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.

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 APA supports this criterion and would recommend that it also include the ability to track prescribed medications history**,** as being able to access comprehensive medication history is essential to high quality, clinical decision making. Simply being able to record, change and access medication orders does not assure the usability of this information. This is of particular relevance to psychiatrists as patients tend to be receiving a significant number of medications for their psychiatric illnesses as well as for co-occurring medical conditions, so it is essential to have a clear and usable medication history. Furthermore, treatment decisions often depend upon prior medication trials and prior histories of response (or adverse events) to other medications of the same class.

§ 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.
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*

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

Public Comment Field:

The APA supports this criterion. In terms of the ability to change a laboratory order, APA seeks clarification as whether this just criterion relates to changes in the software system or whether it requires an ability to re-transmit and make changes to orders in the receiving laboratory system. Since many systems do not currently include bi-directional interfaces to laboratory systems, this may need further specification.

§ 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:

The APA supports this criterion. The APA seeks clarification, however, as whether changing a diagnostic imaging order relates to changes in the software system or whether this requires an ability to re-transmit and make changes to orders in the receiving diagnostic imaging system. Since many systems do not currently include bi-directional interfaces to diagnostic imaging systems, this may need further specification.

§ 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.

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*

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

Public Comment Field:

The APA supports this criterion. With respect to the ability to document responses to drug-drug and drug-allergy interaction checking, APA seeks clarification as to whether this EHR feature is intended for use in all circumstances. Research on clinical decision support suggests that many alerts are not of clinical value and distract the user from other important tasks rather than improving safety. Organizations need to be able to determine whether or not they wish to force users to record actions taken for every alert, even when this may not be clinically indicated.

§ 170.315(a)(5) Demographics

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

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 APA supports this criterion.

§ 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

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

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.

Preamble FR Citation: 80 FR 16817 **Specific questions in preamble?** *Yes*

Public Comment Field:

The APA supports these criteria, as many of these optional features are pertinent to pediatric/child psychiatry.

§ 170.315(a)(7) Problem list

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

§ 170.315(a)(7) Problem list

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 APA supports these criteria, but seeks clarification as to why the problem list is limited only to a given hospitalization rather than reporting on the patient's longitudinal list of problems across encounters. Also, users should be able to flag specific problems as highly sensitive or confidential and have those problems displayed only to those with appropriate access rights. For example, some state regulations note that information about some problems should not be shared with parents of minors. Unless there is a mechanism available in all electronic records that permits secure tagging of content, parents and minors are unable to access any of their information (e.g., via a patient portal) without potentially exposing sensitive information. The same is true of information about substance use disorders under current regulations (42 CFR Part 2) when treatment is provided in certain licensed treatment programs.

§ 170.315(a)(8) Medication list

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

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 APA supports the proposed criteria, but seeks clarification as to why the problem list is limited only to a given hospitalization rather than reporting on the patient's longitudinal list of problems across encounters. Additionally, users should be able to mark specific medications as highly sensitive or confidential and have those medications displayed only to those with appropriate access rights. For example, some state regulations note that information about some treatments should not be shared with parents of minors (e.g., birth control prescriptions). Unless there is a mechanism available in all electronic records that permits secure tagging of content, parents and minors are unable to access any of their information (e.g., via a patient portal) without potentially exposing sensitive information.

§ 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.

§ 170.315(a)(9) Medication allergy list

Preamble FR Citation: 80 FR 16820 **Specific questions in preamble?** *No*

Public Comment Field:

The APA agrees with the proposed criteria, with the exception that the allergy list should be available across encounters regardless of whether the patient is seen on an inpatient or outpatient basis. This is of particular importance to psychiatrists as patients are often unable to provide a complete and accurate medication history when presenting with acute psychiatric symptoms.

§ 170.315(a)(10) Clinical decision support

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

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

§ 170.315(a)(10) Clinical decision support

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 APA supports features related to clinical decision support with several caveats. First, the APA recognizes that the design of clinical decision support is important to psychiatry because its patient population consistently demonstrates a combination of decision support needs related to 1) their psychiatric disorders as well as 2) to co-occurring medical conditions. These co-occurring medical conditions are in turn associated with early mortality and significant morbidity, particularly in individuals with serious and persistent mental illness, thus emphasizing the utility of clinical decision support within EHRs.

The APA appreciates the flexibility afforded by section i, but is concerned that the glut of decision support elements might result in clinicians selecting a collection of various elements that are the most easily completed, simply to meet the requirements of meaningful use as easily as possible. Simply because a clinical decision support can be constructed for each of these items does not mean that it will be needed or useful to the population of patients being served. Instead, APA suggests that this portion of the regulation should focus on evidence-based aspects of decision supports that are most important for improving clinical care.

Furthermore, APA believes that it is essential to have all relevant demographics be incorporated into decision support rather than a single one. For example, age and sex are highly salient, demographically-related factors that should each be able to be incorporated into decision support for all systems. For instance, research has begun to reveal that specific medications have differential efficacy by race/ethnicity, thus making the availability of demographic factors important with respect to the design of decision support.

§ 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 APA agrees with the proposed need to require the checking of drug formularies or preferred drug lists.

APA suggests that, to enhance usability, the Final Rule should also require EHRs to include 1) information about whether a specific drug requires pre-authorization as part of the formulary requirements, 2) a standard set of information that can be submitted if formulary pre-authorization is needed and 3) allow any indicated pre-authorizations to occur electronically from with the electronic record software without additional phone calls, faxes or external web applications. This would alleviate the burden on psychiatrists who frequently use pre-authorizations for medications.

§ 170.315(a)(12) Smoking status

Included in 2015 Edition Base EHR Definition?

Yes

§ 170.315(a)(12) Smoking status

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 APA agrees with this criterion and with the need to be able to record/change/access information about smoking status. In addition, APA suggests that there should be a concerted effort to consolidate the way in which a) smoking status and b) desire for cessation are defined across all regulatory and reporting requirements. This would enable psychiatrists to reduce documentation burdens while simultaneously promoting efforts at smoking cessation among patients, who are at particularly high risk of being smokers.

§ 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:

Click here to enter comments on § 170.315(a)(13) Image results.

§ 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*

§ 170.315(a)(14) Family health history

Public Comment Field:

The APA agrees that EHRs should possess a mechanism for documenting family health history, as family history of psychiatric illness is an essential component to potentially identifying various etiological explanations for patients' illnesses.

The APA recommends that data privacy segmentation should be used to protect information about a family members' history from widespread sharing, particularly when the family member him/herself may not have given permission to share the information.

Additionally, EHRs should also enable individual clinicians to include or hide from the record details that are beyond the scope of the current care to avoid cluttering the chart with extraneous details. Specifically, any mechanisms for the electronic collection of family history must have a clear focus on usability. Given the complex sets of relationships in modern families, the family history would need to be able to handle all manner of relationships (e.g., step-families, half-siblings, monozygotic and dizygotic twins, children from multiple relationships/marriages; homosexual as well as heterosexual couples; transgender individuals). This section of the EHR also needs to include a wide range of possible disorders, ranging from general diagnoses and colloquial terms (e.g. "nervous breakdown") to replicate patient's actual reports as well as very detailed diagnoses (e.g., urothelial bladder carcinoma in situ).

§ 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 APA acknowledges that a pedigree format is easier to read and interpret than a long list of names and dates and that such a format was particularly valuable in the paper era. However, "drawing" of an electronic pedigree can be time consuming and technologically difficult in the electronic era. If such a standard is incorporated into EHR certification in the future, there must be a clear focus on usability. Given the complex sets of relationships in modern families, pedigree drawing approaches would need to be able to handle all manner of relationships (e.g., step-families, half-siblings, monozygotic and dizygotic twins, children from multiple relationships/marriages; homosexual as well as heterosexual couples; transgender individuals).

§ 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*

§ 170.315(a)(16) Patient list creation

Public Comment Field:

The APA agrees that the EHR should be able to create patient lists, both for individual providers and for administrative units (with appropriate access permissions in place). The APA recommends that 16(iv) be expanded to include more than one demographic be included in this section of the requirement as the additional information would be a boon to patient tracking and monitoring of health disparities. Further, the APA suggests that there should also be an ability to include multiple combinations of any or all of these items (e.g., using Boolean logic) rather than a minimum of a single combination. This is of relevance to psychiatric practice for the reasons noted above in terms of physical-psychiatric comorbidities and disparities in mortality in those with serious mental illness. This makes it particularly important to be able to track the health status and other needs of groups of patients in one's practice.

§ 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.

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 APA agrees with this criterion, with the caveat that providers should be able to provide education resources from other sources (e.g., web based) based on individual patient need and included in information transmitted through a portal or API, and not just those resources that are provided by the EHR vendor.

§ 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*

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

Public Comment Field:

The APA seeks clarification as to the scope of these criteria. Specifically, the criteria imply that bar coded medication administration (BCMA) will be required in all settings. In locations where only a small number of ambulatory medications are administered, the hardware costs and training needs associated with BCMA can be prohibitive. Psychiatric outpatient settings are an example of a location where a small proportion of patients receive long-acting injectable antipsychotic medications and these agents are the only ones administered in the clinic. Such medications are typically given by psychiatrists or licensed independent nurse practitioners, as no other clinical staff may be available. Essentially, mandating use of BCMA would be prohibitive for such users and requiring that this technology be incorporated into EHR software that is specific to behavioral health may pose an unrealistic burden for vendors of such products.

§ 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.

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 APA seeks clarification regarding the specific ways in which these features will be implemented into certified EHRs. For example, would patient health information be uploaded as separate file, scanned from a paper record? Or would the EHRs be required to capture patient reported information into discrete data fields? The APA supports the latter method, with patient information being entered into discrete data fields, as this would result in psychiatrists being able to take full advantage of the benefits to using EHR systems, such as obtaining PHQ-9 and other rating scale data that can be useful for clinical care and registry reporting.

§ 170.315(a)(20) Implantable device list

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

§ 170.315(a)(20) Implantable device list

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:

The APA supports this criterion, as information collected from such devices would be beneficial in gleaning health data from individuals who may not be able to provide a coherent health history.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

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).

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

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 APA appreciates the importance of being able to record social, psychological and behavioral health data in a consistent fashion but note that this goal cannot be met if only one of the items on this list needs to be included to fulfill the criterion. Thus, the APA recommends that:

a. It is important to record information on the most common, the most debilitating, and the most costly behavioral health conditions seen in primary and specialty care, such as mood disorders, anxiety disorders, and substance use disorders;
b. That, specifically, items 21(vi) [depression] and 21(viii) [alcohol] should be grouped into a category separate from the other items;
c. and that the category called "Behavioral Health" have a requirement in the stem that states: "Enable a user to records, change, and access, at a minimum, one of the following patient behavioral health problems**."**

§ 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:

Click here to enter comments on § 170.315(a)(22) Decision support – knowledge artifact.

§ 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:

Click here to enter comments on § 170.315(a)(22) Decision support – knowledge artifact.

§ 170.315(b)(1) Transitions of care

Included in 2015 Edition Base EHR Definition?

Yes

§ 170.315(b)(1) Transitions of care

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).

(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).

§ 170.315(b)(1) Transitions of care

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*

Public Comment Field:

Click here to enter comments on § 170.315(b)(1) Transitions of care.

§ 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 APA supports this criterion; however, with respect to medication information, the EHR should clearly be able to note whether the last prescription modification date is the same as the date (or approximate date) that the medication was actually started.

§ 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*

Public Comment Field:

The APA supports this criterion, but recommends that a comment field independent of the Sig Free Text String be added in order to communicate important information that may not be part of the Sig itself. The electronic transmission standard should permit transmission and retrieval of the medication related information in discrete fields (even if it involves parsing on retrieval), rather than taking discrete information and concatenating it for transmission, with no ability to issue renewals or make medication changes without re-entering the information. This is especially relevant to controlled medications (which should also be added to the functional requirements).

§ 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 APA supports this criterion.

§ 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 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*

Public Comment Field:

Click here to enter comments on § 170.315(b)(5) Transmission of laboratory test reports.

§ 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:

Because psychiatry templates are often different than non-psychiatry templates, the APA suggests that the export functionality should not be limited to the above template types. In addition to the information above, the APA proposes that the system needs to be able to generate a copy of the legal record for export in a standard format (e.g., encrypted pdf files for each patient) so that vital information in the record is not lost. Structured data for export also needs to include laboratory and other discrete data, not just the data in the CCD**.**

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

Included in 2015 Edition Base EHR Definition?

No

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).

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

Preamble FR Citation: 80 FR 16841 (also see 80 FR 16840) **Specific questions in preamble?** *No*

Public Comment Field:

The APA is in strong support of this criterion, with DS4P having the capability of designating which data elements are to be kept private when and from whom. The APA also recommends that the EHR certification standards conform to the existing HIPAA laws that exist to protect psychotherapy notes as well as those that protect substance abuse information (42 CFR Part 2).

§ 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 APA is in strong support of this criterion, with DS4P having the capability of designating which data elements are to be kept private when and from whom. The APA also recommends that the EHR certification standards conform to the existing HIPAA laws that exist to protect psychotherapy notes as well as those that protect substance abuse information (42 CFR Part 2).

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§ 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*

Public Comment Field:

Click here to enter comments on § 170.315(b)(9) Care plan.

§ 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 APA supports this criterion but is concerned that it may not be sufficient for successful completion of information for CQMs or for completion of CQMs without undue burden for clinicians. If this criterion is adopted, it should have provisions for presenting the CQM questions to the correct individuals at the correct stages of the workflow (when user-entered information is needed to augment routinely collected information) in order to avoid placing a burden on providers and potentially disrupting clinical thought processes.

§ 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*

Public Comment Field:

The APA agrees with this criterion.

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:

Click here to enter comments on Reserved for § 170.315(c)(3) Clinical quality measures – report.

§ 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*

Public Comment Field:

The APA agrees with this criterion.

§ 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 APA agrees with this criterion.

§ 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 APA agrees with this criterion.

§ 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 APA agrees with this criterion.

§ 170.315(d)(4) Amendments

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

(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*

§ 170.315(d)(4) Amendments

Public Comment Field:

The APA agrees with this criterion.

§ 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 APA agrees with this criterion.

§ 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 APA agrees with this criterion.

§ 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

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

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 APA agrees with this criterion.

§ 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 APA agrees with this criterion

§ 170.315(d)(9) Accounting of disclosures

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

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 APA agrees with this criterion.

§ 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.

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

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.

(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.

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

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 APA agrees with the majority of this criterion. However, although the APA acknowledges that EHRs having API access is useful, the current mandate may prove to be burdensome on smaller vendors (that often cater to behavioral health providers). The APA therefore recommends that this portion of the above criterion be phased in over time rather than mandated at the beginning of Stage 3 implementation**.**

§ 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.

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 APA agrees with this criterion.

§ 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 APA agrees with this criterion.

§ 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.

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*

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

Public Comment Field:

The APA agrees with parts i)A) and ii) of this criterion. However, the information listed under part B as optional seems to incorporate a very broad range of information that may include highly sensitive information that patients may wish to keep confidential. For instance, the scope of information exchange has already been expanded within organizations/hospitals to include healthcare workers with appropriate electronic record access, despite patient concerns that such use may violate their personal privacy. Public health syndromic surveillance is important but should be focused on the ability to transmit discrete elements of information when it can be proven to be essential to public health (e.g., reportable diseases, immunizations). Sharing the full range of items in part B presents significant risk of public disclosure and misuse of information and should not be facilitated.

§ 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 APA agrees with this criterion as long as the transmissions are limited to values within the scope of legislated reporting requirements.

§ 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 APA agrees with this criterion.

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

Included in 2015 Edition Base EHR Definition?

No

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

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 APA agrees with this criterion.

§ 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.

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 APA agrees with this criterion.

§ 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:

Click here to enter text comments on § 170.315(f)(7) Transmission to public health agencies – health care surveys.

§ 170.315(g)(1) Automated numerator recording

Included in 2015 Edition Base EHR Definition?

No, but proposed for the EHR Incentive Programs CEHRT definition

§ 170.315(g)(1) Automated numerator recording

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:

Click here to enter comments on § 170.315(g)(1) Automated numerator recording.

§ 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 APA agrees with this criterion.

§ 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

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

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*

Public Comment Field:

The APA appreciates an increased emphasis on usability testing of electronic record systems as a component of this Proposed Rule. However, the scope of the criteria in part iii seem so all-encompassing (particularly for pre-existing technology), that most vendors will presumably opt out of doing such testing as is possible under section ii)B). The summative usability testing is arguably just as important if not more important in assessing overall usability and workflow integration than is testing of each feature separately.

As an alternative model for EPs to qualify for meaningful use (in lieu of the current set of metrics with numerators and denominators), the APA proposes that an EP could opt to spend several hours in formal summative usability testing of their own EHR. This would permit important feedback from actual users that would improve the usability and safety of EHR systems for all. To participate in such testing would also require a reasonable amount of user familiarity with their EHR and would demonstrate that they have indeed been using the EHR in a way that is meaningful for them and for their patients. Such an approach would also be much less burdensome for EPs. It would be particularly beneficial for specialties that may not routinely need to use all of the aspects of the EHR that are currently being tracked in the Meaningful Use metrics.

§ 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*

§ 170.315(g)(4) Quality management system

Public Comment Field:

Not clear to mewhat a "quality management system" is as compared to the ability to report on CQMs.

§ 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*

Public Comment Field:

The APA agrees with this criterion. The APA suggests that there should also be criteria requiring support of text zooming to support those with milder visual limitations (e.g., due to low vision and/or aging) as well as color customization by the end user for accessibility for those with limits in color vision. (Many systems use red and/or green fonts to indicate that specific actions are needed without alternative modes of display.)

§ 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.

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

Included in 2015 Edition Base EHR Definition?

Yes

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 APA reiterates that mandating API as a part of this certification may prove to be too burdensome to smaller vendors, and therefore recommends that the API feature be phased-in over time.

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

Included in 2015 Edition Base EHR Definition?

No, but a mandatory certification requirement

Stage 3 MU Objective

N/A

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

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:

Click here to enter text comments on § 170.315(g)(8) 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 APA agrees with promoting standards for communication using the Direct Project. This is of particular importance for psychiatrists as it permits secure communication with individuals who are not yet using an EHR, which is the case with most psychiatrists.

§ 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

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:

Click here to enter comments on § 170.315(h)(2) Direct Project, Edge Protocol, and XDR/XDM.

§ 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: Click here to enter comments on § 170.315(h)(3) SOAP Transport and Security Specification and XDR/XDM for Direct Messaging.	

§ 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*
Public Comment Field: The APA agrees with this criterion.	

§ 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.	

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

Preamble FR Citation: 80 FR 16864 **Specific questions in preamble?** *No*

Public Comment Field:

The APA agrees with this criterion.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

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 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*

Public Comment Field:

The APA requests that, in its Final Rule, the ONC make clear as to whether this criterion uses **a hard-token authentication method for signing of clinical documentation with reauthentication required every 10 minutes. The APA believes that if such a standard is intended to be used for all documentation it will lead to further burden and uncompensated increases in documentation time for all clinicians, and would therefore not be in support of this part of EHR certification.**

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:	
No specific comments.	

Pharmacogenomics Data – Request for Comment	
Preamble FR Citation: 80 FR 16869	**Specific questions in preamble?** *Yes*
Public Comment Field:	
The APA notes that pharmacogenomic data should be able to be recorded only when it is relevant to clinical care in a fashion that is retrievable and exportable. It should also be available to use in decision support related to medication choices as specific medications are associated with increased risk of toxicity in the context of specific pharmacogenomic markers. As with any genetic data, however, it is essential that patients should be able to specify what can be done with their specific genetic information. The features of data segmentation for privacy should be incorporated into any inclusion of pharmacogenetic data.	

Base EHR Definitions	
Preamble FR Citation: 80 FR 16870	**Specific questions in preamble?** *No*
Public Comment Field:	
The APA supports the Base HER Definitions, but emphasizes that it is essential to retain mention of the importance of privacy and security in this portion of the Final Rule and note where those regulations are now incorporated.	

Certified EHR Technology Definition	
Preamble FR Citation: 80 FR 16871	**Specific questions in preamble?** *No*
Public Comment Field:	
No specific comments.	

Common Clinical Data Set Definition	
Preamble FR Citation: 80 FR 16871	**Specific questions in preamble?** *No*
Public Comment Field:	
No specific comments.	

Cross Referenced FDA Definitions	
Preamble FR Citation: 80 FR 16872	**Specific questions in preamble?** *No*
Public Comment Field:	
No specific comments.	

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*
Public Comment Field:	
Click here to enter comments on Subpart E – ONC Health IT Certification Program.	

Health IT Modules	
Preamble FR Citation: 80 FR 16873	**Specific questions in preamble?** *No*
Public Comment Field:	
Click here to enter comments on Health IT Modules.	

"Removal" of Meaningful Use Measurement Certification Requirements	
Preamble FR Citation: 80 FR 16873	**Specific questions in preamble?** *No*
Public Comment Field:	
Click here to enter comments on "Removal" of Meaningful Use Measurement Certification Requirements.	

Types of Care and Practice Settings	
Preamble FR Citation: 80 FR 16873	**Specific questions in preamble?** *Yes*
Public Comment Field:	
Click here to enter comments on Types of Care and Practice Settings.	

Referencing the ONC Health IT Certification Program	
Preamble FR Citation: 80 FR 16874	**Specific questions in preamble?** *No*
Public Comment Field:	
Click here to enter comments on Referencing the ONC Health IT Certification Program.	

Privacy and Security	
Preamble FR Citation: 80 FR 16875	**Specific questions in preamble?** *Yes*
Public Comment Field:	
Click here to enter comments on Privacy and Security.	

Design and Performance (§ 170.315(g))	
Preamble FR Citation: 80 FR 16876	**Specific questions in preamble?** *No*

Design and Performance (§ 170.315(g))
Public Comment Field:
Click here to enter comments on Design and Performance (§ 170.315(g)).

"In-the-Field" Surveillance and Maintenance of Certification	
Preamble FR Citation: 80 FR 16876	**Specific questions in preamble?** *Yes*
Public Comment Field:	
Click here to enter comments on "In-the-Field" Surveillance and Maintenance of Certification.	

Transparency and Disclosure Requirements	
Preamble FR Citation: 80 FR 16880	**Specific questions in preamble?** *No*
Public Comment Field:	
Click here to enter comments on Transparency and Disclosure Requirements.	

Open Data Certified Health IT Product List (CHPL)	
Preamble FR Citation: 80 FR 16883	**Specific questions in preamble?** *Yes*
Public Comment Field:	
Click here to enter comments on Open Data Certified Health IT Product List (CHPL).	

Records Retention	
Preamble FR Citation: 80 FR 16885	**Specific questions in preamble?** *No*
Public Comment Field:	
Click here to enter comments on Records Retention.	

Complaints Reporting	
Preamble FR Citation: 80 FR 16885	**Specific questions in preamble?** *No*
Public Comment Field:	
Click here to enter comments on Complaints Reporting.	

Adaptations and Updates of Certified Health IT	
Preamble FR Citation: 80 FR 16885	**Specific questions in preamble?** *Yes*
Public Comment Field:	
Click here to enter comments on Adaptations and Updates of Certified Health IT.	

"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:
Click here to enter comments on "Decertification" of Health IT – Request for Comment.

Collections of Information – Paperwork Reduction Act	
Preamble FR Citation: 80 FR 16893	**Specific questions in preamble?** No
Public Comment Field:	
Click here to enter comments on Collections of Information – Paperwork Reduction Act.	

Regulatory Impact Statement	
Preamble FR Citation: 80 FR 16895	**Specific questions in preamble?** No
Public Comment Field:	