Pharmacy e-Health Information Technology Collaborative Comments on the 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: There are American National Standards Institute (ANSI) accredited standards available for pharmacists to record, access, and search electronic notes in the HL7 Pharmacist/Pharmacy Provider EHR Functional Profile for the ambulatory and inpatient settings.

§ 170.314(a)(12) - Imaging

MU Objective

Imaging results and information are accessible through Certified EHR Technology.

2014 Edition EHR Certification Criterion

<u>Imaging</u>. 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: There are ANSI accredited standards available for pharmacists to access 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 in the HL7 Pharmacist/Pharmacy Provider EHR Functional Profile for the ambulatory and inpatient settings.

§ 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: There are ANSI accredited standards available for pharmacists to record, change and access family history, and search electronic notes in the HL7 Pharmacist/Pharmacy Provider EHR Functional Profile for the ambulatory and inpatient settings.

§ 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: There are ANSI accredited standards available for pharmacists to amend a patient's health record, and search electronic notes in the HL7 Pharmacist/Pharmacy Provider EHR Functional Profile for the ambulatory and inpatient settings.

§ 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.

-) Enable a user to provide patients (and their authorized representatives) with online access to do all of the following:
 - (A) <u>View</u>. 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

§ 170.314(e)(1) - View, download, and transmit to 3rd party

- 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 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(I);
 - (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 §
 - $\underline{170.207(h)}$; and $\underline{(xi)}$ Inpatient setting only. The data elements specified in paragraph $\underline{(e)(1)(i)(A)(2)}$.
 - (3) Images formatted according to the standard adopted at § 170.205(j).
- (C) <u>Transmit to third party</u>. 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) <u>When</u> 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

Public Comment Field: The ANSI accredited standards can provide patients the ability to view online, download, and transmit their health information in the form of a summary of patient care record. ANSI accredited standards also allow pharmacists to transmit data, amend a patient's health record, and search electronic notes in the HL7 Pharmacist/Pharmacy Provider EHR Functional Profile (Pharmacist EHR) for the ambulatory and inpatient settings. Pharmacists using the HL7 standard can transmit to third parties using health information exchanges and electronic prescribing networks. The Pharmacist EHR has the ability to transmit a consolidated CDA including specific medication therapy SNOMED-CT code and other terminology-based standards codes (e.g., LOINC and others listed in the standards and implementation specifications).

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

MU Objective

N/A

2014 Edition EHR Certification Criterion

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

Public Comment Field: Pharmacists are not eligible to receive meaningful use EHR incentives. If pharmacists were recognized as eligible professionals, we would prepare to respond to this section.

§ 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: Pharmacists are not eligible to receive meaningful use EHR incentives. If pharmacists were recognized as eligible professionals, we would prepare to respond to this section.

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

MU Objective

N/A

2014 Edition EHR Certification Criterion

<u>Safety-enhanced design</u>. 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)(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: There are ANSI accredited standards available for pharmacists, but the HL7 Pharmacist/Pharmacy Provider EHR Functional Profile for inpatient settings criterion has yet to be defined. Once defined, user center defined processes will be defined.

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

<u>Ambulatory setting only – secure messaging</u>. 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: The ANSI accredited standards available for pharmacists will use secured messaging to communicate with patients on relevant health care information, including integrity-protected standards.

§ 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) <u>Ambulatory setting only cancer case information</u>. Enable a user to electronically record, change, and access cancer case information.
- (f)(8) <u>Ambulatory setting only transmission to cancer registries</u>. 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: The ANSI accredited standards available for pharmacists will advocate the ability to enable users to record, access, and search cancer case information, including the exchange of HL7 CDA Release 2 structured documents.

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

<u>Inpatient setting only – electronic medication administration record.</u>

- (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 <u>time</u>. 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: There are ANSI accredited standards available for pharmacists to track medication orders from order to administration using assisted technologies in conjunction with the electronic medication record (eMAR). These include the support for the use of bar coding technology (for further information regarding bar-code-enabled medication administration technology, see http://www.ashp.org/DocLibrary/BestPractices/AutoITStBCMA.aspx). Pharmacists working in the inpatient setting often oversee the specifications for eMAR to ensure that the right patient receives the right medication with the right dose at the right route at the right time.

§ 170.314(b)(3) - Electronic prescribing

MU Objective

Generate and transmit permissible discharge prescriptions electronically (eRx).

2014 Edition EHR Certification Criterion

<u>Electronic prescribing</u>. 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: The Pharmacy e-HIT Collaborative (Collaborative) supports the ability of users to create prescriptions and prescription-related information for electronic prescriptions, including the use of NCPDP SCRIPT version 10.6 and RxNorm. NCPDP SCRIPT 10.6 supports the submission of a diagnosis or indication for an electronically prescribed medication. The Collaborative requests consideration to mandate the use of the diagnosis field by EPs receiving meaningful use incentives. Pharmacists are responsible for providing patients with medication therapy management services, including information about the indications for the medication prescribed by EPs. Requiring the diagnosis on every electronic prescription will ensure that each patient receiving prescriptions and pharmacists informing patients about their medications will receive the correct information related to the use of the medications being prescribed.

§ 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

<u>Inpatient setting only – transmission of electronic laboratory tests and values/results to ambulatory providers</u>. 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: There are ANSI accredited standards available for pharmacists to receive electronic laboratory results from inpatient settings. There are instances where pharmacists provide laboratory tests (e.g., glucose monitoring). It is important for pharmacists to have the ability to transmit these electronic test values to ambulatory providers.

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) <u>Interventions</u>. 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: The Pharmacy e-HIT Collaborative supports drug-drug, drug-allergy, and interaction checks by EPs and EHs. Additionally, the NCPDP SCRIPT Standard (electronic prescribing) and Specialized Standard (clinical information requests, medication therapy management functions) supports the ability to exchange this information. For over 20 years, pharmacy systems have included decision support and Drug Utilization Review (DUR) capabilities that have been used to perform drug-drug and drug-allergy interaction checks. This capability has been included in the SCRIPT Standard since version 1.0, allowing entities to exchange DUR information in transactions.

§ 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: The ANSI accredited standard available for pharmacists enables a user to electronically record, change, and access patient demographic data, including preferred language, gender, race, ethnicity, and date of birth. The ANSI accredited standard also enables a user to electronically record, change, and access preliminary cause of death in an inpatient setting.

§ 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

<u>Problem list</u>. 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: There are ANSI accredited standards available for pharmacists to have the ability to maintain an up-to-date problem list for longitudinal care.

§ 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) <u>Evidence-based decision support interventions</u>. 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) <u>Automatically and electronically interact</u>. 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) <u>Source attributes</u>. 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: The Pharmacy e-HIT Collaborative supports the clinical decision support to improve performance on high-priority health conditions. The ANSI accredited standards available for pharmacists enables evidence-based support intervention, including drug-drug, drug-allergy, and contraindication checking based on medication lists and medication allergy lists. Pharmacists in clinical inpatient settings are involved in evidence-based decision support intervention using data elements such as problem list, medication list, medication allergy list, demographics, laboratory tests (values/results), and vital signs. The Collaborative supports pharmacists having a role in system development for adding clinical decision support tools related for automating interactive intervention and enabling a user to retrieve diagnostic or therapeutic reference information.

§ 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

<u>Patient-specific education resources</u>. 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: There are ANSI accredited standards available for pharmacists to identify patient-specific education resources and provide those resources to patients.

§ 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) <u>Transitions of care — incorporate summary care record</u>. 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) <u>Transitions of care – create and transmit summary care record</u>.

- (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) <u>Preferred language</u>. 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) <u>Laboratory value(s)/result(s)</u>. 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) <u>Inpatient setting only</u>. 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: There are ANSI accredited standards available to pharmacists to incorporate summary care records and create and transfer summary records in the form of a consolidated CDA. Pharmacists play an important role in medication reconciliation at transition of care, as noted in in the pharmacy industry's *Improving Care Transitions: Optimizing Medication Reconciliation* (http://www.pharmacist.com/mtm/reconciliation). The Collaborative supports the information outlined in this document as guidelines for medication reconciliation at transitional care for all practice settings.

§ 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

<u>Clinical information reconciliation</u>. 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: There are ANSI accredited standards available for pharmacists to reconcile the data elements that represent a patient's active medication, problem, and medication allergy list.

§ 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) <u>Inpatient setting only</u>. 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) <u>Display test report information</u>. Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).
- (iii) <u>Incorporate tests and values/results</u>. 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: There are ANSI accredited standards available for pharmacists to incorporate clinical laboratory results into the Pharmacist/Pharmacy Provider EHR Functional Profile as structured data.

§ 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) <u>Incorporate</u>. 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) <u>Clinical quality measures reporting</u>. 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: There are ANSI accredited standards available for pharmacists to incorporate clinical laboratory results into the Pharmacist/Pharmacy Provider EHR Functional Profile as structured data. Pharmacists are not eligible to receive meaningful use EHR incentives for calculating results. If pharmacists were recognized as eligible professionals, we would prepare to respond more specifically to this section.

§ 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) <u>Audit report(s)</u>. 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: We agree that patient information should be protected. The HIPAA Security and HITECH Acts should supersede these requirements unless these requirements provide more stringent protections. There are ANSI accredited standards available for pharmacists to record actions related to electronic health information, audit log status, and encryption of end-user devices.

§ 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: We agree that patient information should be protected. The HIPAA Security and HITECH Acts should supersede these requirements unless these requirements provide more stringent protections. There are ANSI accredited standards for pharmacists for encryption of data at rest.

§ 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) <u>Transmission to immunization registries</u>. 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: The ANSI accredited standards for pharmacists enable users to submit electronic data to immunization registries or immunization information systems. We would encourage the support and harmonization of standards, such as the HL7 and NCPDP (SCRIPT and Telecom) standards for this area.

§ 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) <u>Public health surveillance</u>. Enable a user to electronically record, change, and access syndrome-based public health surveillance information.
- (f)(4) <u>Transmission to public health agencies</u>. 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) <u>Inpatient setting only. The standard (and applicable implementation specifications) specified in §</u> 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: Pharmacists play an important role as leaders in administering immunizations, especially for influenza vaccines. There are ANSI accredited standards for pharmacists to electronically record, change, and access syndrome-based public health information in ambulatory and inpatient settings. We would encourage the support and harmonization of standards, such as the HL7 and NCPDP (SCRIPT and Telecom) standards for this area.

§ 170.314(g)(2) - Automated measure calculation

MU Objective

N/A

2014 Edition EHR Certification Criterion

<u>Automated measure calculation</u>. 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: Pharmacists are not eligible to receive meaningful use EHR incentives for calculations. If pharmacists were recognized as eligible professionals, we would prepare to respond to this section and support percentage-based measure calculations.

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

<u>Electronic prescribing</u>. 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: We support NCPDP SCRIPT Standard version 10.6 and anticipate/expect that whenever the version named under the Medicare Modernization Act (MMA) is changed that change will apply here.

§ 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(I);
 - (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: There are ANSI accredited standards available for pharmacists to provide clinical summaries to patients, including a medication action plan during a comprehensive medication review (CMR) in the form of consolidated CDA structured document. Under the Medicare Part D program pharmacists provide CMR and are required to provide a summary document (see http://www.cms.gov/Medicare/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Drug-Coverage/Prescription-Dr

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) <u>Inpatient setting only reportable laboratory tests and values/results</u>. Enable a user to electronically record, change, and access reportable clinical laboratory tests and values/results.
- (f)(6) <u>Inpatient setting only transmission of reportable laboratory tests and values/results</u>. 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: Pharmacists play an important role in exchanging immunization information with public health agencies. Because such registries are maintained at the state and local levels through public health agencies, there must be a uniform standard for reporting.

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

<u>Computerized provider order entry</u>. 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: The Pharmacist e-HIT Collaborative supports the use of computerized provider order entry (CPOE) for medication, laboratory, and radiology orders directly entered by any licensed pharmacist who can enter orders into the medical record per state, local, and professional guidelines to create the first record of the order. There are ANSI accredited standards available for pharmacists to electronically record, change, and access medications, laboratory, and radiology/imaging types. There are industry guidelines available for CPOE (see http://www.ashp.org/DocLibrary/BestPractices/AutoITGdlCPOE.aspx).

§ 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) <u>Vital signs</u>. 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) <u>Calculate body mass index</u>. 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: There are ANSI accredited standards available for pharmacists to electronically record, change, and access recordings of a patient's vital signs, including height/length, weight, blood pressure, calculate body mass index, and growth charts.

§ 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(I).

Standard

§ 170.207(I) (smoking status types)

Preamble FR Citation: 77 FR 13858

Specific questions in preamble? No

Public Comment Field: The Pharmacy e-HIT Collaborative supports the recording of smoking status. Pharmacists play an important role in smoking cessation education. There are ANSI accredited standards available for pharmacists to record, access, electronically record, change, and access the smoking status of a patient.

§ 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

<u>Ambulatory setting only – patient reminders</u>. 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: We support providing patients with reminder notices. Patient identifiable information should be protected. The HIPAA Security and HITECH Acts should supersede these requirements unless these requirements provide more stringent protections.

§ 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 informationn 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: We agree that patient information created or maintained should be protected and measures to verify and authenticate access should be part of any electronic system being used. The HIPAA Security and HITECH Acts should supersede these requirements unless these requirements provide more stringent protections.

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: We agree that patient information created or maintained should be protected and measures to ensure this during access and automatic log-off should be implemented by any electronic system being used. The HIPAA Security and HITECH Acts should supersede these requirements unless these requirements provide more stringent protections.

§ 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: We agree that patient information created or maintained should be protected and measures to ensure this during emergency access should be implemented by any electronic system being used. Emergency situations may arise when emergency access overrides are needed. Our concern, however, is that the proposed clarification in this section does not define "identified set of users", who they are, and who determines and authorizes such users.

§ 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)

Public Comment Field: We agree that patient health information should be protected. The HIPAA Security and HITECH Acts should supersede these requirements unless these requirements provide more stringent protections.

b. Unchanged Certification Criteria Without Refinements

§ 170.314(a)(10) - Drug-formulary checks

MU Objective

Implement drug-formulary checks.

2014 Edition EHR Certification Criterion

<u>Drug-formulary checks</u>. 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: The capacity for electronic bidirectional communication to alleviate the need for exchanging non-electronic information is needed for drug-formulary checks. If the formulary check is not done by the EP at the initial prescribing stage and a drug prescribed is not on a formulary and is transmitted to a pharmacy, this puts the pharmacist in the tenuous position of having to conduct a drug formulary check for the EP. If there is no capacity for electronic bidirectional communication, the pharmacist then will need to phone the EP with the formulary information.

Pharmacies that are connected for electronic prescribing need to have the means for bidirectional exchange of information so that when situations occur in which a physician isn't using the drug formulary check, the pharmacists would have the capability to electronically exchange that information with the physicians.

Pharmacies are not receiving incentives for e-prescribing. If EPs or eligible hospitals that receive incentives for e-prescribing are not using a drug formulary check, this makes the drug formulary check and exchange of information an unfunded mandate for the pharmacist.

§ 170.314(a)(6) - Medication list

MU Objective

Maintain active medication list.

2014 Edition EHR Certification Criterion

<u>Medication list</u>. 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: We support the maintenance and use of medication lists and enabling a user to electronically record, change, and access a patient's active medication list. Pharmacists look at patients in a patient-centered way. That is pharmacists must follow their patients longitudinally through their care to increase medication-related patient safety, especially at points of transition of care. It is at these points of transition where pharmacists may see problems with their patients' medications that were prescribed. There are ANSI accredited standards for pharmacists to electronically record, change, and access patients' active medication lists.

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

MU Objective

Maintain active medication allergy list.

2014 Edition EHR Certification Criterion

<u>Medication allergy list</u>. 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: We support the maintenance and use of medication allergy lists and enabling a user to electronically record, change, and access a patient's active medication allergy list. Pharmacists look at patients in a patient-centered way. That is pharmacists must follow their patients longitudinally through their care to increase medication-related patient safety. Pharmacists' unique experience, expertise, and access to medication information that others may not have bring enormous value to physicians in their prescribing decisions, particularly, with regard to checking drug-drug and drug-allergy interactions. This is especially an important aspect in caring for patients after they are discharged from a hospital. Pharmacists also should be involved in helping to streamline drug-drug, drug-allergy interactions to prevent alert-fatigue.

§ 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

<u>Patient lists</u>. 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: The best medical outcomes happen with an integrated team approach of health care providers. Electronic access to lists of patients by specific conditions and by problem and medication lists, demographics, and laboratory tests/results/values, especially by pharmacists, will enhance efficiencies, and improve safety, security, and patient care. There are ANSI accredited standards available to pharmacists to electronically select, sort, access, and create lists of patients according to the data elements included in problem and medication lists, demographics, and laboratory tests (values/results).

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§ 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

<u>Optional – accounting of disclosures</u>. 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: The Collaborative believes that the certification element related to the HIPAA accounting rule should not be changed from optional to mandatory or that any other changes should be made to this certification criterion. The optional category is appropriate because the HIPAA accounting rule is very much in flux. We believe it is inappropriate to make any changes at all to these certification requirements that are based on the proposed changes to the HIPAA accounting of disclosures rule.

§ 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: There are ANSI accredited standards available for pharmacists to electronically record whether a patient has an advance directive.