Office of the National Coordinator for Health IT
Proposed Rule Public Comment Template

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

Preface

This document is meant to provide the public with a simple and organized way to submit comments on the proposed certification criteria and associated standards and implementation specifications and respond to specific questions posed in the preamble of the proposed rule, which is published in the Federal Register at 77 FR 13832 (March 7, 2012). While use of this document is entirely voluntary, commenters may find it helpful to use the document in lieu of or in addition to unstructured comments on the certification criteria and associated standards and implementation specifications or to use it as an addendum to narrative cover pages.

This document alone is not intended to provide a full and complete opportunity to comment on all of the provisions of the proposed rule. Please keep in mind that it only reflects those proposals included in the proposed rule related to certification criteria and associated standards and implementation specifications. Additionally, while each of the comment tables below indicate whether specific comments on a proposal are solicited, we note that the specific questions are not explicitly included in the tables to keep the size of this document to a minimum and because the preamble serves as the context for the questions.

The proposed rule proposes new, revised, and unchanged certification criteria that would establish the technical capabilities and specify the related standards and implementation specifications that Certified EHR Technology (CEHRT) would need to include to, at a minimum, support the achievement of meaningful use (MU) by eligible professionals (EPs), eligible hospitals (EHs), and critical access hospitals (CAHs) under the CMS Medicare and Medicaid EHR Incentive Programs beginning with the EHR reporting periods in fiscal year (FY) for EHs and CAHs and calendar year (CY) 2014 for EPs. We refer to these new, revised, and unchanged certification criteria as the "2014 Edition EHR certification criteria."

Many of the certification criteria that we propose are intended to support the MU objectives and measures proposed in the CMS Medicare and Medicaid EHR Incentive Programs Stage 2 proposed rule (CMS Stage 2 proposed rule) (77 FR 13698) 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 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.

The following tables align with the presentation of the proposed certification criteria in the preamble of the proposed rule. The tables specify where the proposed 2014 Edition EHR certification criterion or criteria would be included in § 170.314. The tables also specify 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 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 tables permit commenters to easily associate the certification criterion or criteria with the MU objective it supports. The tables note the page(s) of the Federal Register where we discuss the certification criterion or criteria and whether we request specific comments on certain proposals in the preamble. Last, the tables provide a field for submitting public comments on the proposed criterion or criteria, including responses to specific questions or requests for comments posed in the preamble.

To be considered, all comments (including comments provided through this document) must be submitted according to the instructions in the proposed rule, which are available at 77 FR 13832 (March 7, 2012).

Proposed 2014 Edition EHR Certification Criteria

New Certification Criteria

a. Ambulatory and Inpatient Setting

§ 170.314(a)(9) - Electronic notes	
MU Objective Record electronic notes in patient records. *(Not proposed by CMS)*	
2014 Edition EHR Certification Criterion Electronic notes. Enable a user to electronically record, access, and search electronic notes.	
Preamble FR Citation: 77 FR 13838	**Specific questions in preamble?** *No*
Public Comment Field:	

§ 170.314(a)(12) - Imaging	
MU Objective Imaging results and information are accessible through Certified EHR Technology.	
2014 Edition EHR Certification Criterion 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.	
Preamble FR Citation: 77 FR 13838	**Specific questions in preamble?** *Yes*
Public Comment Field:	

§ 170.314(a)(13) - Family health history

MU Objective

Record patient family health history as structured data.

2014 Edition EHR Certification Criterion

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

Preamble FR Citation: 77 FR 13838	**Specific questions in preamble?** *Yes*

Public Comment Field:

§ 170.314(d)(4) – 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

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.

Preamble FR Citation: 77 FR 13838	**Specific questions in preamble?** *Yes*

Public Comment Field:

§ 170.314(e)(1) - 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

View, download, and transmit to 3rd party.

(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).

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

(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).

(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) or images available to download in paragraph (e)(1)(i)(B)(3) in accordance with:

(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)-(C), 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) 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.

Standard(s) and Implementation Specifications

§ 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).

Preamble FR Citation: 77 FR 13838-41	**Specific questions in preamble?** *Yes*

Public Comment Field:

§ 170.314(g)(1) - Automated numerator recording

MU Objective

N/A

2014 Edition EHR Certification Criterion

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

Preamble FR Citation: 77 FR 13841-42	**Specific questions in preamble?** *No*

Public Comment Field:

§ 170.314(g)(3) - Non-percentage-based measure use report

MU Objective

N/A

2014 Edition EHR Certification Criterion

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).

Standard

§ 170.210(g) (synchronized clocks)

Preamble FR Citation: 77 FR 13842	**Specific questions in preamble?** *No*

Public Comment Field:

§ 170.314(g)(4) - Safety-enhanced design

MU Objective

N/A

2014 Edition EHR Certification Criterion

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).

Preamble FR Citation: 77 FR 13842-43	**Specific questions in preamble?** *Yes*

Public Comment Field:

b. Ambulatory Setting

§ 170.314(e)(3) - Secure messaging	
MU Objective Use secure electronic messaging to communicate with patients on relevant health information.	
2014 Edition EHR Certification Criterion Ambulatory setting only – secure messaging. Enable a user to electronically send messages to, and receive messages from, a patient in a manner that ensures: (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). **Standard** § 170.210(f) 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.	
Preamble FR Citation: 77 FR 13843-44	**Specific questions in preamble?** *No*
Public Comment Field:	

§ 170.314(f)(7) - Cancer case information; and (f)(8) - Transmission to cancer registries	
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 (f)(7) Ambulatory setting only – cancer case information. Enable a user to electronically record, change, and access cancer case information. (f)(8) (f)(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 § 170.207(g). **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).	
Preamble FR Citation: 77 FR 13844	**Specific questions in preamble?** *No*
Public Comment Field:	

c. Inpatient Setting

§ 170.314(a)(17) - 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 Inpatient setting only – electronic medication administration record. (i) In combination with an assistive technology that provides automated information on the "rights" specified in paragraphs (i)(A) through (i)(D), 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 at § 170.210(g), and user identification when a medication is administered. **Standard** § 170.210(g) (synchronized clocks).	
Preamble FR Citation: 77 FR 13844	**Specific questions in preamble?** *No*
Public Comment Field:	

§ 170.314(b)(3) - Electronic prescribing	
MU Objective Generate and transmit permissible discharge prescriptions electronically (eRx).	
2014 Edition EHR Certification Criterion 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). **Standards** § 170.205(b)((2) (NCPDP SCRIPT version 10.6) and § 170.207(h) (RxNorm February 6, 2012 Release).	
Preamble FR Citation: 77 FR 13844-45	**Specific questions in preamble?** *No*
Public Comment Field:	

§ 170.314(b)(6) - 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 Criteria 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 ii. At a minimum, the version of the standard specified in § 170.207(g). **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).	
Preamble FR Citation: 77 FR 13845	**Specific questions in preamble?** *No*
Public Comment Field:	

Revised Certification Criteria

a. Ambulatory and Inpatient Setting

§ 170.314(b)(6) - Transmission of electronic laboratory tests and values/results to ambulatory providers	
MU Objective Implement drug-drug and drug-allergy interaction checks.	
2014 Edition EHR Certification Criteria Drug-drug, drug-allergy interaction checks. (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.	
Preamble FR Citation: 77 FR 13846	**Specific questions in preamble?** *No*
Public Comment Field:	

§ 170.314(a)(3) - 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

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).

Standards

§ 170.207(f)(OMB standards); § 170.207(j) (ISO 639-1:2002); and § 170.207(k) (ICD-10-CM).

Preamble FR Citation: 77 FR 13846	**Specific questions in preamble?** *No*

Public Comment Field:

§ 170.314(a)(5) - Problem list

MU Objective

Maintain an up-to-date problem list of current and active diagnoses.

2014 Edition EHR Certification Criterion

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).

Standards

§ 170.207(a)(3)(SNOMED CT® International Release January 2012).

Preamble FR Citation: 77 FR 13846-47	**Specific questions in preamble?** *Yes*

Public Comment Field:

§ 170.314(a)(8) - Clinical decision support

MU Objective

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

2014 Edition EHR Certification Criterion

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;
- (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 (ii)(A) 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) 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.
- (B) Enable interventions to be triggered, based on the data elements specified in paragraph (a)(8)(i), when a summary 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)-(iii) 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 the intervention development technical implementation; and
- (D) Release and, if applicable, revision date of the intervention.

Standards

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

Preamble FR Citation: 77 FR 13847	**Specific questions in preamble?** *Yes*

Public Comment Field:

§ 170.314(a)(16) - 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

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).

Standard

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

Preamble FR Citation: 77 FR 13847-48	**Specific questions in preamble?** *No*

Public Comment Field:

§ 170.314(b)(1) - Transitions of care - incorporate summary care record; and (b)(2) - Transitions of care - create and transmit summary care record

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.

2014 Edition EHR Certification Criteria

(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 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 hospitalization; 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);

(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

§ 170.314(b)(1) - Transitions of care - incorporate summary care record; and (b)(2) - Transitions of care - create and transmit summary care record

(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 (i) in accordance with:

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

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

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).

Preamble FR Citation: 77 FR 13848-49	**Specific questions in preamble?** *Yes*

Public Comment Field:

§ 170.314(b)(4) - 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

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.

(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.

Preamble FR Citation: 77 FR 13849	**Specific questions in preamble?** *Yes*

Public Comment Field:

§ 170.314(b)(5) - Incorporate laboratory tests and values/results

MU Objective

Incorporate clinical laboratory test results into Certified EHR Technology as structured data.

2014 Edition EHR Certification Criteria

Incorporate laboratory tests and values/results.

(i) Receive results.

(A) Ambulatory setting only.

(*1*) Electronically receive clinical laboratory tests and values/results formatted in accordance with the standard (and implementation specifications) specified at § 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.

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).

Preamble FR Citation: 77 FR 13849-50	**Specific questions in preamble?** *Yes*

Public Comment Field:

§ 170.314(c) - Clinical quality measures: (c)(1) - Capture and export; (c)(2) - Incorporate and calculate; and (c)(3) - Reporting

MU Objective

N/A

2014 Edition EHR Certification Criteria

(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 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.

Standard

§ 170.204(c) (NQF Quality Data Model).

Preamble FR Citation: 77 FR 13850-53	**Specific questions in preamble?** *Yes*

§ 170.314(c) - Clinical quality measures: (c)(1) - Capture and export; (c)(2) - Incorporate and calculate; and (c)(3) - Reporting

Public Comment Field:

§ 170.314(d)(2) - Auditable events and tamper-resistance; and (d)(3) - 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

(d)(2) Auditable events and tamper-resistance.

(i) Enabled by default. The capability specified in paragraph (d)(2)(ii) 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 and audit log status in accordance with the standard specified in § 170.210(e).

(iii) Audit log protection. Actions recorded in accordance with paragraph (d)(3)(ii) must not be capable of being changed, overwritten, or deleted.

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

(d)(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).

Standards

§ 170.210(e) Record actions related to electronic health information, audit log status, and encryption of end-user devices.

(1) When EHR technology is used to record, 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 actions(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:
- (i) The date and time in accordance with the standard specified at § 170.210(g); and
- (ii) User identification.

Preamble FR Citation: 77 FR 13853-54	**Specific questions in preamble?** *No*

Public Comment Field:

§ 170.314(d)(7) - 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

Encryption of data at rest. Paragraph (d)(7)(i) or (d)(7)(ii) 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.

Preamble FR Citation: 77 FR 13854-55	**Specific questions in preamble?** *No*

Public Comment Field:

§ 170.314(f)(1) - Immunization information; and (f)(2) - Transmission to 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

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

(f)(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).

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).

Preamble FR Citation: 77 FR 13855	**Specific questions in preamble?** *No*

Public Comment Field:

§ 170.314(f)(3) - Public health surveillance; and (f)(4) - Transmission to 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 (f)(3) **(f)(3) Public health surveillance. Enable a user to electronically record, change, and access syndrome-based public health surveillance information.** (f)(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). **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)	
Preamble FR Citation: 77 FR 13855-56	**Specific questions in preamble?** *No*
Public Comment Field:	

§ 170.314(g)(2) - Automated measure calculation	
MU Objective N/A	
2014 Edition EHR Certification Criterion 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 numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.	
Preamble FR Citation: 77 FR 13856	**Specific questions in preamble?** *No*
Public Comment Field:	

b. Ambulatory Setting

§ 170.314(b)(3) - Electronic prescribing [Note: this is a revised certification criterion for the ambulatory setting and why this table appears twice, see page 7]
MU Objective Generate and transmit permissible prescriptions electronically (eRx).
2014 Edition EHR Certification Criterion 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).

§ 170.314(b)(3) - Electronic prescribing [Note: this is a revised certification criterion for the ambulatory setting and why this table appears twice, see page 7]

Standards

§ 170.205(b)(2) (NCPDP SCRIPT version 10.6) and § 170.207(h)(RxNorm February 6, 2012 Release)

Preamble FR Citation: 77 FR 13856	**Specific questions in preamble?** *No*

Public Comment Field:

§ 170.314(e)(2) - Clinical summaries

MU Objective

Provide clinical summaries for patients for each office visit.

2014 Edition EHR Certification Criterion

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 values/results, including any tests and values/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).

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).

Preamble FR Citation: 77 FR 13856-57	**Specific questions in preamble?** *Yes*

Public Comment Field:

c. Inpatient Setting

§ 170.314(f)(5) - Reportable laboratory tests and values/results; and (f)(6) - Transmission of reportable laboratory tests and values/results	
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 (f)(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. (f)(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 § 170.207(g). **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).	
Preamble FR Citation: 77 FR 13857	**Specific questions in preamble?** *No*
Public Comment Field:	

Unchanged Certification Criteria

a. Refinements to Unchanged Certification Criteria

§ 170.314(a)(1) - Computerized provider order entry	
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 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.	
Preamble FR Citation: 77 FR 13858	**Specific questions in preamble?** *No*
Public Comment Field:	

§ 170.314(a)(4) - 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

Vital signs, body mass index, and growth charts.

(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.

Preamble FR Citation: 77 FR 13858	**Specific questions in preamble?** *No*

Public Comment Field:

§ 170.314(a)(11) - Smoking status

MU Objective

Record smoking status for patients 13 years old or older.

2014 Edition EHR Certification Criterion

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).

Standard

§ 170.207(l) (smoking status types)

Preamble FR Citation: 77 FR 13858	**Specific questions in preamble?** *No*

Public Comment Field:

§ 170.314(a)(15) - 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

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.

Preamble FR Citation: 77 FR 13858	**Specific questions in preamble?** *No*

Public Comment Field:

§ 170.314(d)(1) - 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

Authentication, access control, and authorization.

(iii) 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

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

Preamble FR Citation: 77 FR 13858-59	**Specific questions in preamble?** *No*

Public Comment Field:

170.314(d)(5) - 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

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

Preamble FR Citation: 77 FR 13859	**Specific questions in preamble?** *No*

Public Comment Field:

§ 170.314(d)(6) - 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

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

Preamble FR Citation: 77 FR 13859	**Specific questions in preamble?** *No*

Public Comment Field:

§ 170.314(d)(8) - 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 Integrity. (i) Create a message digest in accordance with the standard specified in 170.210(c). (iii) 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. **Standard** § 170.210(c) (verification that electronic health information has not been altered)	
Preamble FR Citation: 77 FR 13859	**Specific questions in preamble?** *Yes*
Public Comment Field:	

b. Unchanged Certification Criteria Without Refinements

§ 170.314(a)(10) - Drug-formulary checks	
MU Objective Implement drug-formulary checks.	
2014 Edition EHR Certification Criterion Drug-formulary checks. Enable a user to electronically check if drugs are in a formulary or preferred drug list.	
Preamble FR Citation: 77 FR 13859	**Specific questions in preamble?** *No*
Public Comment Field:	

§ 170.314(a)(6) - Medication list	
MU Objective Maintain active medication list.	
2014 Edition EHR Certification Criterion 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.	
Preamble FR Citation: 77 FR 13859	**Specific questions in preamble?** *No*
Public Comment Field:	

§ 170.314(a)(7) - Medication allergy list

MU Objective

Maintain active medication allergy list.

2014 Edition EHR Certification Criterion

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.

Preamble FR Citation: 77 FR 13859	**Specific questions in preamble?** *No*

Public Comment Field:

§ 170.314(a)(14) - Patient Lists

MU Objective

Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.

2014 Edition EHR Certification Criterion

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.

Preamble FR Citation: 77 FR 13859	**Specific questions in preamble?** *No*

Public Comment Field:

§ 170.314(d)(9) - Accounting of disclosures

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

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

Preamble FR Citation: 77 FR 13859, 13871-72	**Specific questions in preamble?** *Yes*

Public Comment Field:

§ 170.314(a)(18) - Advance directives	
MU Objective Record whether a patient 65 years old or older has an advance directive.	
2014 Edition EHR Certification Criterion Inpatient setting only – advance directives. Enable a user to electronically record whether a patient has an advance directive.	
Preamble FR Citation: 77 FR 13860	**Specific questions in preamble?** *No*
Public Comment Field:	