

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

**2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015  
Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT  
Certification Program Modifications**

**Preface**

This document is meant to provide the public with a simple and organized way to submit comments on the proposed certification criteria and modifications to the ONC Health IT Certification Program, and respond to specific questions posed in the preamble of the proposed rule, which is published in the *Federal Register* at 80 FR 16804. 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 modifications to the ONC Health IT Certification Program, 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 modifications to the ONC Health IT Certification Program. 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 can be used to support various care and practice settings. It would also establish the capabilities and specify the related standards and implementation specifications that Certified Electronic Health Record Technology (CEHRT) would need to include, at a minimum, to support the achievement of meaningful use (MU) by providers under the CMS Medicare and Medicaid EHR Incentive Programs.

The following tables align with the presentation of the proposed certification criteria and modifications to the ONC Health IT Certification Program in the preamble of the proposed rule. The tables specify where the proposed 2015 Edition health IT certification criterion or criteria would be included in § 170.315. The tables also specify the proposed MU Stage 3 objective that the proposed 2015 Edition health IT certification criterion or criteria and associated standards and implementation specifications would support. 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. This field can be expanded as necessary for commenting.

To be considered, all comments (including comments provided through this document) must be submitted according to the instructions in the proposed rule. Electronic comment submissions are strongly encouraged and can be easily completed through the regulations.gov website and by clicking here:

[http://www.regulations.gov/#!documentDetail;D=HHS\\_FRDOC\\_0001-0572](http://www.regulations.gov/#!documentDetail;D=HHS_FRDOC_0001-0572).

Proposed 2015 Edition Electronic Health Record (EHR) Certification Criteria, 2015 Edition Base EHR Definition, and ONC Health IT Certification Program Modifications

***A. Provisions of the Proposed Rule affecting Standards, Implementation Specifications, Certification Criteria, and Definitions***

**§ 170.315(a)(1) Computerized provider order entry – medications**

**Included in 2015 Edition Base EHR Definition?**

Yes, as an alternative to § 170.315(a)(2) or (3)

**Stage 3 MU Objective**

Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.

**2015 Edition Health IT Certification Criterion**

- (1) Computerized provider order entry – medications. Technology must enable a user to record, change, and access medication orders.

**Preamble FR Citation:** 80 FR 16814

**Specific questions in preamble?** Yes

**Public Comment Field:**

The Pharmacy Health Information Collaborative supports the adoption of the 2014 Edition CPOE – medication criterion for the 2015 Edition. With regard to the request for comment on whether a health IT module should be able to include any or all of the following data elements: secondary diagnosis codes, reason for order, and comments fields entered by the ordering provider, we support these elements being included for the purposes of testing and certification to the 2015 Edition CPOE criteria; however, primary diagnosis was not required in Meaningful Use Stage 2. Primary diagnosis should be included. We believe that if a secondary diagnosis can be transmitted, a primary diagnosis also could be sent. We recommend that each medication order that has an indication also be used to enhance patient safety. In September 2014, the Agency for Healthcare Research and Quality (AHRQ) announced that Brigham and Woman’s Hospital (BWH) was awarded two competitive grants as part of a \$4 million fund provided by Congress for research on the impact of health IT on patient safety. The project includes design of a prototype for a model “CPOE of the future” that incorporates drug indication.

[http://www.brighamandwomens.org/About\\_BWH/publicaffairs/news/awards/Award\\_Honor.aspx?sub=0&PageID=1865](http://www.brighamandwomens.org/About_BWH/publicaffairs/news/awards/Award_Honor.aspx?sub=0&PageID=1865), accessed May 17, 2015).

**§ 170.315(a)(2) Computerized provider order entry – laboratory**

**Included in 2015 Edition Base EHR Definition?**

Yes, as an alternative to § 170.315(a)(1) or (3)

**Stage 3 MU Objective**

Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.

**§ 170.315(a)(2) Computerized provider order entry – laboratory**

**2015 Edition Health IT Certification Criterion**

- (2) Computerized provider order entry – laboratory.
  - (i) Technology must enable a user to record, change, and access laboratory orders.
  - (ii) Technology must be able to receive and incorporate a new or updated laboratory order compendium in accordance with the standard specified in § 170.205(l)(2) and, at a minimum, the version of the standard in § 170.207(c)(3).
  - (iii) Ambulatory setting only. Technology must enable a user to create laboratory orders for electronic transmission in accordance with the standard specified in § 170.205(l)(1) and, at a minimum, the version of the standard in § 170.207(c)(3).

**Preamble FR Citation:** 80 FR 16814

**Specific questions in preamble?** Yes

**Public Comment Field:**

The Pharmacy Health Information Collaborative supports the adoption of the revised 2015 Edition CPOE certification criterion specific to laboratory ordering to include the HL7 Version 2.5.1 Implementation Guide: S&I framework Laboratory Orders (LOI) from EHR, Draft Standard for Trial Use, Release 2 – US Realm. As noted, Release 2 is currently under ballot recognition with HL7. Release 2 would further harmonize requirements with other laboratory standards and correct errors found in Release 1. The Collaborative also supports the adoption of the most recent version of LOINC for CPOE, which may further facilitate laboratory compliance with clinical laboratory improvement amendments (CLIA).

**§ 170.315(a)(3) Computerized provider order entry – diagnostic imaging**

**Included in 2015 Edition Base EHR Definition?**

Yes, as an alternative to § 170.315(a)(1) or (2)

**Stage 3 MU Objective**

Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.

**2015 Edition Health IT Certification Criterion**

- (3) Computerized provider order entry – diagnostic imaging. Technology must enable a user to record, change, and access diagnostic imaging orders.

**Preamble FR Citation:** 80 FR 16815 (also see 80 FR 16814)

**Specific questions in preamble?** Yes

**Public Comment Field:**

N/A

**§ 170.315(a)(4) Drug-drug, drug-allergy interaction checks for CPOE**

**Included in 2015 Edition Base EHR Definition?**

No

**Stage 3 MU Objective**

Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

**§ 170.315(a)(4) Drug-drug, drug-allergy interaction checks for CPOE**

**2015 Edition Health IT Certification Criterion**

- (4) Drug-drug, drug-allergy interaction checks for CPOE.
- (i) Interventions. Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically indicate to a user drug-drug and drug-allergy contraindications based on a patient's 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.
  - (iii) Interaction check response documentation.
    - (A) Technology must be able to record at least one action taken and by whom in response to drug-drug or drug-allergy interaction checks.
    - (B) Technology must be able to generate either a human readable display or human readable report of actions taken and by whom in response to drug-drug or drug-allergy interaction checks.

**Preamble FR Citation:** 80 FR 16815

**Specific questions in preamble?** Yes

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative supports the revised 2015 Edition “drug-drug, drug-allergy interaction checks for CPOE” certification that includes the capabilities to record user actions for drug-drug, drug-allergy interaction (DD/DAI) interventions. We believe recording user actions is critical for patient system and quality of care, particularly with regard to the recording of the following actions: users viewed, accepted, declined, ignored, overrode, or otherwise commented on the DD/DAI interventions, including taking some other action. The Collaborative also recommends that functionality not be limited to clinical decision support but should include informing a user of new or updated DD/DAI when the medication or medication allergy lists are updated. This functionality should also be included in existing certification criterion.

The Collaborative recommends following the *ASHP Guidelines on Pharmacy Planning for Implementation of Computerized Provider-Order Entry Systems in Hospitals and Health Systems* developed by the American Society for Health-System Pharmacists (ASHP), <http://www.ashp.org/DocLibrary/BestPractices/AutoITGdlCPOE.aspx> (accessed May 17, 2015).

**§ 170.315(a)(5) Demographics**

**Included in 2015 Edition Base EHR Definition?**

Yes

**Stage 3 MU Objective**

N/A

## § 170.315(a)(5) Demographics

### 2015 Edition Health IT Certification Criterion

#### (5) Demographics.

- (i) Enable a user to record, change, and access patient demographic data including preferred language, sex, race, ethnicity, and date of birth.
  - (A) Race and ethnicity.
    - (1) Enable each one of a patient's races to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify race.
    - (2) Enable each one of a patient's ethnicities to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify ethnicity.
    - (3) Aggregate each one of the patient's races and ethnicities recorded in accordance with paragraphs (a)(5)(i)(A)(1) and (2) of this section to the categories in the standard specified in § 170.207(f)(1).
  - (B) Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g)(2) and whether a patient declines to specify a preferred language.
  - (C) Enable sex to be recorded in accordance with the standard specified in § 170.207(n)(1).
- (ii) Inpatient setting only. Enable a user to record, change, and access the preliminary cause of death and date of death in the event of a mortality.

Preamble FR Citation: 80 FR 16816

Specific questions in preamble? *No*

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition "demographics" certification criterion revised from the 2014 edition and the use of HL7 version 3 (Administrative Gender).

## § 170.315(a)(6) Vital signs, body mass index, and growth charts

### Included in 2015 Edition Base EHR Definition?

No

### Stage 3 MU Objective

N/A

### 2015 Edition Health IT Certification Criterion

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

- (i) Vital signs. Enable a user to record, change, and access, at a minimum, a patient's height, weight, diastolic blood pressure, systolic blood pressure, heart rate, respiratory rate, temperature, oxygen saturation in arterial blood by pulse oximetry, body mass index [ratio], and mean blood pressure in accordance with the following (The patient's height/length, weight, diastolic blood pressure, systolic blood pressure, heart rate, respiratory rate, temperature, oxygen saturation in arterial blood by pulse oximetry, body mass index [ratio], and mean blood pressure must be recorded in numerical values only.):
  - (A) The standard specified in § 170.207(k)(1) and with the associated applicable unit of measure for the vital sign in the standard specified in § 170.207(m)(1);
  - (B) Metadata. For each vital sign in paragraph (a)(6)(i) of this section, the technology must also record the following:
    - (1) Date and time of vital sign measurement or end time of vital sign measurement;
    - (2) The measuring- or authoring-type source of the vital sign measurement; and
    - (3) Optional. Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g); and
  - (C) Metadata for oxygen saturation in arterial blood by pulse oximetry. For the oxygen saturation in arterial blood by pulse oximetry, the technology must enable a user to record, change, and access the patient's inhaled oxygen concentration identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with LOINC® code 8478-0.

## § 170.315(a)(6) Vital signs, body mass index, and growth charts

### 2015 Edition Health IT Certification Criterion, 170.315(a)(6) Vital signs, body mass index, and growth charts, continued

- (ii) Optional – Body mass index percentile per age and sex. Enable a user to record, change, and access a patient's body mass index [percentile] per age and sex for patients two to twenty years of age in accordance with the following (The patient's body mass index [percentile] per age and sex must be recorded in numerical values only.):
  - (A) Identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with LOINC® code 59576-9 and with the associated applicable unit of measure in the standard specified in § 170.207(m)(1); and
  - (B) Metadata. The technology must also record the following:
    - (1) Date and time of vital sign measurement or end time of vital sign measurement;
    - (2) The measuring or authoring-type source of the vital sign measurement;
    - (3) The patient's date of birth;
    - (4) The patient's sex in accordance with the standard specified in § 170.207(n)(1); and
    - (5) Optional. Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g).
- (iii) Optional – Weight for length per age and sex. Enable a user to record, change, and access a patient's weight for length per age and sex for patients less than three years of age in accordance with the following (The patient's weight for length per age and sex must be recorded in numerical values only.):
  - (A) Identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with the LOINC® code and with the associated applicable unit of measure in the standard specified in § 170.207(m)(1); and
  - (B) Metadata. The technology must record the following:
    - (1) Date and time of vital sign measurement or end time of vital sign measurement;
    - (2) The measuring- or authoring-type source of the vital sign measurement;
    - (3) The patient's date of birth;
    - (4) The patient's sex in accordance with the standard specified in § 170.207(n)(1); and
    - (5) Optional. Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g).
- (iv) Optional – Head occipital-frontal circumference. Enable a user to record, change, and access a patient's head occipital-frontal circumference for patients less than three years of age in accordance with the following (The patient's head occipital-frontal circumference must be recorded in numerical values only.):
  - (A) Identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with LOINC® code 8287-5 and with the associated applicable unit of measure in the standard specified in § 170.207(m)(1); and
  - (B) Metadata. The technology must also record the following:
    - (1) Date and time of vital sign measurement or end time of vital sign measurement;
    - (2) The measuring or authoring-type source of the vital sign measurement;
    - (3) The patient's date of birth;
    - (4) The patient's age in accordance with the standard specified in § 170.207(n)(1); and
    - (5) Optional. Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g).
- (v) Optional – Calculate body mass index. Automatically calculate and display body mass index based on a patient's height and weight.
- (vi) Optional – Plot and display growth charts. Plot and display, upon request, growth charts for patients.

### § 170.315(a)(6) Vital signs, body mass index, and growth charts

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “vital signs, BMI, and growth charts” certification criterion revised from the 2014 edition, expanding the types of vital signs for recording; requiring that each type of vital sign have a specific LOINC code attributed to it; that the Unified Code of Units and Measures, Revision 1.9, be used to record vital sign measurements; and that certain metadata accompany each vital sign, including date, time, and measuring- or authoring-type source. The Collaborative supports the use of LOINC codes for metadata. The Collaborative also supports self-reported values when those values are captured by an health IT module or devices where the reporting is electronically collected from the health IT module.

Additionally, the Collaborative supports using standardized vocabularies for recording vital signs and the adoption of SNOMED CT and UCUM in this certification criterion edition. Pharmacists use this for documenting, collecting, and exchanging information for the patient-care services they provide.

### § 170.315(a)(7) Problem list

**Included in 2015 Edition Base EHR Definition?**

Yes

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

- (7) Problem list. Enable a user to record, change, and access a patient's active problem list:
- (i) Ambulatory setting. Over multiple encounters in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4); or
  - (ii) Inpatient setting. For the duration of an entire hospitalization in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4).

**Preamble FR Citation:** 80 FR 16819

**Specific questions in preamble?** *No*

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “problem list” certification criterion revised from the 2014 edition. The Collaborative recommends using the most current version of SNOMED CT.

The Collaborative also recommends that consideration be given to integrating comprehensive medication management (CMM) in all practice settings with regard to problem lists, medication lists, and medication allergy lists. As part of the integrated health care team, pharmacists have the expertise and knowledge to perform assessments of patients’ medication-related needs, identify patients’ medication-related problems; develop a medication care plans with individualized therapy goals and personal interventions; and conduct follow-up evaluations to determine actual patient outcomes. CMM advances the appropriateness of medications by eliminating unnecessary medications and initiate necessary medications not being taken; the effectiveness and safety of medications; and increases a patient’s adherence to a medication regimen.

### § 170.315(a)(8) Medication list

**Included in 2015 Edition Base EHR Definition?**

Yes

**Stage 3 MU Objective**

N/A

### § 170.315(a)(8) Medication list

#### 2015 Edition Health IT Certification Criterion

- (8) Medication list. Enable a user to record, change, and access a patient's active medication list as well as medication history:
- (i) Ambulatory setting. Over multiple encounters; or
  - (ii) Inpatient setting. For the duration of an entire hospitalization.

Preamble FR Citation: 80 FR 16819

Specific questions in preamble? *No*

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “medication list” as unchanged from the 2014 Edition.

The Collaborative also recommends that consideration be given to integrating comprehensive medication management (CMM) in all practice settings with regard to problem lists, medication lists, and medication allergy lists. As part of the integrated health care team, pharmacists have the expertise and knowledge to perform assessments of patients’ medication-related needs, identify patients’ medication-related problems; develop a medication care plans with individualized therapy goals and personal interventions; and conduct follow-up evaluations to determine actual patient outcomes. CMM advances the appropriateness of medications by eliminating unnecessary medications and initiate necessary medications not being taken; the effectiveness and safety of medications; and increases a patient’s adherence to a medication regimen.

### § 170.315(a)(9) Medication allergy list

#### Included in 2015 Edition Base EHR Definition?

Yes

#### Stage 3 MU Objective

N/A

#### 2015 Edition Health IT Certification Criterion

- (9) Medication allergy list. Enable a user to record, change, and access a patient's active medication allergy list as well as medication allergy history:
- (i) Ambulatory setting. Over multiple encounters; or
  - (ii) Inpatient setting. For the duration of an entire hospitalization.

Preamble FR Citation: 80 FR 16820

Specific questions in preamble? *No*

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “medication allergy list” certification criterion unchanged from the 2014 edition. The Collaborative supports including other types of allergies and intolerances such as food and environmental allergies.

The Collaborative also recommends that consideration be given to integrating comprehensive medication management (CMM) in all practice settings with regard to problem lists, medication lists, and medication allergy lists. As part of the integrated health care team, pharmacists have the expertise and knowledge to perform assessments of patients’ medication-related needs, identify patients’ medication-related problems; develop a medication care plans with individualized therapy goals and personal interventions; and conduct follow-up evaluations to determine actual patient outcomes. CMM advances the appropriateness of medications by eliminating unnecessary medications and initiate necessary medications not being taken; the effectiveness and safety of medications; and increases a patient’s adherence to a medication regimen.

### § 170.315(a)(10) Clinical decision support

#### Included in 2015 Edition Base EHR Definition?

Yes



## § 170.315(a)(10) Clinical decision support

### Stage 3 MU Objective

Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

### 2015 Edition Health IT Certification Criterion

- (10) Clinical decision support.
- (i) Evidence-based decision support interventions. Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data:
    - (A) Problem list;
    - (B) Medication list;
    - (C) Medication allergy list;
    - (D) At least one demographic specified in paragraph (a)(5)(i) of this section;
    - (E) Laboratory tests; and
    - (F) Vital signs.
  - (ii) Linked referential clinical decision support.
    - (A) Technology must be able to identify for a user diagnostic and therapeutic reference information in accordance with the standard and implementation specifications at § 170.204(b)(3) or (4).
    - (B) For paragraph (a)(10)(ii)(A) of this section, technology must be able to identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (a)(10)(i)(A), (B), and (D) of this section.
  - (iii) Clinical decision support configuration.
    - (A) Enable interventions and reference resources specified in paragraphs (a)(10)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role.
    - (B) Technology must enable interventions to be:
      - (1) Based on the data referenced in paragraphs (a)(10)(i)(A) through (F) of this section.
      - (2) When a patient's medications, medication allergies, problems, and laboratory tests and values/results are incorporated from a transition of care/referral summary received and pursuant to paragraph (b)(2)(iii)(D) of this section.
      - (3) Ambulatory setting only. When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(4) of this section.
  - (iv) CDS intervention interaction. Interventions provided to a user in paragraphs (a)(10)(i) through (iii) of this section must occur when a user is interacting with technology.
  - (v) Source attributes. Enable a user to review the attributes as indicated for all clinical decision support resources:
    - (A) For evidence-based decision support interventions under paragraph (a)(10)(i) of this section:
      - (1) Bibliographic citation of the intervention (clinical research/guideline);
      - (2) Developer of the intervention (translation from clinical research/guideline);
      - (3) Funding source of the intervention development technical implementation; and
      - (4) Release and, if applicable, revision date(s) of the intervention or reference source.
    - (B) For linked referential clinical decision support in paragraph (a)(10)(ii) of this section and drug-drug, drug-allergy interaction checks in paragraph (a)(4) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).
  - (vi) Intervention response documentation.
    - (A) Technology must be able to record at least one action taken and by whom in response to clinical decision support interventions.
    - (B) Technology must be able to generate either a human readable display or human readable report of actions taken and by whom in response to clinical decision support interventions.

Preamble FR Citation: 80 FR 16820

Specific questions in preamble? Yes

## § 170.315(a)(10) Clinical decision support

### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “clinical decision support” certification criterion revised from the 2014 edition, especially, the inclusion of an updated and certified Infobutton standard. The Collaborative also supports the adoption of the HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-Aware Knowledge Retrieval (Infobutton) Domain, Release 1, in the CDS criterion. The Collaborative supports including functionality to record an action taken and by whom when a CDS intervention is provided to a user. The proposal that a health IT module be able to generate either a human readable display or human readable report of the responses and actions taken when a CDS intervention is provided meets what pharmacy is currently required to do.

Pharmacists use clinical decision support knowledge in the pharmacy services they provide to their patients, which includes DDI/DAI.

The Collaborative recommend inpatient settings follow following ASHP Guidelines on Pharmacy Planning for Implementation of Computerized Provider-Order Entry Systems in Hospitals and Health Systems <http://www.ashp.org/DocLibrary/BestPractices/AutoITGdICPOE.aspx> (accessed May 17, 2015).

## § 170.315(a)(11) Drug-formulary and preferred drug list checks

### Included in 2015 Edition Base EHR Definition?

No

### Stage 3 MU Objective

EPs must generate and transmit permissible prescriptions electronically, and eligible hospitals and CAHs must generate and transmit permissible discharge prescriptions electronically (eRx).

### 2015 Edition Health IT Certification Criterion

- (11) Drug-formulary and preferred drug list checks. Technology must either meet paragraph (a)(11)(i) or (ii) of this section.
- (i) Drug formulary checks.
    - (A) Automatically check whether a drug formulary exists for a given patient and medication.
    - (B) Indicate for a user the last update of the drug formulary; and
    - (C) Receive and incorporate a formulary and benefit file in accordance with the standard specified in § 170.205(n)(1).
  - (ii) Preferred drug list checks.
    - (A) Automatically check whether a preferred drug list exists for a given patient and medication.
    - (B) Indicate for a user the last update of the preferred drug list.

Preamble FR Citation: 80 FR 16821

Specific questions in preamble? Yes

### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “drug formulary checks and preferred drug list” certification criterion revised from the 2014 edition. The Collaborative supports that a health IT module must automatically check whether a drug formulary exists for a given patient and medications and receive and incorporate a formulary benefit file according to the NCPDP Formulary and Benefit Standard v3.0. We recommend that the timestamp of when the file was created also be incorporated when indicating the last update of the drug formulary or preferred drug list so the provider knows how recently the information updated. Additionally, the Collaborative supports using the NCPDP Telecommunication Standard in conjunction with the NCPDP Formulary and Benefit Standard v.4.0 to support expanded use cases such as real-time benefit checks.

### § 170.315(a)(12) Smoking status

#### Included in 2015 Edition Base EHR Definition?

Yes

#### Stage 3 MU Objective

N/A

#### 2015 Edition Health IT Certification Criterion

(12) Smoking status. Enable a user to record, change, and access the smoking status of a patient in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4).

Preamble FR Citation: 80 FR 16822

Specific questions in preamble? *No*

#### Public Comment Field:

The Pharmacy HIT Collaborative supports this statement related to smoking status.

### § 170.315(a)(13) Image results

#### Included in 2015 Edition Base EHR Definition?

No

#### Stage 3 MU Objective

N/A

#### 2015 Edition Health IT Certification Criterion

(13) Image results. Indicate to a user the availability of a patient's images and narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable electronic access to such images and narrative interpretations.

Preamble FR Citation: 80 FR 16822

Specific questions in preamble? *No*

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “image results” as unchanged from the 2014 Edition.

### § 170.315(a)(14) Family health history

#### Included in 2015 Edition Base EHR Definition?

No, but proposed for the EHR Incentive Programs CEHRT definition

#### Stage 3 MU Objective

N/A

#### 2015 Edition Health IT Certification Criterion

(14) Family health history. Enable a user to record, change, and access a patient's family health history in accordance with the familial concepts or expressions included in, at a minimum, the version of the standard in § 170.207(a)(4).

Preamble FR Citation: 80 FR 16822

Specific questions in preamble? *No*

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “family health history” certification criterion revised from the 2014 edition. The Collaborative supports the adoption of family health history certification criterion according to the HL7 Pedigree standard and the HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability, Release 1, as well as the use of the September 2014 release of SNOMED CT.

### § 170.315(a)(15) Family health history – pedigree

#### Included in 2015 Edition Base EHR Definition?

No, but proposed for the EHR Incentive Programs CEHRT definition as an alternative to § 170.315(a)(14).

#### Stage 3 MU Objective

N/A

#### 2015 Edition Health IT Certification Criterion

- (15) Family health history – pedigree. Technology must be able to create and incorporate a patient's family health history in accordance with the standard and implementation specification specified in § 170.205(m)(1).

Preamble FR Citation: 80 FR 16822

Specific questions in preamble? *No*

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “family health history -- pedigree” certification criterion revised from the 2014 edition. The Collaborative supports the adoption of family health history certification criterion according to the HL7 Pedigree standard and the HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability, Release 1, as well as the use of the September 2014 release of SNOMED CT.

### § 170.315(a)(16) Patient list creation

#### Included in 2015 Edition Base EHR Definition?

No

#### Stage 3 MU Objective

N/A

#### 2015 Edition Health IT Certification Criterion

- (16) Patient list creation. Enable a user to dynamically select, sort, access, and create patient lists by: date and time; and based on each one and at least one combination of the following data:
- (i) Problems;
  - (ii) Medications;
  - (iii) Medication allergies;
  - (iv) At least one demographic specified in paragraph (a)(5)(i) of this section;
  - (v) Laboratory tests and values/results; and
  - (vi) Ambulatory setting only. Patient communication preferences.

Preamble FR Citation: 80 FR 16823

Specific questions in preamble? *No*

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “patient list creation” as unchanged from the 2014 Edition.

### § 170.315(a)(17) Patient-specific education resources

#### Included in 2015 Edition Base EHR Definition?

No

#### Stage 3 MU Objective

The EP, eligible hospital, or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability.

## § 170.315(a)(17) Patient-specific education resources

### 2015 Edition Health IT Certification Criterion

- (17) Patient-specific education resources. Technology must be able to:
- (i) Identify patient-specific education resources based on data included in the patient's problem list and medication list in accordance with the standard (and implementation specifications) specified in § 170.204(b)(3) or (4); and
  - (ii) Request that patient-specific education resources be identified in accordance with the standard in § 170.207(g)(2).

Preamble FR Citation: 80 FR 16823

Specific questions in preamble? *No*

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “patient-specific education resources” certification criterion revised from the 2014 edition, especially, the inclusion of an updated and certified Infobutton standard and an alternative method. We agree that EHR technology should be required to provide patient-specific education resources in a patient’s preferred language. Providing these resources to a patient is important, especially, in regard to medication-related patient-specific education.

## § 170.315(a)(18) Electronic medication administration record

### Included in 2015 Edition Base EHR Definition?

No

### Stage 3 MU Objective

N/A

### 2015 Edition Health IT Certification Criterion

- (18) Electronic medication administration record.
- (i) In combination with an assistive technology that provides automated information on the “rights” specified in paragraphs (a)(18)(i)(A) through (E) of this section, enable a user to 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.
    - (E) Right time. The time that the medication was ordered to be administered compared to the current time.
  - (ii) Right documentation. Record the time and date in accordance with the standard specified in § 170.210(g), and user identification when a medication is administered.

Preamble FR Citation: 80 FR 16823

Specific questions in preamble? *No*

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “electronic medication administration record” as unchanged from the 2014 Edition.

## § 170.315(a)(19) Patient health information capture

### Included in 2015 Edition Base EHR Definition?

No, but proposed for the EHR Incentive Programs CEHRT definition

### Stage 3 MU Objective

Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.

### § 170.315(a)(19) Patient health information capture

#### 2015 Edition Health IT Certification Criterion

- (19) Patient health information capture. Technology must be able to enable a user to:
- (i) Identify, record, and access patient health information documents;
  - (ii) Reference and link to patient health information documents; and
  - (iii) Record and access information directly shared by a patient.

Preamble FR Citation: 80 FR 16823

Specific questions in preamble? *No*

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “public health information capture” certification criterion revised from the 2014 edition. We agree that advance directives should require a health IT module to be capable of storing and advance directive, be able to reference information documents, and be linked to patient health information documents. The Collaborative also supports the proposal to require a health IT module to demonstrate that it could enable a user to record and access information directly and electronically share by a patient.

### § 170.315(a)(20) Implantable device list

#### Included in 2015 Edition Base EHR Definition?

Yes

#### Stage 3 MU Objective

N/A

#### 2015 Edition Health IT Certification Criterion

- (20) Implantable device list.
- (i) Enable a user to record, change, and access, a list of Unique Device Identifiers associated with a patient’s Implantable Device(s).
  - (ii) Parse the following data elements from a Unique Device Identifier:
    - (A) Device Identifier;
    - (B) Batch/lot number;
    - (C) Expiration date;
    - (D) Production date; and
    - (E) Serial number.
  - (iii) Retrieve the “Device Description” attribute associated with a Unique Device Identifier in the Global Unique Device Identification Database.
  - (iv) For each Unique Device Identifier in a patient’s list of implantable devices, enable a user to access the following:
    - (A) The parsed data elements specified under paragraph (a)(20)(ii) of this section that are associated with the UDI; and
    - (B) The retrieved data element specified under paragraph (a)(20)(iii) of this section.

Preamble FR Citation: 80 FR 16824

Specific questions in preamble? *Yes*

#### Public Comment Field:

N/A

### § 170.315(a)(21) Social, psychological, and behavioral data

#### Included in 2015 Edition Base EHR Definition?

No

#### Stage 3 MU Objective

N/A

**§ 170.315(a)(21) Social, psychological, and behavioral data**

**2015 Edition Health IT Certification Criterion**

- (21) Social, psychological, and behavioral data. Enable a user to record, change, and access, at a minimum, one of the following patient social, psychological, and behavioral data.
- (i) Sexual orientation. Enable sexual orientation to be recorded in accordance with the standard specified in § 170.207(o)(1) and whether a patient declines to specify sexual orientation.
  - (ii) Gender identity. Enable gender identity to be recorded in accordance with the standard specified in § 170.207(o)(2) and whether a patient declines to specify gender identity.
  - (iii) Financial resource strain. Enable financial resource strain to be recorded in accordance with the standard specified in § 170.207(o)(3) and whether a patient declines to specify financial resource strain.
  - (iv) Education. Enable education to be recorded in accordance with the standard specified in § 170.207(o)(4) and whether a patient declines to specify education.
  - (v) Stress. Enable stress to be recorded in accordance with the standard specified in § 170.207(o)(5) and whether a patient declines to specify stress.
  - (vi) Depression. Enable depression to be recorded in accordance with the standard specified in § 170.207(o)(6) and whether a patient declines to specify stress.
  - (vii) Physical activity. Enable physical activity to be recorded in accordance with the standard specified in § 170.207(o)(7) and whether a patient declines to specify physical activity.
  - (viii) Alcohol use. Enable alcohol use to be recorded in accordance with the standard specified in § 170.207(o)(8) and whether a patient declines to specify alcohol use.
  - (ix) Social connection and isolation. Enable social connection and isolation to be recorded in accordance the standard specified in § 170.207(o)(9) and whether a patient declines to specify social connection and isolation.
  - (x) Exposure to violence (intimate partner violence). Enable exposure to violence (intimate partner violence) to be recorded in accordance with the standard specified in § 170.207(o)(10) and whether a patient declines to specify exposure to violence (intimate partner violence).

**Preamble FR Citation:** 80 FR 16826

**Specific questions in preamble?** *Yes, and also see requests for comment on work information (industry/occupation) data and U.S.uniformed/military service data*

**Public Comment Field:**

**The Pharmacy HIT Collaborative supports adoption of the new 2015 Edition “social, psychological and behavioral data” certification criterion that would require a health IT module to be capable of enabling a user to record, change, and access a patient’s social, psychological, and behavioral data based on SNOMED CT and LOINC.**

**§ 170.315(a)(22) Decision support – knowledge artifact**

**Included in 2015 Edition Base EHR Definition?**

No

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

- (22) Decision support – knowledge artifact. Enable a user to send and receive clinical decision support knowledge artifacts in accordance with the standard specified in § 170.204(d)(1).

**Preamble FR Citation:** 80 FR 16830

**Specific questions in preamble?** *Yes*

**Public Comment Field:**

**The Pharmacy Health Information Technology Collaborative supports adoption of a new “decision support – knowledge artifact” certification criterion for the 2015 edition, using the HL7 Version 3 Standard: Clinical Decision Support Knowledge Artifact Specification, Release 1.2 DSTU.**

### § 170.315(a)(23) Decision support – service

#### Included in 2015 Edition Base EHR Definition?

No

#### Stage 3 MU Objective

N/A

#### 2015 Edition Health IT Certification Criterion

(23) Decision support – service. Enable a user to send and receive electronic clinical guidance in accordance with the standard specified in § 170.204(e)(1).

Preamble FR Citation: 80 FR 16831

Specific questions in preamble? Yes

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of a new 2015 Edition “decision support – service” certification criterion, using the HL7 Version 3 Standard: Decision Support Service, Release 1.1, US Realm DSTU Specification.

### § 170.315(b)(1) Transitions of care

#### Included in 2015 Edition Base EHR Definition?

Yes

#### Stage 3 MU Objective

The EP, eligible hospital, or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of certified EHR technology.

#### 2015 Edition Health IT Certification Criterion

- (1) Transitions of care.
- (i) Send and receive via edge protocol. Technology must be able to:
    - (A) Send transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(d); and
    - (B) Receive transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(d) from a service that has implemented the standard specified in §170.202(a).
    - (C) XDM processing. Receive and make available the contents of a XDM package formatted in accordance with the standard adopted in § 170.205(p)(1) if the technology is also being certified using an SMTP-based edge protocol.
  - (ii) Validate and display.
    - (A) Validate C-CDA conformance – system performance. Technology must demonstrate its ability to detect valid and invalid transition of care/referral summaries received and formatted in accordance with both of the standards specified in § 170.205(a)(3) and (4) This includes the ability to:
      - (1) Parse each of the document types formatted according to the following document templates: CCD; Consultation Note; History and Physical; Progress Note; Care Plan; Transfer Summary; Referral Note, and Discharge Summary.
      - (2) Detect errors in corresponding “document-templates,” “section-templates,” and “entry-templates,” including invalid vocabulary standards and codes not specified in either of the standards adopted in § 170.205(a)(3) and (4);
      - (3) Identify valid document-templates and process the data elements required in the corresponding section-templates and entry-templates from either of the standards adopted in § 170.205(a)(3) and (4);
      - (4) Correctly interpret empty sections and null combinations; and
      - (5) Record errors encountered and allow for a user to be notified of or review the errors produced.
    - (B) Technology must be able to display in human readable format the data included in transition of care/referral summaries received and formatted according to the standards specified in § 170.205(a)(3) and (4).



## § 170.315(b)(1) Transitions of care

- (C) Section views. Allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary received and formatted in accordance with either of the standards adopted in § 170.205(a)(3) and (4).

2015 Edition Health IT Certification Criterion (b)(1) Transitions of care, continued

(iii) Create.

- (A) Enable a user to create a transition of care/referral summary:

- (1) Formatted according to the standards adopted in § 170.205(a)(3);
- (2) Formatted according to the standards adopted in § 170.205(a)(4); and
- (3) Includes, at a minimum, the Common Clinical Data Set and the following data expressed, where applicable, according to the specified standard(s):
  - (i) Encounter diagnoses. The standard specified in § 170.207(i) or, at a minimum, the version of the standard specified §170.207(a)(4);
  - (ii) Cognitive status;
  - (iii) Functional status;
  - (iv) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information; and
  - (v) Inpatient setting only. Discharge instructions.

- (B) Patient matching data quality. Technology must be capable of creating a transition of care/referral summary that includes the following data and, where applicable, represent such data according to the additional constraints specified below:

- (1) Data. first name, last name, maiden name, middle name (including middle initial), suffix, date of birth, place of birth, current address, historical address, phone number, and sex.
- (2) Constraint. Represent last/family name according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0.
- (3) Constraint. Represent suffix according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0 (JR, SR, I, II, III, IV, V, RN, MD, PHD, ESQ). If no suffix exists, the field should be entered as null.
- (4) Constraint. Represent the year, month and date of birth are required fields while hour, minute and second should be optional fields. If hour, minute and second are provided then either time zone offset should be included unless place of birth (city, region, country) is provided; in latter local time is assumed. If date of birth is unknown, the field should be marked as null.
- (5) Constraint. Represent phone number (home, business, cell) in the ITU format specified in ITU-T E.123 and ITU-T E.164. If multiple phone numbers are present, all should be included.
- (6) Constraint. Represent sex in accordance with the standard adopted at § 170.207(n)(1).

Preamble FR Citation: 80 FR 16831

Specific questions in preamble? Yes

## § 170.315(b)(1) Transitions of care

### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “transitions of care” certification criterion as a continuation and extension of the 2014 Edition and the use of the updated version of HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.0. Although the updated vocabulary/value set constraints adding two SNOMED CT codes should not affect C-CDA, they may impact certification test scenarios, which may need to be updated with new data elements. The Collaborative also supports the adoption of C-CDA Release 2.0 and updated Common Clinical Data Set for 2015.

With regard to the question of whether a separate 2015 Edition health IT certification criterion for the voluntary testing and certification of health IT to the capability to create a summary record formatted to the C-CDA Release 2.0 with or without the ability to meet the requirements of the Common Clinical Data Set definition, we believe that if the C-CDA Release 1.1 certification requirements are backward compatible with C-CDA Release 2.0 with or without Common Clinical Data Set definition, there would be no need to adopt a separate 2015 certification criterion. If the certification criterion is not backward compatible, then a separate certification would be needed.

NCPDP/HL7 completed joint projects on the National Council for Prescription Drug Programs (NCPDP) Recommendations for Use of the HL7 Consolidated CDA Templates for Pharmacy Version 1.0.<sup>1</sup> Additionally, these may be used in the NCPDP/HL7 Medication Therapy (MTM) Templated CDA. The NCPDP Professional Pharmacy Services Work Group 10 is working on developing guidance on using C-CDA 2.0.<sup>2</sup>

The Collaborative supports the use of HL7 IG for the tagging of health information with provenance metadata in connection with certification criteria such as transition of care and VDT certification requirements.

The role of pharmacists needs to be recognized in this area, particularly, with regard to medication reconciliation at the transition of care. 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. It is at these points of transition where pharmacists may see problems with the patients’ medications that were prescribed.

<sup>1</sup>[http://www.ncdp.org/NCPDP/media/pdf/NCPDP\\_Recommended\\_for\\_Use\\_CDA.pdf](http://www.ncdp.org/NCPDP/media/pdf/NCPDP_Recommended_for_Use_CDA.pdf).

<sup>2</sup><http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=842>.

## § 170.315(b)(2) Clinical information reconciliation and incorporation

### Included in 2015 Edition Base EHR Definition?

No

### Stage 3 MU Objective

The EP, eligible hospital, or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of certified EHR technology.

## § 170.315(b)(2) Clinical information reconciliation and incorporation

### 2015 Edition Health IT Certification Criterion

- (2) Clinical information reconciliation and incorporation.
- (i) General requirements. Paragraphs (b)(2)(ii) and (iii) of this section must be completed based on the receipt of a transition of care/referral summary formatted in accordance with the standard adopted in § 170.205(a)(3) as well as separately to the standard adopted in § 170.205(a)(4) using the Continuity of Care Document, Discharge Summary Document and Referral Summary document templates.
  - (ii) Correct patient. Upon receipt of a transition of care/referral summary formatted according to either of the standards adopted at § 170.205(a)(3) or (4), technology must be able to demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient.
  - (iii) Reconciliation. Enable a user to reconcile the data that represent a patient's active medication list, medication allergy list, and problem list as follows. For each list type:
    - (A) Simultaneously display (i.e., in a single view) the data from at least two sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date;
    - (B) Enable a user to create a single reconciled list of medications, medication allergies, or problems;
    - (C) Enable a user to review and validate the accuracy of a final set of data; and
    - (D) Upon a user's confirmation, automatically update the list, and incorporate the following data expressed according to the specified standard(s):
      - (1) Medications. At a minimum, the version of the standard specified in § 170.207(d)(3);
      - (2) Medication allergies. At a minimum, the version of the standard specified in § 170.207(d)(3); and
      - (3) Problems. At a minimum, the version of the standard specified in § 170.207(a)(4).
  - (iv) System verification. Based on the data reconciled and incorporated, the technology must be able to create a file formatted according to the standard adopted at § 170.205(a)(4) using the Continuity of Care Document document template.

Preamble FR Citation: 80 FR 16835

Specific questions in preamble? *No*

#### Public Comment Field:

**The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “clinical reconciliation and incorporation” certification criterion revised from the 2014 Edition that expands the 2014 Edition criterion to focus on health IT system behavior and performance related to incorporating C-CDAs and their structured content. During clinical information reconciliation, we recommend that each medication order have an indication for use.**

## § 170.315(b)(3) Electronic prescribing

### Included in 2015 Edition Base EHR Definition?

No

#### Stage 3 MU Objective

EPs must generate and transmit permissible prescriptions electronically, and eligible hospitals and CAHs must generate and transmit permissible discharge prescriptions electronically (eRx).

## § 170.315(b)(3) Electronic prescribing

### 2015 Edition Health IT Certification Criterion

- (3) Electronic prescribing.
- (i) Enable a user to prescribe, send, and respond to prescription-related transactions for electronic transmission in accordance with the standard specified at § 170.205(b)(2), and, at a minimum, the version of the standard specified in § 170.207(d)(3), as follows:
    - (A) Create new prescriptions (NEWRX);
    - (B) Change prescriptions (RXCHG, CHGRES);
    - (C) Cancel prescriptions (CANRX, CANRES);
    - (D) Refill prescriptions (REFREQ, REFRES);
    - (E) Receive fill status notifications (RXFILL); and
    - (F) Request and receive medication history information (RXHREQ, RXHRES).
  - (ii) Enable a user to enter, receive, and transmit structured and codified prescribing instructions for the transactions listed in paragraph (b)(3)(i) of this section for electronic transmission in accordance with the standard specified at § 170.205(b)(2) and, at a minimum, for at least the following component composites:
    - (A) Repeating Sig;
    - (B) Code System;
    - (C) Sig Free Text String;
    - (D) Dose;
    - (E) Dose Calculation;
    - (F) Vehicle;
    - (G) Route of Administration;
    - (H) Site of Administration;
    - (I) Sig Timing;
    - (J) Duration;
    - (K) Maximum Dose Restriction;
    - (L) Indication; and
    - (M) Stop.
  - (iii) Technology must limit a user's ability to prescribe all medications in only the metric standard.
  - (iv) Technology must always insert leading zeroes before the decimal point for amounts less than one and must not allow trailing zeroes after a decimal point when a user prescribes medications.

Preamble FR Citation: 80 FR 16835

Specific questions in preamble? Yes

**§ 170.315(b)(3) Electronic prescribing**

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “electronic prescribing” certification criterion revised from the 2014 edition. We agree that a health IT module be required to receive and respond to additional NCPDP SCRIPT Standard Implementation Guide Version 10.6 (v10.6), as well as be required to demonstrate that directions for medication use transmitted as e-prescriptions are codified in a structured format (e.g., Sig format). With regard to a health IT module being required to limit a user to e-prescribing all medications in the metric unit standard only, we recommend that this be for non-solid dose forms only. The sending and receiving of e-prescriptions should be in metric. The Collaborative also supports the adoption of February 2, 2015 monthly version of RxNorm in this criterion as the baseline version minimum standards code set for coding medications.

As noted in the preamble, structured and codified Sig (prescribing instructions) has implications for communication between pharmacists and prescribers and patient safety. If using a free text format, we agree that the pharmacist filling the prescription may not necessarily understand non-standard or conflicting language that is used. Providing structured Sig instructions promotes accurate, consistent, and clear communication of the prescribing information as intended by the prescriber. A field exists in the structured and codified Sig to include a codified indication for use (e.g. SNOMED CT). We recommend that each medication prescription have an indication for use.

Because pharmacists and prescribers may need to “engage in back-and-forth communication” to clarify the prescribing instructions, streamlined bidirectional communication is paramount. Streamlined bidirectional pharmacist-prescriber communication would also allow more time for direct activities of patient care and reduce confusion during the pharmacy verification and dispensing process. NCPDP SCRIPT v10.6 standard includes structured Sig segments that are used to codify the prescribing directions, including the indication for each prescription, in a structured format.

Also as outlined in Table 3, NCPDP SCRIPT v10.6 allows a pharmacist to request a change of a new prescription or a “fillable” prescription; a prescriber to respond to pharmacy requests to change a prescription; notifies the pharmacist that a previously sent prescription should be canceled or filled; allows a pharmacist to request additional approval for refills of a prescription beyond those originally prescribed and the prescriber to grant the pharmacist approval; allows the pharmacist to notify the prescriber about the status of a prescription; and allows a requesting entity to generate a patient-specific medication history request.

The Collaborative recommends that the bidirectional communication functionality, especially those functions outlined in Table 3, be made mandatory. Having these functions as mandatory requirements will further help with health IT adoption by pharmacists.

**§ 170.315(b)(4) Incorporate laboratory tests and values/results**

**Included in 2015 Edition Base EHR Definition?**

No

**Stage 3 MU Objective**

N/A

**§ 170.315(b)(4) Incorporate laboratory tests and values/results**

**2015 Edition Health IT Certification Criterion**

- (4) Incorporate laboratory tests and values/results.
  - (i) Receive results.
    - (A) Ambulatory setting only.
      - (1) Receive and incorporate clinical laboratory tests and values/results in accordance with the standard specified in § 170.205(j)(2); and, at a minimum, the version of the standard specified in § 170.207(c)(3).
      - (2) Display the tests and values/results received in human readable format.
    - (B) Inpatient setting only. Receive clinical laboratory tests and values/results in a structured format and display such tests and values/results in human readable format.
  - (ii) Display the test report information:
    - (A) Specified in 42 CFR 493.1291(a)(1) through (3) and (c)(1) through (7);
    - (B) Related to reference intervals or normal values as specified in 42 CFR 493.1291(d);
    - (C) For alerts and delays as specified in 42 CFR 493.1291(g) and (h); and
    - (D) For corrected reports as specified in 42 CFR 493.1291(k)(2).
  - (iii) Attribute, associate, or link a laboratory test and value/result with a laboratory order or patient record.

**Preamble FR Citation:** 80 FR 16837

**Specific questions in preamble?** Yes

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “incorporate laboratory tests and values/results” certification criterion revised from the 2014 Edition using the HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Draft Standard for Trial Use, Release 2, US Realm (LRI Release 2) for ambulatory settings. We also agree with the proposed that a health IT module must be capable of electronically displaying the information included in a test report and improving the consistency with how laboratory testes and values/results are displayed, particularly for compliance with CLIA. The Collaborative also supports the adoption of LOINC as the vocabulary standard for laboratory orders.

Pharmacists providing patient care need to have access to laboratory tests and values/results for exchanging medication-related information. Additionally, it should be noted that pharmacists providing patient care have the ability to order and receive and have access to laboratory tests and values/results.

**§ 170.315(b)(5) Transmission of laboratory test reports**

**Included in 2015 Edition Base EHR Definition?**

No

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

- (5) Transmission of laboratory test reports. Technology must be able to electronically create laboratory test reports for electronic transmission in accordance with the standard specified in § 170.205(j)(2) and, at a minimum, the version of the standard specified in § 170.207(c)(3).

**Preamble FR Citation:** 80 FR 16838

**Specific questions in preamble?** No

**§ 170.315(b)(5) Transmission of laboratory test reports**

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “transmission of laboratory test reports” certification criterion revised from the 2014 Edition using the HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Draft Standard for Trial Use, Release 2, US Realm (LRI Release 2) for ambulatory settings. We also agree with the proposed that a health IT module must be capable of electronically displaying the information included in a test report and improving the consistency with how laboratory tests and values/results are displayed, particularly for compliance with CLIA. The Collaborative also supports the adoption of LOINC as the vocabulary standard for laboratory orders.

Pharmacists providing patient care need to have access to laboratory tests and values/results for exchanging medication-related information. Additionally, it should be noted that pharmacists providing patient care have the ability to order and receive and have access to laboratory tests and values/results.

**§ 170.315(b)(6) Data portability**

**Included in 2015 Edition Base EHR Definition?**

Yes

**Stage 3 MU Objective**

N/A

## § 170.315(b)(6) Data portability

### 2015 Edition Health IT Certification Criterion

- (6) Data portability.
- (i) General requirements for export summary configuration. A user must be able to set the following configuration options when using technology to create an export summary or set of export summaries for patients whose information is stored in the technology. A user must be able to execute these capabilities at any time the user chooses and without subsequent developer assistance to operate.
  - (ii) Document creation configuration.
    - (A) Document-template types. A user must be able to configure the technology to create an export summary or export summaries formatted according to the standard adopted at § 170.205(a)(4) for any of the following document-template types.
      - (1) Generally applicable. CCD; Consultation Note; History and Physical; Progress Note; Care Plan; Transfer Summary; and Referral Note.
      - (2) Inpatient setting only. Discharge Summary.
    - (B) For any document-template selected the technology must be able to include, at a minimum, the Common Clinical Data Set and the following data expressed, where applicable, according to the specified standard(s):
      - (1) Encounter diagnoses. The standard specified in § 170.207(i) or, at a minimum, the version of the standard at § 170.207(a)(4);
      - (2) Cognitive status;
      - (3) Functional status;
      - (4) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information; and
      - (5) Inpatient setting only. Discharge instructions.
    - (C) Use of the “unstructured document” document-level template is prohibited for compliance with the standard adopted at § 170.205(a)(4).
  - (iii) Timeframe configuration. A user must be able to configure the technology to set the time period within which data would be used to create the export summary or summaries. This must include the ability to enter in a start and end date range as well as the ability to set a date at least three years into the past from the current date.
  - (iv) Event configuration. A user must be able to configure the technology to create an export summary or summaries based on the following user selected events:
    - (A) A relative date or time (e.g., the first of every month);
    - (B) A specific date or time (e.g., on 10/24/2015); and
    - (C) When a user signs a note or an order.
  - (v) Location configuration. A user must be able to configure and set the storage location to which the export summary or export summaries are intended to be saved.

Preamble FR Citation: 80 FR 16839

Specific questions in preamble? *No*

#### Public Comment Field:

**The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “data portability” certification criterion revised from the 2014 Edition. We strongly support the use of C-CDA, especially for comprehensive medication review. The Collaborative also supports the use of ICD-10-CM and SNOW MED CT for encounter diagnoses.**

**The Collaborative is working toward electronically processing of clinical quality measures for pharmacists providing patient care. We support the use of HL7 Health Quality Measures Format (HQMF) standard for representing a clinical quality measure as an electronic document for the 2017 edition. Additionally, we support the HQMF R2 standard within EHR technology (including medications, laboratory, allergies information) for future use by pharmacists.**

## § 170.315(b)(7) Data segmentation for privacy – send

### Included in 2015 Edition Base EHR Definition?

No



**§ 170.315(b)(7) Data segmentation for privacy – send**

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

- (7) Data segmentation for privacy – send. Technology must enable a user to create a summary record formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that is tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1).

**Preamble FR Citation:** 80 FR 16841 (also see 80 FR 16840)

**Specific questions in preamble?** *No*

**Public Comment Field:**

**The Pharmacy Health Information Technology Collaborative supports sending sensitive patient information electronically as part of this criterion provided the transmission of such information is secure and that restrictions, such as a prohibition on re-disclosure without consent, are included.**

**§ 170.315(b)(8) Data segmentation for privacy – receive**

**Included in 2015 Edition Base EHR Definition?**

No

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

- (8) Data segmentation for privacy – receive. Technology must enable a user to:
- (i) Receive a summary record that is tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1);
  - (ii) Apply document-level tagging and sequester the document from other documents received; and
  - (iii) View the restricted document (or data), without incorporating the document (or data).

**Preamble FR Citation:** 80 FR 16842 (also see 80 FR 16840)

**Specific questions in preamble?** *No*

**Public Comment Field:**

**The Pharmacy Health Information Technology Collaborative supports including the receiving of sensitive patient information electronically as part of this criterion provided the transmission of such information in a receiver's system is secure and that restrictions, such as a prohibition on re-disclosure without consent, are included.**

**§ 170.315(b)(9) Care plan**

**Included in 2015 Edition Base EHR Definition?**

No

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

- (9) Care plan. Technology must enable a user to record, change, access, create, and receive care plan information in accordance with the Care Plan document template in the standard adopted in § 170.205(a)(4).

**Preamble FR Citation:** 80 FR 16842

**Specific questions in preamble?** *Yes*

## § 170.315(b)(9) Care plan

### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports the adoption of this new 2015 Edition “care plan” certification criterion using the C-CDA Release 2.0 standard.

The best medical outcomes happen with an integrated team approach of health care providers. Pharmacists provide patient-centered care and services, and as part of the integrated health care team, they are directly involved with other health care providers in various practice settings in providing care plans for patients, including medication action plans.

*The Medicare Part D Medication Therapy Management (MTM) Program Standardized Format (Format) is a written summary of a comprehensive medication review (CMR). A CMR is an interactive, person-to-person or telehealth medication review and consultation of a beneficiary’s medications (including prescriptions, over-the-counter (OTC) medications, herbal therapies, and dietary supplements) by a pharmacist or qualified provider that is intended to aid in assessing medication therapy and optimizing patient outcomes. Part D sponsors must, at a minimum, offer a CMR annually for targeted beneficiaries and provide written summaries. The summaries must comply with requirements as specified by CMS for the Format as of January 1, 2013. The Format for the written summary given to beneficiaries after a CMR includes three documents: CMR Cover Letter (CL), Medication Action Plan (MAP), and Personal Medication List (PML). The Format is not considered marketing material and should not include any marketing messages, marketing disclaimers, or other sales information.<sup>3</sup>*

The electronic version of the MAP is outlined in the HL7 Project Summary for Medication Therapy Management (MTM) Templated CDA.

*The MTM Encounter supporting documentation templates will be based on the HL7 Implementation Guide for CDA Release 2.0: Consolidated CDA and designed to provide a vehicle for reporting the results from MTM Medication Review (e.g. Comprehensive, (CMR) or Targeted (TMR) Medication Reviews), MTM Services (e.g., Clinical Documentation, Medication Therapy Outcomes), and the patient-specific Personal Medication Action Plan and Medication List.<sup>4</sup>*

<sup>3</sup>Medicare Part D Medication Therapy Management (MTM) Program Standardized Format, <http://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/mtm-program-standardized-format-english-and-spanish-instructions-samples-v032712.pdf> (accessed April 21, 2015).

<sup>4</sup>HL7 Project Summary for Medication Therapy Management (MTM) Templated CDA, <http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=842> (accessed April 21, 2015).

## § 170.315(c)(1) Clinical quality measures – record and export

### Included in 2015 Edition Base EHR Definition?

Yes

### Stage 3 MU Objective

N/A

**§ 170.315(c)(1) Clinical quality measures – record and export**

**2015 Edition Health IT Certification Criterion**

- (1) Clinical quality measures – record and export.
- (i) Record. For each and every CQM for which the technology is presented for certification, the technology must be able to record all of the data that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of “patient reason,” “system reason,” or “medical reason.”
  - (ii) Export. A user must be able to export a data file formatted in accordance with the standard specified at § 170.205(h) for one or multiple patients that includes all of the data captured for each and every CQM to which technology was certified under paragraph (c)(1)(i) of this section. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.

**Preamble FR Citation:** 80 FR 16842

**Specific questions in preamble?** Yes

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “clinical quality measures (CQM) – record and export” certification criterion revised from the 2014 Edition that this criterion be part of the set of criteria necessary to satisfy the “2015 Edition Base EHR” definition. We also support the proposed requirement that a system user be able to export CQM data at any time the user chooses without subsequent developer assistance to operate.

With regard to which three QRDA options should be adopted, the Collaborative supports adoption of the HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture (QRDA), DSTU Release (July 2) and the September 2014 Errata. Since QUICK FHIR-based DSTU.CQM standards are not available at this time, we would suggest that ONC and CMS evaluate those once they are released.

Although pharmacists are not currently using these measurements, the Pharmacy Quality Alliance (PQA) is developing a framework for these measurements. The Collaborative is working with PQA regarding these.

**§ 170.315(c)(2) Clinical quality measures – import and calculate**

**Included in 2015 Edition Base EHR Definition?**

No, but proposed for the EHR Incentive Programs CEHRT definition

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

- (2) Clinical quality measures – import and calculate.
- (i) Import. Enable a user to import a data file in accordance with the standard specified at § 170.205(h) for one or multiple patients and use such data to perform the capability specified in paragraph (c)(2)(ii) of this section. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.
  - (ii) Technology must be able to calculate each and every clinical quality measure for which it is presented for certification.

**Preamble FR Citation:** 80 FR 16843

**Specific questions in preamble?** Yes

**§ 170.315(c)(2) Clinical quality measures – import and calculate**

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “clinical quality measures – import and calculate” certification criterion revised from the 2014 Edition. The Collaborative supports the proposed requirement that a system user be able to import CQM data at any time the user chooses without subsequent developer assistance to operate. With regard to which QRDA standards should be considered for this certification criterion, the Collaborative supports adoption of the HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture (QRDA), DSTU Release (July 2) and the September 2014 Errata.

**Reserved for § 170.315(c)(3) Clinical quality measures – report**

**Included in 2015 Edition Base EHR Definition?**

No, but proposed for the EHR Incentive Programs CEHRT definition

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

(3) [Reserved]

**Preamble FR Citation:** 80 FR 16844

**Specific questions in preamble?** *No*

**Public Comment Field:**

**N/A at this time.**

**§ 170.315(c)(4) Clinical quality measures – filter**

**Included in 2015 Edition Base EHR Definition?**

No

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

(4) Clinical quality measures – filter.

- (i) Technology must be able to record the data listed in paragraph (c)(4)(iii) of this section in accordance with the identified standards, where specified.
- (ii) Technology must be able to filter CQM results at the patient and aggregate levels by each one and any combination of the data listed in paragraph (c)(4)(iii) of this section.
- (iii) Data.
  - (A) TIN;
  - (B) NPI;
  - (C) Provider type;
  - (D) Patient insurance;
  - (E) Patient age;
  - (F) Patient sex in accordance with, at a minimum, the version of the standard specified in § 170.207(n)(1);
  - (G) Patient race and ethnicity in accordance with, at a minimum, the version of the standard specified in § 170.207(f)(2);
  - (H) Patient problem list data in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4); and
  - (I) Practice site address.

**Preamble FR Citation:** 80 FR 16844

**Specific questions in preamble?** *Yes*

**§ 170.315(c)(4) Clinical quality measures – filter**

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative supports adoption of the proposed new 2015 Edition “clinical quality measures – filter”. The Collaborative supports the use of SNOMED CT (September 2014 Release) for problem list data. Additionally, we support patient population filtered data for collecting metadata. Because of the role pharmacists’ play, especially with regard to immunizations, this is important.

**§ 170.315(d)(1) Authentication, access control, and authorization**

**Included in 2015 Edition Base EHR Definition?**

No, but a conditional certification requirement

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

- (1) Authentication, access control, and authorization.
  - (i) Verify against a unique identifier(s) (e.g., username or number) that a person seeking access to electronic health information is the one claimed; and
  - (ii) Establish the type of access to electronic health information a user is permitted based on the unique identifier(s) provided in paragraph (d)(1)(i) of this section, and the actions the user is permitted to perform with the technology.

**Preamble FR Citation:** 80 FR 16846

**Specific questions in preamble?** *No*

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “authentication, access control, and authorization” as unchanged from the 2014 Edition.

**§ 170.315(d)(2) Auditable events and tamper-resistance**

**Included in 2015 Edition Base EHR Definition?**

No, but a conditional certification requirement

**MU Objective**

N/A

## § 170.315(d)(2) Auditable events and tamper-resistance

### 2015 Edition Health IT Certification Criterion

- (2) Auditable events and tamper-resistance.
- (i) Record actions. Technology must be able to:
    - (A) Record actions related to electronic health information in accordance with the standard specified in § 170.210(e)(1);
    - (B) Record the audit log status (enabled or disabled) in accordance with the standard specified in § 170.210(e)(2) unless it cannot be disabled by any user; and
    - (C) Record the encryption status (enabled or disabled) of electronic health information locally stored on end-user devices by technology in accordance with the standard specified in § 170.210(e)(3) unless the technology prevents electronic health information from being locally stored on end-user devices (see paragraph (d)(7) of this section).
  - (ii) Default setting. Technology must be set by default to perform the capabilities specified in paragraph (d)(2)(i)(A) of this section and, where applicable, paragraph (d)(2)(i)(B) or (C) of this section, or both paragraphs (d)(2)(i)(B) and (C).
  - (iii) When disabling the audit log is permitted. For each capability specified in paragraphs (d)(2)(i)(A) through (C) of this section that technology permits to be disabled, the ability to do so must be restricted to a limited set of users.
  - (iv) Audit log protection. Actions and statuses recorded in accordance with paragraph (d)(2)(i) of this section must not be capable of being changed, overwritten, or deleted by the technology.
  - (v) Detection. Technology must be able to detect whether the audit log has been altered.

Preamble FR Citation: 80 FR 16846

Specific questions in preamble? *Yes*

#### Public Comment Field:

**The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “auditable events and tamper-resistance” as unchanged from the 2014 Edition and supports the reaffirmation that this would prohibit an EHR technology’s audit log from being disabled by a user.**

## § 170.315(d)(3) Audit report(s)

### Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

### Stage 3 MU Objective

N/A

### 2015 Edition Health IT Certification Criterion

- (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 data specified in the standards at § 170.210(e).

Preamble FR Citation: 80 FR 16847

Specific questions in preamble? *No*

#### Public Comment Field:

**The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “audit report(s)” as unchanged from the 2014 Edition.**

## § 170.315(d)(4) Amendments

### Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

### Stage 3 MU Objective

N/A

## § 170.315(d)(4) Amendments

### 2015 Edition Health IT Certification Criterion

- (4) Amendments. Enable a user to select the record affected by a patient's request for amendment and perform the capabilities specified in paragraph (d)(4)(i) or (ii) of this section.
- (i) Accepted amendment. For an accepted amendment, append the amendment to the affected record or include a link that indicates the amendment's location.
  - (ii) Denied amendment. For a denied amendment, at a minimum, append the request and denial of the request to the affected record or include a link that indicates this information's location.

Preamble FR Citation: 80 FR 16847

Specific questions in preamble? *No*

### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “amendments” as unchanged from the 2014 Edition.

## § 170.315(d)(5) Automatic access time-out

### Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

### Stage 3 MU Objective

N/A

### 2015 Edition Health IT Certification Criterion

- (5) Automatic access time-out.
- (i) Automatically stop user access to health information after a predetermined period of inactivity.
  - (ii) Require user authentication in order to resume or regain the access that was stopped.

Preamble FR Citation: 80 FR 16847

Specific questions in preamble? *Yes*

### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “automatic access time-out” as unchanged from the 2014 Edition.

## § 170.315(d)(6) Emergency access

### Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

### Stage 3 MU Objective

N/A

### 2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16847

Specific questions in preamble? *No*

### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “emergency access” as unchanged from the 2014 Edition.

### § 170.315(d)(7) End-user device encryption

#### Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

#### Stage 3 MU Objective

N/A

#### 2015 Edition Health IT Certification Criterion

- (7) End-user device encryption. Paragraph (d)(7)(i) or (ii) of this section must be met to satisfy this certification criterion.
- (i) Technology that is designed to locally store electronic health information on end-user devices must encrypt the electronic health information stored on such devices after use of the technology on those devices stops.
    - (A) Electronic health information that is stored must be encrypted in accordance with the standard specified in § 170.210(a)(3);
    - (B) Default setting. Technology must be set by default to perform this capability and, unless this configuration cannot be disabled by any user, the ability to change the configuration must be restricted to a limited set of identified users.
  - (ii) Technology is designed to prevent electronic health information from being locally stored on end-user devices after use of the technology on those devices stops.

Preamble FR Citation: 80 FR 16847

Specific questions in preamble? Yes

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “end-user device encryption” as unchanged from the 2014 Edition.

### § 170.315(d)(8) Integrity

#### Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

#### Stage 3 MU Objective

N/A

#### 2015 Edition Health IT Certification Criterion

- (8) Integrity.
- (i) Create a message digest in accordance with the standard specified in § 170.210(c).
  - (ii) Verify in accordance with the standard specified in § 170.210(c) upon receipt of electronically exchanged health information that such information has not been altered.

Preamble FR Citation: 80 FR 16847

Specific questions in preamble? Yes

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “integrity” certification criterion revised from the 2014 Edition that would be tested and certified to support the context for which it was adopted – upon receipt of a summary record in order to ensure the integrity of the information exchanged.

### § 170.315(d)(9) Accounting of disclosures

#### Included in 2015 Edition Base EHR Definition?

No

#### Stage 3 MU Objective

N/A



**§ 170.315(d)(9) Accounting of disclosures**

**2015 Edition Health IT Certification Criterion**

(9) 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:** 80 FR 16848

**Specific questions in preamble?** *No*

**Public Comment Field:**

**The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “accounting disclosures” as unchanged from the 2014 Edition.**

**§ 170.315(e)(1) View, download, and transmit to a third party**

**Included in 2015 Edition Base EHR Definition?**

No

**Stage 3 MU Objectives**

The EP, eligible hospital, or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability.

Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.

## 2015 Edition Health IT Certification Criterion

- (1) View, download, and transmit to 3rd party.
  - (i) Patients (and their authorized representatives) must be able to use technology to view, download, and transmit their health information to a 3rd party in the manner specified below. Access to these capabilities must be online and through a secure channel that ensures all content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).
    - (A) View. Patients (and their authorized representatives) must be able to use health IT to view in accordance with the standard adopted at § 170.204(a)(1), at a minimum, the following data:
      - (1) The Common Clinical Data Set (which should be in their English (i.e., non-coded) representation if they associate with a vocabulary/code set).
      - (2) Ambulatory setting only. Provider's name and office contact information.
      - (3) Inpatient setting only. Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization.
      - (4) Laboratory test report(s). Laboratory test report(s), including:
        - (i) The information for a test report as specified all the data specified in 42 CFR 493.1291(c)(i) through (7);
        - (ii) The information related to reference intervals or normal values as specified in 42 CFR 493.1291(d); and
        - (iii) The information for corrected reports as specified in 42 CFR 493.1291(k)(2)
      - (5) Diagnostic image report(s).
    - (B) Download.
      - (1) Patients (and their authorized representatives) must be able to use EHR technology to download an ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) in only human readable format, in only the format specified in accordance to the standard adopted at § 170.205(a)(4), or in both formats. The use of the "unstructured document" document-level template is prohibited for compliance with the standard adopted at § 170.205(a)(4).
      - (2) When downloaded according to the standard adopted at § 170.205(a)(4), the ambulatory summary or inpatient summary must include, at a minimum, the following data (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set):
        - (i) Ambulatory setting only. All of the data specified in paragraph (e)(1)(i)(A)(1), (2), (4), and (5) of this section.
        - (ii) Inpatient setting only. All of the data specified in paragraphs (e)(1)(i)(A)(1), and (3) through (5) of this section.
      - (3) Inpatient setting only. Patients (and their authorized representatives) must be able to download transition of care/referral summaries that were created as a result of a transition of care (pursuant to the capability expressed in the certification criterion adopted at paragraph (b)(1) of this section).
    - (C) Transmit to third party. Patients (and their authorized representatives) must be able to:
      - (1) Transmit the ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) created in paragraph (e)(1)(i)(B)(2) of this section in accordance with at least one of the following.
        - (i) The standard specified in § 170.202(a).
        - (ii) Through a method that conforms to the standard specified at § 170.202(d) and leads to such summary being processed by a service that has implemented the standard specified in § 170.202(a).
      - (2) Inpatient setting only. Transmit transition of care/referral summaries (as a result of a transition of care/referral) selected by the patient (or their authorized representative) in accordance with at least one of the following:
        - (i) The standard specified in § 170.202(a).
        - (ii) Through a method that conforms to the standard specified at § 170.202(d) and leads to such summary being processed by a service that has implemented the standard specified in § 170.202(a).
  - (ii) Activity history log.
    - (A) When electronic health information is viewed, downloaded, or transmitted to a third-party using the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section or when an application requests electronic health information using the capability specified at paragraph (e)(1)(iii) of this section, the following information must be recorded and made accessible to the patient:
      - (1) The action(s) (i.e., view, download, transmission, API response) that occurred;
      - (2) The date and time each action occurred in accordance with the standard specified at § 170.210(g);
      - (3) The user who took the action; and
      - (4) Where applicable, the addressee to whom an ambulatory summary or inpatient summary was transmitted.

## § 170.315(e)(1) View, download, and transmit to a third party

- (B) Technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of this section if it is also certified to the certification criterion adopted at §170.315(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) is accessible by the patient.

### 2015 Edition Health IT Certification Criterion, §170.315(e)(1) View, download, and transmit to 3rd party, continued

- (i) Application access. Patients (and their authorized representatives) must be able to use an application that can interact with the following capabilities. Additionally, the following technical outcomes and conditions must be met through the demonstration of an application programming interface (API) that can respond to requests from other applications for data specified within the Common Clinical Data Set.
- (A) Security. The API must include a means to establish a trusted connection with the application requesting patient data, including a means for the requesting application to register with the data source, be authorized to request data, and log all interactions between the application and the data source.
- (B) Patient selection. The API must include a means for the application to query for an ID or other token of a patient's record in order to subsequently execute data requests for that record in accordance with (e)(1)(iii)(C) of this section.
- (C) Data requests, response scope, and return format. The API must enable and support both of the following data request interactions:
- (1) Data-category request. The API must support syntax that allows it to respond to requests for each of the individual data categories specified in the Common Clinical Data Set and return the full set of data for that data category (according to the specified standards, where applicable) in either XML or JSON.
- (2) All-request. The API must support syntax that allows it to respond to a request for all of the data categories specified in the Common Clinical Data Set at one time and return such data (according to the specified standards, where applicable) in a summary record formatted according to the standard adopted at § 170.205(a)(4).
- (D) Documentation. The API must include accompanying documentation that contains, at a minimum:
- (1) API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.
- (2) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).
- (E) Terms of use. The terms of use for the API must be provided, including, at a minimum, any associated developer policies and required developer agreements.

Preamble FR Citation: 80 FR 16848

Specific questions in preamble? Yes

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition "view, download, and transmit to a third party" (VDT) certification criterion revised from the 2014 Edition. The Collaborative supports the inclusion of an updated Common Clinical Data Set and referencing the updated version of the C-CDA (Draft Standard for Trial Use, Release 2.0) for this criterion.

Concerning C-CDA creation capability, we believe the scope of C-CDA creation capability within this certification criterion should focus on the creation of a CCD document template based on the C-CDA Release 2.

## § 170.315(e)(2) Secure messaging

Included in 2015 Edition Base EHR Definition?

No

#### Stage 3 MU Objective

Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.

## § 170.315(e)(2) Secure messaging

### 2015 Edition Health IT Certification Criterion

- (2) Secure messaging. Enable a user to send messages to, and receive messages from, a patient in a manner that ensures:
- (i) Both the patient (or authorized representative) and technology user 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).

Preamble FR Citation: 80 FR 16850

Specific questions in preamble? *No*

### Public Comment Field:

**The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “secure messaging” as unchanged from the 2014 Edition.**

## § 170.315(f)(1) Transmission to immunization registries

### Included in 2015 Edition Base EHR Definition?

No

### Stage 3 MU Objective

The EP, eligible hospital, or CAH is in active engagement with a public health agency (PHA) or clinical data registry (CDR) to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

### 2015 Edition Health IT Certification Criterion

- (1) Transmission to immunization registries.
- (i) Technology must be able to create immunization information for electronic transmission in accordance with:
    - (A) The standard and applicable implementation specifications specified in § 170.205(e)(4);
    - (B) At a minimum, the version of the standard specified in § 170.207(e)(3) for historical vaccines; and
    - (C) At a minimum, the version of the standard specified in § 170.207(e)(4) for administered vaccines.
  - (ii) Technology must enable a user to request, access, and display a patient’s evaluated immunization history and the immunization forecast from an immunization registry in accordance with the standard at § 170.205(e)(4).

Preamble FR Citation: 80 FR 16850

Specific questions in preamble? *Yes*

### Public Comment Field:

**The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “transmission to immunization registries” certification criterion revised from the 2014 Edition. The Collaborative supports the adoption of an updated implementation guide, especially the HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5 (October 2014) for greater interoperability between immunization registries and health IT; requiring National Drug Codes (NDC) for recording administered vaccines and CVX codes for historical vaccines; and requiring a health IT module to be able to display an immunization history and forecast from an immunization registry.**

**Pharmacists administering immunizations are capturing NDCs because of billing requirements in the system. If NDCs were to be replaced by CVX for reporting to immunization registries, the impact to other systems and processes would need to be considered (e.g., billing and adverse drug event reporting).**

## § 170.315(f)(2) Transmission to public health agencies – syndromic surveillance

### Included in 2015 Edition Base EHR Definition?

No

### Stage 3 MU Objective

The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

**§ 170.315(f)(2) Transmission to public health agencies – syndromic surveillance**

**2015 Edition Health IT Certification Criterion**

- (2) Transmission to public health agencies—syndromic surveillance.
- (i) Ambulatory setting only.
- (A) Technology must be able to create syndrome-based public health surveillance information for electronic transmission.
  - (B) Optional. Technology must be able to create syndrome-based public health surveillance information for electronic transmission that contains the following data:
    - (1) Patient demographics;
    - (2) Provider specialty;
    - (3) Provider address;
    - (4) Problem list;
    - (5) Vital signs;
    - (6) Laboratory test values/results;
    - (7) Procedures;
    - (8) Medication list; and
    - (9) Insurance.
- (ii) Inpatient setting only. Technology must be able to create syndrome-based public health surveillance information for electronic transmission in accordance with the standard (and applicable implementation specifications) specified in § 170.205(d)(4).

**Preamble FR Citation:** 80 FR 16853

**Specific questions in preamble?** *No*

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “transmission to public health agencies – syndromic surveillance” as unchanged from the 2014 Edition for ambulatory settings, though changes will be made for emergency department, urgent care, and inpatient settings. The Collaborative is supportive of standards used by public health agencies.

**§ 170.314(f)(3) Transmission to public health agencies – reportable laboratory tests and values/results**

**Included in 2015 Edition Base EHR Definition?**

No

**Stage 3 MU Objective**

The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

**2015 Edition Health IT Certification Criterion**

- (3) Transmission to public health agencies – reportable laboratory tests and values/results. Technology must be able to 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)(2); and
  - (ii) At a minimum, the versions of the standards specified in § 170.207(a)(4) and (c)(3).

**Preamble FR Citation:** 80 FR 16853

**Specific questions in preamble?** *No*

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “transmission to public health agencies – reportable laboratory tests and values/results” certification criterion revised from the 2014 Edition. The Collaborative supports the continued use of the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm) and incorporating updated versions of SNOMED CT and LOINC for this criterion.

### § 170.315(f)(4) Transmission to cancer registries

#### Included in 2015 Edition Base EHR Definition?

No

#### Stage 3 MU Objective

The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

#### 2015 Edition Health IT Certification Criterion

- (4) Transmission to cancer registries. Technology must be able to create cancer case information for electronic transmission in accordance with:
- (i) The standard (and applicable implementation specifications) specified in § 170.205(i)(2); and
  - (ii) At a minimum, the versions of the standards specified in § 170.207(a)(4) and (c)(3).

Preamble FR Citation: 80 FR 16854

Specific questions in preamble? Yes

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “transmission to cancer registries” certification criterion revised from the 2014 Edition. The Collaborative supports the use of the HL7 Implementation Guide for CDA Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers Release 1 (HL7 IG Release 1) and incorporating an updated version of SNOMED CT and LOINC version 2.50 in this criterion.

### § 170.315(f)(5) Transmission to public health agencies – case reporting

#### Included in 2015 Edition Base EHR Definition?

No

#### Stage 3 MU Objective

The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

#### 2015 Edition Health IT Certification Criterion

- (5) Transmission to public health agencies – case reporting. Technology must be able to create case reporting information for electronic transmission in accordance with the standard specified in § 170.205(q)(1).

Preamble FR Citation: 80 FR 16855

Specific questions in preamble? Yes

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the new 2015 Edition “transmission to public health agencies – case reporting” certification criterion. The Collaborative recommends giving consideration to the adoption of the HL7 Fast Health Interoperability Resource (FHIR) Implementation Guide: SDC DSTU that will be balloted in mid-2015.

### § 170.315(f)(6) Transmission to public health agencies – antimicrobial use and resistance reporting

#### Included in 2015 Edition Base EHR Definition?

No

#### Stage 3 MU Objective

The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

**§ 170.315(f)(6) Transmission to public health agencies – antimicrobial use and resistance reporting**

**2015 Edition Health IT Certification Criterion**

- (6) Transmission to public health agencies – antimicrobial use and resistance reporting. Technology must be able to create antimicrobial use and resistance reporting information for electronic transmission in accordance with the standard specified in § 170.205(r)(1).

**Preamble FR Citation:** 80 FR 16855

**Specific questions in preamble?** *No*

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative supports adoption of the new 2015 Edition “transmission to public health agencies – antimicrobial use and resistance reporting” certification criterion. The Collaborative supports the use of the HL7 Implementation Guide for CDA Release 2 – Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm (August 2013).

**§ 170.315(f)(7) Transmission to public health agencies – health care surveys**

**Included in 2015 Edition Base EHR Definition?**

No

**Stage 3 MU Objective**

The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

**2015 Edition Health IT Certification Criterion**

- (7) Transmission to public health agencies – health care surveys. Technology must be able to create health care survey information for electronic transmission in accordance with the standard specified in § 170.205(s)(1).

**Preamble FR Citation:** 80 FR 16856

**Specific questions in preamble?** *No*

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative supports adoption of the new 2015 Edition “transmission to public health agencies – health care surveys” certification criterion. The Collaborative supports the use of the HL7 Implementation Guide for CDA Release 2: National Health Care Surveys (NHCS), Release 1, U.S. Realm (December 2014).

**§ 170.315(g)(1) Automated numerator recording**

**Included in 2015 Edition Base EHR Definition?**

No, but proposed for the EHR Incentive Programs CEHRT definition

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

- (1) Automated numerator recording. For each meaningful use objective with a percentage-based measure, technology must be able to create a report or file that enables a user to review the patients or actions that would make the patient or action eligible to be included in the measure's numerator. The information in the report or file created must be of sufficient detail such that it enables a user to match those patients or actions to meet the measure's denominator limitations when necessary to generate an accurate percentage.

**Preamble FR Citation:** 80 FR 16856

**Specific questions in preamble?** *No*

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “automated numerator recording” as unchanged from the 2014 Edition.

### § 170.315(g)(2) Automated measure calculation

#### Included in 2015 Edition Base EHR Definition?

No, but proposed for the EHR Incentive Programs CEHRT definition

#### Stage 3 MU Objective

N/A

#### 2015 Edition Health IT Certification Criterion

- (2) Automated measure calculation. For each meaningful use objective with a percentage-based measure that is supported by a capability included in a technology, 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: 80 FR 16856

Specific questions in preamble? *No*

#### Public Comment Field:

**The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “automated measure calculation” as unchanged from the 2014 Edition.**

### § 170.315(g)(3) Safety-enhanced design

#### Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

#### Stage 3 MU Objective

N/A

#### 2015 Edition Health IT Certification Criterion

- (3) Safety-enhanced design.
- (i) User-centered design processes must be applied to each capability technology includes that is specified in the following certification criteria: paragraphs (a)(1) through (10) and (18), (20), (22), (23), and (b)(2) through (4) of this section.
  - (ii) The following information must be submitted on the user-centered design processed used:
    - (A) Name, description and citation (URL and/or publication citation) for an industry or federal government standard; or
    - (B) Name the process(es), provide an outline of the process(es), a short description of the process(es), and an explanation of the reason(s) why use of any of the existing user-centered design standards was impractical.
  - (iii) The following information/sections from NISTIR 7742 must be submitted for each capability to which user-centered design processes were applied:
    - (A) Name and version of the product; date and location of the test; test environment; description of the intended users; and total number of participants;
    - (B) Description of participants, including: sex; age; education; occupation/role; professional experience; computer experience; and product experience;
    - (C) Description of the user tasks that were tested and association of each task to corresponding certification criteria;
    - (D) List of the specific metrics captured during the testing, including; task success (%); task failures (%); task standard deviations (%); task performance time; and user satisfaction rating (based on a scale with 1 as very difficult and 5 as very easy);
    - (E) Test results for each task using metrics listed above in paragraphs (g)(3)(ii)(A) through (D) of this section;
    - (F) Results and data analysis narrative, including: major test finding; effectiveness; efficiency; satisfaction; and areas for improvement.
  - (iv) Submit test scenarios used in summative usability testing.

Preamble FR Citation: 80 FR 16856

Specific questions in preamble? *Yes*



**§ 170.315(g)(3) Safety-enhanced design**

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “transmission to public health agencies – reportable laboratory tests and values/results” certification criterion revised from the 2014 Edition. In our 2014 comments, we recommended adding additional safety-enhanced certification criteria for medication-related services provided by pharmacists. The Collaborative is pleased to see and supports the adoption of additional certification criteria for error prevention and patient safety with regard to medications; drug-drug, drug-allergy interaction checks; problem, medications, and medication allergy lists; clinical decision support; and electronic medication administration record.

**§ 170.315(g)(4) Quality management system**

**Included in 2015 Edition Base EHR Definition?**

No, but a mandatory certification requirement

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

- (4) Quality management system.
- (i) For each capability that a technology includes and for which that capability's certification is sought, the use of a Quality Management System (QMS) in the development, testing, implementation, and maintenance of that capability must be identified that is:
    - (A) Compliant with a QMS established by the Federal government or a standards developing organization; or
    - (B) Mapped to one or more QMS established by the Federal government or standards developing organization(s).
  - (ii) If a single QMS was used for applicable capabilities, it would only need to be identified once.
  - (iii) If different QMS were applied to specific capabilities, each QMS applied would need to be identified.

**Preamble FR Citation:** 80 FR 16858

**Specific questions in preamble?** *No*

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “quality management system (QMS)” certification criterion revised from the 2014 Edition. We agree that for a health IT module the identified QMS must be compliant with a QMS established or mapped by the federal government or a standards developing organization and certified to this 2015 Edition QMS criterion.

**§ 170.315(g)(5) Accessibility technology compatibility**

**Included in 2015 Edition Base EHR Definition?**

No

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

- (5) Accessibility technology compatibility. For each capability technology includes that is specified in the certification criteria at paragraphs (a), (b), and (e) of this section, the capability must be compatible with at least one accessibility technology that includes text-to-speech functionality.

**Preamble FR Citation:** 80 FR 16858

**Specific questions in preamble?** *Yes*

### § 170.315(g)(5) Accessibility technology compatibility

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the new 2015 Edition “accessibility technology compatibility” that would offer health IT developers that present a health IT module for certification to one or more certification criteria the opportunity to have their health IT demonstrate compatibility with at least one accessibility technology for the user-facing capabilities included in the referenced criteria. Of importance is that health IT developers consider the needs of visually impaired and disabled users when designing their products and integrate accessibility features into their products.

### § 170.315(g)(6) Consolidated CDA creation performance

#### Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

#### Stage 3 MU Objective

N/A

#### 2015 Edition Health IT Certification Criterion

- (6) Consolidated CDA creation performance. The following technical and performance outcomes must be demonstrated related to Consolidated CDA creation. The capabilities required under paragraphs (g)(6)(i) through (iii) of this section can be demonstrated in tandem and do not need to be individually addressed in isolation or sequentially.
- (i) Reference C-CDA match. Upon the entry of clinical data consistent with the Common Clinical Data Set, the technology must be able to create a data file formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that matches a gold-standard, reference data file.
  - (ii) Document-template conformance. Upon the entry of clinical data consistent with the Common Clinical Data Set, the technology must be able to create a data file formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that demonstrates a valid implementation of each of the following document templates (as applicable to the adopted standard):
    - (A) Generally applicable. CCD; Consultation Note; History and Physical; Progress Note; Care Plan; Transfer Summary; and Referral Note.
    - (B) Inpatient setting only. Discharge Summary.
  - (iii) Vocabulary conformance. Upon the entry of clinical data consistent with the Common Clinical Data Set, the technology must be able to create a data file formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that demonstrates the required vocabulary standards (and value sets) are properly implemented.

Preamble FR Citation: 80 FR 16859

Specific questions in preamble? Yes

#### Public Comment Field:

[Click here to enter comments on § 170.315\(g\)\(6\) Consolidated CDA creation performance.](#)

The Pharmacy Health Information Technology Collaborative supports adoption of the new Edition “consolidated CDA creation performance.” The Collaborative supports the proposed performance certification criteria that would focus on reference C-CDA match according to HL7 C-CDA standards; document template conformance applicable to the C-CDA 1.1 and C-CDA 2.0 standards, especially for progress note, transfer summary, care plan, and discharge summary; and vocabulary conformance as specified in the C-CDA standard.

### § 170.315(g)(7) Application access to Common Clinical Data Set

#### Included in 2015 Edition Base EHR Definition?

Yes

**§ 170.315(g)(7) Application access to Common Clinical Data Set**

**Stage 3 MU Objectives**

The EP, eligible hospital, or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability.

Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.

**2015 Edition Health IT Certification Criterion**

- (7) Application access to Common Clinical Data Set. The following technical outcomes and conditions must be met through the demonstration of an application programming interface (API) that can respond to requests from other applications for data specified within the Common Clinical Data Set.
  - (i) Security. The API must include a means to establish a trusted connection with the application requesting patient data, including a means for the requesting application to register with the data source, be authorized to request data, and log all interactions between the application and the data source.
  - (ii) Patient selection. The API must include a means for the application to query for an ID or other token of a patient's record in order to subsequently execute data requests for that record in accordance with paragraph (g)(7)(iii) of this section.
  - (iii) Data requests, response scope, and return format. The API must enable and support both of the following data request interactions:
    - (A) Data-category request. The API must support syntax that allows it to respond to requests for each of the individual data categories specified in the Common Clinical Data Set and return the full set of data for that data category (according to the specified standards, where applicable) in either XML or JSON.
    - (B) All-request. The API must support syntax that allows it to respond to a request for all of the data categories specified in the Common Clinical Data Set at one time and return such data (according to the specified standards, where applicable) in a summary record formatted according to the standard adopted at § 170.205(a)(4).
  - (iv) Documentation. The API must include accompanying documentation that contains, at a minimum:
    - (A) API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.
    - (B) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).
  - (v) Terms of use. The terms of use for the API must be provided, including, at a minimum, any associated developer policies and required developer agreements.

**Preamble FR Citation:** 80 FR 16860

**Specific questions in preamble?** Yes

**Public Comment Field:**

**The Pharmacy Health Information Technology Collaborative supports adoption of the new 2015 Edition “application access to Common Clinical Data Set.” We agree that this certification should require demonstration of an application programming interface (API) that responds to data requests for any data referenced in the Common Clinical Data Set and its definition. We also agree that the API must be secure, allow a query for an ID or other part of a patient’s record to execute data requests for that record, and support at least two types of data requests and responses (“by data category” and “all”).**

**With regard to the feasibility of additional API capabilities that could be made available, the Collaborative recommends that API include secure messaging, schedule, and task list read/write capabilities, and of importance to pharmacists, ordering/e-prescribing capability.**

**The Collaborative would support limiting the scope of C-CDA creation capability within this certification to focus on the creation of a CCD document based on C-CDA Release 2.0.**

**§ 170.315(g)(8) Accessibility - centered design**

**Included in 2015 Edition Base EHR Definition?**

No, but a mandatory certification requirement

**§ 170.315(g)(8) Accessibility - centered design**

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

- (8) Accessibility-centered design. For each capability that a Health IT Module includes and for which that capability's certification is sought, the use of a health IT accessibility-centered design standard or law in the development, testing, implementation and maintenance of that capability must be identified.
- (i) If a single accessibility-centered design standard or law was used for applicable capabilities, it would only need to be identified once.
  - (ii) If different accessibility-centered design standards and laws were applied to specific capabilities, each accessibility-centered design standard or law applied would need to be identified. This would include the application of an accessibility-centered design standard or law to some capabilities and none to others.
  - (iii) If no accessibility-centered design standard or law was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

**Preamble FR Citation:** 80 FR 16861

**Specific questions in preamble?** Yes

**Public Comment Field:**

**The Pharmacy Health Information Technology Collaborative supports adoption of the new 2015 Edition “accessibility – centered design”.**

**§ 170.315(h)(1) Direct Project**

**Included in 2015 Edition Base EHR Definition?**

Yes

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

- (1) Direct Project.
- (i) Applicability Statement for Secure Health Transport. Technology must be able to send and receive health information in accordance with the standards specified in § 170.202(a).
  - (ii) Optional – Applicability Statement for Secure Health Transport and Delivery Notification in Direct. Technology must be able to send and receive health information in accordance with the standard specified in § 170.202(e)(1).

**Preamble FR Citation:** 80 FR 16862

**Specific questions in preamble?** No

**Public Comment Field:**

**The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “direct project” certification criterion that includes the capability to send and receive according to the Applicability Statement for Secure Health Transport.**

**§ 170.315(h)(2) Direct Project, Edge Protocol, and XDR/XDM**

**Included in 2015 Edition Base EHR Definition?**

Yes, as an alternative to § 170.315(h)(1)

**Stage 3 MU Objective**

N/A

### § 170.315(h)(2) Direct Project, Edge Protocol, and XDR/XDM

#### 2015 Edition Health IT Certification Criterion

- (2) Direct Project, Edge Protocol, and XDR/XDM. Technology must be able to send and receive health information in accordance with:
- (i) The standards specified in § 170.202(a);
  - (ii) The standard specified in § 170.202(b); and
  - (iii) Both edge protocol methods specified by the standard in § 170.202(d).

Preamble FR Citation: 80 FR 16863 (also see 80 FR 16862)

Specific questions in preamble? *No*

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “direct project” edge protocol, and XDR/XDM” certification criterion that includes the capability to send and receive according to the Applicability Statement for Secure Health Transport.

### § 170.315(h)(3) SOAP Transport and Security Specification and XDR/XDM for Direct Messaging

#### Included in 2015 Edition Base EHR Definition?

No

#### Stage 3 MU Objective

N/A

#### 2015 Edition Health IT Certification Criterion

- (3) SOAP Transport and Security Specification and XDR/XDM for Direct Messaging. Technology must be able to send and receive health information in accordance with the standards specified in § 170.202(b) and (c).

Preamble FR Citation: 80 FR 16863

Specific questions in preamble? *No*

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports adoption of the 2015 Edition “SOAP transport and security specification and XDR/XDM for direct messaging” certification criterion that includes the capability to send and receive according to the Applicability Statement for Secure Health Transport.

### § 170.315(h)(4) Healthcare Provider Directory – query request

#### Included in 2015 Edition Base EHR Definition?

No

#### Stage 3 MU Objective

N/A

#### 2015 Edition Health IT Certification Criterion

- (4) Healthcare provider directory – query request. In accordance with the standard specified in § 170.202(f)(1), technology must be able to make, at a minimum, the following queries to a directory and subsequently process the response returned:
- (i) Query for an individual provider;
  - (ii) Query for an organizational provider;
  - (iii) Query for both individual and organizational providers in a single query; and
  - (iv) Query for relationships between individual and organizational providers.
  - (v) Optional - federation. In accordance with the standard specified in § 170.202(f)(1), technology must be able to process federated responses.

Preamble FR Citation: 80 FR 16863

Specific questions in preamble? *No*

**§ 170.315(h)(4) Healthcare Provider Directory – query request**

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative supports adoption of the new 2015 Edition “health care provider directory – query request” certification criterion that requires a health IT Module to be capable of querying a directory using the IHE HFD profile.

**§ 170.315(h)(5) Healthcare Provider Directory – query response**

**Included in 2015 Edition Base EHR Definition?**

No

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

- (5) Healthcare provider directory – query response. In accordance with the standard specified in § 170.202(f)(1), technology must be able to, at a minimum, respond to the following queries to a directory:
- (i) Query for an individual provider;
  - (ii) Query for an organizational provider;
  - (iii) Query for both individual and organizational providers in a single query; and
  - (iv) Query for relationships between individual and organizational providers.
- (v) Optional - federation. In accordance with the standard specified in § 170.202(f)(1), technology must be able to federate queries to other directories.

**Preamble FR Citation:** 80 FR 16864

**Specific questions in preamble?** *No*

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative supports adoption of the new 2015 Edition “health care provider directory – query response” certification criterion that requires a health IT module to be capable of responding to individual, organizations, and relationships between individual and organizations providers queries using the IHE HFD profile. The Collaborative supports the optional capability within this certification criterion to address federation requirements.

**§ 170.315(i)(1) Electronic submission of medical documentation**

**Included in 2015 Edition Base EHR Definition?**

No

**Stage 3 MU Objective**

N/A

## § 170.315(i)(1) Electronic submission of medical documentation

### 2015 Edition Health IT Certification Criterion

- (1) Electronic submission of medical documentation.
- (i) Document templates. Health IT must be able to create electronic documents for transmission formatted according to the following standard and applicable implementation specifications adopted at § 170.205(a)(4) and (a)(5)(i). With respect to § 170.205(a)(5)(i):
- (A) Health IT must be able to create the following document types regardless of the setting for which it is designed: Diagnostic Imaging Report; Unstructured Document; Enhanced Operative Note Document; Enhanced Procedure Note Document; and Interval Document.
- (B) Ambulatory setting only. Health IT must be able to create an Enhanced Encounter Document.
- (C) Inpatient setting only. Health IT must be able to create an Enhanced Hospitalization Document.
- (ii) Digital signature.
- (A) Applying a digital signature. Technology must be able to apply a digital signature in accordance with the implementation specification adopted at § 170.205(a)(5)(ii) to a document formatted according to the following standard and applicable implementation specifications adopted at § 170.205(a)(4) and (a)(5)(i). It must also be able to demonstrate that it can support the method for delegation of right assertions.
- (1) The cryptographic module used as part of the technology must: be validated to meet or exceed FIPS 140-2 Level 1; include a digital signature system and hashing that are compliant with FIPS 186-2 and FIPS 180-2; and store the private key in a FIPS-140-2 Level 1 validated cryptographic module using a FIPS-approved encryption algorithm. This requirement may be satisfied through documentation only.
- (2) Technology must support multi-factor authentication that meets or exceeds Level 3 assurance as defined in NIST Special Publication 800-63-2.
- (3) After ten minutes of inactivity, technology must require the certificate holder to re-authenticate to access the private key.
- (4) If implemented as a software function, the system must clear the plain text private key from the system memory to prevent the unauthorized access to, or use of, the private key when the signing module is deactivated.
- (5) Technology must record time and date consistent with the standard adopted at § 170.210(g).
- (B) Validating a digital signature. Technology must be able to validate a digital signature that has been applied to a document according to the implementation specification adopted at § 170.205(a)(5)(ii).
- (iii) Author of record level 1. Using the same system capabilities expressed in paragraph (i)(1)(ii), technology must be able to apply a digital signature according to the implementation specification adopted at § 170.205(a)(5)(iii) to sign single or bundles of documents a document formatted according to the following standard and applicable implementation specifications adopted at § 170.205(a)(4) and (a)(5)(i).
- (iv) Transactions. Using the same system capabilities expressed in paragraph (i)(1)(ii) of this section, technology must be able to apply a digital signature according to the implementation specification adopted at § 170.205(a)(5)(iv) to a transaction and include the signature as accompanying metadata in the signed transaction.

Preamble FR Citation: 80 FR 16864

Specific questions in preamble? *No*

**§ 170.315(i)(1) Electronic submission of medical documentation**

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative supports adoption of the new 2015 Edition “electronic submission of medical documentation” certification criterion. The Collaborative supports:

- **Capability 1** that a health IT module be able to support the creation of a document in accordance with the HL7 Implementation Guide for CDA Release 2: Additional CDA R2 Templates – Clinical Documents for Payers – Set 1, Release 1 – US Realm in combination with the C-CDA Release 2.0 standard;
- **Capability 2** that a health IT module be able to support the use of digital signatures embedded in C-CDA Release 2.0 and CDP1 IG documents templates by adopting the HL7 Implementation Guide for CDA Release 2: Digital Signatures and Delegation of Rights, Release 1;
- **Capability 3** that a health IT module be able to support the creation and transmission of external signatures for documents, and
- **Capability 4** that a health IT module be able to support the creation and transmission of digital signatures for electronic transactions for the purpose of both data integrity and non-repudiation authenticity.

**Gap Certification Eligibility Table for 2015 Edition Health IT Certification Criteria**

Preamble FR Citation: 80 FR 16867

Specific questions in preamble? *No*

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative supports the ONC’s gap certification policy for “unchanged” 2015 Edition certification criteria proposed for adoption.

**Pharmacogenomics Data – Request for Comment**

Preamble FR Citation: 80 FR 16869

Specific questions in preamble? *Yes*

**Public Comment Field:**

The Pharmacy Health Information Technology Collaborative would support including into the 2015 Edition the 10 areas outlined for pharmacogenomics data. Of particular importance to the Collaborative and its pharmacy members are: medication allergy list with the capability to integrate genotype-based drug metabolizer rate information; drug-drug, drug allergy interaction checks for CPOE for pharmacogenomic CDS for drug-genome interactions; and incorporating a patient’s pharmacogenomic genotype data into the CPOE prescribing process for avoiding adverse prescribing outcomes for known drug-genotype interactions. Pharmacists need access to this information.

Pharmacists are in a unique position to move pharmacogenomics into clinical practice environments. Pharmacists are involved in pharmacogenomics and participate in multidisciplinary groups to help develop pharmacogenetic-based therapeutic recommendations and integrate those recommendations into computerized systems for drug prescription, automated medication surveillance, and electronic medical records.

The Collaborative is in the process of completing for publication an *Environmental Scan of Pharmacogenomics Coding: Current Practice and Barriers*.



### Base EHR Definitions

Preamble FR Citation: 80 FR 16870

Specific questions in preamble? *No*

Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports the adoption of a Base EHR definition specific to the 2015 Edition; however, we believe the privacy and security capabilities required by EPs, eligible hospitals, and CAHs should not be removed. Although the new proposed policy places this assurance on health IT developers, we believe that users of health IT also need to ensure they are using secure systems.

### Certified EHR Technology Definition

Preamble FR Citation: 80 FR 16871

Specific questions in preamble? *No*

Public Comment Field:

The Pharmacy Health Information Technology Collaborative agrees with the rationale for removing the CEHRT definition for §170.102, effective with final rule, and have it reside appropriately within the EHR Incentive Programs regulations.

### Common Clinical Data Set Definition

Preamble FR Citation: 80 FR 16871

Specific questions in preamble? *No*

Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports changing the name Common MU Data Set to Common Clinical Data Set in the 2014 and 2015 Editions. The Collaborative also supports the inclusion of the various updated versions of HL7, SNOMED CT, and LOINC into the vocabulary standards, and the inclusion of immunizations into the Common Clinical Data Set.

### Cross Referenced FDA Definitions

Preamble FR Citation: 80 FR 16872

Specific questions in preamble? *No*

Public Comment Field:

N/A

## ***B. Provisions of the Proposed Rule Affecting the ONC Health IT Certification Program***

The following comment tables are meant to capture proposals relevant to the ONC Health IT Certification Program.

### Subpart E – ONC Health IT Certification Program

Preamble FR Citation: 80 FR 16873

Specific questions in preamble? *No*

## Subpart E – ONC Health IT Certification Program

### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports replacing the term “HIT” with the term “health IT” wherever it may occur in subpart E.

## Health IT Modules

Preamble FR Citation: 80 FR 16873

Specific questions in preamble? *No*

### Public Comment Field:

As noted throughout our comments, the Pharmacy Health Information Technology Collaborative supports the changes made in this area.

## “Removal” of Meaningful Use Measurement Certification Requirements

Preamble FR Citation: 80 FR 16873

Specific questions in preamble? *No*

### Public Comment Field:

As noted throughout our comments, the Pharmacy Health Information Technology Collaborative supports the changes made in this area.

## Types of Care and Practice Settings

Preamble FR Citation: 80 FR 16873

Specific questions in preamble? *Yes*

### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports the enhanced functionality changes, particularly the use of Common Clinical Data Set and the C-CDA Release 2.0, which includes document templates for care plan, referral note, transfer summary, and other pertinent functions that are especially important at the transition of care for pharmacists and long-term post acute care (LTPAC). The Collaborative supports the development of certification criteria that would support the LTPAC setting where the certification criteria development included members of the LTPAC providers, including pharmacists practicing in the LTPAC setting.

## Referencing the ONC Health IT Certification Program

Preamble FR Citation: 80 FR 16874

Specific questions in preamble? *No*

### Public Comment Field:

N/A

### Privacy and Security

Preamble FR Citation: 80 FR 16875

Specific questions in preamble? *Yes*

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports the changes made in this area.

### Design and Performance (§ 170.315(g))

Preamble FR Citation: 80 FR 16876

Specific questions in preamble? *No*

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports the changes made in this area to require ONC-ACBs to certify health IT modules consistent with the requirements included in these criteria.

### “In-the-Field” Surveillance and Maintenance of Certification

Preamble FR Citation: 80 FR 16876

Specific questions in preamble? *Yes*

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports the changes made in this area to build on ONC-ACBs' existing surveillance responsibilities.

### Transparency and Disclosure Requirements

Preamble FR Citation: 80 FR 16880

Specific questions in preamble? *No*

#### Public Comment Field:

N/A

### Open Data Certified Health IT Product List (CHPL)

Preamble FR Citation: 80 FR 16883

Specific questions in preamble? *Yes*

#### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports ONC making the CHPL an open data file in both XML and JSON with accompanying API functionality to replace the current PDF format has been used since 2010.

### Records Retention

Preamble FR Citation: 80 FR 16885

Specific questions in preamble? *No*

## Records Retention

### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports the change made in this area to require ONC-ACBs to retain all records related to the certification of complete EHR and/or health IT modules for a minimum of six years rather than five years.

## Complaints Reporting

Preamble FR Citation: 80 FR 16885

Specific questions in preamble? *No*

### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports the changes made in this area to require ONC-ACBs to provide ONC (the National Coordinator), on a quarterly basis, with a list of complaints received.

## Adaptations and Updates of Certified Health IT

Preamble FR Citation: 80 FR 16885

Specific questions in preamble? *Yes*

### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports the new principle of proper conduct that will require ONC-ACBs to obtain monthly reports from health IT developers regarding their certified health IT, including changes to user-facing aspects. We believe monthly reporting would be sufficient.

## “Decertification” of Health IT – Request for Comment

Preamble FR Citation: 80 FR 16886

Specific questions in preamble? *Yes*

## “Decertification” of Health IT – Request for Comment

### Public Comment Field:

The Pharmacy Health Information Technology Collaborative supports the proposal for ONC to decertify products that proactively block the sharing of information as requested by Congress in Public Law 113-235 (Consolidated and Further Continuing Appropriations Act of 2015).

In our August 12, 2014 letter to Senators Wyden and Grassley regarding their *Request for Comments Concerning Availability and Utility of Health Care-Related Data*, we stated:

“The Collaborative believes the main barrier in using existing data sources is that many of these systems use proprietary interfaces rather than using open source or standard exchange, which makes the exchange of data costly.

“Another barrier is that health care data is not flowing as freely as it should. Some organizations limit access to health care data that would improve patient care. Such limitations are generally done because of privacy and security concerns. Because of a perceived liability, limiting access is becoming a hindrance and could also become detrimental overall. There are ways that organizations and systems can ensure that health care data goes to the right provider with patients or consumers consent. Health care providers need to be trusted to be good stewards of health data and information.

“Pharmacists need to be a part of this exchange and have access to health care data. Some health information exchanges will not allow pharmacists access because they believe pharmacists do not need to know this information. Because pharmacists provide patient-centered care, including making clinical decisions regarding medication-related care, access to this health care data is essential to the successful performance of these duties.”

## Collections of Information – Paperwork Reduction Act

Preamble FR Citation: 80 FR 16893

Specific questions in preamble? No

### Public Comment Field:

N/A

## Regulatory Impact Statement

Preamble FR Citation: 80 FR 16895

Specific questions in preamble? No

### Public Comment Field:

N/A