DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 170

RIN 0991-AB82

Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services.

ACTION: Proposed rule.

SUMMARY: Under section 3004 of the Public Health Service Act, the Secretary of Health and Human Services is proposing to revise the initial set of standards, implementation specifications, and certification criteria adopted in an interim final rule published on January 13, 2010, and a subsequent final rule that was published on July 28, 2010, as well as to adopt new standards, implementation specifications, and certification criteria. The proposed new and revised certification criteria would establish the technical capabilities and specify the related standards and implementation specifications that Certified Electronic Health Record (EHR) Technology would need to include to, at a minimum, support the achievement of meaningful use by eligible professionals, eligible hospitals, and critical access hospitals under the Medicare and Medicaid EHR Incentive Programs beginning with the EHR reporting periods in fiscal year and calendar year 2014. This notice of proposed rulemaking also proposes revisions to the permanent

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certification program for health information technology, which includes changing the program's name.

DATES: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, no later than 5 p.m. on [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by RIN 0991-AB82, by any of the following methods (please do not submit duplicate comments). Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

- Federal eRulemaking Portal: Follow the instructions for submitting comments. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word. http://www.regulations.gov.
- Regular, Express, or Overnight Mail: Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention: 2014 Edition EHR Standards and Certification Criteria Proposed Rule, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave, S.W., Washington, D.C. 20201. Please submit one original and two copies.
- Hand Delivery or Courier: Office of the National Coordinator for Health Information Technology, Attention: 2014 Edition EHR Standards and Certification Criteria Proposed Rule, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave, S.W., Washington, D.C. 20201. Please submit one original and two copies. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons

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without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

Enhancing the Public Comment Experience: To enhance the accessibility and ease with which the public may comment on this proposed rule, a copy will be made available in Microsoft Word format. We believe this version will make it easier for commenters to access and copy portions of the proposed rule for use in their individual comments. Additionally, a separate document will be made available for the public to use to provide comments on the proposed rule. This document is meant to provide the public with a simple and organized way to submit comments on the certification criteria and associated standards and implementation specifications and respond to specific questions posed in the preamble of the proposed rule. While use of this document is entirely voluntary, we encourage commenters to consider using the document in lieu of unstructured comments or to use it as an addendum to narrative cover pages. Because of the technical nature of this proposed rule, we believe that use of the document may facilitate our review and understanding of the comments received. The Microsoft Word version of the proposed rule and the document that can be used for providing comments can be found at http://www.regulations.gov as part of this proposed rule's docket and on ONC's website (http://healthit.hhs.gov).

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. Such information includes, but is not limited to: a person's social security number; date of birth; driver's license

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number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered proprietary. We will post all comments that are received before the close of the comment period at http://www.regulations.gov.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov or the 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, D.C. 20201 (call ahead to the contact listed below to arrange for inspection).

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:

1. Commonly Used Acronyms

CAH	Critical Access Hospital
CDA	Clinical Document Architecture
CDS	Clinical Decision Support
CEHRT	Certified EHR Technology
CHPL	Certified HIT Products List
CMS	Centers for Medicare & Medicaid Services
CQM	Clinical Quality Measure
CY	Calendar Year

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EH	Eligible Hospital
EHR	Electronic Health Record
EP	Eligible Professional
FY	Fiscal Year
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
HITPC	HIT Policy Committee
HITSC	HIT Standards Committee
HL7	Health Level Seven
ICD-9-CM	International Classification of Diseases, 9th Revision, Clinical Modification
ICD-10-CM	International Classification of Diseases, 10th Revision, Clinical Modification
ICD-10-PCS	International Classification of Diseases, 10th Revision, Procedure Coding System
LOINC	Logical Observation Identifiers Names and Codes
MU	Meaningful Use
ONC	Office of the National Coordinator of Health Information Technology
NCPDP	National Council for Prescription Drug Programs
NIST	National Institute of Standards and Technology
PHSA	Public Health Service Act
SNOMED-CT®	Systematized Nomenclature of Medicine – Clinical Terms

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Regulation Text

I. Executive Summary

A. Purpose of Regulatory Action

The HIT Standards Committee (HITSC) issued recommendations for standards, implementation specifications, and certification criteria to the National Coordinator for Health Information Technology (the National Coordinator) on September 28, 2011 and October 21, 2011. In fulfilling his duties under sections 3001(c)(1)(A) and (B) of the Public Health Service Act (PHSA), the National Coordinator reviewed the recommendations made by the HITSC, endorsed certain standards, implementation specifications, and certification criteria, and reported his determinations to the Secretary for consideration. This proposed rule serves as the Secretary's publication of her determinations regarding the standards, implementation specifications, and certification criteria endorsed by the National Coordinator, as required by section 3004(a)(3) of the PHSA.

The adoption by the Secretary, under sections 3004(a)(3) and 3004(b)(3) of the PHSA, of the standards, implementation specifications, and certification criteria proposed in this rule would establish the technical capabilities that electronic health record (EHR) technology must include to be certified. EHR technology certified to these standards, implementation specifications, and certification criteria makes it possible for eligible professionals (EPs), eligible hospitals (EHs), and critical access hospitals (CAHs) to adopt Certified EHR Technology (CEHRT) and subsequently attempt to demonstrate its meaningful use (MU) under the Medicare and Medicaid EHR Incentive Programs (the "EHR Incentive Programs") beginning with the

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EHR reporting periods in Federal fiscal year (FY) 2014 for EHs and CAHs and calendar year (CY) 2014 for EPs (hereafter referred to as "FY/CY 2014").

Consistent with Executive Order 13563, we have undertaken a retrospective review of our regulations. The proposed rule introduces multiple means for reducing regulatory burden and increasing regulatory flexibility for stakeholders, including proposed changes to current regulatory requirements and approaches.

B. Summary of Major Provisions

1. Overview of the 2014 Edition EHR Certification Criteria

We propose to adopt certification criteria that will support the proposed changes to the EHR Incentive Programs, including the new and revised objectives and measures for Stages 1 and 2 of MU proposed by CMS. The certification criteria we propose for adoption would also enhance care coordination, patient engagement, and the security, safety, and efficacy of EHR technology. For clarity, we refer to the certification criteria proposed for adoption as the 2014 Edition EHR certification criteria and the currently adopted certification criteria as the 2011 Edition EHR certification criteria. To permit efficient certification methods and reduce regulatory burden, we have identified those certification criteria that we propose to include in the 2014 Edition EHR certification criteria that include unchanged capabilities that were also included in the 2011 Edition EHR certification criteria. For EHR technology previously certified to the 2011 Edition EHR certification criteria, this would permit, where applicable, the use of prior test results for certification to the 2014 Edition EHR certification criteria (see the discussion of "gap certification" in section III.A.7 of this preamble).

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2. Certified EHR Technology

Since the publication of the Standards and Certification Criteria final rule in July 2010, HHS has received significant feedback from stakeholders suggesting that we change our CEHRT policy (and definition) to one that would provide EPs, EHs, and CAHs the flexibility to have only the EHR technology they need to demonstrate MU. Consistent with stakeholder feedback and recommendations received from the HITSC, this rule proposes to revise the definition of CEHRT. Of most significance, beginning with the EHR reporting periods in FY/CY 2014, we are proposing a revised definition of CEHRT that would provide more flexibility for EPs, EHs, and CAHs. In sum, in order to have EHR technology that meets the definition of CEHRT for FY and CY 2014 and subsequent years, EPs, EHs, and CAHs would be required to have a Base EHR (EHR technology that includes fundamental capabilities all providers would need to have) as well as the additional EHR technology necessary to meet the MU objectives and measures for the stage of MU that they seek to meet and to capture, calculate, and report clinical quality measures. We further discuss this proposal, including the concept of a "Base EHR" in section III.C (Redefining Certified EHR Technology and Related Terms).

3. ONC HIT Certification Program

This rule proposes revisions to the permanent certification program which aim to increase regulatory clarity and transparency, reduce regulatory burden, and add flexibility for the health information technology (HIT) community. One of these revisions includes changing the permanent certification program title to the "ONC HIT Certification Program," which provides clearer attribution to the agency responsible for the program and an appropriate description of the program's scope, covering both current and potential future activities. The rule also proposes to

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revise the process for permitting the use of newer versions of "minimum standard" code sets. The proposed new approach seeks to reduce regulatory complexity and burden by providing the industry with the flexibility to quickly utilize newer versions of adopted "minimum standard" code sets. The rule proposes to modify the certification processes ONC-Authorized Certification Bodies (ONC-ACBs) would need to follow for certifying EHR Modules as a means of providing clear implementation direction and compliance with proposed new certification criteria, and also proposes to reduce regulatory burden by eliminating the certification requirement that every EHR Module be certified to the "privacy and security" certification criteria. Instead, the privacy and security capabilities are included in the Base EHR that must be a part of every EP's, EH's, and CAH's CEHRT. To increase clarity for the HIT market, we propose methods for clearly representing certified Complete EHRs and certified EHR Modules, including the representation of a "Base EHR." Finally, we propose to require that test results used for the certification of EHR technology be available to the public in an effort to increase transparency around the certification process.

C. Costs and Benefits

We determined that this proposed rule is not an economically significant rule as its overall costs will be less than $100 million per year. We have, however, estimated the costs and benefits of the proposed rule. The estimated costs expected to be incurred by EHR technology developers to develop and prepare EHR technology (i.e., Complete EHRs and EHR Modules) to be tested and certified in accordance with the proposed certification criteria are represented in monetary terms in Table 1 below. We believe that there will be market pressures to have certified Complete EHRs and certified EHR Modules ready and available prior to when EPs,

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EHs, and CAHs must meet the proposed revised definition of CEHRT for FY/CY 2014. We assume this factor will cause a greater number of developers to prepare EHR technology for testing and certification towards the end of 2012 and throughout 2013, rather than in 2014. As a result, we believe, as represented in Table 1, that the costs attributable to this proposed rule will be distributed as follows: 40% for 2012, 50% for 2013, and 10% for 2014. The dollar amounts expressed in Table 1 are expressed in 2012 dollars.

There are multiple potential benefits from the adoption of the proposed certification criteria in this rule. Foremost, EHR technology certified to the proposed certification criteria would be capable of supporting EPs, EHs, and CAHs' attempts to demonstrate MU under the EHR Incentive Programs. The certification criteria also promote enhanced interoperability, functionality, utility, and security of EHR technology through the capabilities they include and the standards they require EHR technology to meet for certification. Proposals such as the revised definition of CEHRT, the availability of gap certification, and the proposed revisions to the permanent certification program, will, as noted, increase regulatory clarity, improve transparency, and add flexibility, while also reducing the regulatory burden on the HIT industry. Finally, we believe the proposals in this rule will support other initiatives, such as the Partnership for Patients.

Table 1. Estimated Costs of the Proposed Rule: 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)
2012	40%	36.80	95.01	65.91

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Year	Ratio	Total Low Cost Estimate ($M)	Total High Cost Estimate ($M)	Total Average Cost Estimate ($M)
2013	50%	46.01	118.76	82.38
2014	10%	9.20	23.75	16.48
3-Year Totals		**92.01**	**237.52**	**167.53**

II. Background

A. Statutory Basis

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 (the Recovery Act) (Pub. L. 111–5), was enacted on February 17, 2009. The HITECH Act amended the PHSA and created "Title XXX – Health Information Technology and Quality" (Title XXX) to improve health care quality, safety, and efficiency through the promotion of HIT and electronic health information exchange.

1. Standards, Implementation Specifications, and Certification Criteria

With the passage of the HITECH Act, two new Federal advisory committees were established, the HIT Policy Committee (HITPC) and the HIT Standards Committee (HITSC) (sections 3002 and 3003 of the PHSA, respectively). Each is responsible for advising the National Coordinator on different aspects of standards, implementation specifications, and certification criteria. The HITPC is responsible for, among other duties, recommending priorities for the development, harmonization, and recognition of standards, implementation specifications, and certification criteria, while the HITSC is responsible for recommending standards, implementation specifications, and certification criteria for adoption by the Secretary under section 3004 of the PHSA consistent with the ONC-coordinated Federal Health IT Strategic Plan.

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Section 3004 of the PHSA identifies a process for the adoption of health IT standards, implementation specifications, and certification criteria and authorizes the Secretary to adopt such standards, implementation specifications, and certification criteria. As specified in section 3004(a)(1), the Secretary is required, in consultation with representatives of other relevant Federal agencies, to jointly review standards, implementation specifications, and certification criteria endorsed by the National Coordinator under section 3001(c) and subsequently determine whether to propose the adoption of any grouping of such standards, implementation specifications, or certification criteria. The Secretary is required to publish all determinations in the Federal Register.

Section 3004(b)(3) of the PHSA titled "Subsequent Standards Activity" provides that the "Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent" with the schedule published by the HITSC. We consider this provision in the broader context of the HITECH Act to grant the Secretary the authority and discretion to adopt standards, implementation specifications, and certification criteria that have been recommended by the HITSC and endorsed by the National Coordinator, as well as other appropriate and necessary HIT standards, implementation specifications, and certification criteria. Throughout this process, the Secretary intends to continue to seek the insights and recommendations of the HITSC.

2. HIT Certification Programs

Section 3001(c)(5) of the PHSA provides the National Coordinator with the authority to establish a certification program or programs for the voluntary certification of HIT. Specifically, section 3001(c)(5)(A) specifies that the "National Coordinator, in consultation with the Director

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of the National Institute of Standards and Technology, shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this subtitle" (i.e., certification criteria adopted by the Secretary under section 3004 of the PHSA). The certification program(s) must also "include, as appropriate, testing of the technology in accordance with section 13201(b) of the [HITECH] Act."

Section 13201(b) of the HITECH Act requires that with respect to the development of standards and implementation specifications, the Director of the National Institute of Standards and Technology (NIST), in coordination with the HITSC, "shall support the establishment of a conformance testing infrastructure, including the development of technical test beds." The HITECH Act also indicates that "[t]he development of this conformance testing infrastructure may include a program to accredit independent, non-Federal laboratories to perform testing."

B. Regulatory History

1. Initial Set of Standards, Implementation Specifications, and Certification Criteria Interim Final and Final Rules

The Secretary issued an interim final rule with request for comments titled "Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology" (75 FR 2014, Jan. 13, 2010) (the "S&CC January 2010 interim final rule"), which adopted an initial set of standards, implementation specifications, and certification criteria. After consideration of the public comments received on the S&CC January 2010 interim final rule, a final rule was issued to complete the adoption of the initial set of standards, implementation specifications, and

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certification criteria and realign them with the final objectives and measures established for MU Stage 1. Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule, 75 FR 44590 (July 28, 2010) (the "S&CC July 2010 final rule"). On October 13, 2010, an interim final rule with a request for comment was issued to remove certain implementation specifications related to public health surveillance that had been previously adopted in the S&CC July 2010 final rule (75 FR 62686).

The standards, implementation specifications, and certification criteria adopted by the Secretary in the S&CC July 2010 final rule established the capabilities that CEHRT must include in order to, at a minimum, support the achievement of MU Stage 1 by EPs, EHs, and CAHs under the Medicare and Medicaid EHR Incentive Programs Stage 1 final rule (the "EHR Incentive Programs Stage 1 final rule") (see 75 FR 44314 for more information about MU and the Stage 1 requirements).

2. Medicare and Medicaid EHR Incentive Programs Stage 1 Proposed and Final Rules

On January 13, 2010, CMS published the EHR Incentive Programs Stage 1 proposed rule (75 FR 1844). The rule proposed a definition for Stage 1 MU of CEHRT and regulations associated with the incentive payments made available under Division B, Title IV of the HITECH Act. Subsequently, CMS published a final rule (75 FR 44314) for the EHR Incentive Programs on July 28, 2010, simultaneously with the publication of the S&CC July 2010 final rule. The EHR Incentive Programs Stage 1 final rule established the objectives, associated measures, and other requirements that EPs, EHs, and CAHs must satisfy to demonstrate MU during Stage 1.

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3. HIT Certification Programs Proposed Rule and the Temporary and Permanent Certification Programs Final Rules

On March 10, 2010, ONC published a proposed rule (75 FR 11328) titled "Proposed Establishment of Certification Programs for Health Information Technology" (the "Certification Programs proposed rule"). The rule proposed both a temporary and permanent certification program for the purposes of testing and certifying HIT. It also specified the processes the National Coordinator would follow to authorize organizations to perform the certification of HIT. A final rule establishing the temporary certification program was published on June 24, 2010 (75 FR 36158) (the "Temporary Certification Program final rule") and a final rule establishing the permanent certification program was published on January 7, 2011 (76 FR 1262) ("the Permanent Certification Program final rule").

III. Provisions of the Proposed Rule affecting Standards, Implementation Specifications, and Certification Criteria

In the S&CC July 2010 final rule, the Secretary adopted certification criteria in title 45, part 170, §§ 170.302, 170.304, and 170.306 of the Code of Federal Regulations. To make a clear distinction between these previously adopted certification criteria and the ones discussed in this proposed rule, we will refer to the certification criteria adopted in the S&CC July 2010 final rule and included in §§ 170.302, 170.304, and 170.306 collectively as the "2011 Edition EHR certification criteria" and propose to revise § 170.102 to add this definition.

A. 2014 Edition EHR Certification Criteria

This rule proposes new, revised, and unchanged certification criteria that would establish the technical capabilities and specify the related standards and implementation specifications that

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CEHRT would need to include to, at a minimum, support the achievement of MU by EPs, EHs, and CAHs under the EHR Incentive Programs beginning with the EHR reporting periods in FY/CY 2014. We refer to these new, revised, and unchanged certification criteria as the "2014 Edition EHR certification criteria" and propose to add this term and its definition to § 170.102. Additionally, we propose to codify the 2014 Edition EHR certification criteria in section 170.314 to set them apart and make it easier for stakeholders to quickly determine which certification criteria would be required beginning with the EHR reporting periods that start in FY/CY 2014. This approach, coupled with our reference to the 2011 Edition EHR certification criteria, should eliminate any ambiguity and provide a clear distinction between the certification criteria that are part of the 2011 Edition EHR certification criteria and those we propose to include in the 2014 Edition EHR certification criteria. Further, we believe the inclusion of all 2014 Edition EHR certification criteria in one regulatory section will simplify the regulatory framework for stakeholders.

Many of the certification criteria that we propose in this rule are intended to support the MU objectives and measures proposed in the CMS Medicare and Medicaid EHR Incentive Programs Stage 2 proposed rule (Stage 2 proposed rule)[1] as well as the reporting of MU objectives and measures and clinical quality measures (CQMs) to CMS. To the extent CMS may change (e.g., add, revise, or remove) MU objectives, measures, or reporting requirements in a final rule, we may also find it necessary or appropriate to change proposed supporting certification criteria. Commenters recommending changes to the proposed MU objectives and

[1] When we refer to CMS's Medicare and Medicaid EHR Incentive Programs Stage 2 proposed rule, we are referring to the NPRM published elsewhere in this issue of the Federal Register.

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measures, CQMs, or reporting requirements should consider whether changes to the certification criteria would also be needed and offer those suggested changes. Similarly, commenters should consider and specify whether any of their suggested revisions to the proposed certification criteria would impact the proposals in CMS's Stage 2 proposed rule.

We discuss the new, revised, and unchanged certification criteria that we propose to adopt as the 2014 Edition EHR certification criteria in sections A.4 through A.6 below. We specify where the proposed certification criteria would be included in § 170.314. We include a table at the beginning of the discussion of each certification criterion or criteria that specifies the MU objective that the proposed 2014 Edition EHR certification criterion or criteria and associated standards and implementation specifications support. The objective cited is either a proposed Stage 1 or Stage 2 objective that would be effective for the EHR reporting periods in FY/CY 2014. We provide this frame of reference because we propose that beginning in FY/CY 2014 EHR technology would need to be certified to the 2014 Edition EHR certification criteria to meet the definition of CEHRT and the table permits commenters to easily associate the certification criterion with the MU objective it supports. We provide the rationale for the proposed certification criteria, including citing the recommendations of the HITPC and HITSC, where appropriate. Last, in certain instances, we specifically request comment on the maturity and industry-acceptance of various standards and implementation specifications.

1. Applicability

Section 170.300 establishes the applicability of subpart C – Certification Criteria for Health Information Technology. Section 170.300(a) establishes the applicability of the adopted certification criteria to the testing and certification of Complete EHRs and EHR Modules.

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Section 170.300(b) specifies that when a certification criterion refers to two or more standards as alternatives, the use of at least one of the alternative standards will be considered compliant. Section 170.300(c) specifies that Complete EHRs and EHR Modules are not required to be compliant with certification criteria that are designated as optional. We propose to revise § 170.300 to reflect our proposed regulatory structure for the 2014 Edition EHR certification criteria. We propose to revise paragraph (c) to add that Complete EHRs and EHR Modules are also not required to be certified to specific capabilities within a certification criterion that are designated as optional. We also propose to add a paragraph (d) that would clarify which certification criteria or specific capabilities within a certification criterion included in § 170.314 have general applicability (i.e., apply to both ambulatory and inpatient settings) or apply only to an inpatient setting or an ambulatory setting.

2. Scope of a Certification Criterion for Certification

In the certification programs final rules (75 FR 36176, 76 FR 1290-91) and the S&CC July 2010 final rule (75 FR 44622), we clarified that a single certification criterion would encompass all of the specific capabilities referenced below the first paragraph level. As an example in the Permanent Certification Program final rule, we stated that the certification criterion at 45 CFR 170.302, paragraph "(f)" (the first paragraph level) identifies that the certification criterion relates to recording and charting vital signs. The certification criterion includes three specific capabilities at (f)(1), (2), and (3) (the second paragraph level): the ability to record, modify, and retrieve patients' vital signs; the ability to calculate body mass index (BMI); and the ability to plot and display growth charts. We stated that we viewed the entire set of specific capabilities required by paragraph "(f)" (namely, (f)(1), (2), and (3)) as one

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certification criterion, and that the specific capability to calculate BMI would not be equivalent to one certification criterion.

Based on our proposal to codify all the 2014 Edition EHR certification criteria in § 170.314, we are clarifying that certification to the certification criteria at § 170.314 would occur at the second paragraph level of the regulatory section. The first paragraph level in § 170.314 would be used to organize the certification criteria into categories. These categories would be: clinical (§ 170.314(a)); care coordination (§ 170.314(b)); clinical quality measures (§ 170.314(c)); privacy and security (§ 170.314(d)); patient engagement (§ 170.314(e)); public health (§ 170.314(f)); and utilization (§ 170.314(g)). Thus, for this proposed rule, a certification criterion in § 170.314 would be at the second paragraph level and would encompass all of the specific capabilities in the paragraph levels below with, as noted in our discussion of "applicability," an indication if the certification criterion or the specific capabilities within the criterion only apply to one setting (ambulatory or inpatient). For example, we propose to adopt the revised certification criterion for demographics at § 170.314(a)(3) (second paragraph level). The certification criterion includes two specific capabilities at (3)(i) and (ii) (third paragraph level): "(i)" enable a user to electronically record, change, and access patient demographic data including preferred language, gender, race, ethnicity, and date of birth (in accordance with the specified standards for race, ethnicity, and preferred language (§ 170.314(3)(i)(A) and (B)); and, "(ii)" for the inpatient setting only, enable a user to electronically record, change, and access preliminary cause of death in the event of mortality in accordance with the standard specified in § 170.207(k). Consequently, to meet the proposed certification criterion for demographics, for example, EHR technology designed for the inpatient setting would need to meet §

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170.314(a)(3)(i)(A) and (B) and (ii), while EHR technology designed for the ambulatory setting would only need to meet (3)(i)(A) and (B) because the capability at (3)(ii) only applies to the inpatient setting.

3. Explanation and Revision of Terms Used in Certification Criteria

Certain terms are repeatedly used in the proposed 2014 Edition EHR certification criteria. Based on our experience and stakeholder feedback related to how terms in the 2011 Edition EHR certification criteria have been interpreted, we have determined that it is necessary in certain cases to select different terms. The following is a list of terms we repeatedly use in the proposed 2014 Edition EHR certification criteria and the intended meaning for each term.

"User" is used to mean a health care professional or his or her office staff or a software program or service that would interact directly with the CEHRT. This is essentially the same description that we gave to "user" in the S&CC July 2010 final rule (75 FR 44598). We further clarify that, unless expressly stated otherwise, "user" does not mean a patient.

"Record" is used to mean the ability to capture and store information in EHR technology. We consider this meaning complementary to and consistent with related terms, namely "change and "access," and their associated capabilities.

"Change" is used to mean the ability to alter or edit information previously recorded in EHR technology. We are replacing the term "modify" used in the 2011 Edition EHR certification criteria with "change." Although we interpret both terms to have essentially the same meaning, we believe "change" connotes a more plain language meaning as recommended

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by plainlanguage.gov[2]. In certification criteria in which this term is used, we do not intend for it to be interpreted to mean that information previously recorded would be able to be changed without the retention of prior value(s). Rather, a change must be retained as an audited event and in a viewable format that identifies the changed information in a patient's record (similar to how one might see changes represented in a word-processing application). How such changes are displayed is a design decision left to EHR technology developers.

"Access" is used to mean the ability to examine or review information in or through EHR technology. We are proposing to replace the term "retrieve" used in the 2011 Edition EHR certification criteria with "access" because we believe it is clearer and more accurately expresses the capability we intend for EHR technology to include. We note that some stakeholders had interpreted "retrieve" to suggest that the EHR technology also needed to be able to obtain data from external sources. Nevertheless, we interpret both "access" and "retrieve" to have essentially the same meaning, but note that "access" should not be interpreted to include necessarily the capability of obtaining or transferring the data from an external source.

"Incorporate" is used to mean to electronically import, attribute, associate, or link information in EHR technology. With the exception of import, we previously used these terms to describe the "incorporate" capability included in certification criteria as illustrated by the capability specified at § 170.302(h)(3). We only propose to revise its unique meaning for the 2014 Edition EHR certification criteria and the purposes of certification to account for the ability to electronically import information.

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[2] http://www.plainlanguage.gov/howto/wordsuggestions/simplewords.cfm#lm

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"Create" is used to mean to electronically produce or generate information. We are proposing to replace the term "generate" used in the 2011 Edition EHR certification criteria with "create." We believe "create" is clearer and is a better word choice than generate from a plain language perspective.

"Transmit" is used to mean to send from one point to another.

4. New Certification Criteria

In the Permanent Certification Program final rule (76 FR 1302), we described new certification criteria as those that specify capabilities for which the Secretary has not previously adopted certification criteria. We further stated that new certification criteria also include certification criteria that were previously adopted for Complete EHRs or EHR Modules designed for a specific setting and are subsequently adopted for Complete EHRs or EHR Modules designed for a different setting (for example, if the Secretary previously adopted a certification criterion only for Complete EHRs or EHR Modules designed for an ambulatory setting and then subsequently adopts that certification criterion for Complete EHRs or EHR Modules designed for an inpatient setting). Based on our experience trying to appropriately categorize the certification criteria we propose to be part of the 2014 Edition EHR certification criteria, we have determined that our description of new certification criteria needs to be clarified. Accordingly, we list below the factors that we would consider when determining whether a certification criterion is "new:"

- The certification criterion only specifies capabilities that have never been included in previously adopted certification criteria; or
- The certification criterion was previously adopted as "mandatory" for a particular setting and subsequently adopted as "mandatory" or "optional" for a different setting.

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We propose to adopt new certification criteria that will support new MU objectives and associated measures, the reporting of MU measures, and will enable EHR technology to enhance patient engagement. Some of the new criteria would apply to both ambulatory and inpatient settings, while some certification criteria would only apply to one of the settings or would be new for a particular setting.

a. Ambulatory and Inpatient Setting

We propose to adopt 8 certification criteria that would be new certification criteria for both the ambulatory and inpatient settings.

- **Electronic notes**

MU Objective Record electronic notes in patient records.
2014 Edition EHR Certification Criterion § 170.314(a)(9) (Electronic notes)

The HITSC recommended a certification criterion similar to the 2014 Edition EHR certification criterion we propose at § 170.314(a)(9) (with specific reference to "physician, physician assistant, or nurse practitioner" electronic notes) to support the MU objective and measure recommended by the HITPC. CMS has not proposed the MU objective and measure for Stage 2, but has requested public comment on whether the objective and measure should be incorporated into Stage 2.

Consistent with our discussion in the preamble section titled "Explanation and Revision of Terms Used in Certification Criteria," we have replaced the terms "modify" and "retrieve" in the recommended criterion with "change" and "access," respectively. Additionally, we are providing the following clarifications for the electronic "search" capability. "Search" means the

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ability to search free text and data fields of electronic notes. It also means the ability to search the notes that any licensed health care professional has included within the EHR technology, including the ability to search for information across separate notes rather than just within notes. We believe that this certification criterion would encompass the necessary capabilities to support the performance of the MU objective and measure as discussed in the MU Stage 2 proposed rule.

- **Imaging**

MU Objective Imaging results and information are accessible through Certified EHR Technology.
2014 Edition EHR Certification Criterion § 170.314(a)(12) (Imaging)

We propose to adopt the 2014 Edition EHR certification criterion at § 170.314(a)(12) to support the performance of the proposed MU objective and measure. We clarify that the phrase "immediate electronic access" is intended to mean that a user should be able to electronically access images and their narrative interpretations directly and without, for example, having to login to a separate electronic system or repository. This access could be provided by multiple means, including, but not limited to, "single sign-on" and "secure identity parameter passing." We also note that there are data format standards for the transmission of imaging data (Digital Imaging and Communications in Medicine (DICOM)) that we reviewed for this certification criterion, but do not believe that the adoption of these standards is necessary to enable users to electronically access images and their narrative interpretations, as required by this certification criterion. We request public comment regarding whether there are appropriate and necessary standards and implementation specifications for this certification criterion.

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- **Family health history**

MU Objective Record patient family health history as structured data.
2014 Edition EHR Certification Criterion § 170.314(a)(13) (Family health history)

We propose to adopt the 2014 Edition EHR certification criterion at § 170.314(a)(13) to support the performance of the proposed MU objective and measure. In defining family health history, this capability requires, at minimum, the ability to electronically record, change, and access the health history of a patient's first-degree relatives. As proposed in the Stage 2 proposed rule, a first degree relative is a family member who shares about 50 percent of their genes with a particular individual in a family (first degree relatives include parents, offspring, and siblings). We considered adopting specific standards for this certification criterion, including the HL7 Pedigree standard[3] and the use of Systematized Nomenclature of Medicine--Clinical Terms (SNOMED-CT®)[4] terms for familial conditions. We seek comments on the maturity and breadth of industry adoption of the HL7 Pedigree standard format for export and import of family health history and the use of SNOMED-CT® terms for familial conditions and their inclusion, where appropriate, on a patient's problem list. We also note that the Surgeon General has produced a tool that can capture, save, and manage family health histories using standard vocabularies and can export the data in eXtensible Markup Language (XML) format.[5] We seek comments on the maturity and breadth of adoption of this tool and its export format.

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3 http://www.hl7.org/implement/standards/product_brief.cfm?product_id=8
[4] http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html
[5] https://familyhistory.hhs.gov

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- **Amendments**

MU Objective Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.
2014 Edition EHR Certification Criterion § 170.314(d)(4) (Amendments)

We propose to adopt the 2014 Edition EHR certification criterion at § 170.314(d)(4). Based on HITPC recommendations submitted to the National Coordinator on July 25, 2011, the HITSC recommended two versions of a draft 2014 Edition EHR certification criterion for amendments. As part of its recommendation, the HITPC (based on the work done by its Privacy and Security Tiger Team) noted that the technical capabilities included in a certification criterion should be "kept as simple as possible and evolve over time to greater complexity, including potentially greater standardization and automation." The HITPC also recommended that this certification criterion be adopted to assist stakeholders by providing them with some of the technical tools to comply with parts of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule requirements specified at 45 CFR 164.526. In addition, the HITPC considered issues related to "data integrity and quality when a clinician corrects errors that were not reported by the patient or needs to communicate updates to a patient's information." We agree with the HITPC and HITSC recommendations, including that a certification criterion should be adopted that provides some of the basic technical tools necessary to comply with the HIPAA Privacy Rule. The proposed certification criterion does not address all of the requirements specified at 45 CFR 164.526 and we note that EHR technology certification is not a substitute for, or guarantee of, HIPAA Privacy Rule compliance. However, we believe that by adopting the

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proposed certification criterion, EPs, EHs, and CAHs would be provided some of the basic technical tools for compliance with 45 CFR 164.526.

We specifically request comment on whether EHR technology should be required to be capable of appending patient supplied information in both free text and scanned format or only one or these methods to be certified to this proposed certification criteria.

- **View, download, and transmit to 3rd party**

MU Objective EPs Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP. EHs and CAHs Provide patients the ability to view online, download, and transmit information about a hospital admission.
2014 Edition EHR Certification Criterion § 170.314(e)(1) (View, download, and transmit to 3rd party) **Standards** § 170.204(a) (Web Content Accessibility Guidelines (WCAG) 2.0, Level AA Conformance); § 170.205(a)(3) (Consolidated CDA); § 170.205(j) (DICOM PS 3—2011); § 170.207(f) (OMB standards for the classification of federal data on race and ethnicity); § 170.207(j) (ISO 639-1:2002 (preferred language)); § 170.207(l) (smoking status types); § 170.207(a)(3) (SNOMED-CT® International Release January 2012); § 170.207(m) (ICD-10-CM); § 170.207(b)(2) (HCPCS and CPT-4) or § 170.207(b)(3) (ICD-10-PCS); § 170.207(g) (LOINC version 2.38); § 170.207(h) (RxNorm February 6, 2012 Release); § 170.202(a)(1) (Applicability Statement for Secure Health Transport) and § 170.202(a)(2) (XDR and XDM for Direct Messaging); and § 170.210(g) (synchronized clocks)

The HITPC issued a MU recommendation that patients (or their authorized representative(s)) be able to view and download their health information online (i.e., Internet/web-based). The HITPC recommended that this objective should replace or subsume the objectives for providing patients with timely electronic access to their health information and providing patients with an electronic copy of their health information and hospital discharge instructions upon request. Consistent with these recommendations, the HITSC recommended a

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certification criterion that framed the capabilities EHR technology would need to include to support this new objective and that, for the 2014 Edition EHR certification criteria, the criterion should replace the certification criteria previously adopted at §§ 170.304(f), 170.304(g), 170.306(d), and 170.306(e) because the new criterion encompassed the data elements required by these capabilities and was seen as a more efficient and effective means for patients to access their health information. We have made several refinements to the recommended certification criterion, while maintaining the critical elements recommended by the HITSC.

In addition to the view and download capabilities recommended by the HITSC, we propose to include a third specific capability in this certification criterion – the ability to transmit a summary care record to a third party. Given that this objective is about making health information more accessible to patients and their caregivers, we believe that patients should have another option available to access their health information. We also believe that in certain cases patients may want to direct their health care provider(s) to transmit a copy of their electronic health information to another entity the patient might use for centralizing their health information (e.g., a personal health record). This additional capability is consistent with, and supports, the right of access standard at 45 CFR 164.524 of the HIPAA Privacy Rule as expanded by section 13405(e) of the HITECH Act with respect to covered entities that use or maintain an EHR on an individual. Section 13405(e) states that, in applying 45 CFR 164.524, an "individual shall have a right to obtain from [a HIPAA] covered entity a copy of such information in an electronic format and, if the individual chooses, to direct the covered entity to transmit such copy directly to an entity or person designated by the individual…." Coupled with this addition, we have proposed that EHR technology would need to be capable of transmitting a summary care record according

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to both transport standards we propose to adopt. These transport standards include the two transport specifications developed under the Direct Project[6]: 1) Applicability Statement for Secure Health Transport[7] and 2) External Data Representation (XDR) and Cross-Enterprise Document Media Interchange (XDM) for Direct Messaging[8]. The Applicability Statement for Secure Health Transport specification describes how electronic health information can be securely transported using simple mail transport protocol (SMTP), Secure/Multipurpose Internet Mail Extensions (S/MIME), and X.509 certificates. The XDR and XDM for Direct Messaging specification describes the use of XDR and XDM as a means to transport electronic health information and serve as a bridge between entities using/following web services and SMTP transport methods. We believe that these transport standards are ideal for these purposes and will make it possible for patients to transmit a copy of their summary care record to the destination of their choice. Additionally, because we have proposed requiring the capability to perform transmissions in accordance with these transport standards (which provide for encryption and integrity protection) in this criterion and in the "transitions of care – create and transmit summary care record" certification criterion, we have determined that it is not necessary to include in the 2014 Edition EHR certification criteria the "encrypting when exchanging" certification criterion adopted in the 2011 Edition EHR certification criteria (§ 170.302(v)). We believe that to include the 2011 Edition EHR certification criterion would be redundant and that our proposed approach more explicitly ties security to a particular transmission.

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[6] http://wiki.directproject.org/Documentation+Library
[7] http://wiki.directproject.org/Applicability+Statement+for+Secure+Health+Transport

[8] http://wiki.directproject.org/XDR+and+XDM+for+Direct+Messaging

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At the recommendation of the HITSC, this proposed certification criterion requires that EHR technology certified to this criterion include a "patient accessible log" to track the use of the view, download, and transmit capabilities included in this certification criterion (i.e., record the user identification, the user's actions, and the health information viewed, downloaded, or transmitted) and make that information available to the patient. We have required this specific capability within this certification criterion because we believe that it is highly likely numerous EHR Modules could be certified to this criterion without also being certified to the auditable events and tamper resistance certification criterion we propose to adopt at § 170.314(d)(2) due to the proposed policy change we specify in section IV.C.1 below related to EHR Modules and privacy and security. Thus, this express requirement guarantees that an EHR Module certified to this criterion would include the capability to track who has viewed, downloaded, or transmitted to a third party electronic health information and that patients would have access to this information. That being said, we do not intend for this portion of the certification criterion to impose a redundant requirement on EHR technology developers who present a Complete EHR or EHR Module for certification to both this certification criterion and the auditable events and tamper resistance certification criterion. Accordingly, we provide in paragraph (e)(1)(ii)(B) of § 170.314 that EHR technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of § 170.314 if it is also certified to the certification criterion proposed for adoption at § 170.314(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) of § 170.314 is accessible to the patient. In other words, an EHR technology certified to § 170.314(d)(2) would not need to also include the "patient accessible log" capability

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specified in paragraph (e)(1)(ii)(A) of § 170.314 because it would be capable of logging such events and providing the information to the patient.

We also propose for the "patient accessible log" capability to require that the date and time each action occurs be recorded using a system clock that has been synchronized following either Request for Comments (RFC) 1305 Network Time Protocol (NTP) v3 or RFC 5905 Network Time Protocol Version 4: Protocol and Algorithms Specification (NTPv4). These are final standards published by the Internet Engineering Task Force, a voluntary consensus standards body. Having correctly synchronized clocks is an information security best practice and the NTP, especially version 3, has been widely used and implemented since its publication in 1992.[9] RFC 5905 NTPv4 was published in 2010[10] and is backwards compatible with NTPv3. It does, however, include a modified protocol header to accommodate the Internet Protocol version 6 (IPv6) address family. For the same reasons we discuss here, we have included in the new certification criterion for electronic medication administration proposed for adoption at § 170.314(a)(17) and the auditing standard proposed for adoption at § 170.210(e) this same "synchronized clocks" standard because each includes a capability that requires date and time to be recorded. As a general best practice, we highly encourage and expect EHR technology developers that associate date and/or time with capabilities included in certification criteria not specifically mentioned here to utilize a system clock that has been synchronized following NTPv3 or NTPv4. Additionally, the HITSC recommended that we require as a condition of certification other privacy and security oriented capabilities such as single factor authentication

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[9] http://www.ietf.org/rfc/rfc1305.txt
[10] http://www.ietf.org/rfc/rfc5905.txt

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and secure download. We did not include these additional capabilities in our proposals because we believe their technical implementations are commonplace and ubiquitous. Thus, there would seem to be little value added by requiring that these capabilities be demonstrated as a condition of certification.

We propose to require EHR technology to be capable of enabling images formatted according to the Digital Imaging and Communications in Medicine (DICOM) standard[11] to be downloaded and transmitted to a third party. We believe this specific capability has the potential to empower patients to play a greater role in their own care coordination and could help assist in reducing the amount of redundant and duplicative imaging-oriented tests performed. In fact, the National Institutes of Health has recently funded activities focused on personally controlled sharing of medical images[12] and published a solicitation notice on the same topic.[13]

We believe that all patients should have an equal opportunity to access their electronic health information without barriers or diminished functionality or quality. Thus, after consultation with the HHS Office for Civil Rights and HHS Office on Disability and reviewing the efforts of other Federal agencies, we propose that the viewing capability must meet Level AA conformance with the most recent set of the Web Content Accessibility Guidelines (WCAG). Federal agencies are considering, or proposing to adopt, WCAG 2.0 Level AA conformance for industries and technology they regulate. The Architectural and Transportation Barriers Compliance Board (Access Board) is considering applying WCAG 2.0 Level AA conformance

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[11] ftp://medical.nema.org/medical/dicom/2011/
[12] http://report.nih.gov/recovery/investmentreports/ViewARRAInvRpt.aspx?csid=211
[13] https://www.fbo.gov/index?s=opportunity&mode=form&id=ccb2340f4d8711b16f9e625b6b519371&tab=core&_cview=0 [solicitation #: NHLBI-CSB-EB-2012-5-RP]

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to Federal agencies and telecommunications accessibility, which apply to telecommunication manufacturers.[14] The Department of Transportation is proposing to require WCAG 2.0 Level AA conformance for air carrier websites and airport kiosks.[15]

The WCAG were developed through an open process by the World Wide Web Consortium (W3C[16]).[17] The most recent set of guidelines (WCAG 2.0) were published in 2008 and are organized under 4 central principles with testable "success criteria": Perceivable, Operable, Understandable, and Robust.[18] Each guideline offers 3 levels of conformance: A, AA, and AAA. Level A conformance corresponds to the most basic requirements for displaying Web content. Level AA conformance provides for a stronger level of accessibility by requiring conformance with Level A success criteria as well as Level AA specific success criteria. Level AAA conformance comprises the highest level of accessibility within the WCAG guidelines and includes all Level A and Level AA success criteria as well as success criteria unique to Level AAA. We are proposing compliance with Level AA because it provides a stronger level of accessibility and addresses areas of importance to the disabled community that are not included in Level A. For example, success criteria unique to Level AA include specifications of minimum contrast ratios for text and images of text, and a requirement that text can be resized without assistive technology up to 200 percent without loss of content or functionality. In addition to WCAG 2.0 Level AA conformance, we are interested in whether commenters believe

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[14] 76 FR 76640 (December 8, 2011). http://www.gpo.gov/fdsys/pkg/FR-2011-12-08/pdf/2011-31462.pdf#page=1
[15] 76 FR 59307 (September 26, 2011). http://www.gpo.gov/fdsys/pkg/FR-2011-09-26/pdf/2011-24298.pdf.

[16] http://www.w3.org/Consortium/
[17] http://www.w3.org/WAI/intro/wcag
[18] http://www.w3.org/TR/WCAG20/

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additional standards are needed for certification to ensure accessibility for the viewing capability, such as the User Agent Accessibility Guidelines (UAAG)[19]. Version 2.0 of the UAAG is designed to align with WCAG 2.0, but is currently only in draft form.

The HITSC recommended that we move to one summary care record standard. We agree with this recommendation and believe that moving to one summary care record standard would lead to increased interoperability and spur innovation. The Consolidated CDA is the most appropriate standard to achieve this goal because it was designed to be simpler and more straightforward to implement and, in relation to this rulemaking, its template structure can accommodate the formatting of a summary care record that includes all of the data elements that CMS is proposing be available to be populated in a summary care record. Accordingly, we are proposing to require that EHR technology be capable of providing the information that CMS is proposing be required in a summary care record that is provided to patients or their authorized representatives.

In certain instances in § 170.314(e)(1), we propose to require that the capability be demonstrated in accordance with the specified vocabulary standard. These vocabulary standards have been previously adopted or are proposed for adoption in this proposed rule consistent with the recommendations of the HITSC. With the exception of the four standards discussed below (LOINC, ICD-10-CM, ICD-10-PCS, and HCPCS), the vocabulary standards included in this certification criterion are discussed elsewhere in this preamble in connection with the

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[19] http://www.w3.org/WAI/intro/uaag.php

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certification criteria where the vocabulary standard is central to the required data or serves a primary purpose (e.g., RxNorm for e-prescribing).

For encounter diagnoses and procedures, we propose the use of ICD-10 (ICD-10-CM and ICD-10-PCS, respectively). We request comment, however, on whether we should be more flexible with this proposed requirement based on any potential extension of the ICD-10 compliance deadline or possible delayed enforcement approach. More specifically, we are interested in whether commenters believe it would be more appropriate to require EHR technology to be certified to a subset of ICD-10; either ICD-9 or ICD-10; or to both ICD-9 and ICD-10 for encounter diagnoses and procedures. We also ask that commenters consider these options when reviewing and commenting on the other proposed certification criteria that include these standards (i.e., § 170.314(a)(3), (b)(2), and (e)(2)). For procedures, we propose to continue to permit a choice for EHR technology certification, either ICD-10-PCS or the combination of Health Care Financing Administration Common Procedure Coding System (HCPCS) and Current Procedural Terminology, Fourth Edition (CPT–4). For outbound messages including laboratory tests, EHR technology must be capable of transmitting the tests performed in LOINC 2.38 to meet this certification criterion and for all other proposed certification criteria that include the capability to transmit laboratory tests in the LOINC 2.38 standard. We propose to adopt the "view, download, and transmit to 3rd party" certification criterion at § 170.314(e)(1) and the ICD-10-PCS and ICD-10-CM standards at § 170.207(b)(3) and (m), respectively.

In August 2011, we published an advance notice of proposed rulemaking (ANPRM) (76 FR 48769) to seek public comment on the metadata standards we could propose for adoption in this proposed rule. In the ANPRM, we stated:

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"We are considering whether to propose, as a requirement for certification, that EHR technology be capable of applying the metadata standards in the context of the use case selected by the HIT Policy Committee (i.e., when a patient downloads a summary care record from a health care provider's EHR technology or requests for it to be transmitted to their PHR). For example, if a patient seeks to obtain an electronic copy of her health information, her doctor's EHR technology would have to be capable of creating a summary care record and subsequently assigning metadata to the summary care record before the patient receives it."

We noted in the ANPRM that, after reviewing public comments, we would re-consider our proposals and use this proposed rule to seek further public comment on more specific proposals. Given our proposed adoption of solely the Consolidated CDA standard for summary care records and the fact that this standard requires EHR technology developers to follow the requirements specified in the "US Realm Header" (section 2.1 of the Consolidated CDA), which includes the metadata elements we were considering for patient identity and provenance, we do not believe that it would be necessary or prudent to propose separate metadata standards at this time. Accordingly, we believe that for the first use case we identified in the ANPRM our policy goals can be accomplished through the adoption of the Consolidated CDA standard. This approach also addresses the HITSC's recommendation for this certification criterion to include "data provenance" with any health information that is downloaded. Finally, consistent with public comments on the ANPRM, we are not proposing metadata standards for "privacy" and intend to continue to work with the industry to further flesh out what such metadata standards could be. However, we note that one of the metadata elements required by the US Realm Header is the ConfidentialityCode which should be populated with a value from the value set of

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BasicConfidentialityKind (this value set includes 3 possible values: "N" Normal, "R" Restricted, and "V" Very Restricted). We intend to continue to work with SDOs and other stakeholders on some of the HITSC recommendations discussed in the ANPRM relative to the CDA header. For example, we welcome comment on, and will consider moving from, the use of object identifiers (OIDs) to uniform resource identifiers (URIs).

- **Automated numerator recording**

MU Objective N/A
2014 Edition EHR Certification Criterion § 170.314(g)(1) (Automated numerator recording)

To complement the "automated measure calculation" certification criterion adopted at § 170.302(n) (and now proposed for adoption as a revised certification criterion at § 170.314(g)(2)), we propose to adopt a 2014 Edition EHR certification criterion which would apply solely to EHR Modules that include capabilities for an MU objective with a percentage-based measure. This certification criterion would focus on the EHR Module's capability to automatically record the numerator for those measures. While a Complete EHR would need to be capable of meeting the automated measure calculation certification criterion which requires the capability to accurately calculate MU denominators, we do not believe that it would be practicable for an EHR Module to do the same because, in most cases, an EHR Module would likely be unable to record or have access to an accurate denominator, especially in the case where multiple certified EHR Modules are being used by an EP, EH, or CAH. That said, we believe that EHR Modules presented for certification to certification criteria that include capabilities for supporting an MU objective with a percentage-based measure should at least be

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able to readily and accurately record the numerator for those capabilities. Therefore, we propose to adopt this new certification criterion at § 170.314(g)(1).

As noted, a Complete EHR would need to be certified to the proposed automated measure calculation criterion (§ 170.314(g)(2)). We would consider a Complete EHR certified to § 170.314(g)(2) as having met the proposed automated numerator recording certification criterion at § 170.314(g)(1) and, thus, there would be no need for the Complete EHR to be separately certified to § 170.314(g)(1). However, as discussed under section IV.C.2 of this preamble, EHR Modules that are presented for certification to certification criteria that include capabilities for supporting an MU objective with a percentage-based measure would need to be certified to this proposed certification criterion. This would not preclude an EHR Module from being certified to the automated measure calculation certification criterion if the EHR Module developer sought such certification. In such instances, similar to our stance on Complete EHR certification to § 170.314(g)(2), there would be no need for the EHR Module to be separately certified to § 170.314(g)(1).

- **Non-percentage-based measure use report**

MU Objective N/A
2014 Edition EHR Certification Criterion § 170.314(g)(3) (Non-percentage-based measure use report) **Standard** § 170.210(g) (synchronized clocks)

To further complement the certification criteria proposed for adoption at § 170.314(g)(1) and (g)(2), we propose to adopt a new 2014 Edition EHR certification criterion at § 170.314(g)(3) which would apply to any EHR technology presented for certification that

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includes capabilities associated with MU objectives and measures that are not percentage based. This certification criterion would focus on a Complete EHR's or EHR Module's capability to record that a user had certain EHR technology capabilities enabled during an EHR reporting period and had used those capabilities to demonstrate MU. We also propose to require that the date and time be recorded according to the "synchronized clocks" standard that we explain in more detail in the preamble discussion of the new "view, download, and transmit to 3rd party" certification criterion proposed for adoption at § 170.314(e)(1).

In consultation with CMS, we believe that EPs, EHs, and CAHs would benefit from this type of capability being required as a condition of certification. Additionally, we believe that such a capability could provide EPs, EHs, and CAHs with valuable evidence in the event of a MU audit. We propose that any EHR technology presented for certification to any one of the following certification criteria would need to be certified to this certification criterion.

170.314(a)(2)	Drug-drug, drug-allergy interaction checks
170.314(a)(8)	Clinical decision support
170.314(a)(10)	Drug-formulary checks
170.314(a)(14)	Patient lists
170.314(a)(17)	Electronic medication administration record
170.314(f)(2)	Transmission to immunization registries
170.314(f)(4)	Transmission to public health agencies (surveillance)
170.314(f)(6)	Transmission of reportable laboratory tests and values/results
170.314(f)(8)	Transmission to cancer registries

EHR technology that is presented for certification to any of these certification criteria would need to be able to record the date and time and enable a user to create a report that indicates when each capability was enabled and disabled, and/or executed. We intend for the

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term "executed" to apply only to the certification criteria in the table above except those proposed for adoption at § 170.314(a)(2) and (17). The MU measures associated with § 170.314(a)(2) and (17) require that the capabilities CEHRT include be "enabled" or "implemented" for an entire EHR reporting period. Moreover, they do not require unique action(s) by an EP, EH, or CAH. Last, we clarify that the privacy and security certification criteria proposed for adoption in § 170.314(d) which are associated with the MU objective "protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities" and measure which is not percentage based would not be included within the scope of this certification criterion. We do not believe that EHR technology would be able to capture that a security risk analysis was performed by an EP, EH, or CAH except through a manual entry by the EP, EH, or CAH affirming the completion of the risk analysis.

- **Safety-enhanced design**

MU Objective N/A
2014 Edition EHR Certification Criterion § 170.314(g)(4) (Safety-enhanced design)

The International Organization for Standardization (ISO) defines usability as "[t]he extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use."[20] Many industry stakeholders have acknowledged that a gap exists between optimal usability and the usability

[20] ISO 9241-11

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offered by some current EHR technologies. However, to date, little consensus has been reached on what might help close this gap and what role, if any, the Federal government should play related to the usability of EHR technology. In June 2011, the HITPC issued a report to ONC that explored the challenges associated with EHR technology usability and user-centered design (UCD). In its report, the HITPC identified certain "desired outcomes of improved usability" including improved safety and reduced cost, clinician frustration, training time, and cognitive load for clinical and non-clinical users alike.

In November 2011, the Institute of Medicine (IOM) released a report titled "Health IT and Patient Safety: Building Safe Systems for Better Care," in which the usability of EHR technology and quality management was often referenced. The IOM noted that "[w]hile many vendors already have some types of quality management principles and processes in place, not all vendors do and to what standard they are held is unknown." Moreover, given this concern, the IOM recommended that "[t]he Secretary of HHS should specify the quality and risk management process requirements that health IT vendors must adopt, with a particular focus on human factors, safety culture, and usability."

We fundamentally agree with the sentiment expressed by both the HITPC and the IOM. As we consider the shared goals stated by stakeholders from all sides of this discussion, we believe that a significant first step toward improving overall usability is to focus on the process of UCD. While valid and reliable usability measurements exist, including those specified in NISTIR 7804 "Technical Evaluation, Testing and Validation of the Usability of Electronic

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Health Records,"[21] we are concerned that it would be inappropriate at this juncture for ONC to seek to measure EHR technology in this way. Recognizing that EHR technologies exist and are in use today, we have prioritized eight certification criteria[22] and associated capabilities to which this proposed certification criterion would require UCD to have been applied. We chose these eight because we believe they pose the greatest risk for patient harm and, therefore, the greatest immediate opportunity for error prevention and user experience improvement. We believe this approach limits this new certification criterion's potential burden while providing for a much needed focus on the application of UCD to medication-related certification criteria.

The methods for how an EHR technology developer could employ UCD are well defined in documents and requirements such as ISO 9241-11, ISO 13407, ISO 16982, and NISTIR 7741. Presently, we believe it is best to enable EHR technology developers to choose their UCD approach and not to prescribe one or more specific UCD processes that would be required to meet this certification criterion. Thus, the use of any one of these processes to apply UCD would meet this certification criterion. Moreover, we acknowledge and expect that EHR technology developers who have already followed UCD in past development efforts for the identified certification criteria would be performing a retrospective analysis to document for the purposes of testing and certification that UCD had been applied to the specified certification criteria. However, if UCD had not been previously applied to capabilities associated with any of the

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[21] http://www.nist.gov/healthcare/usability

[22] § 170.314(a)(1) (CPOE); § 170.314(a)(2) (Drug-drug, drug-allergy interaction checks); § 170.314(a)(6) (Medication list); § 170.314(a)(7) (Medication allergy list); § 170.314(a)(8) (Clinical decision support); § 170.314(a)(17) (Electronic medication administration record); § 170.314(b)(3) (Electronic prescribing); and § 170.314(b)(4) (Clinical information reconciliation).

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certification criteria proposed, the EHR technology would ultimately need to have such UCD processes applied before it would be able to be certified.

We propose to adopt this certification criterion at § 170.314(g)(4). If we adopt this certification criterion in a final rule, we anticipate that testing[23] to this certification criterion would entail EHR technology developers documenting that their UCD incorporates, in any form or format, all of the data elements defined in the Customized Common Industry Format Template for EHR Usability Testing (NISTIR 7742). We note that with respect to demonstrating compliance with this certification criterion that this information would need to be available to an ONC-ACB for review. This documentation would become a component of the publicly available testing results on which a certification is based (see section IV.D of this preamble for our proposal to make the test results used for certification publicly available).

In addition to our proposed safety-enhanced design certification criterion, we request comment on two other safety-related certification criteria under consideration for adoption by the Secretary.

Quality Systems

The IOM also recommended that we "[establish] quality management principles and processes in health IT." Working with other Federal agencies, we intend to publish a quality management document that is customized for the EHR technology development lifecycle and expresses similar principles to those included in ISO 9001, IEC 62304, ISO 13485, ISO 9001, and 21 CFR 820. The document would provide specific guidance to EHR technology developers

[23] The National Voluntary Laboratory Accreditation Program, as administered by NIST, is responsible for testing under the permanent certification program ("ONC HIT Certification Program") (76 FR 1278).

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on best practices in software design processes in a way that mirrors established quality management systems, but would be customized for the development of EHR technology. We understand that some EHR technology developers already have processes like these in place, but do not believe, especially in light of the IOM recommendation, that the EHR technology industry as a whole consistently follows such processes. We expect that this document would be published around the same time as this proposed rule and would be available for public comment.[24] Accordingly, we are considering including in the final rule an additional certification criterion that would require an EHR technology developer to document how their EHR technology development processes either align with, or deviate from, the quality management principles and processes that would be expressed in the document. We emphasize that this certification criterion would not require EHR technology developers to comply with all of the document's quality management principles and processes in order to be certified. Rather, to satisfy the certification criterion, EHR technology developers would need to review their current processes and document how they do or do not meet principles and processes specified in the document (and where they do not, what alternative processes they use, if any). We expect that this documentation would be submitted as part of testing and would become a component of the publicly available testing results on which a certification is based.

We are considering adopting this additional certification criterion as part of the 2014 Edition EHR certification criteria for three reasons. First, all EHR technology developers that seek certification of their EHR technology would become familiar with quality management

[24] The quality management document will be published on ONC's website during the public comment period of this proposed rule and notice of its availability will be made through a notice published in the Federal Register.

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processes. Second, the public disclosure of the quality management processes used by EHR technology developers would provide transparency to purchasers and stakeholders, which could inform and improve the development and certification of EHR technology. Last, EHR technology developers' compliance with the certification criterion would establish a foundation for the adoption of a more rigorous certification criterion for quality management processes in the future without placing a significant burden on developers. We request public comment on this additional certification criterion and the feasibility of requiring EHR technology developers to document their current processes.

Patient Safety Events

We are considering adopting a certification criterion (as mandatory or optional) that would require EHR technology to enable a user to generate a file in accordance with the data required by the Agency for Healthcare Research and Quality (AHRQ) Common Format[25], including the "Device or Medical/Surgical Supply, including HIT v1.1a." [26] The Common Formats are designed to capture information about patient safety events. In line with IOM's recommendations, we believe that requiring this capability for certification could be an essential first step in creating the infrastructure that would support the reporting of potential adverse events involving EHR technology to patient safety organizations (PSOs). We request public comment on whether we should adopt such a certification criterion and what, if any, challenges EHR technology developers would encounter in implementing this capability.

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[25] http://www.pso.ahrq.gov/formats/commonfmt.htm
[26] https://psoppc.org/web/patientsafety/ahrq-common-formats-device-or-medical/surgical-supply-including-hit-device

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b. Ambulatory Setting

We propose to adopt 3 certification criteria that would be new certification criteria for the ambulatory setting.

- **<u>Secure messaging</u>**

MU Objective Use secure electronic messaging to communicate with patients on relevant health information.
2014 Edition EHR Certification Criterion § 170.314(e)(3) (Ambulatory setting only – secure messaging) **Standard** § 170.210(f)

The HITSC recommended two versions (based in large part on the work of the Implementation Workgroup and Privacy and Security Workgroup) of the 2014 Edition EHR certification criterion for secure messaging to support the MU objective and measure recommended by the HITPC, and now proposed by CMS. We agree with the direction provided by both recommendations and have merged the two into a refined certification criterion. We have also included what we believe should be the baseline standard in terms of encryption and hashing algorithms used to implement secure messaging. More specifically, we are proposing that only those identified in FIPS 140-2 Annex A be permitted to be used to meet this criterion. As such, we propose to adopt a new standard in § 170.210(f) to refer to FIPS 140-2 Annex A's encryption and hashing algorithms. Additionally, we are proposing, consistent with the HITSC's recommendations, that methods for meeting this certification criterion could include, but would not be limited to, designing EHR technology to meet the following standards: IETF RFC 2246 (TLS 1.0) and SMTP/SMIME as well as implementation specifications such as NIST Special

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Publication 800-52 ("Guidelines for the Selection and Use of TLS Implementations") and specifications developed as part of nationwide health information network initiatives. We propose to adopt this new certification criterion at § 170.314(e)(3).

- **Cancer registry**

MU Objective Capability to identify and report cancer cases to a State cancer registry, except where prohibited, and in accordance with applicable law and practice.
2014 Edition EHR Certification Criteria § 170.314(f)(7) (Ambulatory setting only – cancer case information) § 170.314(f)(8) (Ambulatory setting only – transmission to cancer registries) **Standards and Implementation Specifications** § 170.205(i) (HL7 CDA, Release 2 and Implementation Guide for Healthcare Provider Reporting to Central Cancer Registries, Draft, February 2012); § 170.207(a)(3) (SNOMED CT® International Release January 2012); and § 170.207(g) (LOINC version 2.38)

The HITPC provided recommendations that CMS consider requiring EPs to submit reportable cancer conditions. CMS has proposed this as a new objective and measure for EPs. We propose to adopt two new 2014 Edition EHR certification criteria to enable the performance of the objective and measure with the use of CEHRT. The proposed adoption of two criteria, one focused on the data capture and the other focused on the formatting and transmission of such data in the proposed standards is consistent with the HITSC recommendation to consider splitting the public health certification criteria in this manner. In consultation with the Centers for Disease Control and Prevention (CDC), we propose to adopt HL7 CDA, Release 2 as the content exchange standard. We also propose to adopt SNOMED CT® International Release January 2012 and LOINC version 2.38 as the vocabulary standards. Additionally, we propose to adopt the Implementation Guide for Healthcare Provider Reporting to Central Cancer Registries, Draft, February 2012. This implementation guide was jointly developed by the CDC and the

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North American Association of Central Cancer Registries (NAACCR) and is available at http://www.cdc.gov/ehrmeaningfuluse. CDC will consider comments received on this proposed rule in finalizing the guide. Assuming CDC finalizes the guide, we would consider adopting the final version of the guide in a final rule with consideration of public comment on the appropriateness of the guide for certification.

We propose to adopt these certification criteria at § 170.314(f)(7) and (8). We propose to adopt the HL7 CDA standard and implementation guide at § 170.205(i). We propose to adopt SNOMED CT® International Release January 2012 and LOINC version 2.38 at § 170.207(a)(3) and (g), respectively.

c. Inpatient Setting

We propose to adopt 3 certification criteria that would be new certification criteria for the inpatient setting.

- **Electronic medication administration record**

MU Objective Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR).
2014 Edition EHR Certification Criterion § 170.314(a)(17) (Inpatient setting only – electronic medication administration record) **Standard** § 170.210(g) (synchronized clocks)

The HITSC recommended a new 2014 Edition EHR certification criterion to support the MU objective and measure recommended by the HITPC, now proposed by CMS, for EHs and CAHs to automatically track medications from order to administration. We have refined the recommended certification criterion to clearly state the capabilities that must be tested and

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certified. The certification criterion continues to reflect the intent of the HITPC and HITSC, including the basic "rights" (right patient, right medication, right dose, right route, and right time). It is our intent, consistent with the HITSC's recommendation, to permit a range of acceptable technical solutions for certification. However, we wish to make clear that in order to demonstrate compliance with this certification criterion, EHR technology must enable a user to electronically confirm the "rights" in relation to the medication(s) to be administered in combination with an assistive technology (such as bar-coding, location tracking, and radio-frequency identification (RFID)) which provides automated information on the "rights." An electronic "checklist" through which a user would manually confirm the "rights" without any automated and assistive feedback from EHR technology would not be sufficient to demonstrate compliance with this certification criterion. We believe this clarification and distinction are important because an electronic medication administration record together with some type of assistive technology has been shown to decrease medication errors[27] and it is not our intent to digitize a paper process that would not realize the safety benefits that could be provided with the use of an assistive technology. We propose to adopt this new certification criterion at § 170.314(a)(17) with inclusion of the "synchronized clocks" standard as discussed earlier in this preamble under the "view, download, and transmit to 3rd party" certification criterion.

- **Electronic prescribing**

MU Objective
Generate and transmit permissible discharge prescriptions electronically (eRx).

[27] Poon EG, Keohane CA, Yoon CS, et al. (2010) Effect of Bar-Code Technology on the Safety of Medication Administration *New England Journal of Medicine* 362:1698-1707.

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2014 Edition EHR Certification Criterion § 170.314(b)(3) (Electronic prescribing) **Standards** § 170.205(b)(2) (NCPDP SCRIPT version 10.6) and § 170.207(h) (RxNorm February 6, 2012 Release)

In response to the HITPC's recommendation for a new MU Stage 2 objective and measure for e-prescribing of discharge medications by EHs and CAHs (now proposed by CMS), the HITSC recommended a certification criterion for electronic prescribing of discharge medications. As part of the HITSC recommendation, it was recommended that we require as a condition of certification for the inpatient setting that certain HL7 standards be adopted for exchange within a legal entity. We did not accept this part of the recommendation because it is inconsistent with our approach of adopting standards for the electronic exchange of health information between different legal entities. We are proposing to adopt for the inpatient setting the same revised electronic prescribing certification criterion we propose to adopt for the ambulatory setting (i.e., we propose to adopt the certification criterion at § 170.314(b)(3) for both settings). We discuss this revised certification criterion in further detail under the ambulatory setting subsection of the revised certification criteria section of this preamble.

- **Transmission of electronic laboratory tests and values/results to ambulatory providers**

MU Objective Provide structured electronic laboratory results to eligible professionals.
2014 Edition EHR Certification Criterion § 170.314(b)(6) (Inpatient setting only – transmission of electronic laboratory tests and values/results to ambulatory providers) **Standards and Implementation Specifications** § 170.205(k) (HL7 2.5.1 and HL7 Version 2.5.1 Implementation Guide: Standards and Interoperability Framework Lab Results Interface, Release 1 (US Realm)); and § 170.207(g) (LOINC version 2.38)

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The HITSC recommended a new 2014 Edition EHR certification criterion to support the MU objective and measure recommended by the HITPC for EHs and CAHs to send electronic laboratory tests and values/results to eligible professionals. CMS has not proposed the MU objective and measure for Stage 2, but has requested public comment on whether the objective and measure should be incorporated into Stage 2.

We have refined the recommended certification criterion, primarily to include the standards and implementation guide recommended by the HITSC and HITPC. The HITSC recommended that we consider requiring the Standards and Interoperability Framework Laboratory Results Interface Initiative (S&I Framework LRI)[28]. The S&I Framework LRI was created to reduce the variability of ambulatory laboratory interfaces as well as reduce the cost and time to initiate new electronic laboratory tests and values/results interfaces between clinical labs and ambulatory EHR technology. The S&I Framework LRI focused on the identification of a consistent set of data content that would need to be exchanged when laboratory tests and values/results are electronically delivered. We believe that our proposal to require for certification that inpatient EHR technology be capable of creating for transmission laboratory tests and values/results formatted in accordance with the LRI specification could make it more cost effective for electronic laboratory results interfaces to be set up in an ambulatory setting (i.e., minimal additional configuration and little to no additional/custom mapping) and that the electronic exchange of laboratory tests and values/results would improve.

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[28] http://wiki.siframework.org/Lab+Results+Interface+%28LRI%29+Initiative

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To further reduce costs and improve the electronic exchange of laboratory tests and values/results, we are building off the HITSC recommendation and are proposing to adopt a revised certification criterion for the ambulatory setting that would require EHR technology to be capable of incorporating laboratory tests and values/results according to the standards and implementation specifications discussed here, including the LRI implementation guide (see discussion of proposed § 170.314(b)(5) under the revised certification criteria section below). We are also proposing to adopt LOINC version 2.38 as the vocabulary standard. The HITPC recommended using LOINC where available and the HITSC expressed agreement with this approach during their deliberations. Moreover, the LRI implementation guide requires the use of LOINC for laboratory tests. With respect to testing and certification for this certification criterion, we expect, among other aspects, that inpatient EHR technology would need to demonstrate its compliance with the "Common Profile Component" and other required profiles included within the LRI implementation guide.

We propose to adopt this new certification criteria for the 2014 Edition EHR certification criteria at § 170.314(b)(6). We propose to adopt the HL7 2.5.1 standard and LRI implementation guide at § 170.205(k), acknowledging that the LRI specification is currently undergoing HL7 balloting. We intend to continue to monitor its progress and anticipate that a completed specification will be available before we publish a final rule. We propose to adopt LOINC version 2.38 at § 170.207(g).

5. Revised Certification Criteria

In the Permanent Certification Program final rule (76 FR 1302) we described revised certification criteria as certification criteria previously adopted by the Secretary that are modified

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to add, remove, or otherwise alter the specified capabilities and/or the standard(s) or implementation specification(s) referred to by the certification criteria. We also stated that revised certification criteria may also include certification criteria that were previously adopted as optional but are subsequently adopted as mandatory. Again, based on our experience in trying to appropriately categorize the certification criteria we propose to be part of the 2014 Edition EHR certification criteria we have determined that our description of revised certification criteria needs to be refined. Accordingly, we list below the factors that we would consider when determining whether a certification criterion is "revised:"

- The certification criterion includes changes to capabilities that were specified in the previously adopted certification criterion;
- The certification criterion has a new mandatory capability that was not included in the previously adopted certification criterion; or
- The certification criterion was previously adopted as "optional" for a particular setting and is subsequently adopted as "mandatory" for that setting.

To clarify, in some cases, a certification criterion could be both "revised" and "new." For example, a previously adopted certification criterion could have been adopted for only the ambulatory setting. Subsequently, we could revise the certification criterion by adding a new capability and making it mandatory for both the ambulatory and inpatient settings. Once adopted, the certification criterion would be "new" for the inpatient setting and "revised" for the ambulatory setting.

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We propose to adopt revised certification criteria that will support proposed revisions to MU objectives and measures and that will increase the interoperability, functionality, utility, safety, and security of EHR technology.

a. Ambulatory and Inpatient Setting

We propose to adopt the following revised certification criteria for both the ambulatory and inpatient settings.

- **Drug-drug, drug-allergy interaction checks**

MU Objective Implement drug-drug and drug-allergy interaction checks.
2014 Edition EHR Certification Criterion § 170.314(a)(2) (Drug-drug, drug-allergy interaction checks)

The HITSC recommended a revised certification criterion for the 2014 Edition EHR certification criteria to eliminate the ability for EHR technology to permit users to adjust drug-allergy interaction checks and to provide additional clarity for the capabilities that EHR technology must demonstrate. The HITSC reasoned that it would be clinically inappropriate to allow users to adjust drug-allergy interaction checks. The HITSC also reasoned that clarity could be provided with additional revisions. The HITSC recommended replacing the term "real-time" with "before the order is executed." The HITSC also recommended revising the language to specify that notifications should happen during CPOE. Additionally, the HITSC recommended specifying that the level of severity of the notifications is what can be adjusted. The HITSC also recommended limiting the ability to make adjustments to an identified set of users or available as a system administrative function. Last, the HITSC recommended that drug-allergy contraindications should be interpreted to include adverse reaction contraindications. We

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agree with all of the HITSC's recommendations. We have revised and refined the language of the HITSC's recommended certification criterion, but otherwise have included all the recommended capabilities. As to the phrase "identified set of users," we clarify that the EHR technology must enable an EP, EH, and CAH to assign only certain users (e.g., system administrator) with the ability to adjust severity levels. In other certification criteria that use the phrase "identified set of users," a similar principle would apply (i.e., assigning the capability to only certain users). We believe this revised language more clearly indicates the intent of the criterion. We propose to adopt this revised certification criterion at § 170.314(a)(2).

- **Demographics**

MU Objective Record the following demographics: preferred language; gender; race; ethnicity; date of birth; and for the inpatient setting only, date and preliminary cause of death in the event of mortality in the EH or CAH.
2014 Edition EHR Certification Criterion § 170.314(a)(3) (Demographics) **Standards** § 170.207(f)(OMB standards); § 170.207(j) (ISO 639-1:2002); and § 170.207(k) (ICD-10-CM)

The HITSC recommended that we adopt a revised "demographics" certification criterion that requires the use of ISO 639-1 as the vocabulary standard for preferred language.[29] We agree with the HITSC's recommendation because it appropriately limits the burden on EHR technology developers since the ISO 639-1 code set which uses an alpha-2 code for language names is roughly 40% that of the ISO 639-2 code set which uses an alpha-3 code. We also propose to adopt ICD-10-CM for recording the preliminary cause of death. We believe that the

[29] http://www.loc.gov/standards/iso639-2/php/code_list.php -- Also note that The Library of Congress has been designated the ISO 639-2/RA for the purpose of processing requests for alpha-3 language codes comprising the International Standard.

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use of ICD-10-CM will permit additional specificity for this data element. As for the Office of Management and Budget (OMB) standards for the classification of federal data on race and ethnicity, we note that the standard for classifying federal data according to race and ethnicity requires that the option for selecting one or more racial designations be provided. The standard also permits the use of more than the minimum standard categories for race and ethnicity as long as the data can be aggregated to the minimum standard categories, which would be confirmed through the testing and certification processes. We also propose to clarify the reference to the adopted standard as the "Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity," which was issued on October 30, 1997, as referenced at § 170.207(f). Last, we propose to revise this criterion to require that EHR technology be capable of recording that a patient declined to specify his or her race, ethnicity, and/or preferred language. This proposed revision would ensure inclusion of such patients in the numerator of the MU percentage-based measure. We propose to adopt this revised certification criterion for the 2014 Edition EHR certification criteria at § 170.314(a)(3) and the proposed standards at § 170.207(j) and (k).

- **Problem list**

MU Objective Maintain an up-to-date problem list of current and active diagnoses.
2014 Edition EHR Certification Criterion § 170.314(a)(5) (Problem list) **Standards** § 170.207(a)(3) (SNOMED CT® International Release January 2012)

Consistent with our discussion in the preamble section titled "Explanation and Revision of Terms Used in Certification Criteria," we have replaced the terms "modify" and "retrieve" in

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the recommended criterion with "change" and "access," respectively. Further, consistent with the interpretation we provided in the S&CC July 2010 final rule, we are reiterating and clarifying that "longitudinal care" is used to mean over an extended period of time. For the ambulatory setting, this would be over multiple office visits. For the inpatient setting, this would be for the duration of an entire hospitalization, which would include the patient moving to different wards or units (e.g., emergency department, intensive care, and cardiology) within the hospital during the hospitalization. The HITSC suggested that we consider longitudinal care to cover multiple hospitalizations, but we believe this could be difficult to achieve and may not offer added value based on the duration of time between a patient's hospitalizations and the reason for the hospitalizations. To note, our clarification of the meaning of longitudinal care applies equally to its use in other certification criteria, such as "medication list" and "medication allergy list." If we were to change our interpretation of longitudinal care as suggested by the HITSC, it would apply to these certification criteria as well and could constitute a change in the capabilities included in the criteria, which in turn would cause them to become revised certification criteria. We welcome comments on our interpretation of longitudinal care. We also welcome comments on whether a term other than "longitudinal care" could and should be used to express the capability required by this certification criterion and the other referenced certification criteria ("medication list" and "medication allergy list"). We understand that the longitudinal care description we use for the purposes of EHR technology certification may differ from the

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meaning that providers attribute to it, including the meaning given to it by the Longitudinal Coordination of Care Workgroup within the Standards and Interoperability Framework[30].

The HITSC recommended that we adopt the appropriate version of SNOMED CT® for the revised criterion. We have determined, and propose to adopt, the International Release January 2012 version of SNOMED CT®. This is the most recent version of the code set.[31] The HITSC also recommended that ICD-9-CM be replaced with ICD-10-CM. We agree that the use of ICD-9-CM should no longer be required due to the pending move to ICD-10-CM. However, we do not believe it would be appropriate to require the use of ICD-10-CM for problem lists. SNOMED CT® (and not ICD-10-CM) will be required for calculation of CQMs. Therefore, we propose that only SNOMED CT® is an appropriate standard for the recording of patient problems in a problem list. This does not, however, preclude the use of ICD-10-CM for the capture and/or transmission of encounter billing diagnoses. We propose to adopt this revised certification criterion for the 2014 Edition EHR certification criteria at § 170.314(a)(5) and the International Release January 2012 version of SNOMED CT® at § 170.207(a)(3).

- **Clinical decision support**

MU Objective Use clinical decision support to improve performance on high-priority health conditions.

[30] http://wiki.siframework.org/Longitudinal+Coordination+of+Care+WG

[31] http://www.nlm.nih.gov/research/umls/licensedcontent/snomedctfiles.html

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2014 Edition EHR Certification Criterion
§ 170.314(a)(8) (Clinical decision support)

Standard
§ 170.204(b)(1) (HL7 Context-Aware Knowledge Retrieval ("Infobutton") Standard, International Normative Edition 2010)

The HITSC recommended a revised clinical decision support (CDS) certification criterion for the 2014 Edition EHR certification criteria. We have refined the recommended certification criterion to provide a clearer understanding of the capabilities that must be tested and certified and to provide greater flexibility to EHR technology developers in designing EHR technology to meet this proposed certification criterion. We also propose to require the use of the HL7 Context-Aware Knowledge Retrieval ("Infobutton") Standard, International Normative Edition 2010, for retrieving diagnostic or therapeutic reference information and specifically require the use of CDS with the incorporation of a summary care record.

We have replaced the term "clinical decision support rule" used in the 2011 Edition EHR certification criteria and the HITSC recommended criterion with the term "clinical decision support intervention" to better align with, and clearly allow for, the variety of decision support mechanisms available that help improve clinical performance and outcomes. A CDS intervention is not simply an alert, notification, or explicit care suggestion. Rather, it should be more broadly interpreted as the user-facing representation of evidence-based clinical guidance. Our goal in clarifying the nomenclature is to focus more on the representation of the guidance (the CDS intervention) that the EHR technology should offer to the user rather than prescribe the form of either the logical representation of the clinical guidance or how the intervention interacts with the user.

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Referential sources such as medical texts, primary research articles, and clinical practice guidelines have long been available in electronic form, but the means and manner of accessing them have historically been disconnected from the points in providers' patient care workflows when the immediate availability of the reference sources would optimize clinical decisions. Increasingly, these tools are being made available through links in EHRs, offering information at relevant points within the clinical workflow. The Infobutton standard has been in active use for several years with many reference content vendors now providing their products in this form, and we propose to adopt its most recent edition (International Normative Edition 2010) in order to enable a user to retrieve diagnostic or therapeutic reference information. The use of standard reference information retrieval formats will accelerate the delivery of content to providers and hospitals, and will enhance the flexibility of such implementations because these formats reduce the need to "hard wire" the content databases to installed EHR technology. This flexibility allows EPs, EHs, and CAHs more choices and easier migration across content providers, encouraging innovation and competitiveness among these content providers.

We believe it is important for CDS interventions to be triggered when new information is incorporated into EHR technology as a result of a care transition. Therefore, we are proposing that EHR technology enable interventions to be triggered when the specified data elements are incorporated into a summary care record pursuant to the capability specified at § 170.314(b)(1) (transitions of care – incorporate summary care record). We are also considering whether EHR technology should be capable of importing or updating value sets for the expression of CDS vocabulary elements using the HL7 Common Terminology Services, Revision 1, standard. We

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request comment on industry readiness to adopt this standard and on the benefits it could provide if required as a part of this certification criterion.

Consistent with the HITSC stated intent, for EHR technology to be certified to this criterion it must be capable of providing interventions and the reference resources in paragraph (a)(8)(ii)(A) of § 170.314 by leveraging each one or any combination of the patient-specific data elements listed in paragraphs (a)(8)(i) and (ii) of § 170.314 as well as one or any combination of the user context data points listed in paragraph (a)(8)(iii)(A) of § 170.314. EHR technology must also be capable of generating interventions automatically and electronically when a user is interacting with the EHR technology. Last, the HITSC recommended that the source attributes of suggested interventions be displayed or available for users. We agree that this capability is important, but believe further clarification is necessary regarding what types of information must be provided for EHR technology to meet this criterion. We believe that, at a minimum, a user should be able to review the: bibliographic citation (i.e., the clinical research/guideline) including publication; developer of the intervention (i.e., the person or entity who translated the intervention from a clinical guideline into electronic form, for example, Company XYZ or University ABC); funding source of the intervention development; and release and, if applicable, revision date of the intervention. The availability of this information will enable the user to fully evaluate the intervention. The availability of this information will also enhance the transparency of all CDS interventions, and thus improve their utility to healthcare professionals and patients.

We propose to adopt this revised certification criterion at § 170.314(a)(8) and the Infobutton standard at § 170.204(b)(1).

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- **Patient-specific education resources**

MU Objective Use clinically relevant information from Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient.
2014 Edition EHR Certification Criterion § 170.314(a)(16) (Patient-specific education resources) **Standard** § 170.204(b)(1) (HL7 Context-Aware Knowledge Retrieval (Infobutton) Standard, International Normative Edition 2010)

We propose to adopt a revised 2014 Edition EHR certification criterion that does not have the language "as well as provide such resources to the patient" at the end of the paragraph. This language is in the 2011 Edition EHR certification criterion, but is redundant of the capability expressed at the beginning of the paragraph. Additionally, we propose to adopt the HL7 Context-Aware Knowledge Retrieval (Infobutton) Standard, International Normative Edition 2010, as the required standard. Infobutton is being increasingly used by more providers to electronically identify and provide patient-specific education resources. Therefore, we believe it is appropriate now to require EHR technology to enable a user to identify and provide patient-specific education resources based on the specified data elements and in accordance with Infobutton. We propose to adopt this revised certification criterion at § 170.314(a)(16) and the Infobutton standard at § 170.204(b)(1).

- **Transitions of care**

MU Objective The EP, EH, 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 care record for each transition of care or referral.

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2014 Edition EHR Certification Criteria
§ 170.314(b)(1) (Incorporate summary of care record)
§ 170.314(b)(2) (Create and transmit summary care record)

Standards
§ 170.205(a)(3) (Consolidated CDA); § 170.207(f) (OMB standards for the classification of federal data on race and ethnicity); § 170.207(j) (ISO 639-1:2002 (preferred language)); § 170.207(l) (smoking status types); § 170.207(a)(3) (SNOMED-CT® International Release January 2012); § 170.207(m) (ICD-10-CM); § 170.207(b)(2) (HCPCS and CPT-4) or § 170.207(b)(3) (ICD-10-PCS); § 170.207(g) (LOINC version 2.38); § 170.207(h) (RxNorm February 6, 2012 Release); and § 170.202(a)(1) (Applicability Statement for Secure Health Transport); § 170.202(a)(2) (XDR and XDM for Direct Messaging); and § 170.202(a)(3) (SOAP-Based Secure Transport RTM version 1.0)

The HITSC recommended a merged revised certification criterion for the 2014 Edition EHR certification criteria that would be generally applicable to both the ambulatory and inpatient settings, with a deviation based on the setting-specific information that would be included in the summary care record. We have made refinements to the recommended certification criterion. We believe that the criterion should be split into two separate certification criteria based on the capabilities required. We base this revision on stakeholder feedback received after the publication of the S&CC July 2010 final rule, which explained that (especially for inpatient settings) two different EHR technologies are sometimes used to perform the capabilities of incorporation and creation of a summary care record. Consequently, adopting two separate certification criteria provides developers greater flexibility for certification. The first proposed certification criterion would require EHR technology to be able to incorporate a summary care record formatted according to the Consolidated CDA, and the second certification criterion would require that EHR technology be capable of generating and transmitting a summary care record in accordance with the Consolidated CDA, with certain specified vocabulary standards, and two specified transport standards.

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For the same reasons we discussed for the new "view, download, and transmit to 3rd party" certification criterion (§ 170.314(e)(1)), we believe that adopting the Consolidated CDA for this certification criterion is advantageous since its template structure can accommodate the formatting of a summary care record that includes all of the data elements that CMS is proposing be available to be populated in a summary care record. We recognize that care plan, additional care team members, referring or transitioning provider's name and contact information as well as certain hospital discharge information are not explicitly required to be captured by separate certification criteria, unlike most other data elements included in the clinical summary. The ability to capture these data elements is both implicit and necessary to satisfy this certification criterion (as well as the other certification criteria that rely on the same data). Therefore, we considered, but have not proposed, adopting separate data capture certification criteria for each of these data elements in order to make it clear that they are required to be captured. We request public comment on whether in the final rule we should create separate certification criteria for all of these data elements. For certain other data elements in § 170.314(b)(2), we propose to require that the capability to provide the information be demonstrated in accordance with the specified vocabulary standard. These vocabulary standards have been previously adopted or are proposed for adoption in this proposed rule consistent with the recommendations of the HITSC. Additionally, we request public comment on whether we should require, as part of the "incorporate summary care record" certification criterion proposed at § 170.314(b)(1), that EHR technology be able to perform some type of demographic matching or verification between the patient in the EHR technology and the summary care record about to be incorporated. This would help prevent two different patients summary care records from being combined.

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As with the "view, download, and transmit to 3rd party" certification criterion, we are proposing that EHR technology be capable of transmitting a summary care record according to both the transport standards we propose to adopt to enable directed exchange. We believe the use of these standards is a critical first step in achieving a common means of transporting health information to support MU and future exchange needs. For this certification criterion, we also propose to adopt as an optional standard at § 170.202(a)(3) the SOAP-Based Secure Transport RTM version 1.0[32] which was developed under the nationwide health information network Exchange Initiative and to which we believe EHR technology should be able to be certified. We believe including this option provides added flexibility to those EPs, EHs, or CAHs that may seek to use EHR technology with the ability to transmit health information using SOAP as a transport standard in addition to SMTP to meet MU. While we would only permit EHR technology to be certified to these two transport standards, we intend to monitor innovation around transport and would consider including additional transport standards, such as a RESTful implementation, in this certification criterion. The inclusion of additional standards in this certification criterion would permit EHR technology to be certified to added transport standard(s) and could ultimately enable EPs, EHs, and CAHs to meet MU using EHR technology certified with the added transport standard(s).

In deciding whether additional standards are appropriate for inclusion, we would seek the HITSC's recommendation on whether a new transport standard should be adopted. We expect that the HITSC would consider, among other factors, whether the standard is "open" or non-

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[32] http://modularspecs.siframework.org/NwHIN+SOAP+Based+Secure+Transport+Artifacts

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proprietary, the public comment processes involved in its development, and any pilot testing completed/results. If the HITSC were to recommend that we adopt an additional transport standard, we believe that it should be designated as optional (consistent with our discussion at 75 FR 44599) and that we would likely pursue interim final rulemaking with comment to adopt the transport standard, which would enable EHR technology to be expeditiously certified to the transport standard and EPs, EHs, and CAHs to subsequently use EHR technology certified to this added transport standard to meet MU.

We welcome comments on whether equivalent alternative transport standards exist to the ones we propose to exclusively permit for certification. We also welcome comment on our proposed approaches for deciding whether additional transport standards are appropriate and for adopting any such standards through interim final rulemaking with comment. Additionally, in the context of the proposed limitations included as part of the proposed MU Stage 2 measure associated with this objective (which is percentage-based), we request public comment on any difficulties EHR technology developers might face in determining the numerator and denominator values to demonstrate compliance with the automated numerator calculation or automated measure calculation certification criteria we propose to adopt.

We propose to adopt these revised certification criteria for the 2014 Edition EHR certification criteria at § 170.314(b)(1) and (2).

- **Clinical information reconciliation**

MU Objective The EP, EH, 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.
2014 Edition EHR Certification Criterion § 170.314(b)(4) (Clinical information reconciliation)

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In the S&CC January 2010 interim final rule, we adopted a certification criterion for medication reconciliation that stated "[e]lectronically 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." In response to public comments requesting additional clarity and expressing concerns that EHR technology should not automatically (i.e., without any human intervention) be required to perform this capability, we revised this certification criterion (adopted at § 170.302(j) in the S&CC July 2010 final rule) to say "[e]nable a user to electronically compare two or more medication lists."

At the end of one of our responses to comments in the S&CC July 2010 final rule, we stated "[w]e 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" (75 FR 44613). We now propose to revise this certification criterion and adopt as part of the 2014 Edition EHR certification criteria an expanded version that focuses on the reconciliation of data elements in each of a patient's medication, problem, and medication allergy lists. We believe that EHR technology can be designed to assist users in remarkable ways and that reconciling information from multiple sources in a way that is assistive to a user is something at which EHR technology should excel. We also believe that with an increased focus on care coordination and use of CDS for advanced care processes, it will be significantly more important for EPs, EHs, and CAHs to have accurate and updated medication, problem, and medication allergy lists.

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Accordingly, we propose a revised certification criterion which we are labeling as "clinical information reconciliation" to express three specific capabilities that EHR technology would need to include. First, EHR technology would need to be able to electronically display the data elements from two or more sources in a manner that allows a user to view the data elements and their attributes, which must include, at a minimum, the source and last modification date of the information. For example, when assisting a user to reconcile a medication list, the EHR technology would need to display the medication(s) and, at a minimum, the source of medications (e.g., "patient" or "summary care record from XYZ") and the last modification date of the information associated with those medications. The second medication source in this example would be the current medication list the EHR technology maintains for the patient. The second specific capability EHR technology would need to include would be to enable a user to merge and remove individual data elements. For example, if a medication from source #1 and a medication from source #2 were the same, the user would be able to use EHR technology to merge such medications into a single representation. While not required or expected for certification, this capability could be designed to automatically suggest to the user which medications could be merged or removed. The third and final specific capability EHR technology would need to include would be to enable a user to review and validate the accuracy of a final set of data elements and, upon a user's confirmation, automatically update the patient's medication, problem, and/or medication allergy list. Per comments on our prior rules, we want to make clear that EHR technology's role is to be assistive and not to determine without human judgment which data elements should be reconciled. Thus, this third specific capability would require EHR technology to present a final set of merged data elements for a user to validate and

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confirm before updating the prior list. Finally, we request public comment on whether as part of this certification criterion we should require EHR technology to perform some type of demographic matching or verification between the data sources used. This would help prevent two different patients' clinical information from being reconciled. We propose to adopt this revised certification criterion at § 170.314(b)(4).

- **Incorporate laboratory tests and values/results**

MU Objective Incorporate clinical laboratory test results into Certified EHR Technology as structured data.
2014 Edition EHR Certification Criterion § 170.314(b)(5) (Incorporate laboratory tests and values/results) **Standards and Implementation Specifications** § 170.205(k) (HL7 2.5.1 and HL7 Version 2.5.1 Implementation Guide: Standards and Interoperability Framework Lab Results Interface, Release 1 (US Realm)); and § 170.207(g) (LOINC version 2.38)

The HITSC did not recommend that we revise the incorporate laboratory test results certification criterion (adopted as part of the 2011 Edition EHR certification criteria at 45 CFR 170.302(h)). We believe, however, that we should leverage the significant progress made by the S&I Framework LRI discussed under the proposed new certification criterion for the transmission of electronic laboratory tests and values/results to ambulatory providers (§ 170.314(b)(6)). This can be achieved by proposing revisions to this certification criterion for the ambulatory setting. By requiring ambulatory EHR technology to be capable of receiving laboratory tests and values/results formatted in accordance with the HL7 2.5.1 standard and the LRI implementation guide, it would be significantly easier and more cost effective for electronic laboratory results interfaces to be set up in an ambulatory setting (i.e., minimal additional configuration and little to no additional/custom mapping). Moreover, it would increase the

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likelihood that data would be properly incorporated into ambulatory EHR technology upon receipt and thus, facilitate the subsequent use of the data by the EHR technology for other purposes, such as CDS. We propose to adopt LOINC version 2.38 as the vocabulary standard, because the LRI implementation guide requires the use of LOINC for laboratory tests. We request public comment on whether the proposed standards for the ambulatory setting should also apply for the inpatient setting and whether the LRI specification (even though it was developed for an ambulatory setting) is generalizable to an inpatient setting and could be adopted for certification for that setting as well. Besides the proposed revisions discussed, we have used the term "incorporate" to replace the terms "attribute," "associate," and "link" which were used in the 2011 Edition EHR certification criterion.

We propose to adopt this revised certification criteria for the 2014 Edition EHR certification criteria at § 170.314(b)(5). We propose to adopt the HL7 2.5.1 standard and LRI implementation guide at § 170.205(k), acknowledging that the LRI specification is currently undergoing HL7 balloting. We intend to continue to monitor its progress and anticipate that a completed specification will be available before we publish a final rule. We propose to adopt LOINC version 2.38 at § 170.207(g).

- **Clinical quality measures**

MU Objective N/A
2014 Edition EHR Certification Criteria § 170.314(c)(1) (Clinical quality measures – capture and export) § 170.314(c)(2) (Clinical quality measures – incorporate and calculate) § 170.314(c)(3) (Clinical quality measures – reporting) **Standard** § 170.204(c) (NQF Quality Data Model)

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The HITSC recommended certain vocabularies and codes sets for inclusion in the Quality Data Model (QDM)[33], but did not recommend CQM certification criteria or offer recommendations for the certification of CQMs. For the 2014 Edition EHR certification criteria, we propose to revise previously adopted CQM certification criteria for the ambulatory and inpatient settings to specify more explicitly the capabilities EHR technology would need to include, focusing on:

- Data capture – the capability of EHR technology to record the data that would be required in order to calculate CQMs.
- Export – the capability of EHR technology to create a data file that can be incorporated by another EHR technology to calculate CQMs.
- Calculate – The capability of EHR technology to incorporate data (from other EHR technology where necessary) and correctly calculate the result for CQMs.
- Reporting – the capability of EHR technology to create a standard data file that can be electronically accepted by CMS.

By explicitly separating the certification of CQMs into these discrete criteria, we believe that user experiences relative to CQMs can be enhanced, the burden of capturing data elements necessary for CQMs can be reduced, and ultimately, EPs, EHs, and CAHs would be better positioned to assess in real-time the quality of care they provide.

Data Capture

Prior to the EHR Incentive Programs, measure stewards did not routinely or traditionally specify CQMs with consideration of EHR technology and its capacity to capture certain data. To assist in the effort of preparing CQMs in a more uniform manner, the National Quality Forum

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[33] Quality Data Model – National Quality Forum: http://www.qualityforum.org/Projects/h/QDS_Model/Quality_Data_Model.aspx

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(NQF), under contract with CMS, created the QDM which today serves as the information model from which new CQMs are specified. Because older CQMs were not specified as "EHR-ready" when initially developed, they specify certain data capture requirements that most EHR technologies cannot perform (or do not perform in any structured way) as well as constructs that would still require human intervention or judgment (i.e., "chart abstraction"). Despite the best efforts to "re-tool" older measures for inclusion at the beginning of the EHR Incentive Programs, we now understand that the CQMs required for certification as part of the S&CC July 2010 final rule did not, in some cases, adequately reflect a pure "EHR-ready" CQM. We have been informed that as a result EHR technology developers created new data fields and/or advised their customers to use specified (and in some cases alternative and atypical) workflows, templates, or form elements to capture these data elements in a consistent manner that would enable such data to be captured for a CQM calculation.

To build on past feedback and lessons learned, we have, with CMS, jointly conducted extensive research, consulted with subject matter experts, and received recommendations (on CQMs generally) from the HITPC and HITSC. We have sought to determine how to best address the difference between the data capture capabilities we believe most EHR technologies can reasonably perform and the requirements that measure stewards have specified in CQMs. This work has led us to believe that a more explicit and extensible approach for CQM certification is required, an approach that would be able to support the CQMs proposed for MU Stages 1 and 2 beginning in FY/CY 2014 as well as CQMs adopted for future MU stages.

The CQM lifecycle starts with the determination of data elements to be captured and the subsequent capture of clinical or demographic data. Thus, the first specific capability we

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propose for CQM certification (§ 170.314 (c)(1)(i)) focuses on the capability of EHR technology to electronically record all of the data elements that are represented in the QDM. More specifically, EHR technology would need to be able to record data in some representation that can be associated with the categories, states, and attributes represented by the QDM. As a simple example, EHR technology would need to be able to record a representation of "Medication active" or "Problem active" where the first term represents the QDM category and the second represents the QDM "state of being." In certain cases, such as in the prior example with "Problem active," the data capture necessary is already specified by another certification criterion proposed for adoption as part of the 2014 Edition EHR certification criteria (i.e., § 170.314(a)(5) to record active problems). However, in other cases an EHR technology developer would need to review the QDM to ensure the EHR technology presented for certification captures data elements that are not explicitly required to be recorded in other proposed certification criteria. Because the QDM is agnostic to health care settings (e.g., ambulatory and inpatient settings) and all of the CQMs ultimately adopted by CMS in a final rule would be based on the QDM, we do not believe that it would be necessary or possible to propose specific separate ambulatory and inpatient setting certification requirements as we have with other proposed certification criteria. Thus, all EHR technology regardless of the setting for which it is designed would need to meet § 170.314(c)(1)(i) if it is presented for certification to this certification criterion. Furthermore, because data capture is fundamental to the eventual calculation of CQMs, we have proposed an EP, EH, or CAH would need to have EHR technology certified to § 170.314(c)(1) in order to have EHR technology that meets the definition of a Base EHR (discussed later in this preamble).

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We recognize that EPs, EHs, and CAHs may employ many methods to capture the information required by CQMs and we do not intend for this certification criterion to imply that EHR technology developers would need to include manual data entry requirements if such data can be easily obtained from other electronic sources. For example, we anticipate that a patient's smoking status could be captured through a variety of approaches such as an "app" on a mobile phone, a portal, personal health record (PHR), from a patient registration kiosk, or practice management system. Regardless of the data's origin or source system, an EHR technology developer would need to show for certification that its EHR technology can electronically record a representation of that data. Moreover, we do not require for certification that data must be recorded according to a specific vocabulary standard, in recognition of, and to accommodate, environments in which local codes and terminologies have been used or where the data may originate from another electronic source. We do, however, expect that wherever possible, EHR technology developers will use standard vocabularies as this will minimize the need for mapping processes that will require development and maintenance. As described below, we expect that exported quality data would be formatted according to the standard vocabularies in the QDM, where applicable.

Alternative Data Capture Certification Options Considered

The above proposal for data capture represents the certification option that best describes the capabilities that EHR technology would need to include in order to capture the data required for the EHR Incentive Programs CQM proposals from CMS. We recognize that this option may be a suboptimal long-term solution – compared to one that can fundamentally reshape the path measure stewards take to develop "EHR-ready" CQMs. Through our work with CMS, it has

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become clear that gaps still remain between the data capture expectations of the CQMs included by CMS in its Stage 2 proposed rule and the capabilities of EHR technology. While the QDM was created in order to facilitate the development of "EHR-ready" CQMs, it is a model that reflects the data representation of CQMs and does not consider whether a given data type would or should be captured by EHR technology. We recognize that the gap between the data defined by the QDM and the data traditionally captured in EHR technology is, in some areas, broad and we request comments regarding (1) industry readiness for the expansion of EHR technology data capture; (2) how this would impact system quality, usability, safety, and workflow; and (3) how long the industry believes it would take to close this gap. Additionally, we recognize that some specialty-focused EHR technologies may not need to capture all of the data that the QDM describes. We request public comment regarding how certification can accommodate specialty EHR technology developers so that they would not have to take on development work (solely to get certified) for functionality that their customers may not require.

We believe that there are alternative options to our proposal and request public comment with respect to whether we should pursue one or more of the alternative approaches below for certification in the final rule.

- CQM-by-CQM Data Capture: Our proposed data capture certification criterion specifies that EHR technology must be able to capture all of the data elements represented in the QDM. As an alternative to our proposal, we considered an approach to certification for data capture that would be based on the data elements reflected in the individual CQMs selected by CMS instead of the entire QDM. When EHR technology is presented for certification for data capture, the developer would identify the specific CQMs that the

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technology is capable of supporting, and the technology must capture each and every data element reflected in those CQMs in order to be certified. For example, if a developer presents for certification EHR technology designed for an inpatient (e.g., emergency department) setting that would support the hospital quality measures NQF 0495 and 0497, the technology would have to demonstrate that it could capture all of the data elements included in those measures. An EHR technology developer would design its EHR technology to capture the data elements for those CQMs it believed its EHR technology would need to support for the types of providers to which it markets its EHR technology. We believe this approach may be advantageous because it poses a lower initial burden for EHR technology developers. But it also has its disadvantages because it could lead to a void in the market for EHR technology that would support certain CQMs that EPs, EHs and CAHs would need to report beginning in 2014. We request public comment on whether we should take this approach instead of our proposal on certification for data capture.

- Explicit Certification Criteria: In some cases, we recognize that while not required for certification, many EHR technologies already capture data elements included in the QDM. For example, inactive medical problems may be captured and represented as past medical history. For these cases, we considered and believe that it would be clearer (and easier for EHR technology developers) if we were to either add specific CQM data capture requirements to already existing certification criteria or adopt new certification criteria in order to explicitly require the data that is specified by the QDM to be captured. In other cases, despite a measure steward specifying that certain data capture occur, we

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are unaware of a consistent or established method with which EHRs capture certain information. For example, most EHR technology of which we are aware does not consistently capture why a particular medication was not prescribed, nor do they systematically make a distinction between "patient reason," "system reason," and "medical reason." We request public comment on whether this approach would be preferred, which certification criteria should be expanded, and where new certification criteria would be appropriate. We believe this approach could also ensure when EHR Modules are used in combination to meet the definition of CEHRT that all of the data necessary to capture for CQM calculations would be electronically available.

- CQM Exclusions: Our research indicates that CQM exclusions represent the majority of CQM data that are expected by measure stewards to be captured or represented in EHR technology but are not. In cases where a CQM specifies a negation exclusion[34], we propose that EHR technology would not be required to capture the "reason" justification

[34] A negation exclusion or exception is a factor that removes a given patient from the denominator of a CQM with a statement about why a given event or intervention did not occur. For example, a CQM may state that all patients with X condition must have Y intervention, except patients who did not receive the intervention for reason Z. A CQM may state that all patients over the age of 6 months should have an influenza vaccine between October and February (Y intervention), except patients with allergy to egg albumin (reason Z-1) or patients who decline vaccination (reason Z-2). In some measures, the unit of analysis is not a patient, but an encounter or a procedure. In such measures the exclusion or exception can apply to individual patient factors or factors affecting the specific unit of analysis. Additionally, exclusions for ratio measures can also remove a patient from the numerator.

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attribute of any data element in an encoded way. Rather, we would permit "reason" to allow for free text entries. For calculation and reporting purposes, the presence of text in the "reason" field may be used as a proxy for any "reason" attribute. We request public comment regarding the impact this flexibility would have on the accuracy of CQM reporting.

- Constrain the QDM: Working with CMS and NQF, we have considered the creation of a draft "style guide" to constrain the QDM in a manner that would identify a subset of data types and their associated attributes that we believe EHR technology could reasonably be expected to be captured. Measure stewards would then need to constrain CQMs to reference only data elements that are within the boundaries of the data types/attribute pairs expressed in the constrained QDM style guide. Such CQMs would be identified as "2014-EHR-ready" while other CQMs would not. We would subsequently collaborate with CMS to remove CQMs that do not qualify as "2014-EHR-ready" from the EHR Incentive Programs requirements and, as discussed above, could add certification criteria in our final rule in order to explicitly define the data types and attributes that will be necessary for complete CQM data capture according to the constrained QDM style guide. This option would serve to align the capabilities of EHR technology with the expectations of CQMs and would provide a solid path toward an additional alignment of CQMs with CDS for future stages of the EHR Incentive Programs. CDS can provide the interactive capability that would be required in order to capture the granular exclusion data that is expected today by many CQMs. With the inclusion of CDS in the clinical quality improvement strategy for future stages of this program, we expect to be able to

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remove the flexibility outlined above for the capture of "reason" attributes. This would improve the accuracy of CQMs while retaining optimal clinical workflow, as CDS would ideally be engaged to prompt for this information only where indicated, rather than in all cases. We seek public comment, especially from measure stewards, as to the difficulty and timeliness with which CQMs could be re-specified in accordance with the constrained QDM style guide.

- Explicit Data Capture List: Another approach we considered instead of specifying the QDM would be to publish the complete list of unique data elements that would be required for data capture in order to be assured that CQMs could be calculated. The advantage of this list is that it would provide explicit guidance to EHR technology developers and could potentially reduce the upfront work that each individual EHR technology developer would need to do in order to prepare their EHR technology for certification.

Data Export

Equally fundamental to data capture is the ability of EHR technology to put the data that has been captured to use. Thus, we believe that it is prudent to propose that EHR technology presented for certification not only be able to capture data for CQMs based on the QDM, but be able to export this data as it is represented in the QDM in the event that an EP, EH, or CAH chooses to use another certified EHR Module to perform the calculation of CQM results – which is why we include the export capability as part of the certification criterion proposed at § 170.314(c)(1). We recognize that in many care delivery settings, CQM calculation and reporting may occur through the use of different EHR technologies from those used to capture data. For

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example, certified EHR Module #1 may be part of an EH's Base EHR, but the EH may use certified EHR Module #2 to perform the analytics needed for CQM calculation and reporting. By requiring that all EHR technology presented for certification capture CQM data and also export the data, we believe EPs, EHs, and CAHs would be provided the flexibility to use separate EHR Modules for calculation and/or reporting, even if they have purchased or licensed an integrated solution.

We believe this approach preserves portability and flexibility and offers the EPs, EHs, and CAHs the option of using regional or national CQM calculation and/or reporting solutions, such as registries or other types of data intermediaries that could obtain modular certification for the services that they offer. We are unaware of the existence of a widely adopted standard to export captured CQM data. Thus, for certification, it would be at the EHR technology developer's discretion to determine the format of the data file that its EHR technology would be able to produce as well as whether the data would be exported in aggregate or by individual patients. While this scenario is not ideal, we believe that it could also create a market in which EHR Modules focused on CQM calculation (and reporting) could be designed to exploit the disparate data files that EHR technologies produce. We request comment on whether any standards (e.g., QRDA category 1 or 2, or Consolidated CDA) would be adequate for CQM data export as well as whether Complete EHRs (that by definition would include calculation and reporting capabilities) should be required to be capable of data export.

Calculation

In the S&CC July 2010 final rule (75 FR 44611) and finalized in the respective certification program rules (75 FR 36170, 76 FR 1276), we discussed requirements that ONC-

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Authorized Testing and Certification Bodies (ONC-ATCBs) and ONC-Authorized Certification Bodies (ONC-ACBs) must report to ONC the CQMs to which a Complete EHR or EHR Module has been certified and that ONC-ATCBs and ONC-ACBs must ensure that Complete EHR and EHR Module developers include on their websites and in all marketing materials, communications statements, and other assertions related to a Complete EHR or EHR Module's certification the CQMs to which the Complete EHR or EHR Module was certified. These requirements can be found at § 170.423(h)(5) and (k)(1)(ii) and § 170.523(f)(5) and (k)(1)(ii). The posting of this information on the Certified HIT Products List (CHPL) combined with Complete EHR and EHR Module developers making this information available in association with their certified Complete EHRs and EHR Modules provides both transparency and useful information for potential purchasers (e.g., EPs, EHs, and CAHs) that are trying to determine what EHR technology best meets their needs.

In the S&CC July 2010 final rule, we adopted at § 170.304(j) the CQM certification criterion for EHR technology designed for an ambulatory setting. As expressed in the S&CC July 2010 final rule and in ONC FAQ 9-10-012[35] and CMS FAQ 10649[36], this certification criterion was treated as a threshold. In other words, if an EHR technology included all 6 of the core CQMs specified by CMS and at least 3 other additional CQMs, it could meet the certification criterion, and if there was an additional CQM that the EHR technology included, CMS permitted the EP to report on that CQM, even though it was not expressly listed on the CHPL. Some EHR technology developers sought certification to only the 9 CQMs required to

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[35] http://healthit.hhs.gov/portal/server.pt/community/onc_regulations_faqs/3163/faq_12/20774
[36] https://questions.cms.hhs.gov/app/answers/detail/a_id/10649

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meet the threshold, and thus the criterion, but subsequently communicated to EPs that their EHR technology was certified for all of the CQMs it included. Other EHR technology developers took the opposite approach and sought certification for more than the 9 CQMs. Those EHR technologies were consequently listed on the CHPL as being certified to more CQMs. We seek to eliminate this disparity by proposing that EHR technology presented for certification to § 170.314(c)(2) would need to be certified to each and every individual CQM for which the EHR technology developer seeks to indicate its EHR technology is certified. We believe this approach provides transparency and greater certainty regarding the "certified CQMs" that EHR technology includes, given CMS' proposal to only permit EPs, EHs, and CAHs to report on CQMs with EHR technology that has been certified to capture and calculate those CQMs.

As noted above, we anticipate that in many cases the calculation of CQMs could be performed by an EHR technology that is different from the one that was certified to capture the CQM data. For this reason, we propose a separate certification criterion for the calculation of CQMs. We believe this separation enables market flexibility and creates room for innovation. The certification criterion we propose includes two specific capabilities. The first capability would require that EHR technology presented for certification would need to be able to electronically incorporate all of the data elements necessary to calculate CQMs for which it is to be certified. In cases where an EHR technology developer presents an EHR technology for certification that is also being certified to § 170.314(c)(1) and (3) (i.e., the EHR technology would be able to do all three capabilities: capture, calculate, and report), we do not believe that it would be necessary for an EHR technology to demonstrate its compliance to § 170.314(c)(2)(i). However, we specifically request public comment on this assumption before we will add this

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exception to the certification criterion, which we may do in our final rule. In all other cases, an EHR technology would need to meet § 170.314(c)(2)(i) and (ii).

The second specific capability, § 170.314(c)(2)(ii), focuses on an EHR technology's ability to calculate each CQM for which it is presented for certification. For example, if an EHR technology is presented for certification with test results for 20 CQMs, then the most CQMs that could be included as part of its certification and listed on the CHPL would be 20. Furthermore, an ONC-ACB would need to review each of the 20 CQMs for which the EHR technology is presented for certification and make a separate determination as to whether the calculation test results for each CQM are satisfactory and accurate. It is our expectation that EHR technology certified to this criterion would be capable of accurately, and without errors, calculating CQMs. We expect the accuracy of these calculations would be verified through thorough testing. We request public comment, especially from measure stewards and EHR technology developers, on the best way for CQM test data sets to be developed.

Given the separation between capture and calculation, combined with CMS's policy that only CQMs calculated by CEHRT would count for attestation and electronic submission, we could foresee a scenario where an EP's, EH's, or CAH's CEHRT (composed of certified EHR Modules – perhaps from different vendors) could capture more data than it is certified to calculate. We recognize that this scenario could present challenges for providers who possess licenses to such mismatched certified EHR modules and we request comment regarding this scenario and its likelihood and any additional methods we could employ to mitigate this risk.

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Reporting

The last CQM-oriented certification criterion we propose would require EHR technology to enable a user to electronically create for transmission CQM results in a data file defined by CMS. We expect that this capability would require EHR technology to generate an eXtensible Markup Language (XML) data file with aggregate CQM calculation results in the format CMS would have the capacity to accept. Similar to other CMS quality programs' reporting requirements, we expect that CMS would make available the XML data file template in time for us to adopt it in our final rule. We believe that this approach gives EPs, EHs, and CAHs a default solution for reporting CQMs electronically. We note that if EPs, EHs, and CAHs elect to use their CEHRT to pursue an alternative reporting mechanism permitted by CMS for the EHR Incentive Programs, then it would be the EP, EH, or CAH's responsibility for ensuring compliance with the alternative mechanism's requirements.

- **Auditable events and tamper-resistance; and audit report(s)**

MU Objective Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.
2014 Edition EHR Certification Criteria § 170.314(d)(2) (Auditable events and tamper-resistance) § 170.314(d)(3) (Audit report(s)) **Standard** § 170.210(e) (Record actions related to electronic health information, audit log status, and encryption of en user devices)

The HITSC recommended two revised certification criteria – one focused on the capability to record auditable events and another focused on the capability to create audit reports – in place of the single 2011 Edition EHR certification criterion for audit logs adopted at §

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170.302(r). It also recommended, for clarity, that we move the specific capability "detection" from the integrity certification criterion (§ 170.302(s)(3)) to the proposed auditable events and tamper-resistance certification criterion. Further, it recommended two versions of this certification criterion. We agree with the HITSC's recommendations because they provide more flexibility and are consistent with the stakeholder feedback we have received since the publication of the S&CC July 2010 final rule. As for the two recommended versions of the certification criterion, we propose a certification criterion that combines both recommended versions.

Stakeholder feedback has indicated that splitting this 2011 Edition certification criterion into two separate certification criteria would permit a wider variety of EHR technologies to be certified as EHR Modules. We have also expanded upon the scope of the HITSC's recommendation to address input from the HHS Office of Inspector General (May 2011 report[37]) and reflect our general belief that a more stringent certification policy for audit logs will ultimately assist EPs, EHs, and CAHs to better detect and investigate breaches. This expansion includes the specific capabilities that the audit log must be enabled by default (i.e., turned on), immutable (i.e., unable to be changed, overwritten, or deleted), and able to record not only which action(s) occurred, but more specifically the electronic health information to which the action applies. The proposed certification criterion would also require that the ability to enable and disable the recording of actions be limited to an identified set of users (e.g., system administrator). Further, to accommodate these changes, we are proposing a revised standard at §

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[37] http://oig.hhs.gov/oas/reports/other/180930160.pdf

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170.210(e) and proposing to require that: 1) when the audit log is enabled or disabled, the date and time (in accordance with the standard specified at § 170.210(g) (synchronized clocks)), user identification, and the action(s) that occurred must be recorded; and 2) as applicable, when encryption for end-user devices managed by EHR technology is enabled or disabled, the date and time (in accordance with the standard specified at § 170.210(g) (synchronized clocks)), user identification, and the actions that occurred must be recorded.

We did not use the phrase "security-relevant events" in the standard, as recommended by the HITSC, because we believe it is ambiguous and provides insufficient guidance in terms of what constitutes an event that would need to be audited. Rather, we believe that the proposed minimum set of actions that would be required to be captured provides greater clarity for EHR technology developers and allows for consistent testing. Finally, we acknowledge, as recommended by the HITSC, that an example implementation specification which could be followed in designing EHR technology to meet these certification criteria could include, but is not limited to ASTM E2147-01, Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems. We propose to adopt these revised certification criteria at § 170.314(d)(2) and (3); and the revised standard at § 170.210(e).

- **Encryption of data at rest**

MU Objective Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.
2014 Edition EHR Certification Criterion § 170.314(d)(7) (Encryption of data at rest)

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The HITSC recommended that we revise the "general encryption" certification criterion adopted at § 170.302(u) in favor of a certification criterion focused on the capability of EHR technology to encrypt and decrypt electronic health information managed by EHR technology on end-user devices if such electronic health information would remain stored on the devices after use of EHR technology on that device has stopped. Their rationale, with which we agree, was that this approach would be more practical, effective, and easier to implement than the otherwise general encryption requirement adopted at § 170.302(u). Further, we interpret this HITSC recommendation to suggest that we should focus more attention on promoting EHR technology to be designed to secure electronic health information on end-user devices (which are often a contributing factor to a breach of unsecured protected health information[38]). The OIG provided similar rationale in its May 2011 report (cited above) in which it recommended that ONC address IT security controls for encrypting data on mobile devices. Additionally, we understand that the HITSC intended to recommend a certification criterion that would complement already existing HHS policy related to breaches of unsecured protected health information (i.e., the guidance from the HHS Office for Civil Rights on rendering unsecured protected health information unusable, unreadable, or indecipherable to unauthorized individuals[39]). As noted in the guidance provided by the HHS Office for Civil Rights, NIST Special Publication (SP) 800-111[40] serves as a resource to guide how encryption should be applied to end-user devices.

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[38] http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/breachrept.pdf
[39] http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/brguidance.html
[40] http://csrc.nist.gov/publications/nistpubs/800-111/SP800-111.pdf

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This proposed certification criterion is drafted to permit EHR technology developers to demonstrate in one of two ways that a Complete EHR or EHR Module is compliant. The first way, § 170.314(d)(7)(i), accounts for circumstances in which EHR technology is designed to manage electronic health information on end-user devices[41] and on which electronic health information would remain stored on the end-user devices after use of the EHR technology on the devices has stopped. We use "stopped" to mean that the session has been terminated, including the termination of the network connection. In these circumstances, EHR technology presented for certification must be able to encrypt the electronic health information that remains on end-user devices. And, to comply with paragraph (d)(7)(i), this capability must be enabled (i.e., turned on) by default and only be permitted to be disabled (and re-enabled) by a limited set of identified users. We did not include "decrypt" in the proposed certification criterion because we believe that the critical capability to require for certification is the act of encryption after use of the EHR technology on the end-user device has stopped. We presume that EHR technology developers would also include the capability to decrypt the electronic health information, when appropriate; otherwise subsequent use or access to the data would not be possible. We use the phrase "manages electronic health information" in this certification criterion to mean that the EHR technology is designed in a way that it can exert control over the electronic health information that remains on an end-user device after the use of EHR technology on that device has stopped. For example, if an EHR technology is designed to manage a client application that

[41] Consistent with NIST SP 800-111, we consider "end-user devices" to include, but not be limited to: personal computers, laptops, smart phones, tablet computers, external memory devices and similar removable storage media (e.g., universal serial bus [USB] flash drive, memory card, external hard drive, writeable or re-writeable CD or DVD).

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can be executed on a laptop or tablet, and electronic health information would remain stored – even in temporary storage – on that end-user device when a user stops using the client application on the laptop or tablet, the EHR technology would need to meet the requirements specified at § 170.314(d)(7)(i) in order to be certified.

We recognize that in some scenarios EHR technology may not be designed to manage electronic health information on the end-user devices on which a user may ultimately choose to store electronic health information. For example, an EHR technology may not be designed to manage electronic health information on a USB-drive, but a user may choose to store electronic health information from the EHR technology on such an end-user device. We wish to make clear that in order to comply with this certification criterion, an EHR technology developer would not need to anticipate such scenarios. More specifically, the EHR technology developer would not have to demonstrate for certification that the EHR technology could encrypt electronic health information on the USB-drive (or similar end-user device) since the EHR technology was not designed to manage electronic health information on that USB-drive. We further note that if a user chooses to store electronic health information on an end-user device on which EHR technology was not designed to manage electronic health information, then the user would be responsible for ensuring such information is protected in accordance with applicable law.

The second way to demonstrate compliance with this certification criterion would be for an EHR technology developer to demonstrate that its EHR technology can meet § 170.314(d)(7)(ii) and prove that electronic health information managed by EHR technology never remains on end-user devices after use of EHR technology on those devices has stopped. We believe this alternative method is important to include because it: 1) verifies as part of

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certification that the EHR technology was, in fact, designed in a way such that it does not enable electronic health information to remain on end-user devices after use of EHR technology on those devices has stopped; 2) provides EHR technology developers a way to demonstrate compliance with this certification criterion; and 3) it encourages an outcome that is more secure (i.e., when no electronic health information is permitted to remain, the potential for a breach is mitigated). An example of this circumstance would be a situation where an EHR technology is designed to manage a client application on an end-user device (locally or over the Internet) and the client application enables the user to complete a full suite of actions related to electronic health information. Once the use of EHR technology on the end-user device has stopped, the electronic health information does not remain on the device on which the client application was executed.

We propose to adopt this revised certification criterion at § 170.314(d)(7).

- **Immunization registries**

MU Objective Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.
2014 Edition EHR Certification Criteria § 170.314(f)(1) (Immunization information) § 170.314(f)(2) (Transmission to immunization registries) **Standards and Implementation Specifications** § 170.205(e)(3) (HL7 2.5.1 and Implementation Guide for Immunization Messaging Release 1.3); and § 170.207(i) (CVX code set: August 15, 2011 version)

The HITSC recommended that we consider splitting this certification criterion into two criteria – one focused on the data capture and the other focused on the formatting of such data in the proposed standards and implementation specifications. We have followed this recommendation and propose two separate certification criteria. We believe this approach could

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enable additional EHR technologies (likely in the form of EHR Modules) to be certified and provides additional pathways and flexibility to EPs, EHs, and CAHs to have EHR technology that can be used to satisfy the proposed revised definition of CEHRT. We note that we are discussing these criteria together for simplicity and to prevent confusion, but we do not consider the certification criterion we propose to focus on data capture to be a "revised" certification criterion. Rather, we believe that the certification criterion proposed at § 170.314(f)(1) constitutes an unchanged certification criterion because all the capabilities included in the criterion are the same as the capabilities included in the corresponding 2011 Edition EHR certification criterion (§ 170.302(k)).

For the certification criterion proposed at § 170.314(f)(1), consistent with our discussion in the preamble section titled "Explanation and Revision of Terms Used in Certification Criteria," we have replaced the terms "retrieve" and "modify" in the revised criterion with "access" and "change," respectively. For the certification criterion proposed at § 170.314(f)(2), we have stated the "transmission capability" as the capability to electronically create immunization information for electronic transmission in accordance with the applicable standards and implementation specifications. We clarify that this criterion focuses on the capability of EHR technology to properly create for transmission immunization information in accordance with the applicable standards and implementation specifications. The criterion does not address the ability to query and evaluate immunization history from the immunizations information systems (IIS) to determine a patient's vaccination need, nor does it address the specific connectivity requirements that an EP, EH, or CAH would need to establish or meet to

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successfully transmit immunization information, as such requirements are likely to vary from State to State and are outside the scope of certification.

The HITSC recommended, and we agree, that the use of only the HL7 2.5.1 standard should be permitted for submitting immunization information because immunization registries are rapidly moving to this standard. In consultation with the Centers for Disease Control and Prevention, we also propose to adopt the HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.3 as the implementation specification. This release provides corrections and clarifications to Release 1.0 and contains new guidance on how to message vaccines for children (VFC) eligibility. Finally, we propose to adopt the August 15, 2011 version of CVX code sets. We propose to adopt the revised certification criteria for the 2014 Edition EHR certification criteria at § 170.314(f)(1) and (2). We propose to adopt the HL7 2.5.1 standard with implementation guide at § 170.205(e)(3) and the CVX code set at § 170.207(i).

- **Public health agencies**

MU Objective Capability to submit electronic syndromic surveillance data to public health agencies except where prohibited, and in accordance with applicable law and practice.
2014 Edition EHR Certification Criteria § 170.314(f)(3) (Public health surveillance) § 170.314(f)(4) (Transmission to public health agencies) **Standards and Implementation Specifications** § 170.205(d)(2) (HL7 2.5.1) and § 170.205(d)(3) (HL7 2.5.1 and the PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data HL7 Version 2.5.1)

Similar to the immunization certification criteria above, the HITSC recommended that we consider splitting the public health surveillance certification criterion into two separate certification criteria. We have followed this recommendation, and we have made similar wording changes to these proposed certification criteria for the same reasons expressed in the

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revisions to the certification criteria for immunization information and transmission. As noted under the proposed immunization certification criteria, we are discussing these two proposed syndromic surveillance criteria together for simplicity and to prevent confusion, but we do not consider the certification criterion we propose to focus on data capture to be a "revised" certification criterion. Rather, we believe that the certification criterion proposed at § 170.314(f)(3) constitutes an unchanged certification criterion because all the capabilities included in the criterion are the same as the capabilities included in the corresponding 2011 Edition EHR certification criterion (§ 170.302(l)).

The HITSC recommended and we agree that the use of only the HL7 2.5.1 standard should be permitted for formatting syndrome-based public health surveillance information because public health agencies are rapidly moving to this standard and all stakeholders would benefit from focusing on a single public health surveillance standard. The HITSC also recommended and we agree that the standard be constrained for hospitals with the PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data HL7 Version 2.5.1. We also believe that certification of ambulatory EHR technology to this guide can be useful for EHR developers that provide EHR technology to eligible professionals that practice in urgent care settings. Therefore, we propose that certification to this guide be optional for the ambulatory setting. We propose to adopt the revised certification criteria for the 2014 Edition EHR certification criteria at § 170.314(f)(3) and (4) and the HL7 2.5.1 standard and implementation guide for the inpatient setting (and optional for the ambulatory setting) at § 170.205(d)(3). The required exchange standard for the ambulatory setting has already been adopted at § 170.205(d)(2).

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- **Automated measure calculation**

MU Objective N/A
2014 Edition EHR Certification Criterion § 170.314(g)(2) (Automated measure calculation)

We propose to adopt a revised automated measure calculation certification criterion for the 2014 Edition EHR certification criteria. We have revised the certification criterion to clearly identify that the recording, calculating, and reporting capabilities required by this certification criterion apply to the numerator and denominator associated with the capabilities that support an MU objective with a percentage-based measure. To be clear, the capabilities to which we refer are the capabilities included in the certification criteria to which the EHR technology is presented for certification.

We want to emphasize that testing to this certification criterion would not only include verification of the ability of EHR technology to generate numerators and denominators, but would also verify the accuracy of the numerators and denominators generated by the EHR technology. We believe that testing to ensure the accuracy of these calculations would significantly reduce the reporting burden for MU attestation. Additionally, testing and certification to this proposed revised certification criterion would include testing and certifying the ability to electronically record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable MU measure that is supported by a capability in the new certification criteria proposed in this rule that are adopted in a final rule.

We propose to adopt this revised certification criterion at § 170.314(g)(2).

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b. Ambulatory Setting

We propose to adopt the following revised certification criteria for the ambulatory setting.

- **Electronic prescribing**

MU Objectives Generate and transmit permissible prescriptions electronically (eRx).
2014 Edition EHR Certification Criterion § 170.314(b)(3) (Electronic prescribing) **Standards** § 170.205(b)((2) (NCPDP SCRIPT version 10.6) and § 170.207(h) (RxNorm February 6, 2012 Release)

The HITSC recommended that we adopt a revised certification criterion for the ambulatory setting that required the use of RxNorm as the vocabulary standard. We agree that RxNorm should be adopted as the vocabulary standard instead of the current adopted standard which specifies any source vocabulary that is included in RxNorm. Additionally, with respect to content exchange standards, we are proposing to no longer include the use of NCPDP SCRIPT version 8.1 as a way to meet the 2014 Edition EHR certification criterion because we understand that CMS is planning to propose retiring this standard (adopted as a Medicare Part D e-prescribing standard) in a proposed rule that is scheduled to be issued soon after this proposed rule is published. If we should receive information indicating a change in CMS' plans prior to the issuance of our final rule, we may, based also on public comment, reinstate this standard in a final revised certification criterion. We believe that it is appropriate for this certification criterion to be adopted for both the ambulatory and inpatient settings (as discussed under the proposed new certification criteria section) as it supports our desired policy and interoperability

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outcome for content exchange standards to be used when information is exchanged between different legal entities. We propose to adopt this revised certification criterion at § 170.314(b)(3) and the February 6, 2012 Release of the RxNorm standard at § 170.207(h).

- **Clinical summaries**

MU Objective Provide clinical summaries for patients for each office visit.
2014 Edition EHR Certification Criterion § 170.314(e)(2) (Ambulatory setting only – clinical summaries) **Standards** § 170.205(a)(3) (Consolidated CDA); § 170.207(f) (OMB standards for the classification of federal data on race and ethnicity); § 170.207(j) (ISO 639-1:2002 (preferred language)); § 170.207(l) (smoking status types); § 170.207(a)(3) (SNOMED-CT® International Release January 2012); § 170.207(m) (ICD-10-CM); § 170.207(b)(2) (HCPCS and CPT-4) or § 170.207(b)(3) (ICD-10-PCS); § 170.207(g) (LOINC version 2.38); and § 170.207(h) (RxNorm February 6, 2012 Release)

The HITSC recommended that the certification criterion be revised for the 2014 Edition EHR certification criteria to reflect the proposed new and revised standards for problem lists and other vocabulary standards. We agree with these recommendations. We have made several refinements to the recommended revised certification criterion to ensure that EHR technology meets the appropriate standards and is capable of making available the information CMS is proposing be provided to a patient after an office visit.

We further propose that when information is provided electronically, the information be provided according to the Consolidated CDA standard. For the same reasons as provided in the new "view, download, and transmit to 3rd party" certification criterion discussion, we believe that adopting the Consolidated CDA for this certification criterion is advantageous since its template structure can accommodate the formatting of a summary care record that includes all of the data elements that CMS is proposing be provided to a patient after an office visit. As we similarly

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noted in the discussion of the transitions of care certification criteria (§ 170.314(b)(1) and (2)), we considered, but have not proposed, adopting separate certification criteria to explicitly require the capture of unique data elements included in clinical summaries, such as care plans and future scheduled tests. We welcome public comment on whether we should adopt separate certification criteria for these data elements. For certain other data elements in § 170.314(e)(2), we propose to require that the capability to provide the information be demonstrated in accordance with the specified vocabulary standard. These vocabulary standards have been previously adopted or are proposed for adoption in this proposed rule, consistent with the recommendations of the HITSC. We propose to adopt this revised certification criterion for the 2014 Edition EHR certification criteria at § 170.314(e)(2).

c. Inpatient Setting

We propose to adopt the following revised certification criteria for the inpatient setting.

- **<u>Reportable laboratory tests and values/results</u>**

MU Objective Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice.
2014 Edition EHR Certification Criteria § 170.314(f)(5) (Inpatient setting only – reportable laboratory tests and values/results) § 170.314(f)(6) (Inpatient setting only – transmission of reportable laboratory tests and values/results) Standards and Implementation Specifications § 170.205(g) (HL7 2.5.1 and HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with errata); § 170.207(a)(3) (SNOMED CT® International Release January 2012); and § 170.207(g) (LOINC version 2.38)

Similar to the immunization and syndromic surveillance certification criteria above, the HITSC recommended that we consider splitting the "reportable laboratory results" certification criterion into two separate certification criteria. We have followed this recommendation, and for

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the same reasons expressed above, we have made similar wording changes to these proposed certification criteria. Also, as noted under the proposed immunization and syndromic surveillance certification criteria, we are discussing these two proposed laboratory tests and values/results certification criteria together for simplicity and to prevent confusion, but we do not consider the certification criterion we propose to focus on data capture to be a revised certification criterion. Rather, we believe that the certification criterion proposed at § 170.314(f)(5) constitutes an unchanged certification criterion because all the capabilities included in the criterion are the same as the capabilities included in the corresponding 2011 Edition EHR certification criterion (§ 170.306(g)).

The HITSC recommended that we maintain the use of only the HL7 2.5.1 standard and that we adopt the most current version of LOINC as the vocabulary standard. We agree and propose to adopt LOINC version 2.38 as the vocabulary standard as it is the most recent version. Based on our consultation with the Centers for Disease Control and Prevention, we also propose to adopt HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with errata and SNOMED CT® International Release January 2012 version. This version of the implementation guide contains corrections and will require minor changes to conformance testing and certification to account for newly assigned OIDs (object identifiers) identifying the message profiles in the implementation guide. The International Release January 2012 version of SNOMED CT® is the most recent version and SNOMED CT® is required by the implementation guide, as is LOINC. We propose to adopt the revised certification criteria for the 2014 Edition EHR certification criteria at § 170.314(f)(5) and (6). We propose to adopt the HL7 2.5.1 standard with the revised implementation guide at §

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170.205(g). We propose to adopt the version of SNOMED CT® at § 170.207(a)(3) and LOINC version 2.38 standard at § 170.207(g).

6. Unchanged Certification Criteria

In our prior rulemakings, we did not expressly describe what we considered to be "unchanged" certification criteria. Based on our experience with this rulemaking, we take this opportunity to describe the certification criteria that we would consider unchanged. We would consider the following factors in determining whether a certification criterion is unchanged:

- The certification criterion includes only the same capabilities that were specified in previously adopted certification criteria;
- The certification criterion's capabilities apply to the same setting as they did in previously adopted certification criteria; and
- The certification criterion remains designated as "mandatory," or it is re-designated as "optional," for the same setting for which it was previously adopted certification criterion.

For clarity, we explain that an unchanged certification criterion could be a certification criterion that includes capabilities that were merged from multiple previously adopted certification criteria as long as the capabilities specified by the merged certification criterion remain the same. The "authentication, access control, and authorization" certification criterion discussed below and proposed for adoption at § 170.314(d)(1) meets this description. Additionally, an unchanged certification criterion could be a certification criterion that has fewer capabilities than a previously adopted certification criterion as long as the capabilities that remain stay the same. The "integrity" certification criterion discussed below and proposed for

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adoption at § 170.314(d)(8) meets this description. As discussed in the description of revised certification criteria, a certification criterion could be characterized differently based on the setting to which it applies or the designation it is given ("mandatory" or "optional"). For example, a certification criterion that includes the same capabilities that were specified in a previously adopted certification criterion would be considered unchanged for the ambulatory setting if the previously adopted certification criterion only applied to the ambulatory setting and certification to the criterion was "mandatory." However, this same certification criterion would be considered new for the inpatient setting if it were subsequently adopted for both settings.

We identify some of the proposed unchanged certification criteria included in the 2014 Edition EHR certification criteria below and have also identified unchanged certification criteria previously in the preamble. As noted, the capabilities included in the certification criteria below are the same capabilities that were adopted in 2011 Edition EHR certification criteria. We propose to add all of these unchanged certification criteria to the 2014 Edition EHR certification criteria at § 170.314.

a. Refinements to Unchanged Certification Criteria

We propose to refine the following certification criteria as discussed below.

- **<u>Computerized provider order entry</u>**

MU Objective Use computerized provider order entry (CPOE) for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines to create the first record of the order.
2014 Edition EHR Certification Criterion § 170.314(a)(1) (Computerized provider order entry)

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We have merged the separate ambulatory and inpatient CPOE certification criteria in the 2011 Edition EHR certification criteria into one criterion because they are identical. Consistent with our discussion in the preamble section titled "Explanation and Revision of Terms Used in Certification Criteria," we have also replaced the terms "modify" and "retrieve" with "change" and "access," respectively. We have also removed the term "store" from the criterion because it is redundant with our interpretation of the term "record." Finally, we moved the phrase "at a minimum" in the sentence to eliminate any possible ambiguity as to what the phrase modifies. As the proposed certification criterion is now written, we believe it is clear that the phrase modifies the order types and not the terms "record," "change," and "access."

- **Vital signs, body mass index, and growth charts**

MU Objective Record and chart changes in the following vital signs: height/length and weight (no age limit); blood pressure (ages 3 and over); calculate and display body mass index (BMI); and plot and display growth charts for patients 0-20 years, including BMI.
2014 Edition EHR Certification Criterion § 170.314(a)(4) (Vital signs, body mass index, and growth charts)

Consistent with our discussion in the preamble section titled "Explanation and Revision of Terms Used in Certification Criteria," we have replaced the terms "modify" and "retrieve" with "change" and "access," respectively. We have also added the alternative term "length" to go with "height" as it is the clinically appropriate term for newborns and clarified the intent of the "vital signs" capability. The only other refinements that we propose are for the plot and display growth charts capability. First, we propose that this capability be designated "optional" within this certification criterion because even though this certification criterion is proposed to be part of a Base EHR that every EP, EH, and CAH would need to have in order to satisfy the

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proposed revised definition of CEHRT, some EPs, EHs, and CAHs would not (or would never) use such a capability due to scope of practice or other reasons. Thus, to reduce regulatory burden and to not require EHR technology developers to include a specific growth chart capability when they do not intend to market their EHR technology to EPs, EHs, or CAHs that would use such a capability, we have designated it as "optional" for certification. In addition, we propose to remove the age range reference (2-20 years old) from this capability. This is consistent with other certification criteria such as "smoking status" where the MU objective it supports specifies an age threshold (13), but the capability is not dependent on the patient's age.

- **Smoking status**

MU Objective Record smoking status for patients 13 years old or older.
2014 Edition EHR Certification Criterion § 170.314(a)(11) (Smoking status) **Standard** § 170.207(l) (smoking status types)

As part of the 2011 Edition EHR certification criteria, the smoking status certification criterion is codified at § 170.302(g), specifying a list of six smoking status types that EHR technology must be capable of recording, modifying, and retrieving. Consistent with our discussion in the preamble section titled "Explanation and Revision of Terms Used in Certification Criteria," we have replaced the terms "modify" and "retrieve" with "change" and "access," respectively. We also propose to specify the six smoking status types included in the 2011 Edition EHR certification criterion as a standard at § 170.207(l). This refinement will

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provide additional clarity for the certification criterion and consistency with the structure of similar certification criteria.

- Patient reminders

MU Objective Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care.
2014 Edition EHR Certification Criterion § 170.314(a)(15) (Ambulatory setting only – patient reminders)

We clarify and emphasize that EHR technology certified to this certification criterion would need to be capable of creating a patient reminder list that includes a patient's communication preferences, which would be consistent with current testing procedures for this capability as included in the 2011 Edition EHR certification criterion (§ 170.304(d)). We also note that, consistent with patient communication preferences, we would anticipate that EPs, EHs, and CAHs could use communication mediums made available by EHR technology certified to the proposed "secure messaging" certification criterion (§ 170.314(e)(3)) or the "view, download and transmit to 3rd party" certification criterion (§ 170.314(e)(1)) to send patient reminders. We also anticipate that other modes of communication would be available and may be preferred by patients for sending patient reminders, such as regular mail.

Authentication, access control, and authorization

MU Objective Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.
2014 Edition EHR Certification Criterion § 170.314(d)(1) (Authentication, access control, and authorization)

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As part of the 2011 Edition EHR certification criteria, the "access control" certification criterion is codified at § 170.302(o) and the "authentication" certification criterion is codified at § 170.302(t). Based on consultations with NIST, the similarity of the two test procedures that were developed for these certification criteria, and that these capabilities go hand-in-hand, we have determined that it would be best to merge the two certification criteria. We believe this would allow for more efficient testing and is consistent with EHR technology development. Given this proposal, we have adopted in part the recommendations of the HITSC, which are reflected in the proposed certification criterion. We have also expressed the HITSC's authentication recommendation as additional guidance for this certification criterion in that the capability to authenticate human users would consist of the assertion of an identity and presentation of at least one proof of that identity. We intend and believe that it is most appropriate for this certification criterion to focus on users that would be able to access electronic health information in EHR technology at a EP, EH, or CAH and not to focus on external users that may make requests for access to health information contained in the EHR technology for the purpose of electronic health information exchange. The latter purpose would likely require a different/additional security approach(es) and rely on a health care provider's overall infrastructure beyond its EHR technology. We also acknowledge, as recommended by the HITSC, that example standards and implementation specifications which could be followed in designing EHR technology to meet this certification criterion could include, but are not limited to: NIST Special Publication 800-63, Level 2 (single-factor authentication) and ASTM, E1986-09 (Information Access Privileges to Health Information).

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- **Automatic log-off**

MU Objective Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.
2014 Edition EHR Certification Criterion § 170.314(d)(5) (Automatic log-off)

We are not revising or refining this certification criterion as part of the proposed 2014 Edition EHR certification criteria, but are clarifying that to terminate a session should not be confused with locking a session, where access to an active session is permitted after re-authentication. EHR technology must have the capability to terminate the session, including terminating the network connection.

- **Emergency access**

MU Objective Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.
2014 Edition EHR Certification Criterion § 170.314(d)(6) (Emergency access)

We are refining the 2011 Edition EHR certification criterion for emergency access codified at § 170.302(p) for the 2014 Edition EHR certification criteria by removing the parenthetical "who are authorized for emergency situations" from the certification criterion and including the phrase "identified set of users" to more clearly convey this certification criterion's intent and to consistently use this phrase through every certification criterion where we intend for the same capability to be available. The purpose of this criterion is to provide certain users ("identified set of users") with the ability to override normal access controls in the case of an

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emergency. The refinement to the criterion coupled with our explanation should provide sufficient clarity for testing and certifying to this certification criterion.

- **Integrity**

MU Objective Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.
2014 Edition EHR Certification Criterion § 170.314(d)(8) (Integrity) Standard § 170.210(c) (Verification that electronic health information has not been altered)

The certification criterion at § 170.314(d)(8) is consistent with the recommendation and recommended certification criterion by the HITSC for the 2014 Edition EHR certification criteria. The capability to detect changes to an audit log has been removed from this proposed certification criterion and added to the proposed certification criterion for "auditable events and tamper resistance" at § 170.314(d)(2). The adopted certification criterion at § 170.304(b) specifies that EHR technology must be able to create a message digest in accordance with the standard specified at § 170.210(c). The adopted standard is: "A hashing algorithm with a security strength equal to or greater than SHA-1 (Secure Hash Algorithm (SHA-1))…must be used to verify that electronic health information has not been altered." After consultation with NIST, we understand that the strength of a hash function in digital signature applications is limited by the length of the message digest and that in a growing number of circumstances the message digest for SHA-1 is too short for secure digital signatures (SHA-2 produces a 256-bit message digest that is expected to remain secure for a long period of time). We also understand that certain operating systems and applications upon which EHR technology may rely use SHA-

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1 and do not or cannot support SHA-2 at the present time. Thus, we request public comment on whether we should leave the standard as it currently reads or replace SHA-1 with SHA-2.

b. Unchanged Certification Criteria Without Refinements

The following table (Table 2) identifies the proposed unchanged 2014 Edition EHR certification criteria and the corresponding 2011 Edition EHR certification criteria that include the same capabilities that are in the proposed unchanged 2014 Edition EHR certification criteria. We propose to adopt these certification criteria as part of the 2014 Edition EHR certification criteria without any substantial refinements, except, consistent with our discussion in the preamble section titled "Explanation and Revision of Terms Used in Certification Criteria," we have, where appropriate, replaced the terms "generate," "modify," and "retrieve" with "create," "change," and "access," respectively. Table 2 also identifies the corresponding paragraphs of § 170.314 where the certification criteria would be added and the proposed titles of those paragraphs/certification criteria.

Table 2. Unchanged Certification Criteria Without Refinements

2014 Edition		**2011 Edition**	
Regulation Section	**Title of Regulation Paragraph**	**Regulation Section**	**Title of Regulation Paragraph**
170.314(a)(10)	Drug-formulary checks	170.302(b)	Drug-formulary checks
170.314(a)(6)	Medication list	170.302(d)	Maintain active medication list
170.314(a)(7)	Medication allergy list	170.302(e)	Maintain active medication allergy list
170.314(a)(14)	Patient lists	170.302(i)	Generate patient lists
170.314(d)(9)	Accounting of disclosures	170.302(w)	Accounting of disclosures
170.314(a)(18)	Advance directives	170.306(h)	Advance directives

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7. Gap Certification

In the Permanent Certification Program final rule (76 FR 1307), we explained the concept of "gap certification" and defined it at § 170.502 as "the certification of a previously certified Complete EHR or EHR Module(s) to: (1) [a]ll applicable new and/or revised certification criteria adopted by the Secretary at subpart C of [part 170] based on the test results of a NVLAP-accredited testing laboratory; and (2) [a]ll other applicable certification criteria adopted by the Secretary at subpart C of [part 170] based on the test results used to previously certify the Complete EHR or EHR Module(s)." We stated that gap certification will focus on the difference between certification criteria that are adopted through rulemaking at different points in time. We discussed in section III.A of this preamble the factors we would consider in determining whether a proposed 2014 Edition EHR certification criterion is "new" or "revised." Examples of new certification criteria are the "secure messaging" certification criterion we propose for adoption at § 170.314(e)(3) and the "electronic medication administration record" certification criterion we propose for adoption at § 170.314(a)(17). An example of a revised certification criterion is the "CDS" certification criterion we propose for adoption at § 170.314(a)(8). This certification criterion is "revised" because it would add capabilities to the certification criteria for CDS that were previously adopted at §§ 170.304(e) and 170.306(c). An example of a certification criterion that we would consider both new and revised is the "e-prescribing" certification criterion proposed for adoption at § 170.314(b)(3). This certification criterion is a revised certification criterion for the ambulatory setting, but would be considered a new certification criterion for the inpatient setting.

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For a Complete EHR or EHR Module that was previously certified to the 2011 Edition EHR certification criteria to be certified to the 2014 Edition EHR certification criteria, test results from a NVLAP-accredited testing laboratory would be required for all of the applicable new and revised certification criteria that are adopted. However, for the certification criteria that we identify as unchanged, test results that were used previously to certify a Complete EHR or EHR Module to the 2011 Edition EHR certification criteria identified in Table 3 below could be used to certify the Complete EHR or EHR Module to the corresponding 2014 Edition EHR certification criteria identified in the table. To illustrate, for gap certification, an EHR Module that was previously certified to the "CPOE" and "drug-drug, drug-allergy interaction checks" certification criteria (i.e., previously tested and certified to § 170.304(a) or § 170.306(a) and § 170.302(a)) would not need to be retested to the "CPOE" certification criterion we propose to add to the 2014 Edition EHR certification criteria at § 170.314(a)(1) because this criterion has been identified as an unchanged certification criterion. However, the previously certified EHR Module would need to be retested for "drug-drug, drug-allergy interaction checks" because we have proposed to adopt a revised certification criterion for "drug-drug, drug-allergy interaction checks" as part of the 2014 Edition of EHR certification criteria at § 170.314(a)(2). We note, as identified in Table 3, that for the proposed certification criterion at § 170.314(b)(5) (Incorporate laboratory tests and values/results), EHR technology designed for an ambulatory setting would need to be tested by a NVLAP-accredited testing laboratory because we propose to require that such EHR technology meet new standards and implementation specifications, while the capabilities required for the inpatient setting are unchanged.

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Table 3. Gap Certification: Crosswalk of Unchanged 2014 Edition EHR certification criteria to the corresponding 2011 Edition EHR certification criteria.

2014 Edition		2011 Edition	
Regulation Section	**Title of Regulation Paragraph**	**Regulation Section**	**Title of Regulation Paragraph**
170.314(a)(10)	Drug-formulary checks	170.302(b)	Drug-formulary checks
170.314(a)(6)	Medication list	170.302(d)	Maintain active medication list
170.314(a)(7)	Medication allergy list	170.302(e)	Maintain active medication allergy list
170.314(a)(4)	Vital signs, body mass index, and growth charts	170.302(f)	Vital signs
170.314(a)(11)	Smoking status	170.302(g)	Smoking status
170.314(b)(5)	Incorporate laboratory tests and values/results (inpatient setting only)	170.302(h)	Incorporate laboratory test results
170.314(a)(14)	Patient lists	170.302(i)	Generate patient lists
170.314(f)(1)	Immunization information	170.302(k)	Submission to immunization registries
170.314(f)(3)	Public health surveillance	170.302(l)	Public health surveillance
170.314(d)(1)	Authentication, access control, and authorization	170.302(o)	Access control
170.314(d)(6)	Emergency access	170.302(p)	Emergency access
170.314(d)(5)	Automatic log-off	170.302(q)	Automatic log-off
170.314(d)(8)	Integrity	170.302(s)	Integrity
170.314(d)(1)	Authentication, access control, and authorization	170.302(t)	Authentication
170.314(d)(9)	Accounting of disclosures	170.302(w)	Accounting of disclosures
170.314(a)(15)	Patient reminders	170.304(d)	Patient reminders
170.314(a)(1)	CPOE	170. 304(a) 170. 306(a)	CPOE

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2014 Edition		2011 Edition	
Regulation Section	**Title of Regulation Paragraph**	**Regulation Section**	**Title of Regulation Paragraph**
170.314(f)(5)	Reportable laboratory tests and values/results	170.306(g)	Reportable lab results
170.314(a)(18)	Advance directives	170.306(h)	Advance directives

As we have previously stated in our rules (75 FR 11351, 76 FR 1308), we believe gap certification is a less costly and more efficient certification option for EHR technology developers to get their EHR technologies certified without the time and costs associated with retesting to unchanged certification criteria. As we established in the permanent certification program final rule (76 FR 1308), however, gap certification will only be available under the permanent certification program, which we are proposing to rename the "ONC HIT Certification Program." We have extended the sunset date of the temporary certification program (and delayed the start of the ONC HIT Certification Program), which was originally anticipated to be December 31, 2011. The sunset date will now coincide with the effective date of the final rule that will result from this proposed rule (76 FR 68192).

B. Redefining Certified EHR Technology and Related Terms

1. Proposed Revisions to the Definition of Certified EHR Technology

Certified EHR Technology is defined in section 3000(1) of the PHSA as a "qualified electronic health record that is certified pursuant to section 3001(c)(5) as meeting standards adopted under section 3004 that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an

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inpatient hospital electronic health record for hospitals)." In the S&CC July 2010 final rule (75 FR 44590), we further defined Certified EHR Technology (CEHRT) at § 170.102 in relation to the applicable setting-specific certification criteria (ambulatory or inpatient) adopted by the Secretary to mean:

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.

Under the current definition, EPs, EHs, and CAHs must have Certified EHR Technology that has been tested and certified to all applicable certification criteria adopted for the setting (ambulatory or inpatient) for which it was designed. We refer readers to frequently asked question (FAQ) 9-10-017-2 for further explanation.[42] Since the publication of the S&CC July 2010 Final Rule, ONC and CMS have received feedback on the definition of CEHRT from numerous stakeholders, including EPs, EHs, CAHs, EHR technology developers, and multiple associations representing these and other stakeholders. Overall, a majority of stakeholders felt

[42] http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=3163&PageID=20779

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that we should change our CEHRT policy to provide EPs, EHs, and CAHs the flexibility to have or possess only the CEHRT they will use to demonstrate MU. This view was supported by the HITSC in their November 16, 2011 recommendation (transmitted to ONC on January 17, 2012) that we consider requiring EPs, EHs, and CAHs to possess EHR technology that has been certified only to the certification criteria that include capabilities they will use to attempt to achieve MU. Such a change would mean that the definition of CEHRT would be largely determined or driven by how an EP, EH, or CAH chooses to accomplish MU rather than requiring certification to all certification criteria adopted for an applicable setting (ambulatory or inpatient).

We have considered all of the feedback we have received, particularly the recommendation of the HITSC, and are proposing a revised definition of CEHRT that would provide significantly more flexibility for EPs, EHs, and CAHs than exists under the current definition. We are convinced by stakeholder feedback and our own independent fact-finding that when combined with the complexity of the health care delivery environment, the current CEHRT definition has, in some cases, introduced challenges for certain EPs, EHs, and CAHs by requiring them to have EHR technology they would not necessarily choose to use to demonstrate MU under the EHR Incentive Programs. For example, under CMS regulations, an EP who has no office visits during the EHR reporting period may qualify for an exclusion for the MU objective and associated measure requiring clinical summaries to be provided to patients for each office visit, but under our current definition of CEHRT, the EP must still have EHR technology that supports this capability. Accordingly, consistent with the instruction of the President's Executive Order (EO) 13563 to identify and consider regulatory approaches that reduce burden

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and maintain flexibility for the public, we have decided to propose a revised definition of CEHRT that we believe would more closely align with the desired flexibility stakeholders have requested while reducing the potential burden associated with acquiring EHR technology. We propose to revise the definition of CEHRT at § 170.102 to read:

Certified EHR technology means:

1. For any Federal fiscal year (FY) or calendar year (CY) up to and including 2013:

   i. 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 for the 2011 Edition EHR certification criteria or the equivalent 2014 Edition EHR certification criteria; or

   ii. 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 for the 2011 Edition EHR certification criteria or the equivalent 2014 Edition EHR certification criteria, and the resultant combination also meets the requirements included in the definition of a Qualified EHR.

2. For FY and CY 2014 and subsequent years, the following: EHR technology certified under the ONC HIT Certification Program to the 2014 Edition EHR certification criteria that has:

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i. The capabilities required to meet the definition of a Base EHR; and

ii. All other capabilities that are necessary to meet the objectives and associated measures under 42 CFR 495.6 and successfully report the clinical quality measures selected by CMS in the form and manner specified by CMS (or the States, as applicable) for the stage of meaningful use that an eligible professional, eligible hospital, or critical access hospital seeks to achieve.

As noted in the "Executive Summary" (section I.A) of this preamble, FY applies to EHs and CAHs and CY applies to EPs. For the first part of the revised definition of CEHRT that would apply for the FYs/CYs up to and including 2013, we note two specific changes. The first is to include a reference to "the 2011 Edition EHR certification criteria" in order to make clear that these are the certification criteria previously adopted by the Secretary at §§ 170.302, 170.304, and 170.306. This clarification is necessary because if the proposed 2014 Edition EHR certification criteria are subsequently adopted in a final rule at § 170.314, there would be two "editions" of adopted certification criteria in the CFR. Both the 2011 Edition and the 2014 Edition EHR certification criteria must be effective at the same time for EHR technology to continue to be tested and certified to the 2011 Edition EHR certification criteria and so EHR technology developers may begin to have their EHR technology tested and certified to the 2014 Edition EHR certification criteria.

The second change would allow EPs, EHs, and CAHs to satisfy the definition by having EHR technology certified to the 2014 Edition EHR certification criteria that are "equivalent" to the 2011 Edition EHR certification criteria. We would consider

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”equivalent” certification criteria to be those proposed 2014 Edition EHR certification criteria that include capabilities that are at least equal to the capabilities included in certification criteria that were previously adopted as part of the 2011 Edition EHR certification criteria. For a cross-walk between 2011 Edition EHR certification criteria and what we would consider equivalent proposed 2014 Edition EHR certification criteria, see Table 4 below. We believe this revision is necessary and that our proposal provides EPs, EHs, and CAHs with the flexibility to adopt or upgrade to EHR technology certified to the 2014 Edition EHR certification criteria without adversely affecting the certified status of previously adopted EHR technology or their ability to meet the definition of CEHRT. We note, however, that with respect to CQMs, EPs, EHs, and CAHs who adopt or upgrade to EHR technology certified to the 2014 Edition EHR certification criteria during FY/CY 2012 or FY/CY 2013 must ensure that their CEHRT will enable them to report on the CQMs required for the 2012 and 2013 EHR reporting periods. More specifically, the EHR technology required to electronically capture, calculate, and report CQMs during those years will be different than the EHR technology needed to do the same in FY/CY 2014 and subsequent years because CMS has not proposed to change the set of CQMs on which EPs, EHs, and CAHs would need to report until FY/CY 2014. Therefore, EPs, EHs, and CAHs will need to have EHR technology certified to the CQM certification criteria included in the 2011 Edition EHR certification criteria to be able to report on the CQMs required for the 2012 and 2013 EHR reporting periods. For further guidance, we encourage EPs, EHs, and CAHs to read CMS’ Stage 2 proposed rule to understand the CQMs that would need to be reported for a given EHR reporting period.

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Table 4. Equivalent Certification Criteria

2011 Edition		2014 Edition		2014 Edition
Ambulatory	**Inpatient**	**Ambulatory**	**Inpatient**	**Certification Criterion Name**
§ 170.304(a)	§ 170.306(a)	§ 170.314(a)(1)		Computerized provider order entry
§ 170.302(a)		§ 170.314(a)(2)		Drug-drug, drug-allergy interaction checks
§ 170.304(c)	§ 170.306(b)	§ 170.314(a)(3)		Demographics
§ 170.302(f)		§ 170.314(a)(4)		Vital signs, body mass index, and growt charts
§ 170.302(c)		§ 170.314(a)(5)		Problem list
§ 170.302(d)		§ 170.314(a)(6)		Medication list
§ 170.302(e)		§ 170.314(a)(7)		Medication allergy list
§ 170.304(e)	§ 170.306(c)	§ 170.314(a)(8)		Clinical decision support
§ 170.302(b)		§ 170.314(a)(10)		Drug-formulary checks
§ 170.302(g)		§ 170.314(a)(11)		Smoking status
§ 170.302(i)		§ 170.314(a)(14)		Patient lists
§ 170.304(d)		§ 170.314(a)(15)		Patient reminders
§ 170.302(m)		§ 170.314(a)(16)		Patient-specific education resources
	§ 170.306(h)		§ 170.314(a)(18)	Advance directives
§ 170.304(i)	§ 170.306(f)	§ 170.314(b)(1)/ § 170.314(b)(2)		Transitions of care – incorporate/create & transmit summary care record
§ 170.304(b)		§ 170.314(b)(3)		Electronic prescribing
§ 170.302(j)		§ 170.314(b)(4)		Clinical information reconciliation
§ 170.302(h)		§ 170.314(b)(5)		Incorporate lab tests and values/results

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2011 Edition		2014 Edition		2014 Edition
Ambulatory	**Inpatient**	**Ambulatory**	**Inpatient**	**Certification Criterion Name**
§ 170.302(o)		§ 170.314(d)(1)		Authentication, access control, and authorization
§ 170.302(t)		§ 170.314(d)(1)		Authentication, access control and authorization
§ 170.302(r)		§ 170.314(d)(3)		Audit report(s)
§ 170.302(q)		§ 170.314(d)(5)		Automatic log-off
§ 170.302(p)		§ 170.314(d)(6)		Emergency access
§ 170.302(u)		§ 170.314(d)(7)		Encryption of data at rest
§ 170.302(s)		§ 170.314(d)(8)		Integrity
§ 170.302(w)		§ 170.314(d)(9)		Accounting of disclosures (optional)
§ 170.304(g)		§ 170.314(e)(1)		View, download, and transmit to 3rd party
§ 170.304(f)	§ 170.306(d)	§ 170.314(e)(1)		View, download, and transmit to 3rd party
	§ 170.306(e)	§ 170.314(e)(1)		View, download, and transmit to 3rd party
§ 170.304(h)		§ 170.314(e)(2)		Clinical Summaries
§ 170.302(k)		§ 170.314(f)(1)/ § 170.314(f)(2)		Immunization information/Transmission to immunization registries
§ 170.302(l)		§ 170.314(f)(3)/ § 170.314(f)(4)		Public health surveillance/ Transmission to PH agencies

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2011 Edition		2014 Edition		2014 Edition
Ambulatory	**Inpatient**	**Ambulatory**	**Inpatient**	**Certification Criterion Name**
	§ 170.306(g)		§170.314(f)(5)/ §170.314(f)(6)	Reportable lab tests and values/results & Transmission of reportable lab tests and values/results
§ 170.302(n)		§ 170.314(g)(2)		Automated measure calculation

The second part of the revised definition of CEHRT that would apply beginning with FY/CY 2014 would accomplish four main policy goals:

1. It defines CEHRT in plain language and makes the definition and its requirements readily understandable to EPs, EHs, CAHs, EHR technology developers, and other stakeholders.
2. It continues the progress towards increased interoperability requirements for EHR technology by requiring all CEHRT to have, at a minimum, the capabilities of a Base EHR.
3. It accounts for stakeholder feedback, which expressed that the definition should align more closely with MU requirements under the EHR Incentive Programs.
4. It follows the tenets expressed in EO 13563 by reducing regulatory burden, providing more flexibility to the regulated community, and making regulatory text more understandable.

We believe it is important to briefly remind stakeholders that the definition of CEHRT does not speak to just one audience. EPs, EHs, and CAHs may view the

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definition of CEHRT in a way that informs them of the EHR technology that they must possess to accomplish MU. Alternatively, EHR technology developers may see the definition differently and in a way that informs them of the potential market demand for certain EHR technologies and, more specifically, the EHR technology that their customers will need to achieve MU.

Two types of EHR technology, Complete EHRs and EHR Modules, can be certified under the "ONC HIT Certification Program," which is the new name we are proposing for the permanent certification program (see section IV.A below). Under the revised definition of CEHRT that we are proposing for FY/CY 2014 and subsequent years, an EP, EH, or CAH could meet the definition with a certified Complete EHR, a single certified EHR Module, a combination of separately certified EHR Modules, or any combination of the three. For example, an EHR technology developer could get an EHR Module certified that would subsequently enable an EP, EH, or CAH to have EHR technology that would satisfy the proposed revised definition of CEHRT. Alternatively, an EP, EH, or CAH could use a certified Complete EHR and a certified EHR Module to meet the proposed revised definition of CEHRT.

Consistent with stakeholder feedback, an EP, EH, or CAH would generally <u>not need</u> to have or possess EHR technology in the following two scenarios in order to satisfy the proposed revised definition of CEHRT for FY/CY 2014 and subsequent years. One scenario would be where an EP, EH, or CAH qualifies for an exclusion for a MU objective and associated measure. With respect to this scenario, we expect that this new flexibility would apply in situations where the MU objective and associated measure

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would not be applicable to the EP, EH, or CAH. In most cases, we expect this would occur for EPs based on their scope of practice and would be significantly less likely to occur for most EHs and CAHs. For example, a dentist will never give immunizations and, thus, would not need EHR technology with the capability to submit immunization information to immunization registries in order to satisfy the proposed revised definition of CEHRT. As another example, and as noted earlier, an EP may not have any office visits during an EHR reporting period and thus may qualify for the exclusion for the MU objective and associated measure requiring clinical summaries to be provided to patients for each office visit. Under the proposed revised definition of CEHRT, the EP would not need to have EHR technology that supports this capability. The second scenario would be where an EP, EH, or CAH is able to and has chosen to defer a MU "menu set" objective and associated measure for a particular stage of MU. In such a case, the EP, EH, or CAH would not necessarily need to have EHR technology with the capability to meet the menu set objective and associated measure in order to have EHR technology that satisfies the proposed revised definition of CEHRT. Ultimately, under the proposed revised definition of CEHRT for FY/CY 2014 and subsequent years, the EP, EH, and CAH will be responsible for ensuring that they have the necessary EHR technology to meet the definition of a Base EHR and support the MU objectives and measures that they seek to achieve under the EHR Incentive Programs. This means that EPs, EHs, and CAHs could run the risk of not having sufficient CEHRT to support their achievement of MU if, for example, they turn out not to be able to exclude a MU objective and measure

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as anticipated or they end up needing to satisfy a menu objective and measure that they originally expected to defer.

We emphasize that under the proposed revised definition of CEHRT for FY/CY 2014 and subsequent years, all EPs, EHs, and CAHs must have EHR technology certified under the ONC HIT Certification Program to the 2014 Edition EHR certification criteria that meets the definition of a Base EHR as defined below. For example, even if an EP could claim an exclusion from the MU objective and associated measure for CPOE, he or she would still need to have EHR technology that has been certified to the CPOE certification criterion adopted by the Secretary because this capability would be included in a Base EHR.

We have consulted with CMS and have determined that it would be least confusing and burdensome for EPs, EHs, CAHs, and EHR technology developers if this revised definition would apply beginning with the EHR reporting periods that will occur in FY/CY 2014. This approach would account for the proposed start of MU Stage 2 in FY/CY 2014; the policy change we have made related to the definition of a Base EHR; the time it would take EHR developers to update their EHR technology to meet the proposed new and revised certification criteria and have the EHR technology tested and certified to those criteria; and the time it would take EPs, EHs, and CAHs to subsequently implement EHR technology certified to the 2014 Edition EHR certification criteria. We request public comment on alternative approaches we should consider that would provide equivalent simplicity and flexibility for EPs, EHs, and CAHs, as well as EHR technology developers, but that would still meet our programmatic goals and timelines.

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The revised definition of CEHRT would apply for all EPs, EHs, and CAHs, regardless of whether they are in Stage 1 or Stage 2 of MU. For example, EPs, EHs, and CAHs that are in Stage 1 or Stage 2 of MU for the EHR reporting periods in FY/CY 2014 would need to meet the revised definition of CEHRT (which includes the definition of a Base EHR). Table 5 is intended to provide a general overview of the proposed revised definition of CEHRT in relation to the stages of MU and the EHR reporting periods in FY/CY 2011 through 2014 (including the extension of Stage 1 in 2013 as proposed by CMS).

Table 5: Proposed Revised Definition of CEHRT

EHR Reporting Periods			
FY/CY 2011	**FY/CY 2012**	**FY/CY 2013**	**FY/CY2014**
MU Stage 1	**MU Stage 1**	**MU Stage 1**	**MU Stage 1 or MU Stage 2**
All EPs, EHs, and CAHs must have EHR technology that has been certified to all applicable 2011 Edition EHR certification criteria or equivalent 2014 Edition EHR certification criteria adopted by the Secretary.			All EPs, EHs, and CAHs must have EHR technology (including a Base EHR) that has been certified to the 2014 Edition EHR certification criteria that would support the objectives and measures, and their ability to successfully report the CQMs, for the MU stage that they seek to achieve.

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2. Base EHR

Section 3000(1) of the PSHA defines Certified EHR Technology to include a Qualified EHR. Section 3000(13), in turn, defines a "qualified electronic health record" or 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.

This definition of Qualified EHR is codified at 45 CFR 170.102 and is part of the current definition of CEHRT. We now propose to add the term "Base EHR" to § 170.102. This term is essentially a substitution for the term "Qualified EHR" in the revised definition of CEHRT that would apply in FY/CY 2014 and subsequent years. A Base EHR would have all of the capabilities specified in the statutory definition of a Qualified EHR (that is, in section 3000(13) of the PHSA) and additional capabilities as described below. Hereafter, we intend to use the term "Qualified EHR" only as necessary and to refer to the statutory definition, unless otherwise indicated. We believe that the term "Base EHR" is more intuitive and conveys a plain language meaning. Moreover, the term "Qualified EHR" does not inherently convey the kinds of capabilities it includes. The term "Base EHR," though, conveys that the EHR technology

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possesses capabilities that are fundamental and should be a part of any CEHRT that an EP, EH, or CAH must have to demonstrate MU. We also note that the terms "qualified EHR" and "qualified EHR products" have been used by CMS in other programs and with a different meaning. Therefore, we believe that the term "Base EHR" will be more easily understood and readily accepted by stakeholders.

We propose to define a Base 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;
2. Has the capacity:

ii. To provide clinical decision support;

iii. To support physician order entry;

iv. To capture and query information relevant to health care quality;

v. To exchange electronic health information with, and integrate such information from other sources;

vi. To protect the confidentiality, integrity, and availability of health information stored and exchanged; and

3. Meets the certification criteria adopted by the Secretary at: § 170.314(a)(1) through (8); (b)(1) and (2); (c)(1) and (2); (d)(1) through (8); and (e)(1).

We previously adopted, without modification, the statutory definition of Qualified EHR in regulation (§ 170.102). This was due to our requirement that the definition of CEHRT could only be met if the EHR technology an EP, EH, or CAH had in its possession was certified to all

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of the general certification criteria and all applicable ambulatory or inpatient setting specific certification criteria. This requirement ensured that EPs', EHs', and CAHs' CEHRT included capabilities related to privacy and security even though the statutory definition of Qualified EHR did not include a requirement for those capabilities. Based on our proposed revised definition of CEHRT, we believe it is necessary now to expand the Base EHR definition to include a capacity that addresses privacy and security.

In Table 6, we explain the certification criteria specified in paragraph (3) of the proposed Base EHR definition. As discussed in section III.A.1 of this preamble, some capabilities within the proposed 2014 Edition EHR certification criteria may only apply to the ambulatory or inpatient setting. For example, to be certified to the proposed "demographics" certification criterion (§ 170.314(a)(3)), EHR technology designed for either an ambulatory or inpatient setting would need to enable a user to electronically record, change, and access patient demographic data including preferred language, gender, race, ethnicity, and date of birth (§ 170.314(a)(3)(i)), while EHR technology designed specifically for an inpatient setting would also need to enable a user to electronically record, change, and access the "date and preliminary cause of death in the event of mortality in accordance with the standard specified in § 170.207(k)" (§ 170.314(a)(3)(ii)).

In relation to CQMs, we propose that a Base EHR include EHR technology certified to the certification criteria proposed at § 170.314(c)(1) and (2). The inclusion of § 170.314(c)(2) in a Base EHR ensures that EPs, EHs, and CAHs have the capability to incorporate all the data elements of, and calculate, at least one CQM. We anticipate that EHR technology developers would design EHR technology to incorporate the data elements for, and calculate, those CQMs

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they believe their EHR technology would need to include in order to support the providers to which they market their EHR technology. Therefore, we expect that EHR technology certified to § 170.314(c)(2) would be capable of incorporating all necessary data elements and calculating more than one CQM. This approach may, however, leave a void in the market for EHR technology that would support certain CQMs that EPs, EHs, and CAHs would need to report beginning in 2014.

Accordingly, we are interested in comments on whether we should require certification to a set number of CQMs as part of certification to § 170.314(c)(2). For example, we could require EHR technology designed for the ambulatory setting and that would constitute an EP's Base EHR to be able to incorporate data elements and calculate a specific number of CQMs for each of the CQM "domains" proposed by CMS for EPs in the Stage 2 proposed rule. And for EHR technology designed for the inpatient setting and that would constitute an EH's or CAH's Base EHR, we could require that it be able to incorporate data elements and calculate a minimum threshold number of CQMs proposed by CMS for EHs and CAHs (e.g., 24 or 36). However, we see a potential challenge with this more explicit approach. In order for EPs, EHs, and CAHs to have EHR technology that would meet the definition of a Base EHR, their EHR technology developers could be required to demonstrate that their EHR technology can incorporate and calculate data for certain CQMs that may ultimately be irrelevant their customers, but nonetheless are necessary for the EHR technology to be certified. We also request comment on whether a Base EHR should include, in addition to § 170.314(c)(1) and (2), the CQM reporting certification criteria proposed at § 170.314(c)(3), which would enable a user to electronically create a data file for transmission of clinical quality measurement results to CMS.

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With respect to the "privacy and security" certification criteria associated with the capacity to protect the confidentiality, integrity, and availability of health information stored and exchanged, we are proposing that the certification criteria should apply equally to both the ambulatory and inpatient settings. We are, however, interested in public comment on whether there should be a distinction between the ambulatory and inpatient settings for the certification of EHR technology to the privacy and security certification criteria, including for which certification criteria there could be a distinction and the basis for that distinction.

We would like to make clear that the definition of Base EHR is a requirement that must be satisfied to meet the definition of CEHRT. The proposed Base EHR definition is not meant to convey our expectation that EHR technology must be separately certified as a Base EHR. Rather, similar to the proposed revised definition of CEHRT, the definition of a Base EHR can be satisfied through a certified Complete EHR, a single EHR Module certified to all of the certification criteria specified in Table 6 below, or a combination of certified EHR Modules where the resultant combination has been collectively certified to all of the certification criteria specified in Table 6 below. In section IV.D of this preamble, we discuss proposals and options for the representation and marketing of EHR technology that meets the definition of a Base EHR.

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Table 6. Certification Criteria Required to Satisfy the Definition of a Base EHR

Base EHR Capabilities	Certification Criteria
Includes patient demographic and clinical health information, such as medical history and problem lists	Demographics § 170.314(a)(3) Vital Signs § 170.314(a)(4) Problem List § 170.314(a)(5) Medication List § 170.314(a)(6) Medication Allergy List § 170.314(a)(7)
Capacity to provide clinical decision support	Drug-Drug, Drug-Allergy Interaction Checks § 170.314(a)(2) Clinical Decision Support § 170.314(a)(8)
Capacity to support physician order entry	Computerized Provider Order Entry § 170.314(a)(1)
Capacity to capture and query information relevant to health care quality	Clinical Quality Measures § 170.314(c)(1) and (2)

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Base EHR Capabilities	Certification Criteria
Capacity to exchange electronic health information with, and integrate such information from other sources	Transitions of Care § 170.314(b)(1) and (2)
	View, Download, and Transmit to 3rd Party § 170.314(e)(1)
Capacity to protect the confidentiality, integrity, and availability of health information stored and exchanged	Privacy and Security § 170.314(d)(1) through (8)

3. Complete EHR

We are proposing to slightly revise the Complete EHR definition for clarity. A Complete EHR is currently defined as "EHR technology that has been developed to meet, at a minimum, all applicable certification criteria adopted by the Secretary." In the S&CC January 2010 interim final rule, we clarified, based on our understanding of Congress' intent, that the term "applicable" in the definition of Certified EHR Technology meant the adopted certification criteria applicable to either an ambulatory or to an inpatient setting. Therefore, to be certified to the 2011 Edition EHR certification criteria adopted by the Secretary, a Complete EHR designed for an ambulatory setting must meet the mandatory certification criteria adopted at § 170.302 and

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§ 170.304, while a Complete EHR designed for an inpatient setting must meet the mandatory certification criteria adopted under §§ 170.302 and 170.306.

We intend to maintain the concept of a Complete EHR and permit EHR technology developers to seek certification of their EHR technology as Complete EHRs, but propose to revise the definition for clarity. We propose that "Complete EHR" mean "EHR technology that has been developed to meet, at a minimum, all mandatory certification criteria of an edition of certification criteria adopted by the Secretary for either an ambulatory setting or inpatient setting." We believe this revised definition is consistent with the previous definition of Complete EHR and clarifies that a Complete EHR can be setting-specific and must meet all adopted mandatory certification criteria for a setting. Our proposed addition of paragraph (d) to § 170.300 clarifies which certification criteria in proposed § 170.314 have general applicability (apply to both ambulatory and inpatient settings) or apply only to an inpatient setting or an ambulatory setting. This proposed revised definition, if adopted, would be effective upon the final rule's effective date.

While a certified Complete EHR (under the proposed revised definition of CEHRT) will likely have more capabilities than are necessary for any single EP, EH, or CAH to achieve MU, we believe the "Complete EHR" designation still has significant market value in that: it provides purchasing clarity and assurance to EPs, EHs, and CAHs that the EHR technology they have meets the regulatory definition of CEHRT; it can support EPs, EHs, and CAHs if they attempt to achieve <u>all</u> MU objectives and measures; and it ensures all the capabilities the Complete EHR includes have been tested and certified to work properly together. We believe that the choice to adopt or upgrade a Complete EHR may be more appealing (in some cases for EHs and CAHs

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and more so for EPs given that there are over 668 certified ambulatory Complete EHRs (which includes newer versions of the same Complete EHR)), than having to assume the responsibility to determine which certified EHR Modules include the capabilities needed to support the achievement of MU or having the responsibility to ensure that the certified EHR Modules work properly together.

4. Certifications Issued for Complete EHRs and EHR Modules

Following the S&CC July 2010 final rule's publication, some stakeholders contended that the linkage between a certification issued for an EHR technology and the possession of all of that EHR technology's capabilities should be dropped. In other words, they argued that an EHR technology developer should be able to sell any component of a certified Complete EHR or EHR Module as certified and, equally, that an EP, EH, or CAH should be able to buy something less than 100% of a certified Complete EHR or EHR Module and still be able to say it is using "certified" EHR technology. In response to these stakeholder contentions, we issued FAQ 9-10-005-1[43]. This FAQ clarifies that a stand-alone, separate component of a certified Complete EHR cannot derive "certified" status based solely on it having been included as part of the Complete EHR when the Complete EHR was certified. This same principle applies to certified EHR Modules with multiple capabilities in that the components of the EHR Modules cannot be separately sold or purchased as certified EHR technology unless they have been separately certified.

[43] http://healthit.hhs.gov/portal/server.pt/community/onc_regulations_faqs/3163/faq_5/20767

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We believe that allowing separate components of a certified Complete EHR or certified EHR Module to derive "certified" status from the certification of the entire certified Complete EHR or certified EHR Module would undermine the purpose of the ONC HIT Certification Program. In essence, it would permit EHR technology developers to "self-declare" certifications for components of a certified Complete EHR or certified EHR Module that have never been independently reviewed by an ONC-ACB as actually being able to work as separate, independent technologies. This approach could result in inaccurate, deceptive, or false representations about an EHR technology's capabilities.

It is important for all stakeholders to recognize that a certification is assigned to a Complete EHR or EHR Module, not to a capability. And, in the event that combined and/or workflow-based test procedures are developed, one would be unable to infer that a specific component of a certified Complete EHR or certified EHR Module was compliant with a particular certification criterion unless the component had been separately certified as performing the required capability.

As we have stated in prior rulemakings, Congress made clear that the act of seeking certification must be voluntary. We therefore encourage EHR technology developers to seek, where possible, certification for separate components of a certified Complete EHR or certified EHR Module that would provide the solutions that EPs, EHs, and CAHs seek to adopt. Conversely, EPs, EHs, and CAHs should take note that in some cases it may not be practicable for an EHR technology developer to separate out one or more components for certification without adversely affecting the proper functioning of the remaining components.

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5. Adaptations of certified Complete EHRs or certified EHR Modules

As the hardware on which EHR technology can run continues to evolve, we expect and encourage EHR technology developers to pursue innovative ways to facilitate efficient workflows and user interactions. In this regard, we believe that it would be possible for an EHR technology developer of a certified Complete EHR or certified EHR Module (and only that EHR technology developer) to create an adaptation of a certified Complete EHR or certified EHR Module without the need for additional certification of the adaptation. We consider an "adaptation" of a certified Complete EHR or certified EHR Module to be a software application designed to run on a different medium, which includes the exact same capability or capabilities included in the certified Complete EHR or certified EHR Module. For example, an adaptation of a certified Complete EHR that is capable of running on a tablet device or smart phone could include the capabilities of a certified Complete EHR to e-prescribe, take electronic notes, and manage a patient's active medication list. In this example, the adaptation would be covered by the Complete EHR's certification so long as the adaptation included the full and exact same capabilities required for the particular certification criteria to which the Complete EHR was certified (i.e., in this case, the capabilities required by the certification criteria proposed at § 170.314(b)(3), (a)(9), and (a)(6), respectively)). We note that the user of the adaptation would need to ensure, perhaps through contractual assurances from the EHR technology developer that provides such adaptation, that the adaptation does not introduce privacy and security vulnerabilities into the certified Complete EHR or certified EHR Module.

If an adaptation <u>does not</u> make it possible for a user to use the capability or capabilities that were required for the Complete EHR or EHR Module to be certified, then the adaptation

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could jeopardize an EP's, EH's, or CAH's ability to meet MU because the user of the adaptation would not be meaningfully using EHR technology that had been certified. Furthermore, while an EHR technology developer may create an adaptation without needing to obtain an additional certification, the adaptation would be subject to the provisions of the certification issued for the Complete EHR or EHR Module. ONC-ATCBs and ONC-ACBs maintain authority over the certifications that they issue and can take appropriate action when there is evidence of non-conformance with those certifications. We invite comment on our proposed adaptation policy and whether it strikes an appropriate balance between permitting innovation and providing certainty that the EHR technology used by an EP, EH, or CAH has satisfied the certification criteria adopted by the Secretary.

IV. Provisions of the Proposed Rule affecting the Permanent Certification Program for HIT ("ONC HIT Certification Program")

A. Program Name Change

We have established two certification programs, the "temporary certification program for HIT" and the "permanent certification program for HIT" (see 75 FR 36158 and 76 FR 1262, respectively). The permanent certification program will replace the temporary certification program, which we expect will occur upon the effective date of the final rule that would follow this proposed rule. At that time, there will no longer be a need to continue to differentiate between the certification programs based on their expected duration. Therefore, we propose to replace all references in Part 170 of the Code of Federal Regulations to the permanent certification program with "ONC HIT Certification Program." We believe this new program

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name provides clear attribution to the agency responsible for the program and an appropriate description of the program's scope, covering both current and potential future activities.

B. "Minimum Standards" Code Sets

In § 170.555, we allow ONC-ACBs to certify Complete EHRs and/or EHR Modules to newer versions of certain code sets identified as "minimum standards" in Subpart B of part 170 if the Secretary has accepted a newer version for certification and implementation in EHR technology. This approach permits a Complete EHR and/or EHR Module to be certified to a newer version of an adopted code set without the need for additional rulemaking and enables CEHRT to be upgraded with a newer version of an adopted minimum standard code set without adversely affecting its certified status. We finalized two methods through which the Secretary would identify new versions of adopted "minimum standards" code sets (76 FR 1294 - 1295). The first method would allow any member of the general public to notify the National Coordinator about a new version. Under the second method, the Secretary would proactively identify newly published versions. After a new version has been identified, a determination would be issued as to whether the new version constitutes maintenance efforts or minor updates to the adopted code set and consequently may be permitted for use in certification.

The process we have followed involves presenting the identified new version of an adopted "minimum standard" code set to the HITSC for assessment, solicitation of public comments on the new version, and issuing a recommendation to the National Coordinator which would identify whether the Secretary's acceptance of the newer version for voluntary implementation and certification would burden the HIT industry, negatively affect interoperability, or cause some other type of unintended consequence. After considering the

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recommendation of the HITSC, the National Coordinator would determine whether or not to seek the Secretary's acceptance of the new version of the adopted "minimum standard" code set. If the Secretary approves the National Coordinator's request, we would issue guidance indicating that the new version of the adopted "minimum standard" code set has been accepted by the Secretary.

Our experience has shown that newer versions of the "minimum standards" code sets we adopted are issued more frequently than this process can reasonably accommodate. Additionally, based on the "minimum standard" code sets we have previously adopted and are proposing in this rule, we believe that permitting EHR technology to be upgraded and certified to newer versions of these code sets would not normally pose an interoperability risk, cause unintended consequences, or place an undue burden on the HIT industry. We propose to revise § 170.555 such that, unless the Secretary prohibits the use of a newer version of a "minimum standard" code set identified in subpart B of part 170, the newer version could be used voluntarily for certification and implemented as an upgrade to a previously certified Complete EHR or EHR Module without adversely affecting the EHR technology's certified status. We believe this proposed approach would reduce regulatory complexity by providing the industry with the flexibility to utilize newer versions of adopted "minimum standard" code sets. In consideration of this proposed new approach we want to clarify that when we refer to a "newer" version of a "minimum standard" code set, we mean a final version or release as opposed to a draft version or release of a code set.

We expect that we would generally use the same process for determining whether to prohibit the use of a newer version of a "minimum standard" code set. The public could inform

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ONC or the Secretary could proactively identify a newer version of a "minimum standard" code set that may not be appropriate for use. We expect that we would still seek a recommendation from the HITSC, based on their assessment of the newer version and on any public comments that they receive, as to whether the Secretary should prohibit the use of the newer version of the "minimum standard" code set. After considering the HITSC's recommendation, the National Coordinator would make a recommendation to the Secretary as to whether or not to allow the continued use of the newer version. Finally, if the Secretary decides to prohibit the use of a newer version of a minimum standard code set, we would issue guidance indicating that the newer version of the adopted "minimum standard" code set cannot be used for certification under the ONC HIT Certification Program, and thus upgrading previously certified Complete EHRs and EHR Modules to the newer version would adversely affect their certified status.

As an exception to the process outlined above, we believe, in limited circumstances, it may be necessary for the Secretary to act more quickly to prohibit the use of a newer version of a "minimum standard" code set. Instances could arise where the use of a newer version of a "minimum standard" code set may have an immediate negative effect on interoperability, cause an obvious unintended consequence, or pose an undue burden on the HIT industry. Therefore, under such circumstances, the Secretary may choose to prohibit the use of a newer version of a "minimum standard" code set for purposes of certification and upgrading certified EHR technology without seeking a recommendation from the HITSC in advance.

We propose to also make minor revisions to the text of § 170.555, including removing the terms "adopted" and "accepted" and replacing the term "Certified EHR Technology" in §

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170.555(b)(2) with "A certified Complete EHR or certified EHR Module." We believe the revisions provide additional clarity and specificity.

C. Revisions to EHR Module Certification Requirements

1. Privacy and Security Certification

Section 170.550(e) states that "EHR Module(s) shall be certified to all privacy and security certification criteria adopted by the Secretary, unless the EHR Module(s) is presented for certification in one of the following manners:

1. The EHR Modules are presented for certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR, and one or more of the constituent EHR Modules is demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Modules; or

2. An EHR Module is presented for certification, and the presenter can demonstrate and provide documentation to the ONC-ACB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be certified in accordance with such certification criterion."

We propose not to apply the privacy and security certification requirements at § 170.550(e) for the certification of EHR Modules to the 2014 Edition EHR certification criteria. Stakeholder feedback, particularly from EHR technology developers, has identified that this regulatory requirement is causing unnecessary burden (both in effort and cost). EHR Module developers have expressed that they have had to redesign their EHR technology in atypical ways

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to accommodate this regulatory requirement, which sometimes leads to the inclusion of a privacy or security feature that would not normally be found in a certain type of EHR Module. In turn, this has led to EPs, EHs, and CAHs purchasing EHR Modules that have redundant or sometimes conflicting privacy and security capabilities. Based on our proposal that EPs, EHs, and CAHs must have a Base EHR to meet our proposed revised definition of CEHRT that would apply beginning with FY/CY 2014, we believe that we can be responsive to stakeholder feedback with our proposal to not to apply the privacy and security certification requirements at § 170.550(e) for the certification of EHR Modules, while still requiring an equivalent or higher level of privacy and security capabilities to be part of CEHRT.

In section III.B of this preamble, we propose that a Base EHR include all the proposed mandatory privacy and security certification criteria (i.e., all privacy and security certification criteria except the optional "accounting of disclosure" certification criterion at § 170.314(d)(9)). This ensures that EPs, EHs, and CAHs have the capabilities to support the MU objective to protect electronic health information created or maintained by CEHRT through the implementation of appropriate technical capabilities. In addition, EPs, EHs, and CAHs remain responsible for implementing their EHR technology in ways that meet applicable privacy and security requirements under Federal and applicable State law (e.g., the HIPAA Privacy Rule and Security Rule and 42 CFR Part 2). These factors reduce the importance of certifying EHR Modules to all of the privacy and security certification criteria or requiring EHR Module developers to demonstrate that privacy and security certification criteria are inapplicable to or technically infeasible to implement for their EHR Modules. Thus, a regulatory burden and associated costs for EHR Module developers would be eliminated, and EPs, EHs, and CAHs

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would not have to purchase EHR Modules that have privacy and security capabilities that are redundant or conflict with the capabilities of the EHR technology that would make up their Base EHR.

2. Certification to Certain New Certification Criteria

As discussed in section III.A of this preamble, we propose to adopt new 2014 Edition EHR certification criteria that would require the following: electronic recording of the numerator for each MU objective with a percentage-based measure (§ 170.314(g)(1) "automated numerator recording"); electronic recording of activities related to non-percentage-based measures (§ 170.314(g)(3) "non-percentage-based measure use report"); and user-centered design processes to be applied to EHR technology that includes certain capabilities (§ 170.314(g)(4) "safety-enhanced design"). To ensure proper certification of EHR Modules to these proposed certification criteria, we propose to revise § 170.550.

We propose to revise § 170.550 to ensure that EHR Modules that are presented for certification to certification criteria that include capabilities for supporting an MU objective with a percentage-based measure are certified to proposed § 170.314(g)(1). However, we propose that this requirement would not apply if the EHR Module was certified to § 170.314(g)(2) (automated measure calculation) in lieu of certification to § 170.314(g)(1). We propose to revise § 170.550 in order to ensure that EHR Modules that are presented for certification to certification criteria that include capabilities for supporting an MU objective with a non-percentage-based measure are certified to proposed § 170.314(g)(3). We propose to revise § 170.550 to ensure that EHR Modules presented for certification to any of the certification criteria listed in proposed

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§ 170.314(g)(4) are also certified to § 170.314(g)(4). We propose to include these three revisions at § 170.550(f).

D. ONC-ACB Reporting Requirements

In the permanent certification program final rule (76 FR 1318-1323), we adopted (§ 170.523) principles of proper conduct to which ONC-ACBs must adhere for their authorization to remain in good standing under the program. The principle of proper conduct at § 170.523(f) requires an ONC-ACB to provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been certified which includes, at a minimum: the Complete EHR or EHR Module developer name (if applicable); the date certified; the product version; the unique certification number or other specific product identification; the clinical quality measures to which a Complete EHR or EHR Module has been certified; where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion adopted by the Secretary; and where applicable, the certification criterion or certification criteria to which each EHR Module has been certified.

We propose to require that ONC-ACBs include an additional data element in the set of data they are required to provide regarding the Complete EHRs and/or EHR Modules they report as certified to ONC under § 170.523(f). Specifically, we propose that an ONC-ACB would need to provide to ONC a hyperlink for each Complete EHR and EHR Module it certifies that would enable the public to access the test results that the ONC-ACB used to certify the EHR technology. As with all of the other data an ONC-ACB reports to ONC regarding a Complete EHR or EHR Module it certifies, we would make the hyperlink available on the CHPL with the respective certified Complete EHR or certified EHR Module. As with other records related to

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certification, we expect that ONC-ACBs would ensure the functionality of the hyperlink for a minimum of five years consistent with § 170.523(g), unless a certified Complete EHR or certified EHR Module is removed from the CHPL. Under such circumstances, the ONC-ACB would no longer need to ensure the functionality of the hyperlink, although retention of the test results would be required. We believe this additional element is important to increase transparency in the testing and certification processes and would serve to make more information available to prospective purchasers of certified Complete EHRs and certified EHR Modules as well as other stakeholders.

E. Continuation and Representation of Certified Status

1. 2011 or 2014 Edition EHR Certification Criteria Compliant

In our certification program final rules (76 FR 1302, 75 FR 36189), we indicated that we anticipated adopting new and/or revised certification criteria every two years to coincide with changes to the MU objectives and measures under the EHR Incentive Programs. We did not, however, set a specific expiration date for certifications. Rather, we explained that once the Secretary adopts new and/or revised certification criteria, EHR technology may need to be tested and certified again. In other words, the previous certifications may no longer accurately represent what is required to meet the adopted certification criteria. Based on this expectation, we established in the Permanent Certification Program final rule and at § 170.523(k) that ONC-ACBs must require as part of certification that EHR technology developers include on their websites and in all marketing materials, communications, statements, and other assertions, the years ("20[XX]/20[XX]") for which a certification issued for a Complete EHR or EHR Module would be considered compliant. Again, anticipating that every two years certification criteria

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would be adopted and EHR technology would need to be certified to the certification criteria to meet the definition of CEHRT, we clarified this provision in the Permanent Certification Program final rule with examples (76 FR 1305). These examples indicated that EHR technology certified to the adopted certification criteria (i.e., the certification criteria adopted at §§ 170.302, 170.304, and 170.306) would include "2011/2012" compliant and that certifications based on certification criteria adopted through future rulemaking would indicate "2013/2014" compliant.

In this proposed rule, we have referred to the adopted certification criteria collectively as the "2011 Edition EHR certification criteria" and the certification criteria proposed in this rule collectively as the "2014 Edition EHR certification criteria" (terms we also propose to include as defined terms in § 170.102). In line with this convention, we propose to revise § 170.523(k) to require the edition of certification criteria for which a certification issued for a Complete EHR or EHR Module would be considered compliant instead of the years (i.e., "2014 Edition EHR certification criteria compliant)." This proposed revision would apply to all certifications issued after the effective date of a final rule. We believe this proposal would further assist in eliminating confusion about the "expiration" of certifications, align with our proposed revised definition of CEHRT, and provide the market with greater clarity regarding the capabilities of certified Complete EHRs and certified EHR Modules.

For certified EHR technologies that are already designated as "2011/2012" compliant, we have considered multiple options and concluded that the best approach is to not require any changes to the "2011/2012" designation, such as having them re-designated as "2011 Edition EHR certification criteria compliant." Rather, we would simply make clear that certified Complete EHRs and certified EHR Modules that are designated as "2011/2012" compliant

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would remain valid for purposes of the EHR reporting periods in FY/CY 2013. We believe this approach minimizes the burden on EHR technology developers. We request public comment on our approach and any other approach that would present the least burden for EHR technology developers and the least confusion for the market.

Section 170.523(k)(1)(i) states, in part, that "[A] certification does not represent an endorsement by the U.S. Department of Health and Human Services or guarantee the receipt of incentive payments." We propose to revise this statement by removing "…or guarantee the receipt of incentive payments" because although incentives will be available under the Medicaid EHR Incentive Program until 2021, they will no longer be available under the Medicare EHR Incentive Program after 2016. Therefore, to prevent confusion and to defer to CMS in establishing and specifying the parameters of the EHR Incentive Programs, we propose this revision to the statement.

2. Updating a Certification

To ensure that the information required by § 170.523(k)(1)(i) remains accurate and reflects the correct edition of EHR certification criteria, ONC-ACBs, under § 170.550(d), are permitted to provide updated certifications to previously certified EHR Modules under certain circumstances. In the Permanent Certification Program final rule (76 FR 1306) and at § 170.502, we defined "providing or provide an updated certification" to an EHR Module as "the action taken by an ONC-ACB to ensure that the developer of a previously certified EHR Module(s) shall update the information required by § 170.523(k)(1)(i), after the ONC-ACB has verified that the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and that no new certification criteria adopted for privacy and security are

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applicable to the EHR Module(s)." Based on our proposal to not apply the privacy and security certification requirements at § 170.550(e) to EHR Modules certified to the proposed 2014 Edition EHR certification criteria, we propose to revise the definition of "providing or provide an updated certification" to eliminate the requirement that ONC-ACBs would need to verify that any new privacy and security certification criteria apply when they issue an updated certification. However, ONC-ACBs would still need to verify whether the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and that no new certification criteria are applicable to the EHR Module(s).

The certification criteria and certification requirements that apply to previously certified EHR Modules may change with each new edition of certification criteria that is adopted by the Secretary. Therefore, we believe that we can provide the best guidance to stakeholders on when "updating" a certification would be permitted with each rulemaking for an edition of certification criteria. For the 2014 Edition EHR certification criteria, if we were to adopt in a final rule all the proposed new certification criteria discussed above in section IV.C.2 ("Certification to Certain New Certification Criteria") of this preamble, then no previously certified EHR Modules could be issued updated certifications because every EHR Module would require certification to, at a minimum, the certification criterion at § 170.314(g)(1) (automated numerator recording) (or § 170.314(g)(2) in lieu of being certified to § 170.314(g)(1)) or the certification criterion at § 170.314(3) (non-percentage-based measure use report). Although ONC-ACBs would not be able to issue updated certifications to the 2014 Edition EHR certification criteria, "updating" certifications may still be a viable option under certain conditions when the Secretary adopts another edition of certification criteria in the future.

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3. Base EHR Representation

An EHR technology developer's Complete EHR, single EHR Module or combination of EHR Modules could constitute a Base EHR by meeting all the certification criteria required by the definition of Base EHR for the ambulatory setting or inpatient setting. We believe EPs, EHs, and CAHs would benefit from knowing which certified EHR technologies on the market constitute a Base EHR because they would need to have a Base EHR to satisfy the proposed revised definition of CEHRT beginning with FY/CY 2014. We do not believe that it is necessary to expressly propose a requirement for ONC-ACBs related to the identification of EHR technology that meets the definition of a Base EHR. To gain a competitive advantage in the market, we believe EHR technology developers would likely identify on their websites and in marketing materials, communications, statements, and other assertions whether their certified Complete EHR or EHR Module(s) meet the definition of a Base EHR (designed for either the ambulatory or inpatient setting). However, we considered as a potential alternative or complementary approach to permit ONC-ACBs when issuing certifications to Complete EHRs and EHR Modules that meet the definition of a Base EHR to formally indicate such fact to the EHR technology developer and permit the EHR technology developer in association with its EHR technology's certification to represent that the EHR technology meets the definition of a Base EHR. We welcome comments on these and any other approaches that we have not identified.

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V. Request for Additional Comments

A. Certification and Certification Criteria for Other Health Care Settings

The HITECH Act did not authorize the availability of incentives under the EHR Incentive Programs for all health care providers. Consequently, the certification criteria proposed for adoption in this rule focus primarily on enabling EHR technology to be certified and subsequently adopted and used by EPs, EHs, and CAHs who seek to demonstrate MU under the EHR Incentive Programs.

In the Permanent Certification Program final rule (76 FR 1294), we discussed the National Coordinator's statutory authority to establish a voluntary certification program or programs for other types of HIT besides EHR technology. However, as explained in the Permanent Certification Program final rule, any steps towards certifying other types of HIT, including EHR technology such as "Complete EHRs" or "EHR Modules" for settings other than inpatient or ambulatory, would first require the Secretary to adopt certification criteria for other types of HIT and/or other types of health care settings.

As we continue to adopt new and revised certification criteria to support MU, we believe that it is prudent to seek public comment on whether we should focus our efforts on the certification of the HIT used by health care providers that are ineligible to receive incentives under the EHR Incentive Programs. In particular, we are interested in commenters' thoughts on whether we should consider adopting certification criteria for other health care settings, such as the long-term care, post-acute care, and mental and behavioral health settings. For those commenters that believe we should consider certification criteria for other health care settings, we respectfully request that their comments specify the certification criteria that would be

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appropriate as well as the benefits they believe a regulatory approach would provide. Last, we ask that the public consider whether the private sector could alternatively address any perceived need or demand for such certification. For example, we are aware that the Certification Commission for Health Information Technology (CCHIT) has certification programs for long-term and post-acute care as well as behavioral health EHR technology.[44]

B. 2014 Edition EHR Accounting of Disclosures Certification Criterion

We previously adopted an "accounting of disclosures" optional certification criterion for the 2011 Edition EHR certification criteria (§ 170.302(w)), which requires EHR technology to be capable of electronically recording disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(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"). We are proposing to adopt this same certification criterion as an optional certification criterion for the 2014 Edition EHR certification criteria (§ 170.314(d)(9)), but are requesting public comment on whether we should adopt a revised certification criterion. Since publication of the S&CC July 2010 final rule, the HHS Office for Civil Rights issued a proposed rule (76 FR 31426) addressing the changes required by section 13405(c) of the HITECH Act, including changes to the accounting of disclosure requirements under the HIPAA Privacy Rule.[45] We are interested in whether commenters believe that the 2014 Edition EHR certification criterion for

[44] http://www.cchit.org/get_certified/cchit-certified-2011
[45] http://www.gpo.gov/fdsys/pkg/FR-2011-05-31/pdf/2011-13297.pdf

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"accounting of disclosures" should be revised to be a mandatory certification criterion. We are also interested in whether commenters think that the 2014 Edition EHR certification criterion should be revised to include capabilities that would more fully support an EP's, EH's, and CAH's ability to comply with the current HIPAA Privacy Rule accounting for disclosure requirements at 45 CFR 164.528. Additionally, we are interested in receiving input on whether, and what additional, changes to the certification criterion would be needed to support compliance with the proposed HIPAA Privacy Rule accounting for disclosure provisions, if they were to be adopted by final rule in substantially the same form as they were proposed. For those commenters that believe revisions are appropriate, we respectfully request that their comments identify whether the certification criterion should be changed from optional to mandatory and identify the specific capabilities that the certification criterion should include and the rationale for including those capabilities.

C. Disability Status

We are interested in whether commenters believe that EHR technology certified to the 2014 Edition EHR certification criteria should be capable of recording the functional, behavioral, cognitive, and/or disability status of patients (collectively referred to as "disability status"). The recording of disability status could have many benefits. It could facilitate provider identification of patients with disabilities and the subsequent provision of appropriate auxiliary aids and services for those patients by providers. It could also promote and facilitate the exchange of this type of patient information between providers of care, which could lead to better quality of care for those with disabilities. Further, the recording of disability status could help monitor disparities between the "disabled" and "nondisabled" population.

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We are specifically requesting comment on whether there exists a standard(s) that would be appropriate for recording disability status in EHR technology. We are aware of a standard for disability status approved by the Secretary for use in population health surveys sponsored by HHS[46] and standards under development as part of the Standards and Interoperability Framework and the Continuity Assessment Record and Evaluation (CARE) assessment tool[47]. We welcome comments on whether these standards or any other standards would be appropriate for recording disability status in EHR technology.

We ask that commenters consider whether the recording of disability status should be a required or optional capability that EHR technology would include for certification to the 2014 Edition EHR certification criteria. We also ask commenters to consider whether the recording of disability status should be part of a Base EHR and included in a separate certification criterion or possibly the "demographics" certification criterion (§ 170.314(a)(3)). Last, we ask commenters to consider whether disability status recorded according to the standard should also be included in other certification criteria such as "transitions of care – incorporate summary care record" (§ 170.314(b)(1)), "transitions of care – create and transmit summary care record" (§ 170.314(b)(2)), "view, download and transmit to 3rd party" (§ 170.314(e)(1)), and "clinical summaries" (§ 170.314(e)(2)).

D. Data Portability

We seek public comment on whether we should adopt a certification criterion that focuses on the portability of data stored within CEHRT. When a provider seeks to change EHR

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[46] http://www.minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlid=208
[47] http://wiki.siframework.org/file/detail/CARE+Tool+Functional%2C+Cognitive+and+Skin+Status.xls

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technology, we believe that they should have the ability to easily switch EHR technology –at a low cost –and migrate most or all of their data in structured form to another EHR technology. In the absence of this capability, providers may be "locked-in" to their current EHR technology. This could ultimately impede innovation and is a key aspect of the EHR technology market that requires significant maturity. With these considerations, we seek responses to the following questions:

1. Is EHR technology capable of electronically providing a sufficient amount of a patient's health history using summary of care records formatted according to the Consolidated CDA for the scenario described above?
2. Is all of the data in a provider's EHR #1 necessary to migrate over to EHR #2 in the event the provider wants to switch? We recognize that medical record retention laws affect the provider's overall approach in terms of a full archived data set, but our question seeks to determine whether the loss of some data would be tolerable and if so, which data?
3. Considering the standards we have adopted and propose for adoption in this rule, we request comment on what additional standards and guidance would be necessary to meet these market needs for data portability, including the portability of administrative data such as Medicare and Medicaid eligibility and claims. Additionally, we are interested in commenters' thoughts related to an incremental approach where a specific set of patient data could be used as a foundation to improve data portability for the situation described above as well as other situations.
4. Does the concept of a capability to batch export a single patient's records (or a provider's entire patient population) pose unintended consequences from a security perspective?

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What factors should be considered to mitigate any potential abuse of this capability, if it existed?

E. EHR Technology Price Transparency

Section 170.523(k)(3) requires that when an ONC-ACB issues a certification to a Complete EHR or EHR Module based solely on the applicable certification criteria adopted by the Secretary at subpart C of this part, the certification must be separate and distinct from any other certification(s) based on other criteria or requirements (such as those not part of the ONC HIT Certification Program). During implementation of the temporary certification program, we have received feedback from stakeholders that some EHR technology developers do not provide clear price transparency related to the full cost of a certified Complete EHR or certified EHR Module. Instead, some EHR technology developers identify prices for multiple groupings of capabilities even though the groupings do not correlate to the capabilities of the entire certified Complete EHR or certified EHR Module. Thus, with the transparency already required by § 170.523(k)(3) in mind, we believe that the EHR technology market could benefit from transparency related to the price associated with a certified Complete EHR or certified EHR Module. We believe price transparency could be achieved through a requirement that ONC-ACBs ensure that EHR technology developers include clear pricing of the full cost of their certified Complete EHR and/or certified EHR Module on their websites and in all marketing materials, communications, statements, and other assertions related to a Complete EHR's or EHR Module's certification. Put simply, this provision would require EHR technology developers to disclose only the full cost of a certified Complete EHR or certified EHR Module. It would in no way dictate the price an EHR technology developer could assign to its EHR

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technology, just that a single price for all the capabilities in the certified Complete EHR or certified EHR Module be made publicly available. We believe price transparency would provide purchasing clarity for health care providers and lead to more competitive EHR technology pricing. We request comment on the feasibility and value of price transparency for certified Complete EHRs and certified EHR Modules in the manner described.

VI. Response to Comments

Because of the large number of public comments normally received in response to Federal Register documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the DATES section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble of that document.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide 60-day notice in the Federal Register and solicit public comment on a proposed collection of information before it is submitted to the Office of Management and Budget for review and approval. In order to fairly evaluate whether an information collection should be approved by the Office of Management and Budget, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency;
2. The accuracy of the agency's estimate of the information collection burden;
3. The quality, utility, and clarity of the information to be collected; and

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4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Under the PRA, the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section are to be considered. We explicitly seek, and will consider, public comment on our assumptions as they relate to the PRA requirements summarized in this section. To comment on the collection of information or to obtain copies of the supporting statements and any related forms for the proposed paperwork collections referenced in this section, e-mail your comment or request, including your address and phone number to Sherette.funncoleman@hhs.gov, or call the Reports Clearance Office at (202) 690–6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above e-mail address within 60 days.

Abstract

Under the permanent certification program, accreditation organizations that wish to become the ONC-Approved Accreditor (ONC-AA) must submit certain information, organizations that wish to become an ONC-Authorized Certification Bodies (ONC-ACBs) must submit the information specified by the application requirements, and ONC-ACBs must comply with collection and reporting requirements, records retention requirements, and submit annual surveillance plans and annually report surveillance results.

In the Permanent Certification Program final rule (76 FR 1312-14), we solicited public comment on each of the information collections associated with the requirements described above (and included in regulation at 45 CFR 170.503(b), 170.520, and 170.523(f), (g), and (i),

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respectively). These collections of information are currently approved under OMB control number 0990-0378. In this proposed rule, we seek to revise § 170.523(f) and, correspondingly, seek to revise the approved collection of information by requiring ONC-ACBs to include one additional data element in the list of information about Complete EHRs and EHR Modules they report to ONC.

Section 170.523(f) requires an ONC-ACB to provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been certified as well as certain minimum information about each certified Complete EHR and/or EHR Module. We propose to require ONC-ACBs to additionally report to ONC a hyperlink with each EHR technology they certify that provides the public with the ability to access the test results used to certify the EHR technology. We propose to add this requirement at § 170.523(f)(8).

For the purposes of estimating this additional potential burden, we have used the following assumptions. We assume that all of the estimated applicants will apply and become ONC-ACBs (i.e., 6 applicants) and that they will report weekly (i.e., respondents will respond 52 times per year). We assume an equal distribution among ONC-ACBs in certifying EHR technology on a weekly basis. As such, based on the number of Complete EHRs and EHR Modules listed on the CHPL at the end of September of 2011 (approximately one year since the CHPL's inception), we estimate that, on average, each ONC-ACB will report 4 test results hyperlinks to ONC on a weekly basis.

We believe it will take approximately 5 minutes to report each hyperlink to ONC. Therefore, as reflected in the table below, we estimate an additional 20 minutes of work per

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ONC-ACB each week. Under the regulatory impact statement section, we discuss the estimated costs associated with reporting the hyperlinks to ONC.

Estimated Annualized Burden Hours

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
45 CFR 170.523(f)(8)	6	52	.33	103

With the additional proposed collection of information at § 170.523(f)(8), we believe 103 burden hours will be added to our burden estimate in OMB control number 0990-0378. Our estimates for the total burden hours under OMB control number 0990-0378 are expressed in the table below.

Estimated Annualized Total Burden Hours

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
45 CFR 170.503(b)	2	1	1	2
45 CFR 170.520	6	1	1	6
45 CFR 170.523(f)	6	52	1.33	415
45 CFR 170.523(g)	n/a	n/a	n/a	n/a
45 CFR 170.523(i)	6	2	1	12
Total burden hours for OMB control number 0990-0378				435

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VIII. Regulatory Impact Statement

A. Statement of Need

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 Department issued an interim final rule with a request for comments to adopt an initial set of standards, implementation specifications, and certification criteria. On July 28, 2010, the Department published in the Federal Register a final rule to complete the adoption of the initial set of standards, implementation specifications, and certification criteria. This proposed rule is being published to revise previously adopted standards, implementation specifications, and certification criteria and to propose the adoption of new standards, implementation specifications, and certification criteria in order to support future MU Stages' objectives and measures. 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 EPs, EHs, and CAHs to adopt and implement CEHRT. EPs, EHs, and CAHs who seek to qualify for incentive payments under the EHR Incentive Programs are required by statute to use CEHRT.

B. Overall Impact

We have examined the impact of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011), the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532), and Executive Order 13132 on Federalism (August 4, 1999).

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1. Executive Orders 12866 and 13563 – Regulatory Planning and Review Analysis

Executive Orders 12866 and 13563 direct 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 1 year). We have determined that this proposed 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 proposed rule, we have prepared an RIA that to the best of our ability presents the costs and benefits of the proposed rule.

a. Costs

This rule proposes the adoption of standards, implementation specifications, and certification criteria that would establish the capabilities that EHR technology would need to demonstrate to be certified. Our analysis focuses on the direct effects of the provisions of this proposed rule – the costs incurred by EHR technology developers to develop and 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 and preparation costs necessary for a Complete EHR or EHR Module already certified to the 2011 Edition EHR certification criteria to upgrade to the proposed 2014 Edition EHR certification criteria and for developing a new Complete EHR or EHR Module to meet the 2014 Edition EHR

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certification criteria. The estimated costs for having EHR technology actually tested and certified were discussed in the permanent certification program final rule (76 FR 1318-23). Last, we estimate the costs for ONC-ACBs to develop and report to ONC hyperlinks to the test results used to certify EHR technology.

i. Development and Preparation Costs for 2014 Edition EHR Certification Criteria

The development costs we estimate are categorized based on the type of certification criteria discussed in this proposed rule (i.e., new, revised, and unchanged). The numbers of Complete EHRs and EHR Modules that we estimate would be tested and certified to each certification criteria are based on the statistics we obtained from the CHPL on September 11, 2011. We attempted to identify the total number of unique Complete EHRs and EHR Modules that had been certified to the 2011 Edition EHR certification criteria as of September 11th. By this we mean that we attempted to discern how many Complete EHRs and EHR Modules were certified that would not constitute a newer version of the same EHR technology. Using this number, we have adjusted it based on additional considerations such as our proposals related to optional certification criteria, to the Base EHR certification criteria, and to our revised definition of CEHRT. The proposed revised CEHRT definition would only require EPs, EHs, and CAHs to possess the CEHRT they need to demonstrate MU for the stage they seek to accomplish, which could conceivably directly affect the number of EHR technologies developed to certain certification criteria that support MU menu objectives and measures. Using the final estimate of Complete EHRs and EHR Modules that we believe will be certified to each certification criterion, we have then created an estimated range of 10% less and 10% more EHR technologies being developed to each 2014 Edition EHR certification criterion. We believe this will account

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for potential new entrants to the market as well as for those EHR technologies tested and certified to the 2011 Edition EHR certification criteria that may not be tested and certified to the 2014 Edition EHR certification criteria because of such factors and company mergers or acquisitions and the loss of market share for some Complete EHRs and EHR Modules. For unchanged certification criteria, we have only calculated development and preparation costs for a potential 10% increase in new EHR technologies being developed and prepared to meet the certification criteria since there would not be any costs associated with upgrading EHR technologies previously certified to the 2011 Edition EHR certification criteria.

We are not aware of an available independent study (e.g., a study capturing the efforts and costs to develop and prepare Complete EHRs and EHR Modules to meet the requirements of the 2011 Edition EHR certification criteria) that we could rely upon as a basis for estimating the efforts and costs required to develop and prepare EHR technology to meet the 2014 Edition EHR certification criteria. Therefore, we have relied upon our own research to estimate the effort required to develop and prepare EHR technology to meet the requirements of the 2014 Edition EHR certification criteria. We have identified 3 levels of effort that we believe can be associated with the development and preparation of EHR technology to meet the requirements of the 2014 Edition EHR certification criteria. These levels of effort are the average range of hours we would expect to be necessary to develop EHR technology to meet the requirements of the 2014 Edition EHR certification criteria. This means that a few EHR technology developers' costs may be less than this range and a few may exceed the range. Level 1 is for certification criteria that we believe will require the least amount of effort to develop and prepare EHR technology for testing and certification to the criteria, with a range of 40-100 hours. Level 2 is for certification

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criteria that we believe will require a moderate amount of effort to develop and prepare EHR technology for testing and certification to the criteria, with a range of 100-300 hours. Level 3 is for certification criteria that we believe will require the most amount of effort to develop and prepare EHR technology for testing and certification to the criteria, with a range of 300-400 hours.

We have based the effort levels on the hours necessary for a software developer to develop and prepare the EHR technology for testing and certification. The U.S. Department of Labor, Bureau of Labor Statistics estimates that the mean hourly wage for a software developer is $43.47.[48] We have also calculated the costs of an employee's benefits. We have calculated these costs by assuming that an employer expends thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. We have concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. We have rounded up the average software developer's wage with benefits to $60 per hour.

To calculate our low cost estimates for each certification criterion in the tables below, we have multiplied the low number of the estimated range of EHR technologies expected to be developed and prepared by the low number of estimated hours for a software developer to develop and prepare the EHR technologies for testing and certification. To calculate our high cost estimates for each certification criterion in the tables below, we have multiplied the high number of the estimated range of EHR technologies expected to be developed and prepared to

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[48] http://www.bls.gov/oes/current/oes151132.htm

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the criterion by the high number of estimated hours for a software developer to develop and prepare the EHR technologies for testing and certification. For the following tables (Tables 7 through Table 13), dollar amounts are expressed in 2012 dollars.

New Certification Criteria

Table 7. 2014 Edition New EHR Certification Criteria: Level 1 Effort

Regulation Section	Title of Regulation Paragraph	Estimated # of EHR Technologies to be Developed with this capability	Average Development and Preparation Costs	
			Low ($M)	High ($M)
170.314(a)(9)	Electronic notes	420-514	1.01	3.08
170.314(a)(13)	Family health history	420-514	1.01	3.08
170.314(b)(3)	Electronic prescribing (inpatient)	101-123	.24	.74
170.314(f)(7)	Cancer case information	320-392	.77	2.35
170.314(g)(3)	Non-percentage-based measure use report	567-693	1.36	4.16
Total			**4.39**	**13.41**

Table 8. 2014 Edition New EHR Certification Criteria: Level 2 Effort

Regulation Section	Title of Regulation Paragraph	Estimated # of EHR Technologies to be Developed with this capability	Average Development and Preparation Costs	
			Low ($M)	High ($M)
170.314(a)(12)	Imaging	420-514	2.52	9.25
170.314(b)(6)	Transmission of electronic laboratory tests and values/results to ambulatory providers	146-178	.88	3.20
170.314(d)(4)	Amendments	566-691	3.40	12.44
170.314(e)(3)	Secure messaging	320-392	1.92	7.06
170.314(f)(8)	Transmission to cancer registries	320-392	1.92	7.06
170.314(g)(1)	Automated numerator recording	398-486	2.39	8.75
Total			**13.03**	**47.76**

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Table 9. 2014 Edition New EHR Certification Criteria: Level 3 Effort

Regulation Section	Title of Regulation Paragraph	Estimated # of EHR Technologies to be Developed with this capability	Average Development and Preparation Costs	
			Low ($M)	High ($M)
170.314(a)(17)	Electronic medication administration record	101-123	1.82	2.95
170.314(e)(1)	View, download, and transmit to 3rd party	567-693	10.21	16.63
170.314(g)(4)	Safety-enhanced design	567-693	10.21	16.63
Total			**22.24**	**36.21**

Revised Certification Criteria

Table 10. 2014 Edition Revised EHR Certification Criteria: Level 1 Effort

Regulation Section	Title of Regulation Paragraph	Estimated # of EHR Technologies to be Developed with this capability	Average Development and Preparation Costs	
			Low ($M)	High ($M)
170.314(a)(2)	Drug-drug, drug-allergy interaction checks	420-514	1.01	3.08
170.314(a)(3)	Demographics	460-562	1.10	3.37
170.314(a)(5)	Problem list	438-536	1.05	3.22
170.314(a)(16)	Patient-specific education resources	421-515	1.01	3.09
170.314(b)(3)	Electronic prescribing (ambulatory)	328-400	.79	2.40
170.314(b)(5)	Incorporate laboratory tests and values/results (ambulatory setting)	277-339	.66	2.03
170.314(c)(2)	Clinical quality measures – incorporate and calculate	379-463	.91	2.78
170.314(d)(3)	Audit report(s)	567-693	1.36	4.16
170.314(e)(2)	Clinical summaries	314-384	.75	2.30

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Regulation Section	Title of Regulation Paragraph	Estimated # of EHR Technologies to be Developed with this capability	Average Development and Preparation Costs	
			Low ($M)	High ($M)
170.314(f)(2)	Transmission to immunization registries	382-466	.92	2.80
170.314(f)(4)	Transmission to public health agencies	373-455	.90	2.73
170.314(f)(6)	Transmission of reportable laboratory tests and values/results	63-77	.15	.46
Total			**10.61**	**32.42**

Table 11. 2014 Edition Revised EHR Certification Criteria: Level 2 Effort

Regulation Section	Title of Regulation Paragraph	Estimated # of EHR Technologies to be Developed with this capability	Average Development and Preparation Costs	
			Low ($M)	High ($M)
170.314(b)(1)	Transitions of care – incorporate summary care record	381-465	2.29	8.37
170.314(b)(4)	Clinical information reconciliation	434-530	2.60	9.54
170.314(c)(3)	Clinical quality measures – reporting	379-463	2.27	8.33
170.314(d)(2)	Auditable events and tamper resistance	567-693	3.40	12.47
170.314(d)(7)	Encryption of data at rest	566-691	3.40	12.44
170.314(g)(2)	Automated measure calculation	396-484	2.21	8.71
Total			**16.17**	**59.86**

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Table 12. 2014 Edition Revised EHR Certification Criteria: Level 3 Effort

Regulation Section	Title of Regulation Paragraph	Estimated # of EHR Technologies to be Developed with this capability	Average Development and Preparation Costs	
			Low ($M)	High ($M)
170.314(a)(8)	Clinical decision support	409-501	7.36	12.02
170.314(b)(2)	Transitions of care – create and transmit	381-465	6.86	11.16
170.314(c)(1)	Clinical quality measures – capture and export	379-463	6.82	11.11
Total			**21.04**	**34.29**

Unchanged Certification Criteria

Table 13. 2014 Edition Unchanged EHR Certification Criteria: Level 2 Effort

Regulation Section	Title of Regulation Paragraph	Estimated # of New EHR Technologies to be Developed with this capability	Average Development and Preparation Costs	
			Low ($M)	High ($M)
170.314(a)(1)	CPOE	42	.25	.76
170.314(a)(4)	Vital signs, body mass index, and growth charts	48	.29	.86
170.314(a)(6)	Medication list	50	.30	.90
170.314(a)(7)	Medication allergy list	50	.30	.90
170.314(a)(10)	Drug-formulary checks	47	.28	.85
170.314(a)(11)	Smoking status	50	.30	.90
170.314(a)(14)	Patient lists	46	.28	.83
170.314(a)(15)	Patient reminders	36	.22	.65
170.314(a)(18)	Advance directives	11	.07	.20
170.314(b)(5)	Incorporate laboratory tests and values/results (inpatient setting)	16	.10	.29
170.314(d)(1)	Authentication, access control, and authorization	64	.38	1.15
170.314(d)(5)	Automatic log-off	63	.38	1.13
170.314(d)(6)	Emergency access	62	.37	1.12
170.314(d)(8)	Integrity	63	.38	1.13
170.314(d)(9)	Accounting of disclosures	15	.09	.27
170.314(f)(1)	Immunization information	42	.25	.76
170.314(f)(3)	Public health surveillance	41	.25	.74
170.314(f)(5)	Reportable laboratory tests and values/results	7	.04	.13
Total			4.53	13.57

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ii. Overall Development and Preparation Costs Over a 3-year Period

In total, we estimate the overall costs for a 3-year period to be $92.01 million to $237.52 million, with a cost mid-point of approximately $164.77 million. If we were to evenly distribute the overall costs to develop and prepare Complete EHRs and EHR Modules between calendar years 2012 and 2014, we believe they would likely be in the range of $30.67 million to $79.17 million per year with an annual cost mid-point of approximately $54.92 million. However, we do not believe that the costs will be spread evenly over these three years due to market pressures to have certified Complete EHRs and certified EHR Modules ready and available prior to when EPs, EHs, and CAHs must meet the proposed revised definition of CEHRT for FY/CY 2014. We assume this factor will cause a greater number of developers to prepare EHR technology for testing and certification towards the end of 2012 and throughout 2013, rather than in 2014. As a result, we believe as represented in Table 14 that the costs attributable to this proposed rule will be distributed as follows: 40% for 2012, 50% for 2013, and 10% for 2014. The dollar amounts expressed in Table 14 are expressed in 2012 dollars.

Table 14. 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)
2012	40%	36.80	95.01	65.91
2013	50%	46.01	118.76	82.38
2014	10%	9.20	23.75	16.48
3-Year Totals		92.01	237.52	167.53

iii. Costs for Reporting Test Results Hyperlinks

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Costs to ONC-ACBs

Under § 170.523(f)(8), ONC-ACBs will be required to provide ONC, no less frequently than weekly, a hyperlink with each EHR technology it certifies that provides the public with the ability to access the test results used to certify the EHR technology. As stated in the collection of information section, we will require the reporting of this information on a weekly basis and that it will take each ONC-ACB about 20 minutes to prepare and electronically transmit an estimated four test results hyperlinks with the other required information to ONC each week.

We believe that an employee equivalent to the Federal Classification of GS-9 Step 1 could report the hyperlink to ONC. We have utilized the corresponding employee hourly rate for the locality pay area of Washington, D.C., as published by OPM, to calculate our cost estimates. We have also calculated the costs of the employee's benefits while completing the specified tasks. We have calculated these costs by assuming that an ONC-ACB expends thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. We have concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. Our cost estimates are expressed in Table 15 below and are expressed in 2012 dollars.

Table 15. Annual Costs for an ONC-ACB to Report Test Results Hyperlinks to ONC

Program Requirement	Employee Equivalent	Annual Burden Hours Per ONC-ACB	Employee Hourly Wage Rate	Employee Benefits Hourly Cost	Total Cost Per ONC-ACB
45 CFR 170.523(f)(8)	GS-9 Step 1	17.16	$22.39	$8.06	$522.52

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To estimate the highest possible cost, we assume that all of the estimated applicants (i.e., six) that we anticipate will apply under the permanent certification program will become ONC-ACBs. Therefore, we estimate the total annual development and reporting cost for under the permanent certification program to be $3,136 (rounded using a total of 103 hours).

Costs to the Federal Government

We do not believe that we will incur any additional costs to post test results hyperlinks than the costs we estimated for posting a list of all certified Complete EHRs and EHR Modules on our website (i.e., the CHPL), which was $10,784 on an annualized basis (76 FR 1323).

b. Benefits

We believe that there will be several benefits that may arise from this proposed rule. Foremost, the proposed 2014 Edition EHR certification criteria include the capabilities that CEHRT must have to support EPs', EHs', and CAHs' attempts to demonstrate MU and qualify for incentive payments under the EHR Incentive Programs. Additionally, by adopting the proposed new and revised certification criteria, the interoperability, functionality, utility, and security of EHR technology will be further enhanced. 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, and reduce medical errors and unnecessary tests. The standards adopted will aid in fostering greater interoperability. The proposals in this proposed rule would increase the competition and innovation in the HIT marketplace that was spurred by the Secretary's adoption of the 2011 Edition EHR certification criteria. The proposals to revise the definition of CEHRT, the process for approving newer versions of minimum standards, and the privacy and security certification of EHR Modules will reduce the regulatory burden and add

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flexibility for EHR technology developers, EPs, EHs, and CAHs. Further, the proposed splitting of certification criteria into multiple certification criteria should increase the opportunity and flexibility for EHR technology developers to have more EHR technology eligible for certification. Last, we believe the proposals in this proposed rule will be supportive of other initiatives, such as the Partnership for Patients.

2. Regulatory Flexibility Act

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.

The Small Business Administration (SBA) establishes the size of small businesses for Federal government programs based on average annual receipts or the average employment of a firm. 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 proposed 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 SBA size standard associated with this NAICS code is set at $25 million in annual receipts[49] 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

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[49] 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/sites/default/files/Size_Standards_Table.pdf

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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. However, although not correlated to the size standard for NAICS code 541511, we do have information indicating that over 60% of EHR technology developers that have had Complete EHRs and/or EHR Modules certified to the 2011 Edition EHR certification criteria have less than 51 employees.

We estimate that this proposed rule would have effects on Complete EHR and EHR Module developers, some of which may be small entities. However, we believe that we have proposed the minimum amount of requirements necessary to accomplish our policy goals, including a reduction in regulatory burden and additional flexibility for the regulated community; and that no additional appropriate regulatory alternatives could be developed to lessen the compliance burden associated with this proposed rule. In order for a Complete EHR or EHR Module to provide the capabilities that an EP, EH, or CAH would be required to use under the EHR Incentive Programs Stage 2 final rule, it will need to comply with the applicable certification criteria adopted by the Secretary. Moreover, we note that this proposed 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

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to recover with an appropriate rate of return. Accordingly, we do not believe that the proposed rule will create a significant impact on a substantial number of small entities. The Secretary certifies that this proposed rule will not have a significant impact on a substantial number of small entities. We do, however, request comment on whether there are small entities that we have not identified that may be affected in a significant way by this proposed rule.

3. 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 proposed 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 we propose for adoption.

4. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. The current inflation-adjusted statutory threshold is approximately $136 million. This final rule will not impose an unfunded mandate on State, local, and tribal governments or on the private sector that will reach the threshold level.

The Office of Management and Budget reviewed this proposed rule.

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List of Subjects in 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 adding in alphanumeric order the definitions "2011 Edition EHR certification criteria," "2014 Edition EHR certification criteria," and "Base EHR" and revising the definitions of "Certified EHR Technology" and "Complete EHR" to read as follows:

§ 170.102 Definitions.

* * * * *

2011 Edition EHR certification criteria means the certification criteria at §§ 170.302, 170.304, and 170.306.

2014 Edition EHR certification criteria means the certification criteria at § 170.314.

Base EHR means an electronic record of health-related information on an individual that:

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(1) Includes patient demographic and clinical health information, such as medical history and problem lists;

(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;

(iv) To exchange electronic health information with, and integrate such information from other sources;

(v) To protect the confidentiality, integrity, and availability of health information stored and exchanged; and

(3) Meets the certification criteria adopted by the Secretary at: § 170.314(a)(1) through (8); (b)(1) and (2); (c)(1) and (2); (d)(1) through (8); and (e)(1).

* * * * *

Certified EHR Technology means:

(1) For any Federal fiscal year (FY) or calendar year (CY) up to and including 2013:

(i) 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 for the 2011 Edition EHR certification criteria or the equivalent 2014 Edition EHR certification criteria; or

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(ii) 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 for the 2011 Edition EHR certification criteria or the equivalent 2014 Edition EHR certification criteria, and the resultant combination also meets the requirements included in the definition of a Qualified EHR.

(2) For FY and CY 2014 and subsequent years, the following: EHR technology certified under the ONC HIT Certification Program to the 2014 Edition EHR certification criteria that has:

(i) The capabilities required to meet the definition of a Base EHR; and

(ii) All other capabilities that are necessary to meet the objectives and associated measures under 42 CFR 495.6 and successfully report the clinical quality measures selected by CMS in the form and manner specified by CMS (or the States, as applicable) for the stage of meaningful use that an eligible professional, eligible hospital, or critical access hospital seeks to achieve.

Complete EHR means EHR technology that has been developed to meet, at a minimum, all mandatory certification criteria of an edition of certification criteria adopted by the Secretary for either an ambulatory setting or inpatient setting.

* * * * *

3. Add § 170.202 to read as follows:

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§ 170.202 Transport standards.

The Secretary adopts the following transport standards:

(a) Directed exchange. (1) Standard. Applicability Statement for Secure Health Transport (incorporated by reference in § 170.299).

(2) Standard. External Data Representation and Cross-Enterprise Document Media Interchange for Direct Messaging (incorporated by reference in § 170.299).

(3) Standard. Simple Object Access Protocol (SOAP)-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 (incorporated by reference in § 170.299).

(b) [Reserved]

4. Add § 170.204 to read as follows:

§ 170.204 Functional standards.

The Secretary adopts the following functional standards:

(a) Accessibility. Standard. Web Content Accessibility Guidelines (WCAG) 2.0, Level AA Conformance (incorporated by reference in § 170.299).

(b) Reference source. Standard. Health Level Seven Context-Aware Knowledge Retrieval (Infobutton), International Normative Edition 2010 (incorporated by reference in § 170.299).

(c) Clinical quality measure data capture and export. Standard. National Quality Forum (NQF) Quality Data Model, Version 2011 (incorporated by reference in § 170.299).

5. In § 170.205, republish the introductory text and add paragraphs (a)(3), (d)(3), (e)(3), and (g) through (k) to read as follows:

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§ 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) * * *

(3) Standard. HL7 Implementation Guide for Clinical Document Architecture, Release 2.0 (Consolidated CDA) (US Realm), Draft, September 2011(incorporated by reference in § 170.299).

* * * * *

(d) * * *

(3) Standard. HL7 2.5.1 (incorporated by reference in § 170.299). Implementation specifications. PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data HL7 Version 2.5.1 (incorporated by reference in § 170.299).

(e) * * *

(3) Standard. HL7 2.5.1 (incorporated by reference in § 170.299). Implementation specifications. HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.3 (incorporated by reference in § 170.299).

* * * * *

(g) Electronic transmission 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

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Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with errata (incorporated by reference in § 170.299).

(h) [Reserved]

(i) Cancer information. Standard. HL7 Clinical Document Architecture (CDA), Release 2 (incorporated by reference in § 170.299). Implementation specifications. Implementation Guide for Healthcare Provider Reporting to Central Cancer Registries, Draft, February 2012 (incorporated by reference in § 170.299).

(j) Imaging. Digital Imaging and Communications in Medicine (DICOM) PS 3—2011.

(k) Electronic incorporation and transmission of lab results. Standard. HL7 2.5.1 (incorporated by reference in § 170.299). Implementation specifications. HL7 Version 2.5.1 Implementation Guide: Standards and Interoperability Framework Lab Results Interface, Release 1 (US Realm) (incorporation by reference in § 170.299).

6. In § 170.207, republish the introductory text, revise paragraph (f), and add paragraphs (a)(3), (b)(3), and (g) through (m) to read as follows:

§ 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) * * *

(3) Standard. International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) International Release January 2012 (incorporated by reference in § 170.299).

(b) * * *

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(3) Standard. The code set specified at 45 CFR 162.1002(c)(3).

* * * * *

(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, as revised, October 30, 1997 (see "Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity," available at http://www.whitehouse.gov/omb/fedreg_1997standards).

(g) Laboratory tests. Standard. Logical Observation Identifiers Names and Codes (LOINC®) version 2.38 (incorporated by reference in § 170.299).

(h) Medications. Standard. RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, February 6, 2012 Release (incorporated by reference in § 170.299).

(i) Immunizations. Standard. HL7 Standard Code Set CVX - Vaccines Administered, August 15, 2011 version (incorporated by reference in § 170.299).

(j) Preferred language. Standard. ISO 639-1:2002 (incorporated by reference in § 170.299).

(k) Preliminary determination of cause of death. Standard. The code set specified at 45 CFR 162.1002(c)(2) for the indicated conditions.

(l) Smoking status. Standard. 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.

(m) Encounter diagnoses. Standard. The code set specified at 45 CFR 162.1002(c)(2) for the indicated conditions.

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7. In § 170.210 republish the introductory text and add paragraphs (e), (f), and (g) to read as follows:

§ 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:

* * * * *

(e) Record actions related to electronic health information, audit log status, and encryption of end-user devices. (1) When EHR technology is used to create, change, access, or delete electronic health information, the following information must be recorded:

(i) The electronic health information affected by the action(s);

(ii) The date and time each action occurs in accordance with the standard specified at § 170.210(g);

(iii) The action(s) that occurred;

(iv) Patient identification; and

(v) User identification.

(2) When the audit log is enabled or disabled, the following must be recorded:

(i) The date and time each action occurs in accordance with the standard specified at § 170.210(g); and

(ii) User identification.

(3) As applicable, when encryption of electronic health information managed by EHR technology on end-user devices is enabled or disabled, the following must be recorded:

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(i) The date and time each action occurs in accordance with the standard specified at § 170.210(g); and

(ii) User identification.

(f) Encryption and hashing of electronic health information. Any encryption and hashing 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).

(g) Synchronized clocks. The date and time recorded utilize a system clock that has been synchronized following Request for Comments (RFC) 1305 Network Time Protocol (NTP) v3 (incorporated by reference in §170.299) or RFC 5905 NTPv4 (incorporated by reference in §170.299).

8. In § 170.300, republish paragraphs (a) and (b), revise paragraph (c) and add paragraph (d) to read as follows:

§ 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, the 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 or capabilities specified within a certification criterion that are designated as optional.

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(d) In § 170.314, all certification criteria and all capabilities specified within a certification criterion have general applicability (i.e., apply to both ambulatory and inpatient settings) unless designated as "inpatient setting only" or "ambulatory setting only."

(1) "Inpatient setting only" means that the criterion or capability within the criterion is only required for certification of EHR technology designed for use in an inpatient setting.

(2) "Ambulatory setting only" means that the criterion or capability within the criterion is only required for certification of EHR technology designed for use in an ambulatory setting.

9. Add § 170.314 to subpart C to read as follows:

§ 170.314 2014 Edition electronic health record certification criteria.

The Secretary adopts the following 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) Clinical.

(1) Computerized provider order entry. Enable a user to electronically record, change, and access the following order types, at a minimum:

(i) Medications;

(ii) Laboratory; and

(iii) Radiology/imaging.

(2) Drug-drug, drug-allergy interaction checks.

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(i) Interventions. Before a medication order is placed during computerized provider order entry (CPOE), interventions must automatically and electronically indicate to a user at the point of care of drug-drug and drug-allergy contraindications based on medication list and medication allergy list.

(ii) Adjustments.

(A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.

(B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.

(3) Demographics.

(i) Enable a user to electronically record, change, and access patient demographic data including preferred language, gender, race, ethnicity, and date of birth.

(A) Enable race and ethnicity to be recorded in accordance with the standard specified in § 170.207(f) and whether a patient declines to specify race and/or ethnicity.

(B) Enable preferred language to be recorded in accordance with the standard specified in § 170.207(j) and whether a patient declines to specify a preferred language.

(ii) Inpatient setting only. Enable a user to electronically record, change, and access preliminary cause of death in the event of a mortality in accordance with the standard specified in § 170.207(k).

(4) Vital signs, body mass index, and growth charts.

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(i) Vital signs. Enable a user to electronically record and change, and access recordings of a patient's vital signs including, at a minimum, height/length, weight, and blood pressure.

(ii) Calculate body mass index. Automatically calculate and electronically display body mass index based on a patient's height and weight.

(iii) Optional—Plot and display growth charts. Plot and electronically display, upon request, growth charts for patients.

(5) Problem list. Enable a user to electronically record, change, and access a patient's problem list for longitudinal care in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3).

(6) Medication list. Enable a user to electronically record, change, and access a patient's active medication list as well as medication history for longitudinal care.

(7) Medication allergy list. Enable a user to electronically record, change, and access a patient's active medication allergy list as well as medication allergy history for longitudinal care.

(8) Clinical decision support.

(i) Evidence-based decision support interventions. Enable a user to select (or activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in each one or any combination of the following:

(A) Problem list;

(B) Medication list;

(C) Medication allergy list;

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(D) Demographics;

(E) Laboratory tests and values/results; and

(F) Vital signs.

(ii) Linked referential clinical decision support.

(A) Enable a user to retrieve diagnostic or therapeutic reference information in accordance with the standard specified at § 170.204(b)(1).

(B)Enable a user to access the reference information specified in paragraph (a)(8)(ii)(A) of this section relevant to patient context based on the data elements included in each one or any combination of the following:

(1) Problem list;

(2) Medication list;

(3) Medication allergy list;

(4) Demographics;

(5) Laboratory tests and values/results; and

(6) Vital signs.

(iii) Configure clinical decision support.

(A) Enable interventions and reference resources specified in paragraphs (a)(8)(i) and (ii) of this section to be configured by an identified set of users (e.g., system administrator) based on each one of the following:

(1) A user's role;

(2) Clinical setting; and

(3) Identified points in the clinical workflow.

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(B) Enable interventions to be triggered, based on the data elements specified in paragraph (a)(8)(i) of this section, when a summary care record is incorporated pursuant to § 170.314(b)(1).

(iv) Automatically and electronically interact. Interventions selected and configured in accordance with paragraphs (a)(8)(i) through (iii) of this section must automatically and electronically occur when a user is interacting with EHR technology.

(v) Source attributes. Enable a user to review the attributes for each intervention or reference source for all clinical decision support resources including:

(A) Bibliographic citation (clinical research/guideline) including publication;

(B) Developer of the intervention (translation from clinical research/guideline);

(C) Funding source of intervention development technical implementation; and

(D) Release and, if applicable, revision date of the intervention.

(9) Electronic notes. Enable a user to electronically record, change, access, and search electronic notes.

(10) Drug-formulary checks. Enable a user to electronically check if drugs are in a formulary or preferred drug list.

(11) Smoking status. Enable a user to electronically record, change, and access the smoking status of a patient in accordance with the standard specified at § 170.207(l).

(12) Imaging. Electronically indicate to a user the availability of a patient's images and/or narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable immediate electronic access to such images and narrative interpretations.

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(13) Family health history. Enable a user to electronically record, change, and access a patient's family health history.

(14) Patient lists. Enable a user to electronically select, sort, access, and create lists of patients according to, at a minimum, the data elements included in:

(i) Problem list;

(ii) Medication list;

(iii) Demographics; and

(iv) Laboratory tests and values/results.

(15) Ambulatory setting only—patient reminders. Enable a user to electronically create a patient reminder list for preventive or follow-up care according to patient preferences based on, at a minimum, the data elements included in:

(i) Problem list;

(ii) Medication list;

(iii) Medication allergy list;

(iv) Demographics; and

(v) Laboratory tests and values/results.

(16) Patient-specific education resources. Enable a user to electronically identify and provide patient-specific education resources according to:

(i) At a minimum, each one of the data elements included in the patient's: problem list; medication list; and laboratory tests and values/results; and

(ii) The standard specified at § 170.204(b)(1).

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(17) Inpatient setting only—electronic medication administration record.

(i) In combination with an assistive technology that provides automated information on the "rights" specified in paragraphs (a)(17)(i)(A) through (D) of this section, enable a user to electronically verify the following before administering medication(s):

(A) Right patient. The patient to whom the medication is to be administered matches the medication to be administered.

(B) Right medication. The medication to be administered matches the medication ordered for the patient.

(C) Right dose. The dose of the medication to be administered matches the dose of the medication ordered for the patient.

(D) Right route. The route of medication delivery matches the route specified in the medication order.

(ii) Right time. Electronically record the time and date in accordance with the standard specified in § 170.210(g), and user identification when a medication is administered.

(18) Inpatient setting only—advance directives. Enable a user to electronically record whether a patient has an advance directive.

(b) Care coordination.

(1) Transitions of care – incorporate summary care record. Upon receipt of a summary care record formatted according to the standard adopted at § 170.205(a)(3), electronically incorporate, at a minimum, the following data elements: Patient name; gender; race; ethnicity; preferred language; date of birth; smoking status; vital signs; medications; medication allergies; problems; procedures; laboratory tests and values/results; the referring or transitioning provider's name and

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contact information; hospital admission and discharge dates and locations; discharge instructions; reason(s) for hospitalization; care plan, including goals and instructions; names of providers of care during hospitalizations; and names and contact information of any additional known care team members beyond the referring or transitioning provider and the receiving provider.

(2) Transitions of care – create and transmit summary care record.

(i) Enable a user to electronically create a summary care record formatted according to the standard adopted at § 170.205(a)(3) and that includes, at a minimum, the following data elements expressed, where applicable, according to the specified standard(s):

(A) Patient name; gender; date of birth; medication allergies; vital signs; laboratory tests and values/results; the referring or transitioning provider's name and contact information; names and contact information of any additional care team members beyond the referring or transitioning provider and the receiving provider; care plan, including goals and instructions;

(B) Race and ethnicity. The standard specified in § 170.207(f);

(C) Preferred language. The standard specified in § 170.207(j);

(D) Smoking status. The standard specified in § 170.207(1);

(E) Problems. At a minimum, the version of the standard specified in § 170.207(a)(3);

(F) Encounter diagnoses. The standard specified in § 170.207(m);

(G) Procedures. The standard specified in § 170.207(b)(2) or § 170.207(b)(3);

(H) Laboratory test(s). At a minimum, the version of the standard specified in § 170.207(g);

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(I) Laboratory value(s)/result(s). The value(s)/results of the laboratory test(s) performed;

(J) Medications. At a minimum, the version of the standard specified in § 170.207(h); and

(K) Inpatient setting only. Hospital admission and discharge dates and location; names of providers of care during hospitalizations; discharge instructions; and reason(s) for hospitalization.

(ii) Transmit. Enable a user to electronically transmit the summary care record created in paragraph (b)(2)(i) of this section in accordance with:

(A) The standards specified in § 170.202(a)(1) and (2).

(B) Optional. The standard specified in § 170.202(a)(3).

(3) Electronic prescribing. Enable a user to electronically create prescriptions and prescription-related information for electronic transmission in accordance with:

(i) The standard specified in § 170.205(b)(2); and

(ii) At a minimum, the version of the standard specified in § 170.207(h).

(4) Clinical information reconciliation. Enable a user to electronically reconcile the data elements that represent a patient's active medication, problem, and medication allergy list as follows. For each list type:

(i) Electronically display the data elements from two or more sources in a manner that allows a user to view the data elements and their attributes, which must include, at a minimum, the source and last modification date.

(ii) Enable a user to merge and remove individual data elements.

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(iii) Enable a user to review and validate the accuracy of a final set of data elements and, upon a user's confirmation, automatically update the list.

(5) Incorporate laboratory tests and values/results.

(i) Receive results.

(A) Ambulatory setting only.

(1) Electronically receive clinical laboratory tests and values/results in accordance with the standard (and applicable implementation specifications) specified in § 170.205(k) and, at a minimum, the version of the standard specified in § 170.207(g).

(2) Electronically display the tests and values/results received in human readable format.

(B) Inpatient setting only. Electronically receive clinical laboratory tests and values/results in a structured format and electronically display such tests and values/results in human readable format.

(ii) Display test report information. Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).

(iii) Incorporate tests and values/results. Electronically incorporate a laboratory test and value/result with a laboratory order or patient record.

(6) Inpatient setting only—transmission of electronic laboratory tests and values/results to ambulatory providers. Enable a user to electronically create laboratory tests and values/results for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(k); and

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(ii)At a minimum, the version of the standard specified in § 170.207(g).

(c) Clinical quality measures.

(1) Clinical quality measures – capture and export.

(i) Capture. Electronically record all of the data elements that are represented in the standard specified in § 170.204(c).

(ii) Export. Electronically export a data file that includes all of the data elements that are represented in the standard specified in § 170.204(c).

(2) Clinical quality measures – incorporate and calculate.

(i) Incorporate. Electronically incorporate all of the data elements necessary to calculate each of the clinical quality measures that are included in the EHR technology.

(ii) Calculate. Electronically calculate each clinical quality measure that is included in the EHR technology.

(3) Clinical quality measures – reporting. Enable a user to electronically create for transmission clinical quality measurement results in a data file defined by CMS.

(d) Privacy and security.

(1) Authentication, access control, and authorization.

(i) Verify against a unique identifier(s) (e.g., username or number) that a person seeking access to electronic health information is the one claimed; and

(ii) Establish the type of access to electronic health information a user is permitted based on the unique identifier(s) provided in paragraph (d)(1)(i) of this section, and the actions the user is permitted to perform with the EHR technology.

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(2) Auditable events and tamper-resistance.

(i) Enabled by default. The capability specified in paragraph (d)(2)(ii) of this section must be enabled by default (i.e., turned on) and must only be permitted to be disabled (and re-enabled) by a limited set of identified users.

(ii) Record actions. Record actions related to electronic health information, audit log status and, as applicable, encryption of end-user devices in accordance with the standard specified in § 170.210(e).

(iii) Audit log protection. Actions recorded in accordance with paragraph (d)(2)(ii) must not be capable of being changed, overwritten, or deleted.

(iv) Detection. Detect the alteration of audit logs.

(3) Audit report(s). Enable a user to create an audit report for a specific time period and to sort entries in the audit log according to each of the elements specified in the standard at § 170.210(e).

(4) Amendments.

(i) Enable a user to electronically amend a patient's health record to:

(A) Replace existing information in a way that preserves the original information; and

(B) Append patient supplied information, in free text or scanned, directly to a patient's health record or by embedding an electronic link to the location of the content of the amendment.

(ii) Enable a user to electronically append a response to patient supplied information in a patient's health record.

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(5) Automatic log-off. Terminate an electronic session after a predetermined time of inactivity.

(6) Emergency access. Permit an identified set of users to access electronic health information during an emergency.

(7) Encryption of data at rest. Paragraph (d)(7)(i) or (ii) of this section must be met to satisfy this certification criterion.

(i) If EHR technology manages electronic health information on an end-user device and the electronic health information remains stored on the device after use of the EHR technology on that device has stopped, the electronic health information must be encrypted in accordance with the standard specified in § 170.210(a)(1). This capability must be enabled by default (i.e., turned on) and must only be permitted to be disabled (and re-enabled) by a limited set of identified users.

(ii) Electronic health information managed by EHR technology never remains stored on end-user devices after use of the EHR technology on those devices has stopped.

(8) Integrity.

(i) Create a message digest in accordance with the standard specified in § 170.210(c).

(ii) 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.

(9) Optional—accounting of disclosures. Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(d).

(e) Patient engagement.

(1) View, download, and transmit to 3rd party.

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(i) Enable a user to provide patients (and their authorized representatives) with online access to do all of the following:

(A) View. Electronically view in accordance with the standard adopted at § 170.204(a), at a minimum, the following data elements:

(1) Patient name; gender; date of birth; race; ethnicity; preferred language; smoking status; problem list; medication list; medication allergy list; procedures; vital signs; laboratory tests and values/results; provider's name and contact information; names and contact information of any additional care team members beyond the referring or transitioning provider and the receiving provider; and care plan, including goals and instructions.

(2) Inpatient setting only. Admission and discharge dates and locations; reason(s) for hospitalization; names of providers of care during hospitalization; laboratory tests and values/results (available at time of discharge); and discharge instructions for patient.

(B) Download. Electronically download:

(1) A file in human readable format that includes, at a minimum:

(i) Ambulatory setting only. All of the data elements specified in paragraph (e)(1)(i)(A)(1) of this section.

(ii) Inpatient setting only. All of the data elements specified in paragraphs (e)(1)(i)(A)(1) and (2) of this section.

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(2) A summary care record formatted according to the standards adopted at § 170.205(a)(3) and that includes, at a minimum, the following data elements expressed, where applicable, according to the specified standard(s):

(i) Patient name; gender; date of birth; medication allergies; vital signs; the provider's name and contact information; names and contact information of any additional care team members beyond the referring or transitioning provider and the receiving provider; care plan, including goals and instructions;

(ii) Race and ethnicity. The standard specified in § 170.207(f);

(iii) Preferred language. The standard specified in § 170.207(j);

(iv) Smoking status. The standard specified in § 170.207(l);

(v) Problems. At a minimum, the version of the standard specified in § 170.207(a)(3);

(vi) Encounter diagnoses. The standard specified in § 170.207(m);

(vii) Procedures. The standard specified in § 170.207(b)(2) or § 170.207(b)(3);

(viii) Laboratory test(s). At a minimum, the version of the standard specified in § 170.207(g);

(ix) Laboratory value(s)/result(s). The value(s)/results of the laboratory test(s) performed;

(x) Medications. At a minimum, the version of the standard specified in § 170.207(h); and

(xi) Inpatient setting only. The data elements specified in paragraph (e)(1)(i)(A)(2) of this section.

(3) Images formatted according to the standard adopted at § 170.205(j).

(C) Transmit to third party. Electronically transmit the summary care record created in paragraph (e)(1)(i)(B)(2) of this sectionand images available to download in paragraph (e)(1)(i)(B)(3) of this section in accordance with:

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(1) The standard specified in § 170.202(a)(1); and

(2) The standard specified in § 170.202(a)(2).

(ii) Patient accessible log.

(A) When electronic health information is viewed, downloaded, or transmitted to a third-party using the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section, the following information must be recorded and made accessible to the patient:

(1) The electronic health information affected by the action(s);

(2) The date and time each action occurs in accordance with the standard specified at § 170.210(g);

(3) The action(s) that occurred; and

(4) User identification.

(B) EHR technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of this section if it is also certified to the certification criterion adopted at § 170.314(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) is accessible by the patient.

(2) Ambulatory setting only—clinical summaries. Enable a user to provide clinical summaries to patients for each office visit that include, at a minimum, the following data elements: provider's name and office contact information; date and location of visit; reason for visit; patient's name; gender; race; ethnicity; date of birth; preferred language; smoking status; vital signs and any updates; problem list and any updates; medication list and any updates; medication allergy list and any updates; immunizations and/or medications administered during the visit; procedures performed during the visit; laboratory tests and

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values/results, including any tests and value/results pending; clinical instructions; care plan, including goals and instructions; recommended patient decision aids (if applicable to the visit); future scheduled tests; future appointments; and referrals to other providers. If the clinical summary is provided electronically, it must be:

(i) Provided in human readable format; and

(ii) Provided in a summary care record formatted according to the standard adopted at § 170.205(a)(3) with the following data elements expressed, where applicable, according to the specified standard(s):

(A) Race and ethnicity. The standard specified in § 170.207(f);

(B) Preferred language. The standard specified in § 170.207(j);

(C) Smoking status. The standard specified in § 170.207(l);

(D) Problems. At a minimum, the version of the standard specified in § 170.207(a)(3);

(E) Encounter diagnoses. The standard specified in § 170.207(m);

(F) Procedures. The standard specified in § 170.207(b)(2) or § 170.207(b)(3);

(G) Laboratory test(s). At a minimum, the version of the standard specified in § 170.207(g);

(H) Laboratory value(s)/result(s). The value(s)/results of the laboratory test(s) performed; and

(I) Medications. At a minimum, the version of the standard specified in § 170.207(h).

(3) Ambulatory setting only—secure messaging. Enable a user to electronically send messages to, and receive messages from, a patient in a manner that ensures:

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(i) Both the patient and EHR technology are authenticated; and

(ii) The message content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

(f) Public health.

(1) Immunization information. Enable a user to electronically record, change, and access immunization information.

(2) Transmission to immunization registries. Enable a user to electronically create immunization information for electronic transmission in accordance with:

(i) The standard and applicable implementation specifications specified in § 170.205(e)(3); and

(ii) At a minimum, the version of the standard specified in § 170.207(i).

(3) Public health surveillance. Enable a user to electronically record, change, and access syndrome-based public health surveillance information.

(4) Transmission to public health agencies. Enable a user to electronically create syndrome-based public health surveillance information for electronic transmission in accordance with:

(i) Ambulatory setting only.

(A) The standard specified in § 170.205(d)(2).

(B) Optional. The standard (and applicable implementation specifications) specified in § 170.205(d)(3).

(ii) Inpatient setting only. The standard (and applicable implementation specifications) specified in § 170.205(d)(3).

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(5) Inpatient setting only—reportable laboratory tests and values/results. Enable a user to electronically record, change, and access reportable clinical laboratory tests and values/results.

(6) Inpatient setting only—transmission of reportable laboratory tests and values/results. Enable a user to electronically create reportable laboratory tests and values/results for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(g); and

(ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (g).

(7) Ambulatory setting only—cancer case information. Enable a user to electronically record, change, and access cancer case information.

(8) Ambulatory setting only—transmission to cancer registries. Enable a user to electronically create cancer case information for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(i); and

(ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (g).

(g) Utilization.

(1) Automated numerator recording. For each meaningful use objective with a percentage-based measure, electronically record the numerator.

(2) Automated measure calculation. For each meaningful use objective with a percentage-based measure that is supported by a capability included in an EHR technology, electronically record the numerator and denominator and create a report including the

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numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.

(3) Non-percentage-based measure use report.

(i) For each capability included in EHR technology that is also associated with a meaningful use objective and measure that is not percentage based, electronically record the date and time in accordance with the standard specified at § 170.210(g) when the capability was enabled, disabled, and/or executed.

(ii) Enable a user to electronically create a report of the information recorded as part of paragraph (g)(3)(i) of this section.

(4) Safety-enhanced design. User-centered design processes must be applied to each capability an EHR technology includes that is specified in the following certification criteria: § 170.314(a)(1); § 170.314(a)(2); § 170.314(a)(6); § 170.314(a)(7); § 170.314(a)(8); § 170.314(a)(17); § 170.314(b)(3); and § 170.314(b)(4).

§§ 170.500 through 170.599 [Amended]

10. In subpart E, consisting of §§ 170.500 through 170.599, remove the phrases "permanent certification program for HIT" and "permanent certification program" and add in their place "ONC HIT Certification Program" wherever they may occur.

11. Amend § 170.502 by revising the definition of "providing or provide an updated certification" to read as follows:

§ 170.502 Definitions.

* * * * *

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Providing or provide an updated certification means the action taken by an ONC-ACB to ensure that the developer of a previously certified EHR Module(s) shall update the information required by § 170.523(k)(1)(i), after the ONC-ACB has verified that the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and that no new certification criteria are applicable to the EHR Module(s).

* * * * *

12. In § 170.523, republish the introductory text, add paragraph (f)(8), and revise paragraph (k)(1)(i) to read as follows:

§ 170.523 Principles of proper conduct for ONC-ACBs.

An ONC-ACB shall:

* * * * *

(f) * * *

(8) A hyperlink to the test results used to certify the Complete EHRs and/or EHR Modules that can be accessed by the public.

* * * * *

(k) * * *

(1) * * *

(i) "This [Complete EHR or EHR Module] is [specify Edition of EHR certification criteria] compliant and has been certified by an ONC-ACB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services."; and

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* * * * *

13. In § 170.550, revise paragraph (e), redesignate paragraph (f) as paragraph (g), and add a new paragraph (f) to read as follows:

§ 170.550 EHR Module certification.

* * * * *

(e) Privacy and security certification. For certification to the 2011 Edition EHR certification criteria, EHR Module(s) shall be certified to all privacy and security certification criteria adopted by the Secretary, unless the EHR Module(s) is presented for certification in one of the following manners:

(1) The EHR Modules are presented for certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR, and one or more of the constituent EHR Modules is demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Modules; or

(2) An EHR Module is presented for certification, and the presenter can demonstrate and provide documentation to the ONC-ACB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be certified in accordance with such certification criterion.

(f) When certifying an EHR Module to the 2014 Edition EHR certification criteria, an ONC-ACB must certify the EHR Module in accordance with the certification criteria at:

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(1) Section 170.314(g)(1) if the EHR Module has capabilities presented for certification that would support a meaningful use objective with a percentage-based measure;

(2) Section 170.314(g)(3) if the EHR Module has capabilities presented for certification that would support a meaningful use objective with a non-percentage-based measure; and

(3) Section 170.314(g)(4) if the EHR Module is presented for certification to one or more listed certification criteria in § 170.314(g)(4).

* * * * *

14. Revise § 170.555 to read as follows:

§ 170.555 Certification to newer versions of certain standards.

(a) ONC-ACBs may certify Complete EHRs and/or EHR Module(s) to a newer version of certain identified minimum standards specified at subpart B of this part, unless the Secretary prohibits the use of a newer version for certification.

(b) Applicability of a newer version of a minimum standard. (1) ONC-ACBs are not required to certify Complete EHRs and/or EHR Module(s) according to newer versions of standards identified as minimum standards in subpart B of this part, unless and until the incorporation by reference of a standard is updated in the Federal Register with a newer version.

(2) A certified Complete EHR or certified EHR Module may be upgraded to comply with newer versions of standards identified as minimum standards in subpart B of this part without adversely affecting its certification status, unless the Secretary prohibits the use of a newer version for certification.

Dated: ____February 21, 2012_____

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Kathleen Sebelius,

Secretary.

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