final rule.

As CMS explains in more detail in the Medicare and Medicaid EHR Incentive Programs final rule, the subsequent inclusion of administrative simplification requirements as part of meaningful use Stage 2 is an important long-term policy goal. Administrative simplification can improve the efficiency and reduce unnecessary costs in the health care system as a whole; the small percentage of paper claims submitted represents a disproportionately high administrative cost for health plans; the reconciliation of billing charges for services not eligible for payment creates a significant burden for providers, health plans, and most significantly, for patients. Moreover, we believe that the integration of administrative and clinical information systems is necessary to support effective management and coordinated care in physician practices. For example, the ability to: leverage clinical documentation in support of appropriate charge capture (e.g., for preventive counseling, or immunizations provided); link lists of patients needing clinical reminders with patient contact information; stratify quality measures by patient demographic factors (e.g., race/ethnicity) and insurer status (e.g., Medicare beneficiaries).

Additionally, we believe that important benefits can be recognized through the future adoption of administrative transactions standards and certification criteria for Complete EHRs and EHR Modules. Through the use of EHR Modules, eligible professionals and eligible hospitals have the opportunity to use practice management systems or clearinghouses that provide the capability to conduct administrative transactions as components of Certified EHR Technology. In that regard, we recognize

the concerns expressed by some commenters that the developers of some practice

management systems may not be prepared to seek certification for these legacy systems

in 2010 or 2011. We also acknowledge that the required compliance date of January 1,

2012 for ASC X12N version 5010 transactions would further complicate the certification

process associated with meaningful use Stage 1. However, we believe that after the ASC

X12N version 5010 transition has occurred, and we approach the October 1, 2013

compliance date for HIPAA covered entities to use ICD-10, our decision to delay the

adoption of administrative transactions certification criteria will prove beneficial for the

adoption of Certified EHR Technology.

In order to meet upcoming administrative simplification deadlines, most health

care providers will have to upgrade their practice management systems or implement new

ones. This will provide an important opportunity to align EHR technology capabilities

and standards for administrative transactions with the administrative simplification

provisions that the Affordable Care Act provides for health plans and clearinghouses.

Therefore, we intend to include for adoption, administrative transactions standards and

certification criteria to support meaningful use Stage 2 rulemaking, and expect health

care providers and Complete EHR and EHR Module developers to take this into

consideration leading up to 2013.

Comments. Many commenters recommended that we remove the implementation

specification, CORE Phase 1 (CORE), which we previously adopted. Several

commenters noted that CORE is only useful if it has also been adopted by health plans,

and they explained that not all health plans had adopted CORE. A few commenters

expressed concern with CORE stating that it adds requirements to the HIPAA Standard

Transactions and did not follow the work of the standards development organization that maintains administrative transactions. A few commenters also believed that following CORE results in non-compliant ASC X12N 4010 transactions. Other commenters noted that it appeared that we had required CORE for both ASC X12N 4010 and 5010 standard transactions, but that CORE Phase 1 is only applicable to ASC X12N 4010 standard transactions and cannot be used with ASC X12N 5010 standard transactions. A few commenters requested that we clarify whether providers and vendors will be required to receive CORE certification. Several commenters recommended ONC retain CORE Phase 1. A few commenters noted that CORE promotes uniformity and can provide significant reduction in transaction costs. A couple commenters recommended that ONC adopt subsequent CORE standards in future stages.

Response. As previously mentioned, we have decided to align our revisions with the changes made in the Medicare and Medicaid EHR Incentive Programs final rule and to remove, as noted above, the standards, implementation specifications, and certification criteria associated with administrative transactions. Consistent with that approach, we are removing the CORE Phase 1 implementation specification for the reasons submitted in comments.

§170.302(l) - Medication reconciliation

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
The EP, eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation	The EP, eligible hospital or CAH performs medication reconciliation for more than 50% of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23)	**Interim Final Rule Text:** Medication reconciliation. Electronically complete medication reconciliation of two or more medication lists by comparing and merging into a single medication list that can be electronically displayed in real-time.
		Final Rule Text: §170.302(j) Medication reconciliation. Enable a user to

		electronically compare two or more medication lists.

Comments. Many commenters suggested that for this certification criterion we clarify whether we intended for the process of medication reconciliation to be automatic or to support an eligible professional or eligible hospital in performing this task. Many saw the former as a potential risk to patient safety. Although several different reasons were given, many commenters recommended that we revise the certification criterion to indicate that two or more medication lists be simultaneously displayed in order to permit an eligible professional or eligible hospital to then reconcile the medication lists.

Response. We have reviewed commenters' concerns and intend to clarify the language in this certification criterion. We recognize that the technical foundation and safety checks are not currently in place for automated medication reconciliation. We did not intend to imply that automated reconciliation needed to occur through our use of the word "electronically." We used the term "electronically" to express our expectation that eligible professionals and eligible hospitals would be able to use Certified EHR Technology to complete this task. Accordingly, we have revised this certification criterion to require that Certified EHR Technology be capable of providing a user with the ability to electronically compare two or more medication lists (e.g., between an externally provided medication list and the current medication list in Certified EHR Technology). We expect that this could be done in a number of ways and we do not want to preclude Complete EHR and EHR Module developers from innovating, provided that the desired outcome is reached. For example, a user could be presented with two electronic lists side-by-side and move medications from one list to the other and then select the final current list. Alternatively, a user could view one list and two PDFs of

other medications and use this capability to update the current medication list. We do, however, see great promise in making this capability more comprehensive and anticipate exploring ways to improve the utility of this capability before we adopt a subsequent round of certification criteria.

Comments. Several commenters supported this certification criterion, but wanted clarification regarding how we expected testing and certification to be accomplished, especially if only one medication list was in use.

Response. We believe that the clarifications and revisions to the certification criterion and the discussion above clarify how we intend for this certification criterion to be tested.

Comments. Several commenters requested that we clarify the meanings of "medication reconciliation," "transitions of care," and "relevant encounter."

Response. These terms are not used in the certification criterion. We encourage commenters to review the Medicare and Medicaid EHR Incentive Programs final rule to see how these terms have been clarified in response to public comments.

§170.302(m) - Submission to immunization registries

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Capability to submit electronic data to immunization registries or Immunization Information Systems and actual submission in accordance with applicable law and practice	Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries and follow up submission if the test is successful (unless none of the immunization registries to which the EP, eligible hospital or CAH submits such information have the capacity to receive the information electronically)	**Interim Final Rule Text:** Submission to immunization registries. Electronically record, retrieve, and transmit immunization information to immunization registries in accordance with: (1) One of the standards specified in §170.205(h)(1) and, at a minimum, the version of the standard specified in §170.205(h)(2); or (2) The applicable state-designated standard format.
		Final Rule Text: §170.302(k) Submission to immunization registries. Electronically record, modify, retrieve, and submit immunization information in accordance with:

| | | (1) The standard (and applicable implementation specifications) specified in §170.205(e)(1) or §170.205(e)(2); and |
| | | (2) At a minimum, the version of the standard specified in §170.207(e). |

Comments. A significant majority of commenters recommended that we remove paragraph (m)(2) related to the applicable state-designated format. These commenters contended that such a requirement was vague, could be problematic from an interoperability perspective, and would make certification impracticable.

Response. We agree with those commenters that requested we explicitly focus the certification criterion and certification in general on Federal requirements. We have therefore removed the reference to "applicable stated-designated standard format" in the certification criterion. Additionally, we have reviewed this certification criterion and have determined that our reference to "immunization registries" is unnecessary. We are primarily concerned with Certified EHR Technology's ability to transmit the immunization information in a standardized format, and do not believe that it is necessary to specify a particular recipient in the certification criterion.

Comments. Many commenters supported our adoption of both HL7 2.3.1 and HL7 2.5.1. Some commenters acknowledged that HL7 2.3.1 was more commonly used for the purpose of submitting information to immunization registries while other commenters suggested that we only adopt HL7 2.5.1. Some commenters recommended that we keep our adopted standards the way they are. Others recommended that we only adopt HL7 2.3.1 because most immunization registries cannot comply with HL7 2.5.1.

Response. We appreciate that commenters support our adoption of both HL7 2.3.1 and HL7 2.5.1. We understand that both standards are currently in use and for that

reason we have permitted either to be used for purposes of certification. We also

understand that eligible professionals and eligible hospitals will have to use the standard

that the immunization registry or Immunization Information System in their jurisdiction

can receive and, as a result, we have adopted the two most common standards utilized for

the transmission of immunization information.

Comment. One commenter noted that it would be very helpful to provide a

source for mapping from the NDC code on the vaccine packaging to the CVX/MVX

codes used for interoperability, in anticipation of supporting barcode scanning of

vaccines. Another commenter noted that while some mapping has occurred between

CPT and CVX, they were not aware of a translation map from NDC to CVX. They also

stated that even though a list of CVX codes is available, they were not aware of a

downloadable immunization database using CVX codes. They considered this lack of a

database a significant burden and impediment to compliance. The commenter concluded

by suggesting that CPT codes be used instead of CVX codes, because CPT codes are

used for billing purposes and would be readily available.

Response. The CDC maintains an openly available list of updated CVX codes as

well as a mapping of CVX codes to CPT codes on their website.[4] Moreover, we believe

that CVX codes are more appropriate than CPT codes because as the commenter

referenced, CPT codes are used for billing purposes. In that regard, we believe that

because there is a publicly available mapping between CVX and CPT, it would not be

difficult or burdensome to map CPT codes to CVX codes. NDC codes were not adopted

as a standard to represent immunizations and we do not believe that requiring their use

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[4] www.cdc.gov/vaccines/programs/iis/stds/cpt.htm

for the purposes of demonstrating compliance with this certification criterion would be appropriate.

Comment. One commenter recommended that we revise the certification criterion combined with associated standards to state "For the purposes of electronically submitting information to immunization registries Certified EHR Technology must be capable of using a certified EHR module or portal provided by a state immunization registry which is capable of submitting and retrieving coded immunization information or capable of using HL7 2.3.1 or HL7 2.5.1 as a content exchange standard and the CDC maintained HL7 standard code set CVX—Vaccines Administered as the vocabulary standard." The basis for this commenter's suggestion was that providers in its state link to the state's immunization module through EHRs and that all immunization data are stored immediately in the state's registry. The commenter further clarified that since the data resides in the state registry natively, there is no need to transmit this information.

Response. In light of this commenter's suggestion, we have revised the certification criterion to replace the word "transmit" with "submit" to better align this certification criterion with the meaningful use objective and measure. We believe that submission of immunization data would encompass this commenter's existing method.

Comment. One commenter stated that they believed the use of CVX is neither mature nor widespread.

Response. We disagree. Our information indicates that CVX codes are widely used for reporting to immunization registries.

Comment. Some commenters identified implementation specifications that are available for the standards we had adopted for transmitting immunization information. A

couple of these commenters specifically recommended using implementation

specifications that would identify message types necessary for transmissions to

immunization registries. Commenters also suggested using the CDC's implementation

guides, and explicitly recommended that we adopt the CDC public health information

network (PHIN) implementation guide version 2.2 associated with HL7 2.3.1 for the

transmission of immunization information and the CDC implementation guide as well as

the implementation guide associated with HL7 2.5.1.

Response. In the Interim Final Rule, we expressed our interest in receiving public

comment on whether there were additional implementation specifications that we should

adopt. We also noted that we would consider adopting implementation specifications for

any or all of the standards adopted in the Interim Final Rule. After further consideration

of commenters' recommendations and consultation with the CDC, we agree with these

commenters and believe that adopting implementation specifications for the transmission

of immunization information would benefit EHR technology developers and users.

Moreover, given commenters' general requests for greater specificity and our stated goal

of greater interoperability, we believe that it would be appropriate to adopt the following

implementation specifications for the submission of immunization data. For HL7 2.3.1

we have adopted the "Implementation Guide for Immunization Data Transactions using

Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol, Implementation Guide

Version 2.2." We are aware that this implementation specification has been successfully

adopted numerous times in various contexts since its publication four years ago and do

not believe that it will be burdensome for Complete EHR and EHR Module developers to

implement these specifications. For HL7 2.5.1, we have adopted the "Implementation

Guide for Immunization Messaging Release 1.0." This implementation specification represents the collaborative effort of the American Immunization Registry Association (AIRA) and the CDC. We have also consulted with CDC, and the CDC confirms the appropriateness and supports the usage of these implementation specifications in this context. We encourage migration to this newer implementation specification and believe that it will likely advance interoperability across the country and improve query capabilities.

Comment. A commenter recommended that we clarify that the certification criterion should be limited to verifying the ability of the system to record, retrieve, and transmit immunization information.

Response. The purpose of testing and certifying a Complete EHR or EHR Module to this certification criterion is to verify that it can perform the capabilities included in the certification criterion.

Comment. A couple of commenters strongly supported the transmission of immunization data to state and local immunization registries but requested that the data requirements be expanded to include the transmission of information regarding diseases such as cystic fibrosis to pediatric registries.

Response. Presently, we do not believe that it is necessary or appropriate to expand this certification criterion in this manner. We emphasize, though, that this should not preclude eligible professionals or eligible hospitals from using Certified EHR Technology to submit other types of information as medically appropriate and if the recipient of the information is capable of receiving the data.

Comment. A commenter recommended including the term "modify" in the certification criterion.

Response. We agree, and consistent with our other certification criteria that include the term "modify," we have added this term.

§170.302(n) - Public health surveillance

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Capability to submit electronic syndromic surveillance data to public health agencies and actual submission in accordance with applicable law and practice	Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies and follow-up submission if the test is successful (unless none of the public health agencies to which an EP, eligible hospital or CAH submits such information have the capacity to receive the information electronically)	**Interim Final Rule Text:** Public health surveillance. Electronically record, retrieve, and transmit syndrome-based public health surveillance information to public health agencies in accordance with one of the standards specified in §170.205(g).
		Final Rule Text: §170.302(l) Public health surveillance. Electronically record, modify, retrieve, and submit syndrome-based public health surveillance information in accordance with the standard (and applicable implementation specifications) specified in §170.205(d)(1) or §170.205(d)(2).

Comments. A couple of commenters supported the adoption of certification criteria related to public health reporting. One commenter believed that this certification criterion should be implemented as adopted.

Response. We appreciate commenters' support of this certification criterion.

Comment. One commenter recommended that we defer any vocabulary standard for public health reporting and surveillance until a later date. Another commenter expressed concern that we would adopt as a standard, "according to applicable public health agency requirements," because they thought it could be problematic for hospital systems with facilities in two or more states, as their EHR technology would have to meet whatever standards each state elected to use.

Response. We clarify for commenters that we adopted two content exchange

standards for electronic submission to public health agencies for surveillance and

reporting. We did not adopt a specific vocabulary standard, nor did we include the

phrase one commenter stated that we included. However, we have, consistent with our

rationale in the immunization submission certification criterion, removed our reference to

"public health agencies" as the recipient of information. Also, consistent with the

certification criterion above, we have replaced the term "transmit" with "submit."

Comments. A couple of commenters stated that compliance with HL7 2.5.1 not

be included in this adopted set of standards. One commenter suggested HL7 2.5.1 should

be adopted in a future rulemaking. Another commenter suggested that HL7 2.3.1 be

required for the purposes of certification. Another commenter recommended that the

standard be HL7 2.3.1, because in its opinion many public health agencies cannot comply

with HL7 2.5.1 while another commenter took the opposite position and recommended

HL7 2.5.1.

Response. Given the diversity in implementations and public health agencies'

ability to receive information in a given standard, we believe that the flexibility included

in this criterion is necessary for the foreseeable future. However, relative to the general

comments we received regarding the adoption of implementation specifications for

adopted standards, we have adopted the following implementation specifications 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. We believe that

these implementation specifications provide the additional clarity commenters were

seeking and will enable Complete EHR and EHR Module developers to focus their efforts on a more specific implementation of the HL7 2.5.1 standard. We do not believe that a suitable implementation specification for HL7 2.3.1 exists for the purpose of public health surveillance and reporting.

Comments. Multiple commenters stated concerns that the Federal government and state governments, as well as other public health agencies, do not have the capability to receive information electronically in a standardized format. One commenter stated that while they supported using the HL7 standards, some agencies are only able to accept public health submissions if they have an HL7-based feed. Several commenters suggested that the public health reporting requirement be delayed until a single, national standard exists. One commenter stated that requiring EHRs to "electronically record, retrieve, and transmit syndrome-based public health surveillance information to public health agencies" is a worthwhile future goal, but they strongly questioned the likelihood that it could be accomplished within the 2011-2012 timeframe. The commenter also noted that the certification criterion did not specify which agencies (local, state, Federal) are included, and that most of those agencies are not prepared to receive biosurveillance data electronically in the format specified. The commenter concluded that it would be difficult for any EHR to prove compliance with the certification criterion as written and recommended the following alternative: "Electronically record, retrieve, and be capable of producing an electronic message containing syndrome-based public health surveillance information in accordance with one of the standards specified in §170.205(g)."

Response. We recognize that some public health agencies do not yet have the capability of electronically receiving information. We do not believe that this should

serve as a limiting factor, however, or preclude Certified EHR Technology from having the capability to transmit information in a standard format.

Comment. One commenter commented that if a public health agency is unable to accept the data, separate reports could be filed with the public health agency to ensure compliance with the standards.

Response. The commenter's point is unclear, as is its proposal. We therefore reiterate that Certified EHR Technology must be capable of transmitting health information in accordance with the standards adopted by the Secretary, regardless of whether a specific public health agency can accept or receive the information.

Comment. One commenter suggested that if current interfaces comply with public health surveillance data using older versions of HL7, the organizations should be allowed to keep these versions and not be required to upgrade to a newer version.

Response. We permit a Complete EHR or EHR Module to be tested and certified to either HL7 2.3.1 or HL7 2.5.1. No other versions will be considered compliant with the adopted standards or certification criterion.

Comment. One commenter recommended that we specify acceptable testing methods. The commenter also recommended that the testing methods should include an evaluation of HL7 conformance, completeness, and accuracy of test messages sent to a state public health agency with a demonstrated capability for electronic laboratory reporting.

Response. We do not specify the testing methods applicable to the certification criterion, because that information is outside the scope of this final rule.

Comment. One commenter suggested that adverse events be reported to public health agencies.

Response. Our certification criterion does not preclude other types of reportable events from occurring. Presently, we do not believe that it is appropriate to modify the certification criterion to explicitly refer to adverse events.

Comment. One commenter recommended that because some public health agencies do not have the ability to receive public health surveillance information in electronic format, we should clarify that this certification criterion is limited to verifying the ability of the system to record, modify, retrieve, and submit such information based on at least one test of these capabilities.

Response. We reiterate, that the purpose of certification is to verify that a Complete EHR or EHR Module can perform these capabilities. That should not be construed to mean that an eligible professional or eligible hospital is exempt from using Certified EHR Technology to meet the meaningful use objective and measure.

Comment. A commenter recommended including the word "modify" in the certification criterion.

Response. Consistent with our rationale above, we have added the word modify to the certification criterion.

§170.302(o) - Access control

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process	**Interim Final Rule Text:** 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.
		Final Rule Text: §170.302(o)

		Unchanged

Comment. One commenter explicitly noted its support for this certification criterion. We received other comments that included some mention of "access" but did not expressly focus on the certification criterion or provide any related suggestions or recommendations.

Response. We appreciate the comment supporting this certification criterion. This certification criterion remains unchanged from the certification criterion adopted in the Interim Final Rule.

§170.302(p) - Emergency access

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process	**Interim Final Rule Text:** Emergency access. Permit authorized users (who are authorized for emergency situations) to access electronic health information during an emergency.
		Final Rule Text: §170.302(p) Unchanged

Comment. One commenter asked that we clarify the circumstances that would qualify as an "emergency" and further clarify whether compliance with this certification criterion is intended to pre-empt conflicting or stricter state laws that may limit this type of access or require patient consent. Further, the commenter questioned whether we were implying that some authorized users of Certified EHR Technology would not be authorized for emergency situations or whether we intended for any authorized user to be entitled to access in an emergency situation. Finally, another commenter requested clarification as to whether emergency access is driven by organizational policies and whether capturing such access in an audit log is appropriate.

<u>Response.</u> We have adopted certification criteria to ensure that Certified EHR

Technology includes certain capabilities, in this case that Certified EHR Technology be

capable of permitting authorized users to access electronic health information during an

emergency. The criterion is not intended to specify what constitutes an emergency or

who would be authorized to access electronic health information in an emergency. In a

medical emergency, those determinations would be made under specific factual

circumstances and in accordance with applicable state and federal laws, organizational

policies and procedures, and the relevant standard of care.

With respect to emergency access, we note that HHS stated in the HIPAA

Security Final Rule (68 FR 8355):

> We believe that emergency access is a necessary part of access controls and, therefore, is properly a required implementation specification of the ''Access controls'' standard. Access controls will still be necessary under emergency conditions, although they may be very different from those used in normal operational circumstances. For example, in a situation when normal environmental systems, including electrical power, have been severely damaged or rendered inoperative due to a natural or manmade disaster, procedures should be established beforehand to provide guidance on possible ways to gain access to needed electronic protected health information.

We believe that this certification criterion is consistent with the HIPAA Security Rule.

Some commenters appeared to interpret our reference to "emergency" in

"emergency access" as solely constituting a clinical or life threatening emergency related

to a patient for which access would be required. We believe that emergency could

encompass that scenario, as well as a broader range of possibilities, including normal

patient care when timely access to electronic health information becomes critical.

Therefore, we have not sought to limit the development of emergency access capabilities

for Certified EHR Technology to a particular scenario.

Comment. One commenter suggested that we require automated notification of user activity to system administrators when emergency access is invoked.

Response. We appreciate this suggestion. However, at the present time, we do not believe that this requirement should be a condition of certification because a person or entity's organizational policies and procedures may ensure timely notification of appropriate personnel.

§170.302(q) - Automatic log-off

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process	**Interim Final Rule Text:** Automatic log-off. Terminate an electronic session after a predetermined time of inactivity.
		Final Rule Text: §170.302(q) Unchanged

Comments. One commenter supported this requirement. Another commenter concurred with the purpose of the certification criterion, but noted that it may be difficult in some circumstances for eligible professionals or eligible hospitals to implement this capability if the Certified EHR Technology is offered as a service and multiple individuals are using the Certified EHR Technology at the same time.

Response. We appreciate the commenters' support for the adoption of this certification criterion. We believe that automatic logoff capabilities are commonplace and that this certification criterion can be met by any Complete EHR or EHR Module developer. We are aware that many web services today logoff customers after a period of inactivity and do not believe this requirement is unduly burdensome for any Complete EHR or EHR Module developer.

§170.302(r) - Audit log

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process	**Interim Final Rule Text:** (1) <u>Record actions.</u> Record actions related to electronic health information in accordance with the standard specified in §170.210(b). (2) <u>Alerts.</u> Provide alerts based on user-defined events. (3) <u>Display and print.</u> Electronically display and print all or a specified set of recorded information upon request or at a set period of time.
		Final Rule Text: §170.302(r) (1) <u>Record actions.</u> Record actions related to electronic health information in accordance with the standard specified in §170.210(b). (2) <u>Generate audit log.</u> Enable a user to generate an audit log for a specific time period and to sort entries in the audit log according to any of the elements specified in the standard at 170.210(b).

Comments. Several commenters recommended that we add to the standard specified at §170.210(b) "access," "reading," or "viewing" as triggers for when actions needed to be recorded as part of an audit log. One commenter recommended expanding the audit content to include maintaining the before-access content of the information accessed as well as the after-access content. Some commenters requested clarification of the intended meaning of the reference to recording the action of "printing." Commenters recommended expanding or replacing "print" in the standard with other types of output methods such as extraction, copy, exchange, report, and export. Some commenter stated that the print function in many operating systems and software products is a multiple step process that is difficult for any system to audit. Other commenters expressed concerns that the requirement to audit all printing would be difficult because there were numerous ways to circumvent the specific action of printing, such as using the print screen function and printing out the image of the screen shot. One commenter stated that auditing of the print function would be possible, but complete auditing of all possible ways of printing would be impracticable.

Response. We appreciate the thoughtfulness and thoroughness of the comments

provided on this standard. We agree with commenters that auditing the action of

printing, as it was originally envisioned, could be circumvented in such ways as to make

the burden of trying to accurately audit such occurrences outweigh the benefit.

Accordingly, we have removed "printed" from the standard. We also agree with

commenters that our omission of "access" should be corrected and we have added

"accessed" to the standard. We view the action of "access" to encompass "reading" or

"viewing" and consequently have not included those terms as well. Finally, we believe

that the action of "accessed" is a superset of actions which may include "export" and for

that reason have not included, per some commenters' suggestions, the word "exported" in

the standard. Additionally, to provide greater clarity, we have added in "and by whom"

toward the end of the standard in order to more clearly specify that the actions recorded

should be associated with the user identification that is recorded.

The final standard will read as follows: "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."

Comments. Some commenters requested that we clarify the term "user

identification" in the standard specified at §170.210(b) and recommended the use of

existing standards-based definitions, such as HL7's definition of *author* which includes

person, organization, or device.

Response. We specified in the standard that the date, time, patient identification,

and user identification must be recorded when certain actions take place. The HL7's

definition of author is consistent with our expectation. While we believe that in most cases a user will be a health care professional performing an action using Certified EHR Technology, it is also possible that a device or another software process or program could perform any one of these actions. We do not intend to preclude Complete EHR and EHR Module developers from including these and other types of specific features.

Comment. One commenter stated that the audit alert criterion exceeds reasonable expectations for Certified EHR Technology to provide automatic alerts, and recommended that the audit criteria focus on record access rather than electronic alerts. Several commenters suggested that alerts are not well defined and should be removed from the criteria. Several commenters expressed concern that the audit alerting criterion goes beyond what is required by HITECH and HIPAA and exceeds the current capabilities of products in the market, and recommends that the alerting criterion be eliminated from the final rule. Some commenters recommended against the adoption of certification criterion that requires EHR systems to create an unlimited and open-ended series of rules to produce user-defined alerts, and suggested that we should clearly define which actions should be recorded and what alerts should be defined and provided in an audit log. Several commenters stated that the use of the phrase "based on user-defined events" in the criterion could be easily misinterpreted or misunderstood to extend beyond "entity-defined" events to include individual patient preferences. Some of the commenters that expressed concerns also contended that it would be difficult to test and certify this portion of the certification criterion.

Response. Again, we appreciate the thoroughness of the commenters' suggestions. With respect to alerts based on user-defined events, we had intended for

Complete EHRs or EHR Modules designed to provide this capability to be capable of being configured by a specific user of Certified EHR Technology or based on organizational policy to generate alerts when certain actions (defined in the standard) had taken place. For example, a user-defined event could be when a patient's health information is accessed outside of normal business hours. In this case, it was our expectation that Certified EHR Technology would alert a specific user of the Certified EHR Technology or the organization's information security staff. We understand the point that commenters raise, however, about the potential for misinterpretation of this certification criterion and the consequent potential burden.

Our overall intent for the third paragraph of this certification criterion was to ensure that Certified EHR Technology provided the capability for eligible professionals and eligible hospitals to gain access to a specified portion, or a complete representation, of the Certified EHR Technology's audit log. We believe that this capability is essential for eligible professionals and eligible hospitals for risk analysis and other purposes. Therefore, in concert with the feedback commenters provided on the second paragraph, we analyzed whether combining the third paragraph with the second paragraph into a single paragraph would express a clearer requirement. Accordingly, we have merged the two paragraphs and have adopted in the final rule a requirement that we believe more clearly expresses our intent for this certification criterion. We also note for clarification that the phrase "any of the elements specified by 170.210(b)" would also include, for example, "date" or that information has been "deleted."

Finally, we believe that it is important for our privacy and security certification criteria to remain consistent with the HIPAA Security Rule to the degree that Certified

EHR Technology includes technical capabilities that are associated with assisting HIPAA covered entities comply with applicable legal requirements. We disagree, however, with those commenters who stated that we did not have a sufficient legal basis to adopt this certification criterion the way we did because it went beyond the HIPAA Security Rule. What a HIPAA covered entity must do to remain in compliance with the HIPAA Security Rule is separate and distinct from the capabilities that a Complete EHR or EHR Module must include in order to be certified. We do not believe that we are precluded by the HITECH Act from adopting certification criteria that go beyond the requirements specified by the HIPAA Security Rule. We believe that the HITECH Act, while directing that standards, implementation specifications, and certification criteria be consistent with the HIPAA standards, authorizes the Secretary to adopt certification criteria more broadly for the electronic use and exchange of health information. Section 3004(b)(1) of the PHSA, as added by the HITECH Act, requires the Secretary, for instance, to adopt an initial set of standards, implementation specifications, and certification criteria to enhance the interoperability, functionality, utility, and security of health information technology.

With respect to the concern expressed that this certification criterion requires capabilities that exceed the current capabilities of products in the market, we disagree. Based on our understanding of the current EHR technology in the market, we believe that the capabilities we have specified in the criterion and the embedded standard are already common industry practice, and further, that the industry has expanded the functionality available in audit logs.

Comment. One commenter suggested we defer our adoption of the standard until the next rulemaking related to meaningful use.

Response. We disagree. As stated above, we believe that audit log capabilities are an essential component of Certified EHR Technology. As we mentioned above, we believe that the actions we have specified in the standard, in response to public comment, are already common industry practice. Moreover, audit logs will provide valuable information to eligible professionals and eligible hospitals in the event of a security incident.

Comments. Several commenters acknowledged the importance of the audit log, but emphasized that the audit log requirements should address the availability of the audit log and its security. Several commenters recommended that additional requirements be added, including that the audit log always be on during normal production for the minimum elements specified in 170.210(b), be maintained in a secure manner, be produced in a human readable format, and be retained in conjunction with the retention period of the record.

Response. We agree with these commenters on the merits of their suggestions. In particular, we note that audit logs provide an important resource for eligible professionals and eligible hospitals. Audit logs can assist in the identification of security incidents, such as unauthorized access, as well as serve to deter users from conducting fraudulent or abusive activities and detect such activities. The purpose of adopted certification criteria is to specify the capabilities Complete EHRs and EHR Modules must include in order to be certified, not when such capabilities must be used. Accordingly, we do not believe that it would be appropriate to specify in this certification criterion the time period for which an audit log should be "on." We agree with commenters that audit logs should be maintained in a secure manner. For this reason, we have preserved the capability we

adopted in the Interim Final Rule as part of the integrity certification criterion that specified that Certified EHR Technology must be capable of detecting alterations to audit logs. We encourage the HIT Standards Committee to consider additional capabilities that could be specified related to audit logs.

Comment. One commenter recommended that the IHE Audit Trail and Node Authentication (ATNA) Integration Profile be used, but that its use be constrained to the electronic transactions among organizations, rather than electronic transmissions within an organization.

Response. We decided to defer our adoption of the ATNA standard because it can be configured in multiple ways and we did not believe that it would be appropriate at this time to require a specific implementation as a condition of certification. Our deferral does not preclude Complete EHR and EHR Module developers from using the standard, however.

Comment. One commenter requested clarification between "read" audits and "write" audits, and how each is to be used. The commenter suggested that not requiring the capability of "read" audits will significantly reduce the ability of auditors to identify and investigate inappropriate use of health information when records are accessed but not manipulated. The commenter noted that auditing all read operations for all data elements within an EHR is infeasible. The commenter further suggested that "read" operations should be audited only when certain demographic health information needed to identify a patient (e.g., name, record number, date of birth, address) is presented to or can be known by the user.

Response. As discussed above, we have adopted in the standard the action of "accessed" which would encompass the action of "read." At the present time, we only identify certain data elements in the adopted standard that must be recorded and believe that this specificity will help reduce any potential burden associated with recording the action of "accessed."

§170.302(s) - Integrity

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process	**Interim Final Rule Text:** (1)In transit. Verify that electronic health information has not been altered in transit in accordance with the standard specified in §170.210(c). (2) Detection. Detect the alteration and deletion of electronic health information and audit logs, in accordance with the standard specified in §170.210(c).
		Final Rule Text: §170.302(s) (1) Create a message digest in accordance with the standard specified in 170.210(c). (2) Verify in accordance with the standard specified in 170.210(c) upon receipt of electronically exchanged health information that such information has not been altered. (3) Detection. Detect the alteration of audit logs.

Comments. Several commenters requested a definition of "in transit." Other commenters suggested that hashing of messages in transit be limited to circumstances of transmission over public networks only. These commenters suggested that messages transmitted over private networks be exempt from complying with this standard. One commenter suggested that in addition to message hashing, digital signatures should be required on messages in transit. Another commenter stated that requiring hashing of messages in transit is overly burdensome. One commenter requested that we clarify whether we intended §170.302(s)(1) to require that the receiver of a message always verify messages received rather than simply demonstrate the capability to use hashing.

Response. We intend for this certification criterion to support, at a minimum, the

HIPAA Security Rule implementation specification provided at 45 CFR 164.312(e)(2)(i)

"[i]mplement security measures to ensure that electronically transmitted electronic

protected health information is not improperly modified without detection until disposed

of." Because this certification criterion specifies a capability that Certified EHR

Technology must include, we do not believe that it is necessary or appropriate for us to

address whether hashing is applicable to public and private networks. Additionally, we

clarify that Certified EHR Technology must include the capability to check the integrity

of health information that has been received through electronic exchange. However,

similar to our approach to many adopted certification criteria, we do not specify the

instances in which this capability needs to be executed. Nevertheless, in response to

public comments we have attempted to clarify this certification criterion. We clarify that

we expect Certified EHR Technology to be capable of creating a message digest and

when in receipt of a message digest, to use the message digest to verify that the contents

of the message have not been altered. We have revised the certification criterion to

clarify our intent.

Additionally, based on these revisions in the certification criterion, we wish to

clarify the wording of the integrity standard specified at 170.210(c). The standard

currently includes the words "or higher" at the end of the standard. To provide more

certainty to the industry of our intended meaning, we are replacing those words with

more accurate terminology. We have modified the standard to read as follows: "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." More information on

SHA-1 and other secure hash algorithms can be found in FIPS 180-3[5] while more information on the security strength of certain hashing algorithms can be found in NIST Special Publication 800-107.[6]

Comments. Some commenters noted that §170.302(s)(2) refers to the use of the adopted standard which specifies the use of hashing to detect audit log alteration or deletion and that such a requirement is inappropriate. Other commenters recommended that hashing should not, at the present time, be used for detecting alterations to data at rest.

Response. We have considered these comments and agree with these commenters that this requirement requires further clarification. We note that part of this requirement as adopted in the Interim Final Rule ("detect … deletion of electronic health information") is redundant with the standard we specify for audit logs which requires that deletions of electronic health information be recorded. For this reason, we have removed the reference to the detection of deleted electronic health information and have opted for a more concise requirement that alterations to audit logs be detected. In response to public comment, we have chosen not to specify a standard for detecting alterations to audit logs at this time.

Comment. One commenter requested clarification as to how message hashing should work when messages are part of a multi-part transmission process, e.g., through switches, clearinghouses, and other brokers.

Response. We expect Certified EHR Technology to be capable of generating a hash of electronic health information and upon receipt of such information, verifying that

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[5] http://csrc.nist.gov/publications/fips/fips180-3/fips180-3_final.pdf
[6] http://csrc.nist.gov/publications/nistpubs/800-107/NIST-SP-800-107.pdf

it has not been altered when it has been electronically exchanged. We recognize that certain situations may not be conducive to the use of hashes, which is why, as we noted above, we do not specify the instances in which hashing must be used, just that Certified EHR Technology include these capabilities.

Comment. One commenter stated that secure transmission requirements are "inappropriate" because they do not support any meaningful use requirements.

Response. We disagree. Meaningful use requires the electronic exchange of health information and the protection of such information. We believe that the only practical and effective way that electronic health information can be exchanged in a meaningful manner is if the integrity of the information can be maintained. Information "integrity" is also one of the three pillars of securing or "protecting" electronic information.

§170.302(t) - Authentication

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process	**Interim Final Rule Text:** (1)Local. Verify that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information. (2)Cross network. Verify that a person or entity seeking access to electronic health information across a network is the one claimed and is authorized to access such information in accordance with the standard specified in §170.210(d).
		Final Rule Text: §170.302(t) Authentication. Verify that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information.

Comments. One commenter expressly supported this certification criterion. A majority of commenters expressed concerns related to §170.302(t) and the cross-enterprise authentication standard specified at §170.210(d). Some commenters

misinterpreted our example and stated that Security Assertion Markup Language (SAML) should not be required or be a named standard. One commenter suggested expanding the set of examples we provided. Other commenters requested that the standard and the related portion of the certification criterion be removed because it was too burdensome to implement at the present time, was overly broad, and could be subject to multiple interpretations. Other commenters contended that there is an insufficient infrastructure to support cross-enterprise authentication. One commenter stated that cross-enterprise authentication would not reside in an EHR application, but rather in the network infrastructure.

Response. We have considered the concerns issued by commenters and agree that the burden associated with cross enterprise authentication is unnecessarily high and cross-network authentication should not be a condition of certification at the present time. As a result, we have removed this specific part of the certification criterion and the associated standard.

Comment. A commenter requested clarification as to whether "user name and password" would be sufficient to authorize a user or whether biometrics would be required.

Response. We do not believe that it is appropriate to specify, as a condition of certification, the types of factors that users could utilize to authenticate themselves.

§170.302(u) - Encryption

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Protect electronic health information created or maintained by the certified EHR	Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement	**Interim Final Rule Text:** (1) General. Encrypt and decrypt electronic health information according to user-defined preferences in accordance with the standard specified in §170.210(a)(1). (2) Exchange. Encrypt and decrypt electronic health

technology through the implementation of appropriate technical capabilities	security updates as necessary and correct identified security deficiencies as part of its risk management process	information when exchanged in accordance with the standard specified in §170.210(a)(2).
		Final Rule Text: §170.302(u) General encryption. Encrypt and decrypt electronic health information in accordance with the standard specified in §170.210(a)(1), unless the Secretary determines that the use of such algorithm would pose a significant security risk for Certified EHR Technology. §170.302(v) Encryption when exchanging electronic health information. Encrypt and decrypt electronic health information when exchanged in accordance with the standard specified in §170.210(a)(2).

Comments. A number of commenters stated that transmissions of health information over leased or private network lines should not be subject to the encryption of data in transit requirement.

Response. Certified EHR Technology must include the capability to encrypt and decrypt information regardless of the transmission method used. This certification criterion and related standard do not specify the circumstances under which encryption and decryption must be performed; they simply require the capability. If an eligible professional or eligible hospital determines that encryption is an appropriate and necessary safeguard, we believe that Certified EHR Technology should provide the capability to implement encryption. Overall, we want to ensure that Certified EHR Technology is capable of assisting eligible professionals and eligible hospitals to implement more secure technical solutions if they determine, based on their risk analysis, that technical safeguards such as encryption are reasonable and appropriate, or required.

Comment. One commenter requested further clarification of the phrase "encrypted and integrity protected link." Several commenters recommended that Transport Layer Security (TLS) ought to be specifically named as a required protocol.

Other commenters also expressed concern that unless TLS is explicitly named, all example protocols would be required to be supported.

Response. The example list of protocols that would meet the certification criterion is not intended to be exhaustive or suggest that Complete EHRs or EHR Modules must be capable of using all of the listed protocols to be certified. The example list of protocols in the Interim Final Rule was included solely for illustrative purposes. We have, however, consistent with the way we have restructured the regulatory text for some standards (to better associate them with the adopted certification criterion that reference them), modified this standard to simply express that the standard is any encrypted and integrity protected link.

Comments. Several commenters suggested replacing the functional description of the encryption standard with a specific reference to FIPS 140-2. These commenters also noted that HHS had included such a reference in an update to its guidance specifying the technologies and methodologies that render protected health information unusable, unreadable, or indecipherable that was included in the Breach Notification for Unsecured Protected Health Information Interim Final Rule, published on August 24, 2009 (74 FR 42740), and further, requested that we make our standard consistent with this guidance. Some commenters explicitly recommended that AES be specified as the encryption algorithm standard.

Response. We have considered these commenters' points and have decided to revise our adopted standard to be more flexible regarding the encryption algorithms we permit EHR Technology to implement to be certified. We have also sought to clarify how our adopted standard relates to the guidance included in the breach notification

interim final rule. We have revised the general encryption standard to read as follows:

"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."

The National Institute of Standards and Technology (NIST) published Federal

Information Processing Standards (FIPS) Publication 140-2 to specify the security

requirements for cryptographic modules. As part of FIPS 140-X conformance, NIST

publishes "annexes" of different "approved" security protocols. For purposes of

encryption, NIST maintains "Annex A" which identifies "approved security functions."

Annex A identifies both symmetric and asymmetric key encryption algorithms that NIST

has identified for use in accordance with FIPS 140-2. In response to commenters'

concerns, we believe that leveraging NIST's work in this area provides for a clearer

requirement for compliance and provides Complete EHR and EHR Module developers

with the ability to use one or more secure encryption algorithms for the purposes of

demonstrating compliance with this certification criterion. We believe this flexibility will

benefit eligible professionals and eligible hospitals because they may be able to leverage

a broader suite of secure encryption algorithms. As noted in Special Publication 800-

111, which is specified in the guidance included in the breach notification interim final

rule for the encryption of data at rest, "[w]henever possible, AES should be used for the

encryption algorithm because of its strength and speed."

We point out that the adopted certification criterion identifies certain discretionary

authority that the Secretary is retaining with respect to acceptable encryption algorithms.

We have adopted the list of approved encryption algorithms that NIST has identified and

referenced in FIPS 140-2 Annex A, which is being incorporated by reference. While the

list is intended to be current, we anticipate that NIST will on an as-needed basis revise

and update the list, based on the development of new technologies or perhaps on

identified vulnerabilities associated with a particular algorithm. Regardless of any

revisions to this list by NIST, this version of Annex A that is incorporated by reference

will remain effective for purposes of serving as the adopted encryption standard. With

that said, if the Secretary determines that one of the listed encryption algorithms poses a

significant security risk for Certified EHR Technology, the Secretary will notify the

public on the Department's website (and perhaps with some time delay in the Federal

Register), and will direct ONC-ATCBs or ONC-ACBs not to test and certify Complete

EHRs and EHR Modules according to the specified compromised algorithm. The

Department would then follow-up with rulemaking as necessary and appropriate to

update the adopted list of acceptable encryption algorithms.

Comments. Many commenters expressed concerns that the rule would require the

encryption of data at rest. One commenter recommended that encryption not be a

required functionality of EHR systems, but defined as limited to devices. Some

commenters stated that requiring EHR systems to be capable of encryption would hinder

adoption.

Response. We require that Certified EHR Technology must be capable of

encrypting electronic health information. We do not specify the policies surrounding the

use of encryption by an eligible professional or eligible hospital nor do we specify that it

should only apply to devices. Rather we intend for Certified EHR Technology to be

technologically capable of encryption, thereby allowing, if desired or required, an eligible

professional or eligible hospital who adopts Certified EHR Technology to use this capability. We disagree that requiring Certified EHR Technology be capable of encryption would hinder adoption. To the contrary, we believe that Certified EHR Technology capable of encrypting electronic health information will be desired, especially in light of the new breach notification requirements established by the HITECH Act and the Breach Notification for Unsecured Protected Health Information Interim Final Rule. We also take this opportunity to make a technical correction to this certification criterion. We inadvertently combined both encryption capabilities under the same paragraph and per our reaffirmed interpretation expressed in the Temporary Certification Program, we believe that the scope of one certification criterion starts at the first paragraph level and includes all subparagraphs. As a result, we view these as two distinct capabilities and have created a separate certification criterion for each.

Comments. One commenter stated that the security requirements, particularly for encryption, are lower than the security standards it already meets. This commenter consequently believes that our adoption of this standard would require it to reduce the security of its products. Another commenter stated that encryption technology should not be integrated into an EHR product, but should instead be implemented through other means as part of the system on which an EHR may be installed.

Response. We believe that Certified EHR Technology must be capable of performing encryption. Because of the flexibility in the adopted standard, however, how encryption is technically implemented is up to the Complete EHR or EHR Module developer to determine within the parameters of Annex A of FIPS 140-2. Given the changes we have made to the general encryption standard, we believe that the full range

of the most secure encryption algorithms are available for Complete EHR and EHR

Module developers to implement.

Comments. A few commenters stated that the term "user-defined preferences" in

the certification criteria was too vague and allowed too much latitude for divergent

interpretations of the requirement. Other commenters noted that users do not always get

to define such preferences as they would conflict with overarching organizational

policies.

Response. We intended the phrase, "according to user-defined preferences" in the

Interim Final Rule, to mean that users would have the ability to elect when they wanted

encryption to occur, for example, at log-off. We recognize that organizational policies,

software as service models and other architectures in which Certified EHR Technology

may be implemented, could lead to encryption being instituted in significantly different

ways and, as a result, we have removed the reference to "user-defined preferences."

§170.302(v) - Accounting of disclosures

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process	**Interim Final Rule Text:** Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in §170.210(e).
		Final Rule Text: §170.302(w) Certification criterion made optional, while the text of this certification criterion remains unchanged

Comments. Many commenters asserted that the certification criterion and

accompanying standard for accounting of disclosures for treatment, payment, and health

care operations (as these terms are defined at 45 CFR 164.501) would be a resource

intensive process and too administratively, technically, and financially burdensome. A large portion of commenters further conveyed specific challenges including: the ability to differentiate between a "use" and a "disclosure" (as these terms are defined at 45 CFR 160.103); storing three years worth of disclosures, which many noted could be voluminous; that health care providers, especially hospitals, have decentralized systems, which today are manually accessed to create an accounting of disclosures; the development time for such a capability would take more time than is available before the meaningful use Stage 1 effective date; that it would be difficult to account for these types of disclosures in real-time without a code set for disclosures; that this requirement could affect workflow; and the scope of electronic exchanges that the term "disclosure" would encompass is unclear. A majority of commenters also echoed that the Secretary should use discretion provided by the HITECH Act to delay the compliance date for accounting of disclosures for treatment, payment, and health care operations. Commenters supported this suggestion by pointing out that the Secretary has not yet formally established the policies for accounting of disclosures. They explained that the HITECH Act requires the Secretary to promulgate a rule no later than six months after the Secretary has adopted a standard for accounting of disclosures, which has not yet occurred. Many of these commenters suggested that the certification criterion and standard should be removed or their adoption delayed until after the technical specifications for accounting of disclosures can be harmonized with the Secretary's forthcoming promulgation of a regulation on this issue. Other commenters noted that the HIT Policy Committee included accounting of disclosures in its suggestions as a meaningful use Stage 3 objective. In response to the questions we posed, several commenters noted that to whom

the disclosure was made (recipient) should be an important element included in an accounting of disclosures. One commenter noted that the standard should be the same as what is currently applicable to disclosures that are not for treatment, payment, and health care operations and cited the requirements at 45 CFR 164.528(b)(2). Other commenters stated that the adopted certification criterion should be an audit log.

Response. We appreciate the thoroughness, specificity, and detail provided by many of those who commented on this certification criterion. We recognize that significant technical and policy challenges remain unresolved. Accordingly, we do not believe that the capability to account for disclosures should be a condition of certification at the present time. As discussed in the beginning of the preamble of this final rule, we have decided to make this certification criterion "optional" instead of removing it. Additionally, the standard will remain unchanged as currently worded and as applicable to the certification criterion to provide guidance to Complete EHR and EHR Module developers that choose to adopt this capability at this time. As an optional certification criterion, though, Complete EHR or EHR Module will not be required to possess the capability for certification. As we stated previously in the Interim Final Rule, we plan to work collaboratively with the Office for Civil Rights (OCR) as it develops the regulatory policy related to this requirement. We anticipate updating this certification criterion and the related standard in a future rulemaking to reflect OCR's final policies regarding accounting of disclosures.

Comment. Several commenters requested that we clarify what is meant by a "description of the disclosure." Some commenters noted that it would not be possible to include these descriptions in an accounting without code sets for the various types of

disclosures. These commenters also indicated that this requirement could have serious

workflow implications unless it can be fully automated.

Response. We recognize the technological challenges associated with effectively

and efficiently addressing this aspect of the standard which some commenters mentioned.

We also recognize that the regulated community is awaiting the proposed rule and

subsequent final rule that will implement important privacy provisions of the HITECH

Act. As we discussed in the Interim Final Rule, we intended to leave Complete EHR and

EHR Module developers with the flexibility to innovate in this area and to develop new

solutions to address the needs of their customers. We anticipated that a "description of

the disclosure" would, at the present time, be a free text field that would have included

any information that could be readily and electronically associated with the disclosure.

For example, we envisioned that some descriptive information could be included such as

the words "treatment," "payment," or "health care operations" separately or together as a

general category. We also assumed that Complete EHR and EHR Module developers

could find innovative ways to associate certain electronically available information with

the disclosures, such as, to whom the disclosure was made. Again, for the time being, we

have made this certification criterion optional, and will wait for OCR to promulgate final

regulations for accounting of disclosures, before revisiting whether this certification

criterion should be required.

b. Specific Certification for Complete EHRs or EHR Modules Designed for an

Ambulatory Setting - §170.304

§170.304(a) - Computerized provider order entry

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion

Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines	More than 30% of unique patients with at least one medication in their medication list seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one medication order entered using CPOE	**Interim Final Rule Text:** Enable a user to electronically record, store, retrieve, and manage, at a minimum, the following order types: (1) Medications; (2) Laboratory; (3) Radiology/imaging; and (4) Provider referrals.
		Final Rule Text: §170.304(a) Computerized provider order entry. 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.

Comments. A couple of commenters noted that within the confines of many hospitals, just about any "order" can be entered, so the process of order entry is defined. For providers, the commenter noted that the ability to perform orders varies. The commenter inquired whether a specific meaning for order entry was intended for this certification criterion. A few commenters supported the certification criterion. One commenter recommended that referrals to dieticians, speech therapists, child life and social services be added to the order types, as well as durable medical equipment, orthotics, and prosthetics. Another commenter recommended that CPOE include a Patient Plan of Care (PPOC) because, according to the commenter, PPOC requires the content necessary for electronic data interoperability. The commenter felt that PPOC within an EHR would help to achieve the integration goals that promote the appropriate exchange of medical information for the optimal coordination of patient care in different healthcare settings. Another commenter suggested that we narrow the CPOE requirements to focus on medications, laboratory tests, and imaging tests. One commenter stated that based on the discussions of CPOE in the Interim Final Rule and the Medicare and Medicaid EHR Incentive Programs proposed rule, we should consider a

request for a consultation or a provider referral made by an eligible professional in a private practice to constitute an order that should be handled functionally through CPOE.

Response. We agree with the commenter that suggested that we narrow our focus, in order to reduce the burden associated with this certification criterion. Accordingly, we have removed "provider referrals" from the certification criterion. Complete EHR and EHR Module developers may include additional orders as they see fit and as recommended by some commenters, however in order to be certified they must include at a minimum the three order types (medications, laboratory, and radiology/imaging) specified in the certification criterion. Many commenters generally supported these three specified order types and we note that while the final meaningful use Stage 1 objective focuses on medication orders, we believe that for the purposes of certification and to equip eligible professionals with a basic set of ordering capabilities, it is appropriate to continue to maintain these three order types. (This response also applies to the change we made in the CPOE certification criterion for Complete EHRs or EHR Modules designed for an inpatient setting). Finally, in further reviewing this certification criterion in light of comments received, we have also determined that it would be appropriate and clearer to replace the term "manage" with "modify" to be more consistent with the terminology used in other certification criteria. We have also made this change in the CPOE certification criterion for Complete EHRs and EHR Modules designed for an inpatient setting.

Comment. A commenter stated that the lab industry does not have any standards for order entry, and even among lab providers, their operating units utilize different standards. The commenter contended that this lack of consistency in order entry would

require EHRs to build custom interfaces to every lab. They recommended that we require that Certified EHR Technology provide the ability to link the results to the original order. Another commenter recommended that the certification criterion include the requirement for standardized bi-directional laboratory interfaces, including functionality pertinent to all the laboratory order data needed for the laboratory to conduct proper testing, patient matching and billing (including limited coverage rules and printing of Advance Beneficiary Notices (ABNs)).

Response. In the certification criterion discussed above regarding incorporating laboratory test results, we have required that Certified EHR Technology be capable of electronically attributing, associating, or linking a laboratory test result to a laboratory order or patient record. Bidirectional exchange (including electronic transmission of laboratory orders) is not a requirement of meaningful use Stage 1 and is beyond the scope of this rule.

Comments. Several commenters recommended we clarify that the user of CPOE includes the eligible professional and any authorized user in the office of the eligible professional (EP). They also recommended that CPOE be deemed to include the scenario in which only the actual orders are entered by the EP, with the additional billing and demographic information entered by authorized users in the EP's office or even by third parties (e.g. laboratory personnel in the patient service center of a laboratory that collects specimens from the patient).

Response. As we stated in an earlier response, the standards, implementation specifications, and certification criteria adopted in this final rule apply to Complete EHRs and EHR Modules. We have focused on whether Certified EHR Technology must

include a capability and how it must perform the capability. As a result, it is not within the scope of this rulemaking to specify the persons who would need to use CPOE.

Comment. A commenter suggested that we not create controlled vocabularies or value sets in the regulation but rather refer to and adopt existing controlled vocabularies or subsets. The commenter also stated that the regulation introduces a requirement to record, store, retrieve and manage orders, though no vocabularies are specified and further pointed out that there are no vocabularies or standards for orders, images, or referrals in any part of the Interim Final Rule. The commenter recommended that the Department focus its efforts on identifying and adopting standards for computable and interoperable representations of these elements and processes before directing eligible professionals to implement "CPOE."

Response. We appreciate the commenter's concern. This is an initial set of standards, implementation specifications, and certification criteria and we expect to adopt more standards, implementation specifications, and certification criteria in the future as necessary to improve the comprehensiveness of certain capabilities.

Comment. A commenter requested that we clarify whether only imaging and radiology reports were intended to be included in this capability, or, if we intended to include the images themselves in addition to the imaging reports as part of the certification criteria. The commenter recommended that we further clarify the criterion and moreover, adopt the DICOM standard in the initial set of standards, as an essential step in meeting the CPOE capability.

Response. We clarify that the adopted certification criteria related to CPOE pertain only to the ordering, and not to the delivery of results (reports or images). As a

result, we do not believe that this commenter's recommendation is applicable to this certification criterion.

Comment. A commenter recommended that the CPOE certification criterion should include a prompt for an authorized user of the CPOE to include diagnosis codes at order entry.

Response. We do not believe that it would be appropriate to specify this type of capability as a condition of certification because it is not central to the meaningful use objective and measure this certification criterion is intended to support.

§170.304(b) - Electronically exchange prescription information

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Generate and transmit permissible prescriptions electronically (eRx)	More than 40% of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology	**Interim Final Rule Text:** Enable a user to electronically transmit medication orders (prescriptions) for patients in accordance with the standards specified in §170.205(c).
		Final Rule Text: §170.304(b) Electronic prescribing. Enable a user to electronically generate and transmit prescriptions and prescription-related information in accordance with: (1) The standard specified in §170.205(b)(1) or §170.205(b)(2); and (2) The standard specified in 170.207(d).

Comments. Many commenters supported the adoption of NCPDP SCRIPT 8.1 and the inclusion of NCPDP SCRIPT 10.6. These commenters also encouraged the exclusive adoption of NCPDP 10.6 for meaningful use Stage 2. One commenter stated that more clarification was needed as to which NCPDP SCRIPT standard was required for certification.

Response. In the Interim Final Rule, we stated that we expected that CMS would identify as a backwards compatible standard NCPDP SCRIPT 10.6 and permit its use as

an alternative to NCPDP SCRIPT 8.1 for the electronic transmission of prescription and certain other prescription-related information for Medicare Part D covered drugs prescribed for Part D eligible individuals (75 FR 38026). Further, we stated that "if SCRIPT 10.6 is permitted, prior to any modification of the provisions of this interim final rule in response to public comment, we would expect to change our requirement to simply permit either SCRIPT 8.1 or SCRIPT 10.6." Accordingly, we have modified this certification criterion to specify that Complete EHR and EHR Module developers may seek to have their Complete EHR or EHR Module tested and certified to either solely NCPDP SCRIPT 8.1 or 10.6. Additionally, we have also replaced the standard adopted in the Interim Final Rule and have adopted both NCPDP SCRIPT 8.1 and NCPDP SCRIPT 10.6. As discussed in the beginning of the preamble, we have revised our approach to specifying the certification criteria to more clearly focus on the capabilities with which they must be associated. Therefore, we have modified this certification criterion to specify that a Complete EHR or EHR Module would be compliant with this certification criterion if it has the capability of generating and transmitting prescription and prescription-related information according to NCPDP SCRIPT 8.1 while also using the adopted vocabulary standard, or if it is capable of generating and transmitting prescriptions and prescription-related information according to NCPDP SCRIPT 10.6 while also using the adopted vocabulary standard.

Comments. Several commenters supported the adoption of RxNorm and the use of RxNorm code sets as a vocabulary standard. One commenter recommended that RxNorm be adopted in Stage 1 while one commenter stated that Stage 2 is likely the earliest timeframe practicable for implementation. Others suggested that more testing

was needed before RxNorm could be adopted in full. Some commenters stated that RxNorm is not complete and requested guidance on how gaps in RxNorm will be addressed. A couple commenters stated a concern that current drug databases do not map to RxNorm and that in order to develop interfaces for electronic prescribing services, pharmacies and developers will need to expend significant effort. Other commenters stated that more clarification was needed with respect to the description of the adopted standard and one of those commenters recommended that the description be changed to "a drug data source provider that demonstrates group domain comprehensiveness."

Response. We have consolidated and addressed our adopted vocabulary standard for medications under this certification criterion. However, our response and subsequent clarifications are applicable to all certification criteria that reference this vocabulary standard.

As we explained in the Interim Final Rule, we determined that the HIT industry would benefit from a certain degree of flexibility with respect to the coding of medications. To provide this flexibility while also establishing a glide path to full adoption of RxNorm, we adopted a standard that permits the use of one of many different vocabulary standards. We specified that a Complete EHR or EHR Module would be compliant with the adopted vocabulary standard if it utilized "[a]ny 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." We specified the standard this way in order to establish what we believe is an important bridge to full RxNorm adoption and will help facilitate this transition over time. Our adoption of this standard stems from our belief that Complete EHRs and EHR Modules

should be capable of classifying and categorizing medications for the purpose of clinical quality measurement and clinical decision support. The National Library of Medicine (NLM) maintains the Unified Medical Language System® (UMLS®), which contains the mapping between RxNorm and commonly utilized drug vocabularies.

At the time we published the Interim Final Rule, we noted that NLM, according to the most recent RxNorm release, listed a number of RxNorm drug data source providers with complete data sets integrated within RxNorm. After the Interim Final Rule was published, NLM subsequently released several more RxNorm versions. NLM has also reorganized the RxNorm documentation in a way that we believe more clearly specifies the intent of our standard. Accordingly, we believe that this standard, particularly in response to public comments, can be further clarified. In addition, to permit the development or mapping and use of other vocabularies independent of NLM, we have dropped the requirement that NLM explicitly identify the acceptable data sources. Instead, the standard now permits the use of codes from any drug vocabulary successfully included in RxNorm. To provide guidance and clarification to the industry, we will recognize any source vocabulary that is identified by NLM's RxNorm Documentation as a source vocabulary included in RxNorm. We are therefore revising the standard to state: "Any source vocabulary that is included in RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine." We note that in section 3.1, of the most recent release of the "RxNorm Documentation (06/07/10, Version 2010-3)[7]," NLM has identified the following source vocabularies as being included in RxNorm.

- GS - Gold Standard Alchemy

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[7] http://www.nlm.nih.gov/research/umls/rxnorm/docs/2010/rxnorm_doco_full_2010-3.html

- MDDB - Medi-Span Master Drug Data Base

- MMSL - Multum MediSource Lexicon

- MMX - Micromedex DRUGDEX

- MSH - Medical Subject Headings (MeSH)

- MTHFDA - FDA National Drug Code Directory

- MTHSPL - FDA Structured Product Labels

- NDDF - First DataBank NDDF Plus Source Vocabulary

- NDFRT - Veterans Health Administration National Drug File - Reference Terminology

- SNOMED CT - SNOMED Clinical Terms (drug information)

- VANDF - Veterans Health Administration National Drug File

We clarify for commenters that the standard we have adopted is a functional standard that enables the use of any source vocabulary that is included within RxNorm. Consequently, any one of these "source vocabularies" identified by NLM may be used, or any other source vocabulary successfully included within RxNorm.

Comments. A few commenters stated concerns about this certification criterion causing two different workflows because of the restrictions placed on the electronic prescribing of controlled substances.

Response. The Drug Enforcement Agency has since published an interim final rule (75 FR 16236) on the requirements related to the electronic prescribing of controlled substances. At the present time, we do not require as a condition of certification for Complete EHRs and EHR Modules that they be capable of enabling compliance with the current DEA provisions for the electronic prescribing of controlled substances.

Comments. A couple of commenters stated that the prescribing capabilities must allow for weight-based dosing calculation with intelligent rounding and that without this, e-prescribing will not be helpful to pediatricians.

Response. We recognize that this is an important capability for pediatricians; however, we do not believe that it necessary to require it as a condition of certification at the present time. Again, this does not preclude Complete EHR and EHR Module developers from including this capability.

Comments. A few commenters expressed concerns about some pharmacies not being capable of receiving electronic prescriptions which they stated could cause a negative impact on the workflow. One commenter suggested that we add a "where possible" to the certification criterion.

Response. While we recognize that some pharmacies may be unable to receive electronic prescriptions at the present time, we do not believe this limitation should affect the capability that Certified EHR Technology must provide. Further, we do not believe that inserting "where applicable" would be beneficial because it would make the criterion unnecessarily ambiguous. This phrase would relate to when electronic prescribing should be conducted, not how it should be done, which is the focus of this certification criterion.

Comment. A commenter stated that the electronic prescribing process should be linked to the contraindication and formulary conflict process and should provide automatic alerts. Another commenter recommended that information relating to the language the patient speaks should be required as part of the electronic prescribing process, so that pharmacy is notified of a patient's need for language assistance.

Response. We do not believe that it would be appropriate to expand the

certification criterion as suggested at this time. This does not preclude a Complete EHR

or EHR Module developer from pursuing other ways to optimize how a Complete EHR

or EHR Module may function.

§170.304(c) - Record demographics

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Record demographics • preferred language • gender • race • ethnicity • date of birth	More than 50% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have demographics recorded as structured data	**Interim Final Rule Text:** Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, insurance type, gender, race, ethnicity, and date of birth.
		Final Rule Text: §170.304(c) Record demographics. Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, gender, race, ethnicity, and date of birth. Enable race and ethnicity to be recorded in accordance with the standard specified at 170.207(f).

Comments. Several commenters recommended that we adopt the OMB race and

ethnicity codes.

Response. We agree with these commenters and have adopted the OMB race and

ethnicity codes. In the Medicare and Medicaid EHR Incentive Programs proposed rule

(75 FR 1855), CMS stated that race and ethnicity codes should follow current Federal

standards. We note that the OMB race and ethnicity codes constitute a government-

unique standard for the purposes of the National Technology Transfer and Advancement

Act of 1995 (NTTAA). We have adopted this standard because it provides an easily

understood structure and format for electronically transmitting the data elements

identified in the meaningful use Stage 1 objective, the standard is readily available, in

general it provides the best standard to use to support our policies goals. Moreover, we

are unaware of any alternative voluntary consensus standard that accomplishes the same purpose.

Comments. Several commenters recommended additional elements for the certification criterion for us to consider adding. One commenter recommended that we include more demographic data items to allow successful matching with prior admissions and further that we consider requiring the inclusion of social security number, birthplace, and years of education, if available. A couple commenters requested that we add occupation and industry status as well because they are already required for cancer registries. Another commenter suggested that we add family history to demographics that should be captured and reported. One commenter suggested that we also include a patient's functional status. Many commenters suggested that we encourage self-reporting of demographics and indicate whether information was self-reported. Finally, one commenter stated that EHRs are not appropriate source of legal documentation for births and deaths.

Response. While we understand commenters' intentions, we do not believe that it would be appropriate to expand this certification criterion beyond what is required to support meaningful use. Again, as we have previously stated, this does not preclude a Complete EHR or EHR Module developer from including the capability to record additional demographic information. Finally, consistent with the Medicare and Medicaid EHR Incentive Programs final rule, we have removed the capability to record insurance type from the certification criterion.

§170.304(d) - Generate patient reminder list

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion

Send reminders to patients per patient preference for preventive/ follow up care	More than 20% of all unique patients 65 years or older or 5 years old or younger were sent an appropriate reminder during the EHR reporting period	**Interim Final Rule Text:** Electronically generate, upon request, a patient reminder list for preventive or follow-up care according to patient preferences based on demographic data, specific conditions, and/or medication list.
		Final Rule Text: §170.304(d) 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.

Comments. Several commenters stated that they support this certification criterion. Other commenters requested further definition of the term "specific conditions," particularly whether this term refers to data as contained in the problem list. One commenter suggested that the criterion text be modified to read: "Electronically generate, upon request, a patient reminder list for preventive or follow-up care according to patient or physician preferences based on demographic data, specific conditions, and/or medication list." Several commenters requested further definition of the term "patient preferences." Clarification was requested about the meaning of the term, how these preferences would be recorded, how the preferences would be used, and whether the preferences should be automated. A question was raised by two commenters about how many choices should be allowed for the preferred reminder delivery method due to additional EHR system programming that may be needed to support the set of choices. One commenter was concerned about whether there would be a cost to physician practices to implement this requirement and whether the practices will have the capacity to accommodate this requirement. Another commenter suggested that this requirement be moved to meaningful use stage 2 to allow more time for EHRs to be enhanced.

Several commenters requested clarification of the term "upon request." One commenter wanted to know which persons would be authorized to request the patient reminder list and how often. Another commenter suggested that the phrase "upon request" be removed, as it believed that outpatient physicians could make significant advances in the health of their patients by generating and delivering reminders at every encounter.

Response. In response to comments, we have revised this certification criterion to more clearly articulate the capability we expect Certified EHR Technology to include. CMS discusses and clarifies the intended meaning of "patient preferences" in the Medicare and Medicaid EHR Incentive Programs final rule and because this term is derived from the meaningful use objective, we encourage commenters to review CMS's responses to their requests for clarification. Consistent with the revisions we made to the "generate patient lists" certification criterion, we believe that Certified EHR Technology should be able to leverage the information, specifically the structured data it had available to it, to assist eligible professionals and eligible hospitals generate a patient reminder list. We have removed "upon request" from the certification criterion, because, after further review, we believe that the action of requesting a list is implied by the certification criterion and the meaningful use measure, and therefore, unnecessary to further specify.

Comments. Two commenters stated that specialists will use patient reminders differently than primary care providers. These commenters worried that some patients' preferences may exceed a system's current capabilities and one commenter requested that the phrase "with respect to system capability" be added after "patient preferences."

Response. We understand these commenters' points of view, however, we do not believe that this addition is necessary given the references in the certification criterion to

specified data elements and CMS's express desire to consider patient preferences as described in the Medicare and Medicaid EHR Incentive Programs final rule.

Comments. Two commenters asked whether this requirement refers to the creation of a list for the internal purposes of the eligible professional and his/her staff only and does not refer to or require electronic communication to a patient.

Response. Yes, we expect Certified EHR Technology to be capable of generating a patient reminder list for an eligible professional and his/her staff. The meaningful use measure establishes the requirement for an eligible professional to take action once the reminder list has been generated.

Comments. Two commenters suggested that the set of variables contained in the demographic information for the patient lists note the preferred language of the patient.

Response. Preferred language is included in demographics and we do not believe that it is necessary to expressly call it out as part of this certification criterion.

§170.304(e) - Clinical decision support

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Implement one clinical decision support rule relevant to specialty or high clinical priority along with the ability to track compliance that rule	Implement one clinical decision support rule	**Interim Final Rule Text:** (1) Implement rules. 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) Alerts. Automatically and electronically generate and indicate in real-time, alerts and care suggestions based upon clinical decision support rules and evidence grade. (3) Alert statistics. Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.
		Final Rule Text: §170.304(e) (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 electronically generate and indicate in real-time, notifications and care suggestions based upon clinical decision support rules. |

Comments. Several commenters were explicitly supportive of this certification criterion, while others offered specific suggestions and requests for clarification. Several commenters requested that we specify the decisions support rules that should be included. One commenter asked if we could clarify whether a Complete EHR or EHR Module developer would have to include specific rules that individual eligible professionals would want or whether those rules could be added later. Another commenter asked for clarification regarding several terms including "diagnostic test results," whether a "condition" was equivalent to "problem," as well as whether the rules would be associated with quality measures.

Response. In consideration of commenters' request for clarification and to more closely align this certification criterion with the meaningful use measure, we have revised this certification criterion. We have removed the terms that caused some confusion with commenters and believe that these revisions will provide more specificity and will make compliance with the certification criterion easier. Moreover, we clarify that with respect to notifications, that "real-time" means at the point of clinical decision making (i.e., notifications must be provided when an eligible professional is using Certified EHR Technology and not run overnight and provided in the morning, for instance).

Comments. A number of commenters asked questions and requested clarifications regarding "alerts." One commenter requested whether it is the number of alerts that is important or the type of alerts that is important and how we expect an eligible professional to respond to an alert. The commenter also asked if we could clarify

what would qualify as a "response." One commenter stated that whether we intended for the examples (pop-up or sound) to be inclusive of the types of alerts we expected Certified EHR Technology would include and whether this was deemed more valuable than a more passive notification. The commenter suggested that the word "alert" be replaced with "notification" while another suggested the word "advisory." Some commenters requested clarification regarding "alerts responded to by a user" and whether there was an expectation that alerts communicate structured reasons. These commenters also asked whether users would enter a reason for any overrides or, in the case of notifications, the user would simply acknowledge the alert by clicking "OK." The commenters also questioned whether ignored alerts should be tracked? Many of these commenters recommended removing §170.304(e)(3). Alternatively, one commenter recommended that we not only consider the number of alerts "responded to" but also the action prompted and whether or not that action was taken.

Response. We thank commenters for the thorough feedback on this certification criterion. We have already addressed in our responses above the concerns raised by commenters and will not repeat them here. With respect to the third part of this certification criterion, we have considered public comment and have decided to remove the requirement from the certification criterion. We also removed this requirement to be more consistent with CMS's expectations for meaningful use, which do not include requiring the tracking of alerts at this time.

Comments. A few commenters asked for clarification on what we meant by "evidence grade" and what standard for evidence grading will be applied in order to determine compliance with this objective. Other commenters noted that "evidence

grade" as a part of the rules to trigger alerts is not widely available in the marketplace and that using evidence grade in this manner could be burdensome and present a significant maintenance issue.

Response. We have considered public comment, and agree that evidence grade is not as widely available in the marketplace as we had anticipated. We therefore remove our reference to "evidence grade" in the certification criterion.

§170.304(f) - Electronic copy of health information

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies), upon request	More than 50% of all patients of the EP or the inpatient or emergency departments of the eligible hospital or CAH (POS 21 or 23) who request an electronic copy of their health information are provided it within 3 business days	**Interim Final Rule Text:** Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures in: (1) Human readable format; and (2) On electronic media or through some other electronic means in accordance with: (i) One of the standards specified in §170.205(a)(1); (ii) The standard specified in §170.205(a)(2)(i)(A), or, at a minimum, the version of the standard specified in §170.205(a)(2)(i)(B); (iii) One of the standards specified in §170.205(a)(2)(ii); (iv) At a minimum, the version of the standard specified in §170.205(a)(2)(iii); and (v) The standard specified in §170.205(a)(2)(iv).
		Final Rule Text: §170.304(f) Electronic copy of health information. 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 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 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).

Comment. A commenter recommended that durable medical equipment and supplies be added to the minimum list.

Response. In the context of the Meaningful Use Stage 1 objective and measure, we do not believe that it is appropriate, at the present time, to add durable medical equipment in the certification criterion. However, that does not preclude Complete EHRs and EHR Modules from having that additional capability.

Comments. A few commenters requested clarification as to the underlying intent of the certification criterion and whether it was intended that a patient be provided with a complete medical record or simply a "snapshot." Commenters also asked how longitudinal the copy must be and requested that we specify a time period that the electronic copy must cover. A commenter stated that eligible professionals should be able to limit the applicable time period by episode of care or other parameters. The commenter noted that state law also specifies the information that can be provided to a patient without the provider serving as an intermediary. A few commenters requested clarification that the medication list is limited to the current medication list. A commenter recommended that the certification criterion be limited only to information readily available to the provider at the conclusion of a patient encounter.

Response. We expect Certified EHR Technology to be capable of generating an electronic copy of health information that includes the minimum elements required as a condition of certification. We do not believe that it is appropriate to dictate the timeframe such information must encompass, but we would expect that it would include, at a minimum, the most current information that is available and accessible within the

Certified EHR Technology. We do not believe that limiting this certification criterion to specify that just the information available at the end of an encounter is consistent with our policy objectives.

Comments. Many commenters requested a definition of "diagnostic test results." One commenter suggested that for Stage 1, the definition of diagnostic test result be made clear and be limited to, at a minimum, lab results.

Response. This term is derived from the Medicare and Medicaid EHR Incentive Programs final rule, and its meaning is described there. We encourage commenters to review the Medicare and Medicaid EHR Incentive Programs final rule.

Comments. Several commenters requested that ONC define how relevant procedures are determined for the certification criterion. The commenters suggested that a subset of procedures (e.g., surgeries, catheterizations) be defined to avoid generating huge lists of "small" procedures (e.g., venipunctures). These commenters expressed that it was critical for the rule to provide a clear, clinically-relevant definition of which types of procedures are to be included.

Response. We appreciate the comment and have revised this certification criterion to remove "procedures" as well as "immunizations," to be more consistent with the final meaningful use objective and measure and for greater clarity.

Comment. A commenter requested clarification on how an electronic copy will be disseminated, and provided examples such as a web-portal, email, and compact disc.

Response. We do not specify the method by which an individual must receive an electronic copy of the specified health information, only that Certified EHR Technology be capable of electronically generating an electronic copy in human readable format and

in accordance with one of the adopted summary record standards. While Certified EHR Technology must be capable of creating an electronic copy of a patient's health information as specified in this certification criterion, we encourage Complete EHR and EHR Module developers to also include the capability to generate an electronic copy in a manner that allows eligible professionals (and eligible hospitals as this capability relates to Complete EHRs and EHR Modules designed for an inpatient setting) to comply with applicable provisions of the HIPAA Privacy and Security Rules.

Comment. A commenter requested that we add a requirement for alerts to prompt users to ask patients if they want a copy of their health information and include the ability to record whether the information was actually provided and the patient's preference on the format of the information. The commenter believed that this requirement is necessary because many patients are not aware that they can make such a request.

Response. While potentially useful as a reminder, we do not believe that this capability should be a condition of certification. This capability would exceed the scope of the relevant meaningful use Stage 1 objective and measure. We also note that Complete EHR and EHR Module developers are not precluded from including this capability in their EHR technology.

Comment. A commenter noted that with our emphasis on the representation of clinical information in the format of a CCD or CCR, it is unclear whether the certification criterion is enough to meet patients' expectations.

Response. We recognize that this minimum information may not satisfy every patient's interests, however, we believe that the information specified represents a core set of information that most patients will appreciate is more readily accessible to them.

Comment. A commenter requested clarification on the use of the word "and" in the certification criterion and questioned whether it suggested that the Certified EHR Technology must generate two outputs to produce an electronic copy (i.e., a copy in human readable format and a copy as a CCD or CCR). The commenter made this inquiry because it believed that the certification criterion could be met through the production of a CCD or CCR with an appropriate style sheet. Additionally, a commenter stated that it is unclear whether the electronic copy of the health information provided to patients must be in a CCD or CCR format for Stage 1 or if alternative formats are allowed. This commenter recommended that we clarify and distinguish between the electronic medium carrying the information and the content enclosed.

Response. Yes, in order to meet this certification criterion, Certified EHR Technology must be able to generate an electronic copy that is in human readable format and as a CCD or CCR. If Certified EHR Technology is capable of generating one copy that could meet both of these requirements, we would consider that to be a compliant implementation of this capability.

§170.304(g) - Timely access

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, medication allergies) within four business days of the information being available to the EP	More than 10% of all unique patients seen by the EP are provided timely (available to the patient within four business days of being updated in the certified EHR technology) electronic access to their health information subject to the EP's discretion to withhold certain information	**Interim Final Rule Text:** Enable a user to provide patients with online access to their clinical information, including, at a minimum, lab test results, problem list, medication list, medication allergy list, immunizations, and procedures.
		Final Rule Text: §170.304(g) Timely access. 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.

Comments. Many commenters suggested that we should replace the word "online" with "electronic" to be more clearly aligned with meaningful use and to not preclude other forms of legitimate electronic access.

Response. We disagree. The purpose and intent of this certification criterion and its associated meaningful use objective and measure (as clarified in the Medicare and Medicaid EHR Incentive Programs final rule) is to ensure that patients have the ability to access their health information when they see fit to do so. Accordingly, referring to "electronic" in this certification criterion would not ensure that Certified EHR Technology provides the desired capability.

Comments. A few commenters asked for clarification on the meaning of "procedures" and type of results to be listed in the electronic copy, for example, lab test results, problem list, medication lists, or others specified by the eligible professional.

Response. As discussed above, we have revised this certification criterion to remove "procedures" as well as "immunizations," to be more consistent with the final meaningful use objective and measure.

§170.304(h) - Clinical summaries

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Provide clinical summaries for patients for each office visit	Clinical summaries provided to patients for more than 50% of all office visits within 3 business days	**Interim Final Rule Text:** (1) Provision. Enable a user to provide clinical summaries to patients for each office visit that include, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations and procedures. (2) Provided electronically. If the clinical summary is provided electronically it must be: (i) Provided in human readable format; and (ii) On electronic media or through some other electronic means in accordance with: (A) One of the standards specified in §170.205(a)(1); (B) The standard specified in §170.205(a)(2)(i)(A), or, at a minimum, the version of the standard specified in §170.205(a)(2)(i)(B);

		(C) One of the standards specified in §170.205(a)(2)(ii); (D) At a minimum, the version of the standard specified in §170.205(a)(2)(iii); and (E) The standard specified in §170.205(a)(2)(iv).
		Final Rule Text: §170.304(h) <u>Clinical summaries.</u> Enable a user to provide clinical summaries to patients for each office visit that include, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list. If the clinical summary is provided electronically it must be: (1) Provided in human readable format; and (2) Provided on electronic media or through some other electronic means in accordance with: (i) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and (ii) For the following data elements the applicable standard must be used: (A) <u>Problems.</u> The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2); (B)<u>Laboratory test results.</u> At a minimum, the version of the standard specified in §170.207(c); and (C) <u>Medications.</u> The standard specified in §170.207(d).

<u>Comments.</u> Several commenters requested that "diagnostic test results" be further defined, with one commenter suggesting that lab results be the minimum and other commenters suggesting a more comprehensive list, including diagnostic imaging results. Many commenters requested clarification on the list of procedures and asked whether this would include only procedures in a recent hospitalization or historically all procedures performed on the patient. One commenter questioned why immunization data appeared in the list and believed its inclusion was inconsistency with the other items.

<u>Response.</u> We have made revisions to this certification criterion consistent with the changes that we have already discussed above, including the removal of certain terms.

<u>Comment.</u> One commenter expressed concern that patient summaries are most useful when the patient/family literacy and the context of the health and follow-up care are taken into consideration. The commenter noted further that as written there is little

flexibility in this certification criterion and that many patients will be overwhelmed with technical data that comes with little context for understanding it.

Response. We understand the commenter's point; however, we do not believe that certification (which will validate whether a Complete EHR or EHR Module can perform this capability in a manner compliant with the standards adopted by the Secretary) is the appropriate mechanism to address this commenter's concerns.

Comment. One commenter urged that patient summaries be affirmatively offered to the patient, without their requesting them, and that the offer be provided in their native language with the offer documented in the EHR.

Response. We do not believe that it is within the scope of this final rule to require eligible professionals to offer patient summaries to patients.

Comments. Several commenters requested that this rule clarify that providers would only be responsible for the completeness and accuracy of the clinical summary to the extent they provided or did not provide the relevant data (e.g. if another provider has not forwarded data, they are not responsible).

Response. We do not believe that this behavior can be addressed by the certification criterion, nor do we believe that it is within the scope of this final rule.

§170.304(i) - Exchange clinical information and patient summary record

Meaningful Use Stage 1 Objectives	Meaningful Use Stage 1 Measures	Certification Criterion
Capability to exchange key clinical information (for example, problem list, medication list, medication allergies, diagnostic test results), among providers of care	Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information	**Interim Final Rule Text:** (1) Electronically receive and display. Electronically receive a patient's summary record, from other providers and organizations including, at a minimum, diagnostic tests results, problem list, medication list, medication allergy list, immunizations, and procedures in accordance with §170.205(a) and upon receipt of a patient summary record formatted in an alternate standard specified in §170.205(a)(1), display it in human readable format. (2) Electronically transmit. 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:
and patient authorized entities electronically		(i)One of the standards specified in §170.205(a)(1); (ii)The standard specified in §170.205(a)(2)(i)(A), or, at a minimum, the version of the standard specified in §170.205(a)(2)(i)(B);
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The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary of care record for each transition of care or referral	The EP, eligible hospital or CAH who transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50% of transitions of care and referrals	(v)The standard specified in §170.205(a)(2)(iv).
		Final Rule Text: §170.304(i) (1) <u>Electronically receive and display.</u> Electronically receive and display a patient's summary record, from other providers and organizations including, at a minimum, diagnostic tests results, problem list, medication list, and medication allergy list in accordance with the standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2). Upon receipt of a patient summary record formatted according to the alternative standard, display it in human readable format. (2) <u>Electronically transmit.</u> Enable a user to electronically transmit a patient summary record to other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list in accordance with: (i) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and (ii) For the following data elements the applicable standard must be used: (A) <u>Problems.</u> The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2); (B) <u>Laboratory test results.</u> At a minimum, the version of the standard specified in §170.207(c); and (C) <u>Medications.</u> The standard specified in §170.207(d).

Comments. A few commenters supported our adoption of the Continuity of Care Record (CCR) standard for patient summary records; a couple commenters expressed no preference; while many commenters were opposed to our adoption of CCR as an alternate standard and did not believe that it was an appropriate selection. Several commenters did not comment on the merits of adopting CCD and CCR but rather expressed general concern that adopting two standards would be wasteful, counter-

productive, confusing, time-consuming, and reduce interoperability. Of the commenters that supported the adoption of CCR, most expressed their appreciation for the flexibility we had provided. These commenters contended that CCR was easier to implement and would make it easier for smaller Complete EHR and EHR Module developers to enter the market and get certified. One commenter suggested that if we intended to keep both CCD and CCR as adopted standards that we specify the transactions for which each standard should apply. This commenter recommended that CCD be used for exchanging summary records between health care providers and that CCR be used for exchanging summary records to PHRs. Of the commenters that opposed our selection of CCR, many of them recommended that we adopt the CCD standard as the sole standard for summary records. These commenters principally referenced that the CCD was a harmonization of CDA and CCR. Some commenters stated that we did not provide sufficient rationale for adopting CCR and we had reopened a debate over the two standards that was purportedly previously settled. Some commenters were concerned that CCR could not support certain information, particularly, in the hospital setting. These commenters contended that CCR could not support discharge information and that CCR cannot provide input into clinical decision support due to the lack of a common definition of how data is structured. Other commenters referenced that CCR is not extensible and questioned its ability to be used for quality reporting. Several commenters recommended that, short of adopting solely CCD, we provide clearer guidance to the industry regarding what standard we expect to adopt for future stages of meaningful use because CCD and CCR are not based on a common information model.

Response. We appreciate the constructive comments and recommendations

provided by commenters. We address our adoption of the patient summary record

standards in this certification criterion because we believe that it is the most applicable

place to do so. Section 3004(b)(1) of the PHSA requires the Secretary to adopt an initial

set of standards, implementation specifications, and certification criteria. Section

3004(b)(2) of the PHSA provided the Secretary with additional flexibility in considering

what standards, implementation specifications, and certification criteria to adopt in the

initial set. Section 3004(b)(2) states that "[t]he standards, implementation specifications,

and certification criteria adopted before the date of the enactment of this title through the

process existing through the Office of the National Coordinator for Health Information

Technology may be applied towards meeting the requirement of paragraph (1)."

Accordingly, we looked at all of the standards, implementation specifications, and

certification criteria recognized by the Secretary at any point in time prior to the

enactment of the HITECH Act to determine whether they should be included in this

initial set. Contrary to some commenters statements, the CCR patient summary record

standard was in fact recognized by the Secretary in 2008 (73 FR 3976) as part of the

HITSP Consumer Empowerment Interoperability Specification (HITSP V2.1 2007 IS03).

We understand that in January, 2009, the Secretary recognized (74 FR 3604) an updated

HITSP IS03 which removed the CCR standard. We do not believe that section

3004(b)(2) precludes the Secretary from considering all possible standards that were part

of the "prior process." To the contrary, we believe the HITECH Act provided the

Secretary with the authority and flexibility to determine which standards would be best to

include in this initial set. Accordingly, we adopted both the CCR and CCD as patient

summary record standards.

We adopted both standards for a few reasons. First, we are aware, contrary to

some commenters' statements, that a significant segment of the HIT industry still uses the

CCR patient summary record standard and that some health care providers prefer the

CCR over the CCD. For this reason, we did not want to mandate, at such an early stage,

that all of these early adopters adopt a different summary record standard for the purposes

of meaningful use Stage 1, given that electronic health information exchange is not

required. Second, we understand that in some circumstances the CCR is easier, faster,

and requires fewer resources to implement than the CCD. We have therefore concluded

that it was appropriate to adopt the CCR standard for patient summary records in this

initial set of standards. Finally, we believe that at the present time, each standard could

equally be used to satisfy the requirements of meaningful use Stage 1.

Comments. Numerous commenters questioned why we did not adopt the HITSP

C32 implementation specification for the CCD. These commenters requested that we

adopt the C32 implementation specification. They noted that it had been accepted by the

industry, tested and implemented in several operating environments, and was supported

by multiple EHR technology developers. A few commenters requested additional

clarification regarding our adoption of a "level 2" CCD as part of this standard and stated

that use of a level 2 CCD was inconsistent with our adoption of several adopted

vocabulary standards. These commenters questioned whether we intended to adopt a

level 3 CCD. At least one commenter recommended the removal of our reference to

levels. Another commenter stated that problem list, medication list, medication allergy

list, procedures, etc. are commonly referred to as "sections" of the CDA or CCD

document, not "fields." They stated that sections may contain narrative text using the

CDA XML format for text, and need not contain level 3 entries; however, they believed

that in order to use the specified clinical vocabularies found in the Interim Final Rule in

an interoperable fashion, the codes from these selected vocabularies must appear in level

3 entries. Some commenters also noted this and recommended that we adopt CCD and

specify that the standard must be implemented in accordance with the HITSP C32

implementation specification, using the vocabulary standards we had adopted in the

Interim Final Rule. One commenter noted that units of measure are components of

structured entries (CDA level 3) in these sections. The commenter supported specified

clinical vocabularies and level 3 CCD because the commenter felt that level 3 would be

necessary to properly communicate the information.

    Response. We have considered public comments and, in response, have made

two changes. Both are related to our adoption of the CCD standard. In the Interim Final

Rule we explicitly included a reference to "level 2" to indicate that we expected a

Complete EHR or EHR Module would be capable of generating a level 2 CCD. After

further consideration, we agree that removing "level 2" from the adopted standard will

help clarify the requirements regarding the implementation of CCD. As some

commenters pointed out, the coded data elements we expect to populate the fields of the

CCD would necessitate "level 3" entries. Thus, we have removed the reference to "level

2." We also agree, that the HITSP C32 (version 2.5) implementation specification for

CCD would be appropriate to adopt. We understand that a majority of Complete EHR

and EHR Module developers who have implemented the CCD standard do so according

to the HITSP C32 implementation specification, and consequently we do not believe that this would be a significant burden. We further clarify that, for the purposes of testing and certification, a compliant CCD implemented according to the HITSP C32 must include the information for those entries "required" by the HITSP C32. Additionally, we note that as specified by this certification criterion, we expect that certain health information for which other certification criteria require to be recorded will be used to populate certain "optional" entries specified by the HITSP C32 implementation specification (e.g., problems from a problem list should in most cases be available to populate the "condition content module" section of the HITSP C32). Accordingly, we expect that the test data used to evaluate whether a Complete EHR or EHR Module can successfully generate a CCD according to the HITSP C32 will include the data specified in the certification criterion to populate the "optional" entries for which we have adopted vocabulary standards (e.g., problems). Moreover, from a consistency perspective, we expect that the same test data referenced above, which would be used to test and certify a CCD implemented according to the HITSP C32 would also be used to test and certify a Complete EHR or EHR Module's ability to populate a CCR. This principle is also applicable to Complete EHRs and EHR Modules designed for an inpatient setting.

Comment. One commenter noted that although CVX is identified as the required standard for interaction with state immunization registries, no standard for "immunizations" is outlined for the clinical summary. They presumed that CVX could be used for this purpose, but stated that CVX does not include a dose or date or reaction.

Response. Consistent with the changes we have made elsewhere in the final rule, we have removed "immunizations" from this certification criterion.

Comment. A commenter suggested that ONC strike the following from the certification criteria "and upon receipt of a patient summary record formatted in an alternate standard specified in §170.205(a)(1), display it in human readable format." Another commenter stated that data transport is not addressed in the standards, and the criterion instead refers to "transmit." The commenter suggested changing the first part of the criterion to "display" instead of "receive," and the second part of the criterion to "export" instead of "transmit."

Response. We disagree and have not made these changes. We believe that this certification criterion expresses the capabilities we expect Certified EHR Technology will include. Furthermore, the action of "exporting" a patient summary record does not indicate or require that Certified EHR Technology is actually capable of transmitting a patient summary record to Certified EHR Technology implemented by a different eligible professional or eligible hospital.

Comment. A commenter requested clarification on how historical data from paper records should be treated for the purpose of certification. If historical data is on paper, the standards for display are inapplicable.

Response. Data from paper records would not be a relevant factor for the purposes of testing and certification. We are concerned with whether Complete EHRs and EHR Modules have implemented specific capabilities in compliance with the certification criteria adopted by the Secretary.

Comments. A couple of commenters requested definition of "diagnostic test result" and "procedures" in the context of this criterion.

Response. Again, we do not believe that it is appropriate to define "diagnostic test result" in this final rule since the term is derived from the Medicare and Medicaid EHR Incentive Programs final rule. Consistent with other revisions we have made in the final rule, we have removed "procedures" from the certification criterion.

Comment. At least one commenter requested that we clarify what Certified EHR Technology needs to be capable of meeting this certification criterion.   The commenter asked whether the generation of a CCD or CCR would constitute compliance with this criterion or would the import and human readable display of both document types be required.

Response. We clarify that compliance with this certification criterion can be achieved by demonstrating that the Complete EHR or EHR Module is capable of receiving and displaying patient summary records that comply with either patient summary record standard (and if the alternative standard is used, displaying the non-natively implemented patient summary record standard in human readable format) and generating and transmitting a patient summary record according to one of the patient summary record standards populated with the specified data types and their applicable standard(s). For example, a Complete EHR designed to generate patient summary records in the CCD standard would need to be capable of generating and transmitting patient summary records in accordance with CCD. Upon receipt of a patient summary record formatted according to the CCR standard, the Complete EHR must also be capable of displaying the CCR-formatted patient summary record in human readable format. We clarify that we also expect that the Complete EHR designed to natively generate a CCD would be tested and certified as being capable of properly displaying any CCD that it

receives and have added the term "display" in the beginning of the certification criterion. This change is also applicable to the certification criterion for Complete EHRs and EHR Modules designed for an inpatient setting.

Comment. A commenter requested that we clarify how we intended adopted vocabularies to be used. The commenter queried whether vocabulary standards that we had adopted apply to EHRs or to transactions that EHRs conduct. The commenter further requested that we clarify whether a local/proprietary medication vocabulary could be mapped to RxNorm, and whether a local/proprietary problem list vocabulary could be mapped to SNOMED-CT®. Finally, the commenter asked if mapping is permitted, and if so, requested that we identify the subsets of these vocabularies that should be used.

Response. For purposes of electronically exchanging a patient summary record, we expect the patient summary record to include health information that is coded, where applicable, in accordance with adopted vocabulary standards. Therefore, unless otherwise required in the context of a meaningful use objective and measure, an eligible professional (or eligible hospital) would be permitted to map or crosswalk local/proprietary codes to the adopted vocabulary standards prior to transmitting a patient summary record. We do not believe that it would be appropriate to specify subsets of adopted vocabularies at this time and would seek additional input from the HIT Standards Committee or public comment prior to specifying vocabulary subsets.

Comment. A commenter stated that the adopted data exchange standards do not provide for the inclusion of narrative text results, such as a radiology report, or images of scanned paper documents. The commenter questions how meaningful use objectives will

be achieved without these and recommends that implementation guidance be issued that includes specific references to content or vocabulary standards.

Response. We have not adopted standards for radiology reports or images; however, both the CCR and CCD can be used to convey narrative text and objects such as scanned documents.

Comments. A couple of commenters requested clarification as to the testing we expected to occur related to a Complete EHR or EHR Module's compliance with this certification criterion. These commenters questioned whether the generation of a CCD and XDS (HITSP/TP13)/FTP/email of a document would meet the certification criterion requirements.

Response. We clarify that because we have removed the adopted transport standards, we do not require as a condition of certification that a specific transport standard be used to transmit a generated CCD.

Comments. One commenter expressly agreed with the expectations of the certification criterion. Another commenter stated that this functionality is crucial to support the patient/family-centered medical home. One commenter recommended that the Certified EHR Technology be designed so that the amount of data transmitted could be adjusted by physicians so they do not violate the HIPAA Privacy Rule's "minimum necessary" requirements.

Response. We appreciate commenters' support for this certification criterion and agree that patient summary records serve a valuable purpose. Presently, we do not believe that it is appropriate to require as a condition of certification a capability associated with the HIPAA Privacy Rule's minimum necessary requirements because

such requirements are generally context specific and determined when a HIPAA covered

entity uses or discloses protected health information or when a HIPAA covered entity

requests protected health information from another HIPAA covered entity. We do not

preclude, however, Complete EHR and EHR Module developers from including

additional features to assist HIPAA covered entities comply with these and other HIPAA

Privacy Rule requirements.

Comment. A commenter recommended that the summary care record should

include the durable medical equipment and supplies used by the patient.

Response. Presently, the correlated meaningful use objective and measure do not

specify that a patient summary record must contain information regarding durable

medical equipment. Accordingly, we do not believe that it would be appropriate to

require this as a condition of certification.

c. Specific Certification for Complete EHRs or EHR Modules Designed for an Inpatient

Setting - §170.306

§170.306(a) - Computerized provider order entry

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines	More than 30% of unique patients with at least one medication in their medication list seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one medication order entered using CPOE	**Interim Final Rule Text:** Enable a user to electronically record, store, retrieve, and manage, at a minimum, the following order types: (1) Medications; (2) Laboratory; (3) Radiology/imaging; (4) Blood bank; (5) Physical therapy; (6) Occupational therapy; (7) Respiratory therapy; (8) Rehabilitation therapy; (9) Dialysis; (10) Provider consults; and (11) Discharge and transfer.
		Final Rule Text: §170.306(a) Computerized provider order entry. 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.

A commenter recommended that we clarify what is meant by order entry because the commenter believes that within the confines of many hospitals, just about any "order" can be performed. A few commenters requested that "diet orders" be added to the list of CPOE order types in order to prevent inconsistent patient care. Another commenter recommended that speech-language pathology and audiology also be added. Two commenters noted that the certification criterion specifies a long list of order types. The commenters recommended that we not attempt to create an exhaustive list. One of the commenters also noted that no information is given as to what constitutes adequate functionality for any of the orders after the first three order types and that some, such as "dialysis" may not be appropriate order functionality for a general EHR system for hospitals. Both commenters recommended that we remove all orders from four through 10 and replace them with a single provision "other order types."

Response. Consistent with the revisions we made to the CPOE certification criterion associated with Complete EHRs and EHR Modules designed for an ambulatory setting, we agree with those commenters who recommended that we specify a minimum core set of orders as a condition of certification. Accordingly, we identify medication, laboratory, and radiology/imaging as the minimum types of orders a Complete EHR or EHR Module designed for inpatient settings must include in order to be certified. While this certification criterion is now the same as the certification criterion for Complete EHRs and EHR Modules designed for an ambulatory setting, we have not combined and

moved the CPOE certification criteria to the general certification criteria section. Rather,

we have kept the certification criteria for CPOE separate because we anticipate that these

certification criteria could in the future include different requirements, specific to the

settings for which Complete EHRs and EHR Modules are developed.

Comment. A commenter repeated a question it raised with respect to CPOE for

eligible professionals. The commenter requested that we clarify whether only imaging

and radiology reports were intended to be included in this capability, or, if we intended to

include the images themselves in addition to the imaging reports as part of the

certification criteria. The commenter recommended that we further clarify the criterion

and requested that the DICOM standard be adopted in the initial set of standards, as an

essential step in meeting the CPOE capability.

Response. We refer this commenter to our previous response above regarding

this issue.

§170.306(b) - Record demographics

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Record demographics • preferred language • gender • race • ethnicity • date of birth • date and preliminary cause of death in the event of mortality in the eligible hospital or CAH	More than 50% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have demographics recorded as structured data	**Interim Final Rule Text:** Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, insurance type, gender, race, ethnicity, date of birth, and date and cause of death in the event of mortality. **Final Rule Text:** §170.306(b) Record demographics. Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, gender, race, ethnicity, date of birth, and date and preliminary cause of death in the event of mortality. Enable race and ethnicity to be recorded in accordance with the standard specified at §170.207(f).

Many commenters expressed the same comments with respect to this certification

criterion as they did for the record demographics certification criterion for Complete

EHRs and EHR Modules designed for ambulatory setting. These commenters recommended the addition of other demographic information for additional clarity, as discussed above.

Comment. A commenter stated that an EHR is not an appropriate source of legal documentation for births and deaths because they indicated that it is not possible to obtain official birth and death certificates from a provider or hospital.

Response. In concert with and following the changes made to this meaningful use objective which are explained in more detail in the Medicare and Medicaid EHR Incentive Programs final rule, we believe that the changes we have made to this specific part of the certification criterion address this commenter's concern.

§170.306(c) - Clinical decision support

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Implement one clinical decision support rule related to a high priority hospital condition along with the ability to track compliance with that rule	Implement one clinical decision support rule	**Interim Final Rule Text:** (1) Implement rules. 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. (2) Alerts. Automatically and electronically generate and indicate in real-time, alerts and care suggestions based upon clinical decision support rules and evidence grade. (3) Alert statistics. Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.
		Final Rule Text: §170.306(c) (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 electronically generate and indicate in real-time, notifications and care suggestions based upon clinical decision support rules.

This certification criterion is now exactly the same as the certification criterion applicable to Complete EHRs and EHR Modules designed for an ambulatory setting. As a result, our responses and subsequent changes to the certification criterion above are also applicable to this certification criterion. While this certification criterion is now the same as the certification criterion for Complete EHRs and EHR Modules designed for an ambulatory setting, we have not combined and moved the clinical decision support certification criteria to the general certification criteria section because the focus of the meaningful use objective is different and specific to eligible hospitals. We also believe that it is useful to keep these certification criteria separate because we anticipate that these certification criteria could in the future include different requirements, specific to the settings for which Complete EHRs and EHR Modules are developed.

Comments. Some commenters requested that we clarify the meaning of high priority hospital condition.

Response. We have removed this term, consistent with the other revisions we made to this certification criterion.

§170.306(d) - Electronic copy of health information

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies, discharge summary, procedures), upon request	More than 50% of all patients of the EP or the inpatient or emergency departments of the eligible hospital or CAH (POS 21 or 23) who request an electronic copy of their health information are provided it within 3 business days	**Interim Final Rule Text:** Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, procedures, and discharge summary in: (1) Human readable format; and (2) On electronic media or through some other electronic means in accordance with: (i) One of the standards specified in §170.205(a)(1); (ii) The standard specified in §170.205(a)(2)(i)(A), or, at a minimum, the version of the standard specified in §170.205(a)(2)(i)(B); (iii) One of the standards specified in §170.205(a)(2)(ii); (iv) At a minimum, the version of the standard specified in

		§170.205(a)(2)(iii); and
		(v) The standard specified in §170.205(a)(2)(iv).
		Final Rule Text:
		§170.306(d)
		(1) Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, and procedures:
		(i) In human readable format; and
		(ii) On electronic media or through some other electronic means in accordance with:
		(A) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and
		(B) For the following data elements the applicable standard must be used:
		(1) <u>Problems.</u> The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2);
		(2) <u>Procedures.</u> The standard specified in §170.207(b)(1) or §170.207(b)(2);
		(3) <u>Laboratory test results.</u> At a minimum, the version of the standard specified in §170.207(c); and
		(4) <u>Medications.</u> The standard specified in §170.207(d).
		(2) Enable a user to create an electronic copy of a patient's discharge summary in human readable format and on electronic media or through some other electronic means.

Comment. A commenter expressed concern that requiring organizations to provide anything on electronic media was dangerous and counterproductive to the HITECH Act's HIPAA Privacy and Security Rule changes. This commenter also stated that thumb drives and CD/DVD burners are not available to staff. The commenter recommended that we remove this certification criterion and adopt a patient portal requirement in the next round of rulemaking.

Response. While we understand that in certain locations (e.g., areas that are readily accessible to patients) health care professionals do not normally have access to use certain ancillary features at their workstations, we disagree that requiring organizations to provide patients with an electronic copy present problems related to HITECH modifications to the HIPAA privacy and security requirements. We do not

specify that electronic media such as thumb drives or CDs must be used. An eligible

hospital will be able to determine, consistent with its security posture, if certain electronic

media is permissible and if so, what types. It will also be able to determine the means

and location through which an electronic copy may be provided, e.g., at the records

management department or office. As the commenter suggested, a patient portal would

be an acceptable mechanism to provide an electronic copy.

Comment. A commenter stated the certification criterion for eligible hospitals

should be limited to information or tests performed during the course of a patient visit or

hospital stay and include only summary information of diagnostic test results or of

information that is clinically significant and discovered during the encounter or

admission. Other commenters requested that we clarify the reference to procedures. The

commenters asked that the regulations specify whether the EHR technology must enable

the user to create an electronic copy of procedures associated with the most recent

hospitalization, or any historical procedures, or the procedures that the patient should

follow-up to do after discharge.

Response. At a minimum, Certified EHR Technology must be capable of

generating an electronic copy of health information that includes the elements specified

by the certification criterion in an electronic copy. We do not specify the time period for

which the electronic copy must cover as a condition of certification.

Comment. A commenter requested that we consider eliminating the reference to

standards in this certification criterion for Stage 1 and focusing on human readable

formats.

Response. We disagree, as doing so would run counter to our long term goals and would not help build the foundation necessary for more comprehensive capabilities to be added in the future.

Comments. A few commenters noted that neither the CCD nor CCR contain an applicable section for discharge summary. One commenter recommended that because the provision of an electronic copy of discharge instructions was required by another certification criterion, that discharge instructions should be removed as an element in this electronic copy.

Response. We reviewed commenters' concerns and agree that there is no applicable section for a discharge summary. Therefore, we have revised this certification criterion to reflect that while the other data elements can be conveyed using the patient summary record standards (CCR or CCD), we are not requiring the use of any standards for the discharge summary section. In order to support the meaningful use objective and measure, however, we note that we do expect Certified EHR Technology to be capable of providing a electronic copy of a discharge summary like a patient summary record, in human readable format and on electronic media or through some other electronic means. Other electronic means could include, for example, the discharge summary represented as a CCD plus the "Hospital Course" CDA section or provided as a PDF. We have revised the certification criterion accordingly.

We note that our responses to the following comments also apply to other certification criteria that reference procedures.

Comments. A commenter requested clarification as to what we meant by "procedures" for hospitals, because coding for medical procedures typically occurs after

the patient has been discharged. Another commenter requested that we further clarify the subset of relevant procedures that should be included. The commenter explained that it believed including CPT-4 or ICD-9 codes seemed inappropriate for clinical summaries since these codes are used for "procedures as billed," and the commenter further asked whether we intended to include only major procedures.

Response. We clarify that the adopted standard pertains to the vocabulary that would be used to express procedures, regardless of how they are selected, or included.

Comments. A commenter stated that with an X12 837 standard transaction, ICD-9-CM is accompanied by a flag that indicates whether this code is being used to bill for services meant to eliminate a diagnosis. The commenter stated that neither the CCR nor the CCD support such a flag, and concluded that there was no way to know whether ICD-9-CM codes used in either CCD or CCR could accurately convey a patient's problems. The commenter also recommended SNOMED-CT® should be used with a CCD, because ICD-9 codes have too little clinical detail. Another commenter favored the use of SNOMED-CT® as well and stated that SNOMED-CT® would be more clinically accurate and better suited for our purposes. Another commenter encouraged us to adopt the Current Dental Terminology.

Response. The diagnoses included within the patient summary record are meant to convey clinically relevant conditions as recorded in Certified EHR Technology's problem list, rather than billing diagnoses. While we agree that SNOMED-CT® provides additional clinical detail, this is often not available in current practice. Furthermore, while its use is not precluded, we do not believe that it is necessary to adopt the Current

Dental Terminology as a condition of certification for all Complete EHRs and EHR

Modules.

Comments. A commenter recommended against the adoption of the alternative

standard (CPT-4), unless we subsidized the cost of licensing CPT-4 as has been done for

certain other code sets. Some commenters expressed concerns about the license

requirements and one commenter stated that the license cost will likely be passed down

from the EHR developer to the eligible professional or eligible hospital. Some

commenters believed that if we intended to keep this alternative standard, we should

make it freely available.

Response. We understand that most current EHR technology already includes the

CPT-4 code-sets, and we believe that this indicates that the licensing costs are not

prohibitive. Regardless, we have adopted an alternative standard to CPT-4, SNOMED-

CT®, which is freely available.

Comment. A commenter noted that the certification criterion references

immunizations but the Medicare and Medicaid EHR Incentive Programs proposed rule

did not include immunizations in the objective. The commenter suggested that we

modify our certification criterion to match the proposed rule.

Response. We have removed this term, consistent with the previous revisions we

have made to other certification criteria above.

§170.306(e) - Electronic copy of discharge information

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Provide patients with an electronic copy of their discharge instructions at time	More than 50% of all patients who are discharged from an eligible hospital or CAH's inpatient	**Interim Final Rule Text:** Enable a user to create an electronic copy of the discharge instructions and procedures for a patient, in human readable format, at the time of discharge on electronic media or through some other electronic means.

of discharge, upon request	department or emergency department (POS 21 or 23) and who request an electronic copy of their discharge instructions are provided it	**Final Rule Text:** §170.306(e) <u>Electronic copy of discharge instructions.</u> Enable a user to create an electronic copy of the discharge instructions for a patient, in human readable format, at the time of discharge on electronic media or through some other electronic means.

Comment. A few commenters expressed support for this certification criterion. Some commenters requested that we clarify the meaning of "procedures" in the context of this certification criterion.

Response. We have revised this certification criterion to be consistent with the changes to the meaningful use objective and measure in the Medicare and Medicaid EHR Incentive Programs final rule, which removes the word "procedures" from the meaningful use objective.

Comment. A commenter requested that we clarify the meaning of the phrase "at time of discharge" and specifically, whether it means literally at the time when a patient is discharged or more broadly, soon after the discharge occurs, in which case the instructions could be made available to the patient, for example, through a web portal.

Response. This phrase is derived from the Medicare and Medicaid EHR Incentive Programs final rule, and CMS has provided clarifying remarks related to this comment.

Comment. One commenter recommended that the certification criterion include consideration of the patient's preferred language.

Response. Like our prior responses, we do not believe that requiring this information is appropriate or necessary to include as a condition of certification.

However, we do not preclude Complete EHRs and EHR Modules from being designed to reference a patient's preferred language.

§170.306(f) - Exchange clinical information and summary record.

Meaningful Use Stage 1 Objectives	Meaningful Use Stage 1 Measures	Certification Criterion
Capability to exchange key clinical information (for example, discharge summary, procedures, problem list, medication list, medication allergies, diagnostic test results), among providers of care and patient authorized entities electronically ---------------------- The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary of care record for each transition of care or referral	Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information ---------------------- The EP, eligible hospital or CAH who transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50% of transitions of care and referrals	**Interim Final Rule Text:** (1) Electronically receive and display. Electronically receive a patient's summary record from other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, procedures, and discharge summary in accordance with §170.205(a) and upon receipt of a patient summary record formatted in an alternate standard specified in §170.205(a)(1), display it in human readable 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, immunizations, procedures, and discharge summary in accordance with: (i) One of the standards specified in §170.205(a)(1); (ii) The standard specified in §170.205(a)(2)(i)(A), or, at a minimum, the version of the standard specified in §170.205(a)(2)(i)(B); (iii) One of the standards specified in §170.205(a)(2)(ii); (iv) At a minimum, the version of the standard specified in §170.205(a)(2)(iii); and (v) The standard specified in §170.205(a)(2)(iv). **Final Rule Text:** §170.306(f) (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 procedures in accordance with the standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2). Upon receipt of a patient summary record formatted according to the alternative standard, display it in human readable format. (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 procedures in accordance with: (i) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and (ii) For the following data elements the applicable standard must be used: (A) 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) <u>Procedures.</u> The standard specified in §170.207(b)(1) or §170.207(b)(2); (C) <u>Laboratory test results.</u> At a minimum, the version of the standard specified in §170.207(c); and (D) <u>Medications.</u> The standard specified in §170.207(d).

Overall this certification criterion is very similar to the certification criterion applicable to Complete EHRs and EHR Modules designed for an ambulatory setting. As a result, our responses and subsequent changes to the certification criterion above are also applicable to this certification criterion. Below are the comments that are unique to this certification criterion.

<u>Comment.</u> A few commenters requested clarification on what is meant by the term "discharge summary." The commenter stated that neither the CCD nor the CCR has a document section or module for a "discharge summary." One commenter suggested that we either define the term or remove it. At least one commenter suggested that discharge summary be initially permitted to be an unstructured CDA instead of requiring the use of a CCD. As an alternative, it was suggested that the CCD combined with the "Hospital Course" CDA section be allowed to qualify as the discharge summary.

<u>Response.</u> As noted in one of our responses above, we recognize that neither CCD nor CCR specifically supports the inclusion of discharge summary. In the Medicare and Medicaid EHR Incentive Program final rule, CMS references discharge summary in the meaningful use objective as an example of "key clinical information" but further clarifies within the preamble of that rule that it is up to an eligible professional or eligible hospital to determine what constitutes key clinical information. In that regard, CMS notes that we specify the minimum set of information that Certified EHR Technology must be capable of electronically transmitting. Given our prior statements regarding the

ability of CCD and CCR to support the inclusion of the discharge summary and the

principle expressed by CMS that we specify a minimum set of information in the adopted

certification criterion, we believe that in this instance it is appropriate to exclude

discharge summary from the certification criterion.

§170.306(g) - Reportable lab results

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Capability to submit electronic data on reportable (as required by state or local law) lab results to public health agencies and actual submission in accordance with applicable law and practice	Performed at least one test of certified EHR technology's capacity to provide electronic submission of reportable lab results to public health agencies and follow-up submission if the test is successful (unless none of the public health agencies to which eligible hospital or CAH submits such information have the capacity to receive the information electronically)	**Interim Final Rule Text:** Electronically record, retrieve, and transmit reportable clinical lab results to public health agencies in accordance with the standard specified in §170.205(f)(1) and, at a minimum, the version of the standard specified in §170.205(f)(2).
		Final Rule Text: §170.306(g) Reportable lab results. Electronically record, modify, retrieve, and submit reportable clinical lab results in accordance with the standard (and applicable implementation specifications) specified in §170.205(c) and, at a minimum, the version of the standard specified in §170.207(c).

Comment. One commenter requested that we clarify the meaning of "LOINC

when LOINC codes have been received from a laboratory." The commenter questioned

whether the information exchange for which this criterion would apply is solely exchange

within an organization or only between organizations.

Response. For a more detailed response to this request for clarification, we refer

to the relevant comments and responses relating to the "incorporate laboratory test

results" certification criterion, where we discuss this issue at length.

Comment. One commenter stated that it believed the standards we have adopted

are too general or at too high a level for vendors to be able to implement them uniformly.

This commenter suggested that we clarify when lab results should be transmitted, for

instance upon the occurrence of particular trigger events, or in response to specific

messages, and in accordance with a reporting time table. The commenter queries, for

example, if EHR systems should use discharge as a trigger for the transmission of a

reportable condition using encounter level demographic segments, or whether EHR

systems should provide a periodic batch reporting of reportable conditions (e.g. daily or

weekly).

Response. We clarify that the certification criterion does not specify, and is not

intended to specify, the requirements for how the reports are to be triggered nor the

periodicity of the reporting requirements. As a certification criterion, it only specifies

capabilities necessary for certification.

Comment. A commenter recommended that we clarify the meaning of

"reportable" in the certification criterion.

Response. Each public health jurisdiction maintains its list of diseases or

conditions that require notification of public health authorities by law. The CDC and the

Council of State and Territorial Epidemiologists also maintain a list of nationally

notifiable conditions (www.cdc.gov/ncphi/disss/nndss/phs/infdis.htm). We reiterate, the

adoption of this certification criterion is not intended to affect applicable Federal or state

law concerning public health authority notification requirements.

Comments. Many commenters requested further specification of the data format

for transmitting information to public health agencies. Most of these comments

recommended HL7 2.5.1 version, although at least one commenter noted that HL7 2.3.1

was still being used by some public health agencies. Another commenter suggested that

either standard be allowed to accommodate for the variation in public health departments'

ability to receive these reports. Many commenters raised the concern that the criterion appears to place the burden of compliance on the sender. This problem could be compounded if states and localities adopt multiple standards, which would make both compliance and certification testing difficult and burdensome. Several commenters raised the concern that some public health agencies are not capable of receiving electronic data. One commenter suggested removing the language "or applicable state-designated standard format" and directly specifying the format in the final rule. One commenter suggested having the states agree upon a standard format. At least one commenter requested additional clarity, suggesting that the HL7 message profile types be specified: ORU message for public health reporting, ADT for syndromic surveillance, and VXU for immunizations. One commenter also requested that we clarify whether HL7 V3 constructs would be allowable.

Response. We agree with the majority of commenters, who requested greater specificity for this certification criterion. Many of these commenters suggested adopting implementation specifications for the adopted standard (HL7 2.5.1). In response to those comments, and to more fully support this meaningful use objective and measure which specify the submission of laboratory results to public health, we have decided to adopt the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) to further constrain how HL7 2.5.1 is formatted for the purposes of submitting laboratory test results to public health. With respect to the comment regarding HL7 V3, we do not believe that the industry and public health departments are currently able to support the HL7 V3 constructs on a widespread basis and are therefore not adopting them.

Comment. One commenter suggested adding the term "modify" to the certification criterion, while one commenter requested clarification on the term "retrieve."

Response. Consistent with the changes we have made to the other certification criterion, we have included the word "modify."

Comments. A few commenters suggested the use of SNOMED-CT® and UCUM for reporting.

Response. We do not believe that the industry and public health departments are currently able to support the use of SNOMED-CT® and UCUM for reporting on a widespread basis.

d. Adoption and Realignment of Certification Criteria to Support the Final Requirements for Meaningful Use Stage 1.

In the Interim Final Rule, we noted that the Secretary was adopting an initial set of standards, implementation specifications, and certification criteria to "establish the capabilities and related standards that certified electronic health record (EHR) technology will need to include in order to, at a minimum, support the achievement of the proposed meaningful use Stage 1." We also noted that the reason we routinely referred to eligible professionals and eligible hospitals in the Interim Final Rule was "because we have closely aligned the initial set of standards, implementation specifications, and certification criteria adopted by this rule to focus on the capabilities that Certified EHR Technology must be able to provide in order to support the achievement of the proposed criteria for meaningful use Stage 1 by eligible professionals and eligible hospitals under the Medicare and Medicaid EHR Incentive Programs." In this regard, and as many

commenters acknowledged and expressed in their comments, this final rule and the Medicare and Medicaid EHR Incentive Program final rule are closely and inextricably linked. Recognizing the unique connection between these two rules, some commenters went so far as to issue CMS and ONC a single set of comments recommending changes to both rules in context. Many other commenters treated both rules as almost being one in the same, acknowledging that a change in Medicare and Medicaid EHR Incentive Programs final rule would need to be reflected in this final rule. Other commenters submitted comments to ONC on the Medicare and Medicaid EHR Incentive Programs proposed rule, and to CMS on the Interim Final Rule. As we discussed previously, CMS and ONC shared these comments between the offices and we included within our review all comments that could be reasonably identified as comments on the Interim Final Rule.

The following three certification criteria have been adopted as part of the initial set of certification criteria, implementation specifications, and standards in order to realign the adopted certification criteria with the final meaningful use Stage 1 requirements and to ensure that Certified EHR Technology will provide such capabilities.

Record Advance Directives

In the Medicare and Medicaid EHR Incentive Programs proposed rule, the Department explained that the HIT Policy Committee had recommended that eligible hospitals "record advance directives." Due in part to the ambiguity of the recommendation, the Department discussed but did not include the objective "Record Advance Directives" for the reasons explained by CMS. In its final rule, however, the Department stated that based on comments received as well as resolution of some of the ambiguity associated with the measure, CMS was including this objective among its

meaningful use Stage 1 objectives. The Department noted that some commenters

reported that having this information available would allow eligible hospitals to make

decisions that were better aligned with the patient's express wishes. The "record advance

directives" certification criterion would ensure that Certified EHR Technology enables

users to electronically record whether a patient has an advance directive, which in turn

will help ensure that a patient's wishes are known and can be followed.

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion
Record advance directives for patients 65 years old or older	More than 50% of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) have an indication of an advance directive status recorded	**Final Rule Text:** §170.306(h) Advance directives. Enable a user to electronically record whether a patient has an advance directive.

Comments. The Department received several comments that we should include

the capability to record advance directives as part of meaningful use of Certified EHR

Technology and, specifically, that it should be a requirement that pertains to eligible

hospitals. Other commenters reported that having this information available for the

patient would allow eligible hospitals to make decisions that were better aligned with the

patient's express wishes. The HIT Policy Committee clarified that the purpose of the

meaningful use Stage 1 measure would be to indicate whether a patient has an advanced

directive. Furthermore, the committee recommended limiting this measure to patients 65

and older.

Response. We agree that the capability for a Complete EHR or EHR Module

designed for an inpatient setting should be included as a condition of certification.

Including this certification criterion in this final rule will enable eligible hospitals to meet

a meaningful use objective they would otherwise not have been able to meet. We do not believe that the capability we have required will be a significant burden for Complete EHR and EHR Module developers and assume that some already have this or a similar type of capability already built in.

Patient-Specific Education Resources

The Medicare and Medicaid EHR Incentive Programs proposed rule discussed but did not include the objective of providing "access to patient specific education resources upon request," primarily because of the belief that there was a paucity of knowledge resources integrated within EHRs that are also widely available. CMS also noted that the ability to provide patient education resources in multiple languages might be limited. In response to comments, the Medicare and Medicaid EHR Incentive Programs final rule included this objective and a related measure, finding that the availability of education resources linked to EHRs is in fact more widely available than the Department had previously indicated in the proposed rule. The Medicare and Medicaid EHR Incentive Programs final rule expressly requires that more than 10 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period must be provided patient-specific education resources in order to meet the related meaningful use stage 1 objective. To support the achievement of this objective and measure, we are therefore adopting as a certification criterion the capability of enabling a user to electronically identify and provide patient-specific education resources that include particular types of data elements.

Meaningful Use Stage 1 Objective	Meaningful Use Stage 1 Measure	Certification Criterion

Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate	More than 10% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient-specific education resources	**Final Rule Text:** §170.302(m) <u>Patient-specific education resources.</u> Enable a user to electronically identify and provide patient-specific education resources according to, at a minimum, the data elements included in the patient's: problem list; medication list; and laboratory test results; as well as provide such resources to the patient.

Comments. The Department received many comments, including comments from both the HIT Policy Committee and MedPAC, that this capability should be included among the certification criteria for Certified EHR Technology, to enable eligible professionals and eligible hospitals to achieve meaningful use. Commenters indicated that the availability of education resources that could be linked to EHR technology is widely available.

Response. We agree that this capability should be included as a certification criterion for a Complete EHR or EHR Module designed for an ambulatory or inpatient setting. Accordingly, we have included this certification criterion in the general certification section. We clarify that we do not specify how Certified EHR Technology must be used to provide such resources to a patient. That is, such resources could be printed out, faxed, or emailed.

Automated Calculation of Percentage-based Meaningful Use Measures

While the Interim Final Rule only expressly provided for the calculation of BMI and the calculation and electronic display of certain quality measures, the Department's operating assumption in the Interim Final Rule was that Certified EHR Technology would provide for the automated calculation of meaningful use Stage 1 measures. The Medicare and Medicaid EHR Incentive Programs proposed rule for instance stated that

CMS and ONC had worked together to define certain terms, such as numerator and denominator, for the calculation of percentages to demonstrate the successful attainment of the meaningful use objectives. The Medicare and Medicaid EHR Incentive Programs final rule confirmed that "the ability to calculate the measure is included in certified EHR technology." To make explicit the Department's operating assumption, to confirm some commenters' original understanding, and to respond to other commenters' points, we are adopting the following certification criterion regarding the automated calculation of percentage-based meaningful use measures.

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

Comments. The Department received several comments noting that Certified EHR Technology should be expressly required, as a condition of certification, to automatically calculate the meaningful use measures for which eligible professionals and eligible hospitals would need to report percentages to CMS or States at the end of an EHR reporting period. Some commenters explicitly noted that ONC should require the automated calculation of certain measures as a condition of certification. Commenters pointed out that this was already a certification requirement for clinical quality measures and it would be inconsistent not to require automated calculation for the functionality measures as part of certification. Many commenters expressed concerns about the difficulties of capturing the denominators for the meaningful use measures that required

percentage calculations. They pointed out that the formulas CMS identified for many objectives would require providers to conduct labor-intensive counts of paper documents such as prescriptions or laboratory results in order to compute the denominators of the percentage based measures. Commenters also indicated that if Certified EHR Technology did not include this capability that it would dramatically increase the burden on potential meaningful users to demonstrate meaningful use and could potentially serve as a factor in their decision to participate in the Medicare and Medicaid EHR incentive programs.

Response. We agree with commenters that unless we expressly adopt a certification criterion to specify that Certified EHR Technology must be capable of performing percentage-based calculations for meaningful use measures that it would present a significant burden to eligible professionals and eligible hospitals and could deter them from participating in the Medicare and Medicaid EHR incentives programs. Accordingly, we believe that it is critical to adopt the certification criterion specified above. We clarify that Certified EHR Technology must be capable of calculating all denominators for those meaningful use measures which are percentage-based and for which CMS requires an eligible professional or eligible hospital to submit the results at the end of an EHR reporting period. (CMS provides a detailed discussion in the Medicare and Medicaid EHR Incentive Programs final rule on denominators.) We note that as discussed in the Medicare and Medicaid EHR Incentive Programs final rule under the heading "Discussion of the Burden Created by the Measures associated with the Stage 1 Meaningful Use Objectives," an eligible professional or eligible hospital is responsible for verifying that the denominator produced by Certified EHR Technology is complete.

The eligible professional or eligible hospital would be expected to know whether data

had been incorrectly entered into Certified EHR Technology or whether all patient

records were included in Certified EHR Technology. For Stage 1 meaningful use

criteria, CMS identifies these measures in the table in its final rule with the headings:

"Measures with a Denominator of Unique Patients Regardless of Whether the Patient's

Records Are Maintained Using Certified EHR Technology" and "Measures with a

Denominator of Based on Counting Actions for Patients whose Records are Maintained

Using Certified EHR Technology." We do not require, as a condition of certification,

that a Complete EHR or EHR Module provide results for the meaningful use measures

that only require a "yes/no" attestation since these results should be readily apparent.

These measures are also identified by CMS in the table in its final rule with the heading

"Measures Requiring Only a Yes/No Attestation." We do not believe that adoption of

this certification criterion poses a significant technical challenge. Rather, we believe that

this capability will provide Complete EHR and EHR Modules developers with a platform

from which to innovate and compete regarding, for example, the EHR products' ease of

use.

E. Additional Comments

    Comments. In response to our request for public comment, several commenters

recommended that we adopt certification criteria requiring technical capabilities to

provide greater access for people with disabilities. These commenters also pointed to a

few standards currently being used to assure accessibility, including the Web Content

Accessibility Guidelines (WCAG 2.0) and the Electronic and Information Technology

Accessibility Standards. The commenters requested that we coordinate more with the

disability communities on accessibility and usability and how HIT will impact members

of this community. The commenters requested that we clarify the applicability of

accessibility standards and that we add technological non-discrimination as a goal to

guide future standards work.

Response. We appreciate the thorough and thoughtful comments provided related

to accessibility. We believe that HIT has the potential to provide all persons with more

efficient access to their health information. In that regard, we solicited public comment

on the issue of accessibility and certification to garner more information about available

standards and to begin a path forward that included these standards as part of the overall

standards adoption process. We reiterate what we discussed in the interim final rule

when we provided the context for our solicitation of public comment on accessibility.

> "Nothing required by this interim final rule should be construed as affecting
> existing legal requirements under other Federal laws. While the capabilities
> provided by Certified EHR Technology may assist in the compliance with certain
> legal requirements, they do not in any way remove or alter those
> requirements….As another example, in providing patients with access to their
> online health information, it is important to note that the accessibility
> requirements of the Americans with Disabilities Act of 1990 and Section 504 of
> the Rehabilitation Act of 1973 still apply to entities covered by these Federal civil
> rights laws. Additionally, Title VI of the Civil Rights Act of 1964 and its
> implementing regulations protect persons from unlawful discrimination on the
> basis of race, color and national origin. Under Title VI and its implementing
> regulations, recipients of Federal financial assistance must take reasonable steps
> to ensure meaningful access to their programs, services, and activities by eligible
> limited English proficient persons."

While we have not yet adopted specific accessibility standards as a condition of

certification, we believe that the adoption of such standards in a future rulemaking would

prove beneficial, to enable all persons (including health care providers with disabilities)

to have equitable access to EHR technology and the electronic information it generates.

In the interim, we encourage Complete EHR and EHR Module developers to design their

EHR technology with the needs of users of assistive technology in mind, and remind

eligible professionals and eligible hospitals who seek to adopt Certified EHR Technology

to review and comply with applicable legal obligations regarding accessibility. Among

the ways of designing certain capabilities with accessibility in mind, we would encourage

Complete EHR and EHR Module developers to consider implementing, for example, the

WCAG 2.0[8] when providing web-oriented content so that it is more accessible to persons

with disabilities. We expect the HIT Standards Committee to identify accessibility-

oriented standards[9] when it issues recommendations regarding the standards that the

Secretary should adopt in future years.

Comments. Several commenters made recommendations related to standards that

we could adopt to support future stages of meaningful use. Other commenters expressed

concerns related to the "candidate Stage 2 standards" that we referenced in the Interim

Final Rule. Finally, commenters requested that Certified EHR Technology include

specific capabilities that had no relationship to meaningful use.

Response. We have reviewed these comments and appreciate the forethought

provided by commenters. Given that these suggestions were not germane to the policies

associated with the Interim Final Rule we have not considered them for the purposes of

promulgating this final rule.

F. Comments Beyond the Scope of this Final Rule

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[8] http://www.w3.org/TR/WCAG20/
[9] As previously mentioned, there are several accessibility standards for electronic and information technology currently in use. For example, Section 508 of the Rehabilitation Act requires Federal agencies to ensure that electronic and information technology that they develop, procure, maintain, or use is accessible to persons with disabilities and authorizes the Architectural and Transportation Barriers Compliance Board (Access Board) to promulgate standards setting forth the technical and functional performance criteria necessary to implement the requirements of Section 508. Information regarding the Electronic and Information Technology Standards can be found on the Access Board's website at http://www.access-board.gov/508.htm.

In response to the Interim Final Rule, some commenters chose to raise issues that are beyond the scope of our proposals. We do not summarize or respond to those comments in this final rule.

IV. Collection of Information Requirements

This final rule contains no new information collection requirements subject to review by the OMB under the Paperwork Reduction Act (PRA).

V. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532) (UMRA), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). We have determined that this final rule is not an economically significant rule because we estimate that the costs to prepare Complete EHRs and EHR Modules to be tested and certified will be less than $100 million per year. Nevertheless, because of the public interest in this final rule, we have prepared an RIA that to the best of our ability presents the costs and benefits of the final rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For more information on Small Business Administration's (SBA's) size standards, see the SBA's website.[10] We examine the burden of the final regulation in Section V.D below.

Section 202 of the UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2010, that threshold is approximately $135 million. This rule will not impose an unfunded mandate on States, tribal government or the private sector of more than $135 million annually.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs of compliance on State and local governments, preempts State law, or otherwise has Federalism implications. We do not believe that the final rule imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications.

B. Why is this Rule Needed?

Section 3004(b)(1) of the PHSA requires the Secretary to adopt an initial set of standards, implementation specifications, and certification criteria. On January 13, 2010, the Secretary published in the Federal Register an interim final rule to adopt the initial set of standards, implementation specifications, and certification criteria. This final rule has been published to amend previously adopted standards, implementation specifications, and certification criteria in order to realign such standards, implementation specifications, and certification criteria with final meaningful use Stage 1 objectives and measures, and

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[10] http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf.

to respond to public comments received. Certification criteria and associated standards

and implementation specifications will be used to test and certify Complete EHRs and

EHR Modules in order to make it possible for eligible professionals and eligible hospitals

to adopt and implement Certified EHR Technology. The use of Certified EHR

Technology is one of the requirements an eligible professional or eligible hospital needs

to meet in order to qualify for an incentive payment under the Medicare and Medicaid

EHR Incentive Programs.

<u>C. Executive Order 12866 – Regulatory Planning and Review Analysis</u>

1. Comment and Response

Comments. A few commenters offered opinions related to the cost estimates

included in the Interim Final Rule. One commenter disagreed with our approach. This

commenter contended that our analysis followed a simplistic, linear model that did not

account for the other potential costs that Complete EHR and EHR Module developers

and health care providers would bear. The commenter suggested that we address other

costs in our calculations including: whether a Complete EHR or EHR Module developer

has adequate resources available to modify its HIT in order to prepare for certification;

the loss of a Complete EHR or EHR Module developer's net worth and dislocation of

jobs if it fails and goes out of business; and the resulting impacts that would occur if a

Complete EHR and EHR Module developer went out of business and left behind

customers (some or many of which could then be ineligible for Medicare and Medicaid

EHR Incentive Programs) with unsupported HIT. Another commenter questioned the

cost estimates in the Interim Final Rule, but acknowledged that it was not prepared to

offer alternative cost estimates. The commenter did state that it believed our dollar

values seemed low and that the gap of 25%, representing previously CCHIT-certified-EHRs that will need additional preparation to be tested and certified to the certification criteria adopted by the Secretary, also seemed low. The commenter suggested a 40-50% gap. The commenter also recommended that we revise our cost estimates based on the certification criteria in the final rule to: consider costs associated with workflow redesign within an eligible professional or eligible hospitals environment; factor in the costs for "interoperability implementation" (no further explanation was provided); account for the costs associated with implementing the clinical quality measures certification criterion; account for the costs for hardware capable of supporting the adopted security requirements; and factor in the costs for internal resources and customer resources. One commenter noted that the cost related to dentistry EHR technology may be higher due to what it perceived as a lack of commercially available EHR technology and that additional costs may be incurred by dentistry EHR developers that are not as familiar as EHR developers for other health providers with the certification criteria adopted by the Secretary. One commenter agreed with the $10,000 to $250,000 cost range we estimated for the per-certification-criterion preparation, while another commenter seemed to misinterpret this estimate as being the total cost to prepare a Complete EHR or EHR Module. This commenter offered that it could take over 2,500 hours to prepare a Complete EHR for certification. One commenter appeared to associate the costs related to the preparation of a Complete EHR to be tested and certified with the actual cost to be tested and certified, but nonetheless expressed concern that we had estimated that it would cost a Complete EHR developer whose EHR technology had not previously been certified no less than $1.2 million to become compliant with the Interim Final Rule's

requirements. The commenter requested that HHS provide assistance to EHR vendors with revenues of less than $1 million in order to help offset the costs of the certification process.

Response. We appreciate commenters' recommendations and suggestions related to our cost analysis. While we understand why some commenters recommended additional factors for us to consider as part of our analysis, we do not believe many of those factors are relevant for two primary reasons: 1) we believe that it is improbable that this rule will result in the outcomes speculated and their associated costs; and 2) the factors contributing to or causing the increased costs are outside the scope of this rule (e.g., hypothetical business failure and job loss, workflow redesign) and could not be reasonably or accurately estimated. In this regard, we reiterate what we stated in the Interim Final Rule related to how costs would be estimated. "This interim final rule estimates the costs commercial vendors, open source developers, and relevant Federal agencies will incur to prepare Complete EHRs and EHR Modules to be tested and certified to adopted standards, implementation specifications, and certification criteria. The Medicare and Medicaid EHR Incentive Programs proposed rule estimates the impacts related to the actions taken by eligible professionals or eligible hospitals to become meaningful users, including purchasing or self-developing Complete EHRs or EHR Modules. The HIT Certification Programs proposed rule estimates the testing and certification costs for Complete EHRs and EHR Modules." Accordingly, we disagree with the commenter who contended that our estimates were too simplistic and linear. We believe that in the absence of any additional data or an alternative model (which no

commenter provided), our assumptions are sound and our analysis is reasonable for estimating the costs associated with complying with this final rule.

We believe that it is important to note to commenters that compliance with this final rule is voluntary and as such, seeking to have a Complete EHR or EHR Module certified is voluntary. A Complete EHR or EHR Module developer is not required to comply with this final rule in order to operate its business. Rather, a Complete EHR or EHR Module developer will need to rely upon this final rule only if it ultimately seeks to have its EHR technology tested and certified as being compliant with the certification criteria adopted by the Secretary. Consequently, if a Complete EHR or EHR Module developer does not have the resources available to redesign its Complete EHR or EHR Module to incorporate the standards and implementation specifications or meet the certification criteria adopted in this rule, this rule does not create any new expenses for its business. Given this clarification, we believe that our estimates represent a higher than likely number of Complete EHR and EHR Module developers that will prepare their HIT to be tested and certified to the certification criteria adopted by the Secretary, and thus, the highest potential cost.

We considered whether an hourly preparation cost should replace the assumptions we made in the Interim Final Rule, but found it difficult to determine what reasonable low and high hour ranges would be even if we were to assume 2500 hours to be the average. Further, for the purposes of testing this alternative approach, we assumed that it would be reasonable for the employees of a Complete EHR or EHR Module developer responsible for preparing a Complete EHR or EHR Module for testing and certification to be paid equivalent to a Federal employee with a Federal Salary Classification of GS-15

Step 1 ($59.30/hr plus 21.35/hr for benefits) given the educational and professional experience we believe would be necessary to lead this type of activity. Multiplying the total hourly rate by the 2500 hours yields a total preparation cost of approximately $201,000. Thus, even if we were to assume that a high average for preparation of a Complete EHR or EHR Module would be double what the commenter stated, it would only represent close to $400,000 in preparation costs. Accordingly, we believe that our estimates are in fact comparatively high and the estimate range covers a wide range of possibilities.

In the absence of additional data or any evidence to the contrary from public comment to guide revisions to our estimates, we are finalizing them according to the data and assumptions we identified in the Interim Final Rule. We believe that our estimates are sound, based on reasonable assumptions and data, and sufficiently accommodate varying costs for different types of Complete EHR and EHR Module developers. We believe that the additional clarity and specificity we have provided for some certification criteria and the removal of some required capabilities would further contribute to lowering the cost estimates for complying with this final rule. Consequently, we anticipate actual costs will fall somewhere between the low and mid-point ranges of our estimates rather than between the mid-point and high ranges of our estimates.

Finally, with respect to the commenter who expressed concern regarding the total costs associated with developing a Complete EHR which had never been certified, we note that our estimates should not be construed to imply that a Complete EHR developer would have to spend over $1 million in order to prepare a Complete EHR. To the contrary, had we calculated our low range for preparing a Complete EHR based on the

absolute low we estimated for a per certification cost ($10,000), the total cost would have

only been $240,000, or one-fifth the cost we estimated in the Interim Final Rule. The

approach we took in the Interim Final Rule was designed to be inclusive of a middle

range of possibilities, but was never meant to preclude the possibility that a Complete

EHR developer could design a Complete EHR that was compliant with the certification

criteria adopted by the Secretary for less than we estimated. Also in response to the

commenter's request, we do not believe that it would be appropriate, nor are we

authorized, to provide subsidies to Complete EHR or EHR Module developers for the

costs of the preparing a Complete EHR or EHR module for testing and certification.

2. Executive Order 12866 Final Analysis

a. Costs

This final rule adopts standards, implementation specifications, and certification

criteria and consequently establishes the capabilities that Complete EHRs or EHR

Modules will need to demonstrate in order to be certified. Our analysis focuses on the

direct effects of the provisions of this final rule – the costs incurred by Complete EHR

and EHR Module developers to prepare Complete EHRs and EHR Modules to be tested

and certified in accordance with the certification criteria adopted by the Secretary. That

is, we focus on the technological development costs necessary to include the capabilities

in a Complete EHR or EHR Module that will be compliant with the certification criteria

adopted by the Secretary. Again, as noted above, the actual cost a Complete EHR or

EHR Module developer will incur to be tested and certified is accounted for in our

certification programs final rules.

As we noted in the Interim Final Rule, we analyzed previously developed CCHIT ambulatory and inpatient certification criteria and believe that many of those criteria, but not all, require the exact same capabilities as the certification criteria adopted by the Secretary at 45 CFR 170.302, 45 CFR 170.304, and 45 CFR 170.306. Generally speaking, we believe this overlap includes most of the clinically oriented capabilities required by the certification criteria adopted by the Secretary. Accordingly, we believe that a significant number of previously CCHIT-certified-EHRs will only incur moderate costs to prepare for certification. For the purpose of estimating costs, we presume that previously CCHIT-certified-EHRs include the functionality to meet the definition of a Complete EHR. As a result, for our estimates in Table 1, we anticipate that these previously CCHIT-certified-EHRs will again be prepared for certification as Complete EHRs. We estimated in the Interim Final Rule that there were 74 CCHIT-certified-EHRs certified to its 2008 ambulatory certification criteria and 17 CCHIT-certified-EHRs certified to its 2007 or 2008 inpatient certification criteria.[11,12,13] Of these 74 and 17 previously CCHIT-certified-EHRs, we expect that 90% will be prepared and submitted for certification according to the certification criteria adopted by the Secretary. We do not believe that it is realistic to assume that 100% of previously CCHIT-certified-EHRs will be prepared for certification for a number of reasons. These reasons include: 1) a recognition that mergers and acquisitions within the marketplace have reduced the

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[11] Some are marked with a conditional certification either "Pre-Market: These are conditionally certified EHRs which are new products that are fully certified once their operational use at a physician office site has been verified." or "eRx Conditional: These are conditionally certified pending advanced ePrescribing EHRs that are in the process of verifying their ability to conduct medication history, formulary and eligibility checking through a national network for electronic-prescribing transactions." We do not believe that these caveats have any discernible effect on our estimates.

[12] http://www.cchit.org/products/Ambulatory -- when certification years 2006 and 2007 are unchecked. While 78 EHRs are now listed, we do not believe that changing our estimate would have a measureable effect on the overall costs.

[13] http://www.cchit.org/products/Inpatient

number of previously CCHIT-certified-EHRs; 2) that the subsequent resources needed to market and promote Certified EHR Technology may not be available at the present time; and 3) that some previously CCHIT-certified-EHRs will be tested and certified as EHR Modules rather than Complete EHRs. Given these assumptions, we have estimated the number of previously CCHIT-certified-EHRs that will be prepared to be tested and certified will be 65 and 15, ambulatory and inpatient, respectively. We also believe it is reasonable to assume that of these 65 and 15, some will require more preparation than others (i.e., we assume that some EHRs that were previously CCHIT-certified will include more capabilities than what they had when CCHIT originally tested and certified them, and they may consequently be able to more easily meet the certification criteria adopted by the Secretary). Based on this assumption, we have created low and high ranges for the costs to prepare previously CCHIT-certified ambulatory and inpatient EHRs.

In creating our low and high ranges for the tables below, we assumed based on our analysis of previously developed and required CCHIT certification criteria that certain capabilities (e.g., the capability to maintain a medication list) will have been widely implemented and deployed in HIT so that there will be little or no need to modify Complete EHRs or EHR Modules for certification. We also assumed that the certification criteria adopted by the Secretary range from relatively simple capabilities (e.g., recording a patient's smoking status) to more sophisticated capabilities (e.g., clinical decision support). As a result, we have made a general assumption that the costs to prepare Complete EHRs and EHR Modules to be tested and certified will vary depending on a number of factors including, but not limited to, whether the Complete

EHR or EHR Module: 1) already includes the capability; 2) includes some aspect of the capability which would need to be updated; 3) does not currently include the capability at all. We believe it is reasonable to estimate that it will cost somewhere between $10,000 and $250,000 per certification criterion to prepare a Complete EHR for testing and certification taking into account the factors identified directly above. We have used this per certification criterion range as the basis for our low and high cost range estimates. For the ease of our calculations, we have rounded to "40" the number of certification criteria that the Secretary is adopting.

For Table 1 we have made the following assumptions based on our understanding of the capabilities present in previously CCHIT-certified-EHRs: 1) in general, Complete EHR developers who previously obtained a CCHIT certification for their EHR technology will possess a Complete EHR that will meet approximately 75% of the adopted certification criteria and, as a result, these Complete EHR developers may need to make more comprehensive adjustments to their Complete EHRs in order to prepare the Complete EHRs to be tested and certified to the remaining 25% of the certification criteria adopted by the Secretary; 2) the average low and high per certification criterion cost for ambulatory EHRs previously certified by CCHIT which need to be prepared for testing and certification will be $50,000 and $150,000, respectively; and 3) the average low and high per certification criterion cost for previously CCHIT-certified inpatient EHRs to be prepared for testing and certification will be $75,000 and $200,000, respectively.

Table 1. Estimated One-Time Costs for Complete EHR Developers to Prepare Previously CCHIT-Certified-EHRs to be Tested and Certified (3-year-period) – Totals Rounded			
Type	Number Prepared	One Time Cost Per EHR ($M)	Total Cost for All EHRs over 3-year Period ($M)

	for Certification	Low	High	Mid-point	Low	High	Mid-point
2008 Ambulatory CCHIT-Certified-EHR	65	$0.50	$1.5	$1.0	$32.5	$97.5	$65.0
2007/2008 Inpatient CCHIT-Certified-EHR	15	$0.75	$2.0	$1.38	$11.25	$30.0	$20.63
Total	80				$43.75	$127.50	$85.63

The second type of cost we estimate includes the costs that we expect for CCHIT-certified ambulatory EHRs certified prior to 2008 ("out-of-date CCHIT-Certified-EHRs") and never previously CCHIT-certified-EHRs to be prepared to be tested and certified as Complete EHRs rather than as EHR Modules.[14] We assume the EHR technology that falls into this category may require more extensive changes than previously CCHIT-certified-EHRs identified in Table 1. Again, we have estimated low and high preparation cost ranges. We assume that there will be very little growth in the Complete EHR market due to the market share[15] represented by the previously CCHIT-certified-EHRs included in Table 1 and the upfront costs required to bring a Complete EHR to market. As a result, we expect there to be 8 and 5 Complete EHRs (for use by eligible professionals and eligible hospitals, respectively) prepared to be tested and certified to all of the applicable certification criteria adopted by the Secretary.[16]

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[14] CCHIT began testing and certifying inpatient EHRs in 2007 and we assume that all of those EHRs are included in Table 1 which is why they are not included in this discussion.

[15] http://www.cchit.org/about -- "...EHR products certified by mid-2009, representing over 75% of the marketplace."

[16] This estimate is premised in part on the fact that IHS's RPMS EHR was not included in Table 1 and that it will be preparing the RPMS EHR as a Complete EHR to meet the applicable certification criteria adopted by the Secretary for both ambulatory and inpatient settings.

Again, using our general assumptions discussed above (40 certification criteria and a low and high range of $10,000 to $250,000 per certification criterion) we have made the following additional assumptions in our Table 2 calculations based on our understanding of the capabilities currently present in these EHR technologies: 1) in general, Complete EHR developers who have out-of-date CCHIT-Certified-EHRs or who never previously had their Complete EHRs certified by CCHIT will possess Complete EHRs that will meet approximately 40% of the adopted certification criteria and, as a result, these Complete EHR developers may need to make more comprehensive adjustments to their Complete EHRs in order to prepare the Complete EHRs to be tested and certified to the remaining 60% of the certification criteria adopted by the Secretary; 2) the average low and high per certification criterion costs for Complete EHRs for eligible professionals to be prepared to be tested and certified will be $50,000 and $150,000, respectively; and 3) the average low and high per certification criterion costs for Complete EHRs for eligible hospitals to be prepared to be tested and certified will be $75,000 and $200,000, respectively.

Table 2. Estimated One-Time Costs for Complete EHR Developers to Prepare Never CCHIT-Certified-EHRs and Out-of-Date CCHIT-Certified-EHRs to be Tested and Certified (3 year period) – Totals Rounded							
		One Time Cost Per EHR ($M)			Total Cost for All EHRs over 3-year Period ($M)		
Type	Number Prepared for Certification	Low	High	Mid-point	Low	High	Mid-point
Complete EHRs for Eligible Professionals	8	$1.2	$3.6	$2.4	$9.6	$28.8	$19.2
Complete EHRs for Eligible Hospitals	5	$1.8	$4.8	$3.3	$9.0	$24.0	$16.5
Total	13				$18.60	$52.80	$35.70

Finally, the third type of cost we estimate relates to the number of EHR Modules we expect to be prepared to be tested and certified and the costs associated with that preparation. We clarify as noted in the Temporary Certification Program final rule that these EHR Modules are not "self-developed," and we assume that an EHR Module developer interested in commercially marketing its EHR Module to eligible professionals and eligible hospitals would develop them. We assumed in the Interim Final Rule that certain types of EHR Modules (e.g., computerized provider order entry; quality reporting; online patient portals) would be more likely than others to be prepared to be tested and certified, and we estimated based on our assumption that there would be 7 EHR Modules prepared to be tested and certified for each of the 7 types of EHR Modules we identified. This estimate (number of modules X types of modules) resulted in an approximate number of 50 EHR Modules that would be prepared to be tested and certified. Again, we have provided low and high preparation cost estimates in Table 3 below. We assume that some of EHR Modules prepared for certification will be capable of meeting applicable certification criteria with little modification while other EHR Modules will not. Given the potential differences in preparation costs and combinations of certification criteria to create EHR Modules, we believe it is reasonable to estimate a wide range of costs for preparing these types of EHR Modules for testing and certification. We estimated in the Interim Final Rule and reiterate below a low average one-time cost of $100,000 to prepare an EHR Module, based on the assumption that some of the less sophisticated EHR Modules would only be prepared to be tested and certified to 1 or 2 certification criteria. We estimated in the Interim Final Rule and reiterate below, a high average cost one-time cost of $500,000 to prepare an EHR Module, based on the assumption that some

of the more sophisticated EHR Modules would only be prepared to be tested and certified to 1 or 2 of the more complicated certification criteria or would be prepared to be tested and certified to multiple certification criteria.

Table 3. Estimated One-Time Costs to EHR Module Developers to Prepare EHR Modules to be Tested and Certified (3 year period) – Totals Rounded							
		One Time Cost Per EHR Module ($M)			Total Cost All EHR Modules over 3-year Period ($M)		
Type	Number Prepared	Low	High	Mid-point	Low	High	Mid-point
EHR Modules	50	$0.1	$0.5	$0.3	$5.0	$25.0	$15.0
Total	50				$5.0	$25.0	$15.0

In total, if we were to distribute the costs to prepare Complete EHRs and EHR Modules between 2010 and 2012 evenly per year, we believe they would likely be in the range of $67.35 to $205.3 million or $22.45 to $68.43 million per year with an annual cost mid-point of approximately $45.44 million. However, we do not believe that the costs will be spread evenly over these three years due to market pressures and the fact that higher upfront incentive payments are available under the Medicare and Medicaid EHR Incentive Programs. We assume this factor will motivate a greater ratio of commercial vendors and open source developers of Complete EHRs and EHR Modules to prepare such technology for testing and certification in 2010 and 2011 rather than 2012. As a result, we believe as represented in Table 4 that the costs attributable to this final rule will be distributed as follows: 45% for 2010, 40% for 2011 and 15% for 2012.

Table 6. Distributed Total Preparation Costs for Complete EHR and EHR Module Developers (3 year period) – Totals Rounded				
Year	Ratio	Total Low Cost Estimate ($M)	Total High Cost Estimate ($M)	Total Average Cost Estimate ($M)
2010	45%	$30.31	$92.39	$61.35
2011	40%	$26.94	$82.12	$54.53

| 2012 | 15% | $10.10 | $30.80 | $20.45 |
| 3-Year Totals | | $67.35 | $205.3 | $136.33 |

Note that these cost estimates do not include additional costs to prepare for testing and certification that will likely be incurred when we adopt additional standards, implementation specifications, and certification criteria to support meaningful use Stages 2 and 3. We will account for costs associated with these additional standards, implementation specifications, and certification criteria in future rulemaking.

b. Benefits

We believe that there will be several benefits arising from this final rule. By adopting the revisions to this initial set, the Secretary will set in motion what we believe will be an iterative process to further enhance the interoperability, functionality, utility, and security of health information technology and to support the meaningful use of Certified EHR Technology. The capabilities specified in the adopted certification criteria will help ensure that health care providers have the necessary information technology tools to improve patient care, reduce medical errors and unnecessary tests. The standards adopted will aid in fostering greater interoperability. We also believe that this final rule will serve as a catalyst for a more competitive and innovative marketplace. Finally, adopted certification criteria can be used by Complete EHR and EHR Module developers as technical requirements to ensure that their HIT can be tested and certified and subsequently adopted and implemented as Certified EHR Technology. Adopting these certification criteria will also ultimately help enable eligible professionals and eligible hospitals to qualify for incentive payments under Medicare and Medicaid EHR Incentive Programs.

D. Regulatory Flexibility Act Analysis

1. Comment and Response

Comment. Some commenters noted that we incorrectly referenced the proportion of businesses in the marketplace that would qualify as small businesses under the SBA's size standard. The commenters cited a presentation by CCHIT which indicated that potentially up to 75% of Complete EHR developers who design Complete EHRs for ambulatory settings would qualify as small businesses.

Response. We appreciate commenters pointing out this additional information. We have revised the discussion accordingly in the final RFA analysis. However, we do not believe that this additional information substantially changes our analysis. We do not believe that any relief can be provided to small businesses under the SBA size standard that would not undercut our programmatic goals and objectives. A Complete EHR or EHR Module developer will need to design a Complete EHR or EHR Module that can be tested and successfully certified to all applicable certification criteria adopted by the Secretary in order for the Complete EHR or EHR Module to attain certification. Accordingly, we see no viable alternatives to reducing the requirements in the final rule or providing for alternatives to adopted certification criteria. Additionally, we believe that the regulation builds in a certain amount of flexibility already in that a small business without the resources available to develop a Complete EHR has the option to develop an EHR Module which will presumably require less of an investment (time and money) to develop.

2. Final RFA Analysis

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities.

While Complete EHRs and EHR Module developers represent a small segment of the overall information technology industry, we believe that the entities impacted by this final rule most likely fall under the North American Industry Classification System (NAICS) code 541511 "Custom Computer Programming Services" specified at 13 CFR 121.201 where the SBA publishes "Small Business Size Standards by NAICS Industry." The size standard associated with this NAICS code is set at $25 million in annual receipts[17] which "indicates the maximum allowed for a concern and its affiliates to be considered small entities."

Based on our analysis, we believe that there is enough data generally available to establish that between 75% and 90% of entities that are categorized under the NAICS code 541511 are under the SBA size standard, but note that the available data does not show how many of these entities will develop a Complete EHR or EHR Module. We also note that with the exception of aggregate business information available through the U.S. Census Bureau and the SBA related to NAICS code 541511, it appears that many Complete EHR and EHR Module developers are privately held or owned and do not regularly, if at all, make their specific annual receipts publicly available. As a result, it is difficult to locate empirical data related to many of the Complete EHR and EHR Module developers to correlate to the SBA size standard.

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[17] The SBA references that annual receipts means "total income" (or in the case of a sole proprietorship, "gross income") plus "cost of goods sold" as these terms are defined and reported on Internal Revenue Service tax return forms.
http://www.sba.gov/idc/groups/public/documents/sba_homepage/guide_to_size_standards.pdf

We estimate that this final rule could have effects on Complete EHR and EHR Module developers, some of which may be small entities. However, we believe that we have established the minimum amount of requirements necessary to accomplish our policy goals and that no appropriate regulatory alternatives could be developed to lessen the compliance burden associated with this final rule. In order for a Complete EHR or EHR Module to provide the capabilities an eligible professional or eligible hospital will be required to use under the Medicare and Medicaid EHR Incentive Programs final rule, it will need to comply with the applicable certification criteria adopted by the Secretary. Moreover, we note that this final rule does not impose the costs cited in the regulatory impact analysis as compliance costs, but rather as investments which Complete EHR and EHR Module developers voluntarily take on and expect to recover with an appropriate rate of return. Accordingly, we do not believe that the final rule will create a significant impact on a substantial number of small entities. The Secretary certifies that this final rule will not have a significant impact on a substantial number of small entities.

E. Executive Order 13132--Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications.

Nothing in this final rule imposes substantial direct compliance costs on State and local governments, preempts State law or otherwise has federalism implications. We are not aware of any State laws or regulations that are contradicted or impeded by any of the standards, implementation specifications, or certification criteria that have been adopted.

The Office of Management and Budget reviewed this final rule.

List of Subjects

45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Health care, Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

▪ For the reasons set forth in the preamble, 45 CFR subtitle A, subchapter D, part 170, is

amended as follows:

PART 170 – HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

▪ 1. The authority citation for part 170 continues to read as follows:

Authority: 42 U.S.C. 300jj-11; 42 U.S.C. 300jj-14; 5 U.S.C. 552.

▪ 2. Amend §170.102 by revising the definitions of "Complete EHR," "Certified EHR

Technology," and "Disclosure" and adding the definition of "Human readable format"

to read as follows:

§170.102 Definitions.

* * * * *

Certified EHR Technology means:

(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.

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

Disclosure is defined as it is in 45 CFR 160.103.

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Human readable format means a format that enables a human to read and easily comprehend the information presented to him or her regardless of the method of presentation.

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▪ 3. Revise subpart B to read as follows:

Subpart B—Standards and Implementation Specifications for Health Information Technology

Sec.
170.200 Applicability.
170.202 [Reserved]
170.205 Content exchange standards and implementation specifications for exchanging electronic health information.
170.207 Vocabulary standards for representing electronic health information.
170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.
170.299 Incorporation by reference.

§170.200 Applicability.

The standards and implementation specifications adopted in this part apply with respect to Complete EHRs and EHR Modules.

§170.202 [Reserved]

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

The Secretary adopts the following content exchange standards and associated implementation specifications:

(a) Patient summary record. (1) Standard. Health Level Seven Clinical Document Architecture (CDA) Release 2, Continuity of Care Document (CCD) (incorporated by reference in §170.299). Implementation specifications. The Healthcare Information Technology Standards Panel (HITSP) Summary Documents Using HL7 CCD Component HITSP/C32 (incorporated by reference in §170.299).

(2) Standard. ASTM E2369 Standard Specification for Continuity of Care Record and Adjunct to ASTM E2369 (incorporated by reference in §170.299).

(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 (incorporated by reference in §170.299)

(2) Standard. NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 (incorporated by reference in §170.299).

(c) Electronic submission of lab results to public health agencies. Standard. HL7 2.5.1 (incorporated by reference in §170.299). Implementation specifications. HL7

Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public

Health, Release 1 (US Realm) (incorporated by reference in §170.299).

(d) <u>Electronic submission to public health agencies for surveillance or reporting. (1)</u>

<u>Standard.</u> HL7 2.3.1(incorporated by reference in §170.299).

(2) <u>Standard.</u> HL7 2.5.1(incorporated by reference in §170.299). <u>Implementation</u>

<u>specifications.</u> 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

(incorporated by reference in §170.299).

(e) <u>Electronic submission to immunization registries. (1) Standard.</u> HL7 2.3.1

(incorporated by reference in §170.299). <u>Implementation specifications.</u>

Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the

Health Level Seven (HL7) Standard Protocol Implementation Guide Version 2.2

(incorporated by reference in §170.299).

(2) <u>Standard.</u> HL7 2.5.1 (incorporated by reference in §170.299). <u>Implementation</u>

<u>specifications.</u> HL7 2.5.1 Implementation Guide for Immunization Messaging

Release 1.0 (incorporated by reference in §170.299).

(f) <u>Quality reporting.</u> <u>Standard.</u> The CMS Physician Quality Reporting Initiative (PQRI)

2009 Registry XML Specification (incorporated by reference in §170.299).

<u>Implementation specifications.</u> Physician Quality Reporting Initiative Measure

Specifications Manual for Claims and Registry (incorporated by reference in

§170.299).

§170.207 Vocabulary standards for representing electronic health information.

The Secretary adopts the following code sets, terminology, and nomenclature as the vocabulary standards for the purpose of representing electronic health information:

(a) Problems. (1) Standard. The code set specified at 45 CFR 162.1002(a)(1) for the indicated conditions.

(2) Standard. International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) July 2009 version (incorporated by reference in §170.299).

(b) Procedures. (1) Standard. The code set specified at 45 CFR 162.1002(a)(2).

(2) Standard. The code set specified at 45 CFR 162.1002(a)(5).

(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 (incorporated by reference in §170.299).

(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 (incorporated by reference in §170.299).

(f) Race and Ethnicity. Standard. The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, October 30, 1997 (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.

The Secretary adopts the following standards 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 (incorporated by reference in §170.299).

   (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.

§170.299 Incorporation by reference.

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce

any edition other than that specified in this section, the Department of Health and Human Services must publish notice of change in the Federal Register and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Also, it is available for inspection at U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave, S.W., Washington, DC 20201, call ahead to arrange for inspection at 202-690-7151, and is available from the sources listed below.

(b) Health Level Seven, 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104; Telephone (734) 677-7777 or http://www.hl7.org/.

(1) Health Level Seven Standard Version 2.3.1 (HL7 2.3.1), An Application Protocol for Electronic Data Exchange in Healthcare Environments, April 14, 1999, IBR approved for §170.205.

(2) Health Level Seven Messaging Standard Version 2.5.1 (HL7 2.5.1), An Application Protocol for Electronic Data Exchange in Healthcare Environments, February 21, 2007, IBR approved for §170.205.

(3) Health Level Seven Implementation Guide: Clinical Document Architecture (CDA) Release 2 – Continuity of Care Document (CCD), April 01, 2007, IBR approved for §170.205.

(4) HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) HL7 Version 2.5.1: ORU^R01, HL7 Informative Document, February, 2010, IBR approved for §170.205.

(5) [Reserved]

(c) ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA, 19428-2959 USA; Telephone (610) 832-9585 or http://www.astm.org/.

(1) ASTM E2369-05: Standard Specification for Continuity of Care Record (CCR), year of adoption 2005, ASTM approved July 17, 2006, IBR approved for §170.205.

(2) ASTM E2369-05 (Adjunct to E2369): Standard Specification Continuity of Care Record, - Final Version 1.0 (V1.0), November 7, 2005, IBR approved for §170.205.

(d) National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260– 7518; Telephone (480) 477–1000; and Facsimile (480) 767–1042 or http://www.ncpdp.org.

(1) National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005, IBR approved for §170.205.

(2) SCRIPT Standard, Implementation Guide, Version 10.6, October, 2008, (Approval date for ANSI: November 12, 2008), IBR approved for §170.205.

(3) [Reserved]

(e) Regenstrief Institute, Inc., LOINC® c/o Medical Informatics The Regenstrief Institute, Inc 410 West 10th Street, Suite 2000 Indianapolis, IN 46202-3012; Telephone (317) 423-5558 or http://loinc.org/.

    (1) Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, June 15, 2009, IBR approved for §170.207.

    (2) [Reserved]

(f) U.S. National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894; Telephone (301) 594-5983 or http://www.nlm.nih.gov/.

    (1) International Health Terminology Standards Development Organization Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), International Release, July 2009, IBR approved for §170.207.

    (2) [Reserved]

(g) Centers for Disease Control and Prevention, National Centers for Immunization and Respiratory Diseases Immunization Information System Support Branch – Informatics 1600 Clifton Road Mailstop: E-62 Atlanta, GA 30333

    (1) HL7 Standard Code Set CVX - Vaccines Administered, July 30, 2009, IBR approved for §170.207.

    (2) Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol Implementation Guide Version 2.2, June 2006, IBR approved for §170.205.

    (3) HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0, May 1, 2010, IBR approved for §170.205.

(4) Public Health Information Network HL7 Version 2.5 Message Structure

Specification for National Condition Reporting Final Version 1.0, including

Errata and Clarifications, National Notification Message Structural

Specification, 8/18/2007, August 18, 2007, IBR approved for §170.205.

(5) [Reserved]

(h) Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality,

7500 Security Boulevard, Baltimore, Maryland 21244; Telephone (410) 786-3000

(1) CMS PQRI 2009 Registry XML Specifications, IBR approved for §170.205.

(2) 2009 Physician Quality Reporting Initiative Measure Specifications Manual for

Claims and Registry, Version 3.0, December 8, 2008 IBR approved for §170.205.

(i) National Institute of Standards and Technology, Information Technology Laboratory,

National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD

20899–8930, http://csrc.nist.gov/groups/STM/cmvp/standards.html

(1) Annex A: Approved Security Functions for FIPS PUB 140-2, Security

Requirements for Cryptographic Modules, Draft, January 27, 2010, IBR

approved for §170.210.

(2) [Reserved]

(j) American National Standards Institute, Health Information Technology Standards

Panel (HITSP) Secretariat, 25 West 43rd Street – Fourth Floor, New York, NY

10036, http://www.hitsp.org

(1) HITSP Summary Documents Using HL7 Continuity of Care Document (CCD)

Component, HITSP/C32, July 8, 2009, Version 2.5, IBR approved for

§170.205.

- 4. Revise subpart C to read as follows:

Subpart C—Certification Criteria for Health Information Technology

Sec.

170.300 Applicability.
170.302 General certification criteria for Complete EHRs or EHR Modules.
170.304 Specific certification criteria for Complete EHRs or EHR Modules designed for an ambulatory setting.
170.306 Specific certification criteria for Complete EHRs or EHR Modules designed for an inpatient setting.

§170.300 Applicability.

(a) The certification criteria adopted in this subpart apply to the testing and certification

of Complete EHRs and EHR Modules.

(b) When a certification criterion refers to two or more standards as alternatives, use of at

least one of the alternative standards will be considered compliant.

(c) Complete EHRs and EHR Modules are not required to be compliant with certification

criteria that are designated as optional.

§170.302 General certification criteria for Complete EHRs or EHR Modules.

The Secretary adopts the following general certification criteria for Complete EHRs or

EHR Modules. Complete EHRs or EHR Modules must include the capability to perform

the following functions electronically, unless designated as optional, and in accordance

with all applicable standards and implementation specifications adopted in this part:

(a) Drug-drug, 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.

(b) Drug-formulary checks. Enable a user to electronically check if drugs are in a formulary or preferred drug list.

(c) Maintain 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 standard specified in §170.207(a)(1); or

(2) At a minimum, the version of the standard specified in §170.207(a)(2).

(d) 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.

(e) 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.

(f) 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 charts for patients 2-20 years old.

(g) 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.

(h) <u>Incorporate laboratory test results--(1) Receive results.</u> Electronically receive clinical

laboratory test results in a structured format and display such results in human

readable format.

(2) <u>Display test report information.</u> Electronically display all the information for a test

report specified at 42 CFR 493.1291(c)(1) through (7).

(3) <u>Incorporate results.</u> Electronically attribute, associate, or link a laboratory test

result to a laboratory order or patient record.

(i) <u>Generate patient lists.</u> Enable a user to electronically select, sort, retrieve, and

generate lists of patients according to, at a minimum, the data elements included in:

(1) Problem list;

(2) Medication list;

(3) Demographics; and

(4) Laboratory test results.

(j) <u>Medication reconciliation.</u> Enable a user to electronically compare two or more

medication lists.

(k) <u>Submission to immunization registries.</u> Electronically record, modify, retrieve, and

submit immunization information in accordance with:

(1) The standard (and applicable implementation specifications) specified in

§170.205(e)(1) or §170.205(e)(2); and

(2) At a minimum, the version of the standard specified in §170.207(e).

(l) <u>Public health surveillance.</u> Electronically record, modify, retrieve, and submit syndrome-based public health surveillance information in accordance with the standard (and applicable implementation specifications) specified in §170.205(d)(1) or §170.205(d)(2).

(m) <u>Patient-specific education resources.</u> Enable a user to electronically identify and provide patient-specific education resources according to, at a minimum, the data elements included in the patient's: problem list; medication list; and laboratory test results; as well as provide such resources to the patient.

(n) <u>Automated measure calculation.</u> For each meaningful use objective with a percentage-based measure, electronically record the numerator and denominator and generate a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.

(o) <u>Access control.</u> Assign a unique name and/or number for identifying and tracking user identity and establish controls that permit only authorized users to access electronic health information.

(p) <u>Emergency access.</u> Permit authorized users (who are authorized for emergency situations) to access electronic health information during an emergency.

(q) <u>Automatic log-off.</u> Terminate an electronic session after a predetermined time of inactivity.

(r) <u>Audit log. (1)—Record actions.</u> Record actions related to electronic health information in accordance with the 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 standard at §170.210(b).

(s) Integrity. (1) Create a message digest in accordance with the standard specified in §170.210(c).

(2) Verify in accordance with the standard specified in §170.210(c) upon receipt of electronically exchanged health information that such information has not been altered.

(3) Detection. Detect the alteration of audit logs.

(t) Authentication. Verify that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information.

(u) General encryption. Encrypt and decrypt electronic health information in accordance with the standard specified in §170.210(a)(1), unless the Secretary determines that the use of such algorithm would pose a significant security risk for Certified EHR Technology.

(v) Encryption when exchanging electronic health information. Encrypt and decrypt electronic health information when exchanged in accordance with the standard specified in §170.210(a)(2).

(w) Optional. Accounting of disclosures. Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in §170.210(d).

§170.304 Specific certification criteria for Complete EHRs or EHR Modules designed for an ambulatory setting.

The Secretary adopts the following certification criteria for Complete EHRs or EHR Modules designed to be used in an ambulatory setting. Complete EHRs or EHR Modules must include the capability to perform the following functions electronically and in accordance with all applicable standards and implementation specifications adopted in this part:

(a) Computerized provider order entry. 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.

(b) Electronic prescribing. Enable a user to electronically generate and transmit prescriptions and prescription-related information in accordance with:

    (1) The standard specified in §170.205(b)(1) or §170.205(b)(2); and

    (2) The standard specified in §170.207(d).

(c) Record demographics. Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, gender, race, ethnicity, and date of birth. Enable race and ethnicity to be recorded in accordance with the standard specified at §170.207(f).

(d) 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.

(e) <u>Clinical decision support—(1) Implement rules.</u> Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in: problem list; medication list; demographics; and laboratory test results.

(2) <u>Notifications.</u> Automatically and electronically generate and indicate in real-time, notifications and care suggestions based upon clinical decision support rules.

(f) <u>Electronic copy of health information.</u> Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list in:

(1) Human readable format; and

(2) On electronic media or through some other electronic means in accordance with:

    (i) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and

    (ii) For the following data elements the applicable standard must be used:

        (A) <u>Problems.</u> The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2);

        (B) <u>Laboratory test results.</u> At a minimum, the version of the standard specified in §170.207(c); and

        (C) <u>Medications.</u> The standard specified in §170.207(d).

(g) Timely access. 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.

(h) Clinical summaries. Enable a user to provide clinical summaries to patients for each office visit that include, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list. If the clinical summary is provided electronically it must be:

(1) Provided in human readable format; and

(2) Provided on electronic media or through some other electronic means in accordance with:

(i) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and

(ii) For the following data elements the applicable standard must be used:

(A) 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).

(i) Exchange clinical information and patient summary record—(1) Electronically receive and display. Electronically receive and display a patient's summary record, from other providers and organizations including, at a minimum, diagnostic tests results, problem list, medication list, and medication allergy list in accordance with the standard (and applicable implementation specifications) specified in

§170.205(a)(1) or §170.205(a)(2). Upon receipt of a patient summary record

formatted according to the alternative standard, display it in human readable format.

(2) Electronically transmit. Enable a user to electronically transmit a patient summary

record to other providers and organizations including, at a minimum, diagnostic test

results, problem list, medication list, and medication allergy list in accordance with:

    (i) The standard (and applicable implementation specifications) specified in

       §170.205(a)(1) or §170.205(a)(2); and

    (ii) For the following data elements the applicable standard must be used:

       (A) 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).

(j) Calculate and submit clinical quality measures—(1) Calculate (i)Electronically

    calculate all of the core clinical measures specified by CMS for eligible professionals.

    (ii) Electronically calculate, at a minimum, three clinical quality measures

    specified by CMS for eligible professionals, in addition to those clinical quality

    measures specified in paragraph (1)(i).

(2) Submission. Enable a user to electronically submit calculated clinical quality

measures in accordance with the standard and implementation specifications specified

in §170.205(f).

§170.306 Specific certification criteria for Complete EHRs or EHR Modules

designed for an inpatient setting.

The Secretary adopts the following certification criteria for Complete EHRs or EHR Modules designed to be used in an inpatient setting. Complete EHRs or EHR Modules must include the capability to perform the following functions electronically and in accordance with all applicable standards and implementation specifications adopted in this part:

(a) <u>Computerized provider order entry.</u> Enable a user to electronically record, store, retrieve, and modify, at a minimum, the following order types:

    (1) Medications;

    (2) Laboratory; and

    (3) Radiology/imaging.

(b) <u>Record demographics.</u> Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, gender, race, ethnicity, date of birth, and date and preliminary cause of death in the event of mortality. Enable race and ethnicity to be recorded in accordance with the standard specified at §170.207(f).

(c) <u>Clinical decision support—(1) Implement rules.</u> Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in: problem list; medication list; demographics; and laboratory test results.

<u>(2) Notifications.</u> Automatically and electronically generate and indicate in real-time, notifications and care suggestions based upon clinical decision support rules.

(d) <u>Electronic copy of health information.</u> (1) Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, and procedures:

   (i) In human readable format; and

   (ii) On electronic media or through some other electronic means in accordance with:

   (A) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and

   (B) For the following data elements the applicable standard must be used:

   (1) <u>Problems.</u> The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2);

   (2) <u>Procedures.</u> The standard specified in §170.207(b)(1) or §170.207(b)(2);

   (3) <u>Laboratory test results.</u> At a minimum, the version of the standard specified in §170.207(c); and

   (4) <u>Medications.</u> The standard specified in §170.207(d).

(2) Enable a user to create an electronic copy of a patient's discharge summary in human readable format and on electronic media or through some other electronic means.

(e) <u>Electronic copy of discharge instructions.</u> Enable a user to create an electronic copy of the discharge instructions for a patient, in human readable format, at the time of discharge on electronic media or through some other electronic means.

(f) <u>Exchange clinical information and patient summary record</u>—(1) <u>Electronically receive and display.</u> Electronically receive and display a patient's summary record from other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, and procedures in accordance with the standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2). Upon receipt of a patient summary record formatted according to the alternative standard, display it in human readable format. (2) <u>Electronically transmit.</u> Enable a user to electronically transmit a patient's summary record to other providers and organizations including, at a minimum, diagnostic results, problem list, medication list, medication allergy list, and procedures in accordance with:

    (i) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and

    (ii) For the following data elements the applicable standard must be used:

        (A) <u>Problems.</u> The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2);

        (B) <u>Procedures.</u> The standard specified in §170.207(b)(1) or §170.207(b)(2);

        (C) <u>Laboratory test results.</u> At a minimum, the version of the standard specified in §170.207(c); and

        (D) <u>Medications.</u> The standard specified in §170.207(d).

(g) <u>Reportable lab results.</u> Electronically record, modify, retrieve, and submit reportable clinical lab results in accordance with the standard (and applicable implementation

specifications) specified in §170.205(c) and, at a minimum, the version of the

standard specified in §170.207(c).

(h) <u>Advance directives.</u> Enable a user to electronically record whether a patient has an

advance directive.

(i) <u>Calculate and submit clinical quality measures—(1) Calculate.</u> Electronically

calculate all of the clinical quality measures specified by CMS for eligible hospitals

and critical access hospitals.

<u>(2) Submission.</u> Enable a user to electronically submit calculated clinical quality

measures in accordance with the standard and implementation specifications specified

in §170.205(f).

*Dated:*__July 9, 2010_____

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Kathleen Sebelius,

<u>Secretary.</u>

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