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May 29, 2015

Karen DeSalvo, MD, MPH, MSc  
National Coordinator for Health Information Technology  
Attention: 2015 Edition Health IT Certification Criteria Proposed Rule  
Hubert H. Humphrey Building, Suite 729D  
200 Independence Ave, S.W.  
Washington, D.C. 20201

Attention: File Code 0991-AB93

Dear Dr. DeSalvo,

The Electronic Health Records Association (EHRA) appreciates this opportunity to comment on the proposed *2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications*. As companies that design, develop, implement, and support electronic health record (EHR) systems, we have extensive experience with developing products for ONC certification and assisting EHR users in participating in the meaningful use (MU) Stage 1 and Stage 2 programs, which informs our attached suggestions.

Established in 2004, EHRA is comprised of almost 40 companies that supply the vast majority of operational EHRs, in addition to other forms of health IT, to ambulatory practices and hospitals across the United States to support more effective, efficient care delivery. EHRA operates on the premise that the rapid, widespread adoptions of health IT will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation and delivery system reform initiatives. We are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The proposed 2015 Edition greatly increases the scope and complexity of certification. Past complexity and insufficient time for development and implementation have resulted in many challenges for ONC, CMS, providers and vendors, including the unfortunate need to modify program requirements and CEHRT mid-stream. We are very concerned that further complexity and inefficiency may result from adoption of additional criteria to support various care and practice settings. We encourage ONC to carefully and systematically reassess all changes proposed in the 2015 edition, and also to provide consistent guidance to other programs that might use these criteria regarding appropriate earliest timing for adoption of

any new 2015 criteria. Adequate time for industry preparation is essential for successful adoption.

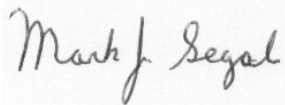
In the attached detailed comments and in our corresponding comments to CMS on the *Medicare and Medicaid Programs, Electronic Health Record Incentive Program-Stage 3*, we have made recommendations that we believe will improve the program (e.g., the adoption of standards and implementation guides that have been piloted successfully before adoption in CEHRT). We have also noted areas where past experience leads us to believe there will be a material risk of undesirable complexity and inefficiency.

We encourage ONC to carefully consider the impact upon implementation and successful utilization of CEHRT when so many revised and new criteria are adopted. We have commented on many criteria that raise significant concern as proposed for the 2015 Edition, and ask that ONC carefully review the potential impact. We encourage fundamental simplification of the program.

In conclusion, we want to underscore that EHRA has consistently advocated that, for successful implementation of new EHR features, sufficient time must be given for development and rollout. The large scope of the 2015 Edition Certification proposed rule will result in few certified EHRs available prior to 2017, potentially jeopardizing the proposed 2018 Stage 3 timeline. Many of the proposed functions in the 2015 Edition are not essential for achievement of MU Stage 3 objectives. We encourage ONC to reduce the timeline necessary for development by minimizing dependency on certification requirements that are not necessary for Stage 3, narrowing the definition of CEHRT, and considering whether some Stage 3 objectives can be met with 2014 Edition CEHRT in which providers have already invested.

Thank you for your consideration of our suggestions. We look forward to working with EHR users to make the 2015 Edition a success.

Sincerely,

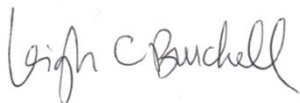


Mark Segal, PhD  
Chair, EHR Association  
GE Healthcare IT

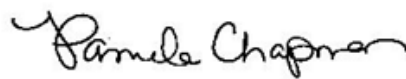


Sarah Corley, MD  
Vice Chair, EHR Association  
NextGen Healthcare

### HIMSS EHR Association Executive Committee



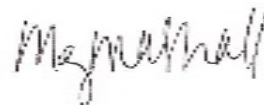
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Allscripts



Pamela Chapman  
e-MDs



Richard Loomis, MD  
Practice Fusion



Meg Marshall, JD  
Cerner Corporation



Ginny Meadows, RN  
McKesson Corporation



Sasha TerMaat  
Epic

#### **About the EHR Association**

Established in 2004, the Electronic Health Record (EHR) Association is comprised of nearly 40 companies that supply the vast majority of operational EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit [www.ehrassociation.org](http://www.ehrassociation.org).

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

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

**Preface**

This document is meant to provide the public with a simple and organized way to submit comments on the proposed certification criteria and modifications to the ONC Health IT Certification Program, and respond to specific questions posed in the preamble of the proposed rule, which is published in the *Federal Register* at 80 FR 16804. While use of this document is entirely voluntary, commenters may find it helpful to use the document in lieu of or in addition to unstructured comments on the certification criteria and modifications to the ONC Health IT Certification Program, or to use it as an addendum to narrative cover pages.

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

The proposed rule proposes new, revised, and unchanged certification criteria that can be used to support various care and practice settings. It would also establish the capabilities and specify the related standards and implementation specifications that Certified Electronic Health Record Technology (CEHRT) would need to include, at a minimum, to support the achievement of meaningful use (MU) by providers under the CMS Medicare and Medicaid EHR Incentive Programs.

The following tables align with the presentation of the proposed certification criteria and modifications to the ONC Health IT Certification Program in the preamble of the proposed rule. The tables specify where the proposed 2015 Edition health IT certification criterion or criteria would be included in § 170.315. The tables also specify the proposed MU Stage 3 objective that the proposed 2015 Edition health IT certification criterion or criteria and associated standards and implementation specifications would support. The tables note the page(s) of the *Federal Register* where we discuss the certification criterion or criteria and whether we request specific comments on certain proposals in the preamble. Last, the tables provide a field for submitting public comments on the proposed criterion or criteria, including responses to specific questions or requests for comments posed in the preamble. This field can be expanded as necessary for commenting.

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

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

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

Provisions of the Proposed Rule affecting Standards, Implementation

## General Comments

- EHRA is concerned with the inclusion of a number of criteria that are not associated with a particular CMS or federal government payment program, such as EHR Incentive Program, IPPS, or other program. Without a clear understanding as to which program requirements the criterion is intended to support, it is difficult to assess the appropriateness of such criteria and associated standards. EHRA suggests that until this intended purpose is clarified, such criteria should not be included. ONC should still work with providers, vendors, and standards development organizations (SDOs) to establish pilots and early deployments so that when standards have been sufficiently matured as applicable and it is clear which program(s) requires their support and what the program needs, national adoption can be expedited.
- We are also surprised not to see any reference to imaging appropriate use criteria (AUCs), particularly in the decision support sections, as we expect that the standards used to support an AUC service, or to obtain AUC knowledge to incorporate into an approved method, are consistent across the 2015 Edition and the AUCs. We urge ONC to work closely with CMS to ensure that CMS adopts a standard for AUC services and knowledge artifacts that are consistent with the 2015 Edition.

## *A. Specifications, Certification Criteria, and Definitions*

<b>§ 170.315(a)(1) Computerized provider order entry – medications</b>	
<b>Included in 2015 Edition Base EHR Definition?</b>	
Yes, as an alternative to § 170.315(a)(2) or (3)	
<b>Stage 3 MU Objective</b>	
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.	
<b>2015 Edition Health IT Certification Criterion</b>	
(1) <u>Computerized provider order entry – medications</u> . Technology must enable a user to record, change, and access medication orders.	
<b>Preamble FR Citation:</b> 80 FR 16814	<b>Specific questions in preamble?</b> Yes

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

#### Public Comment Field:

EHRA supports the adoption of three separate criteria for testing and certification of CPOE for order entry of medications, lab, and diagnostic imaging orders. This change provides appropriate flexibility to developers whose products focus on one type of orders.

EHRA appreciates inclusion of CPOE medication order entry as gap eligible criterion. Gap certification provides important testing efficiencies.

EHRA does not support adding any additional data field requirements such as secondary diagnosis codes, reason for order, or comment fields as requirements for CPOE order entry. Similarly, we do not support any additional field requirements for use as measures of completeness of orders for calculating CPOE thresholds. Overall, we are concerned that these requirements might add unnecessary steps to the order entry process.

### § 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:

EHRA supports the adoption of three separate criteria for purposes of testing and certification of CPOE for order entry of medications, lab, and diagnostic imaging orders. This change provides appropriate flexibility to developers whose products focus on one type of orders.

EHRA does not support adding any additional data field requirements such as secondary diagnosis codes, reason for order, or comment fields as requirements for CPOE order entry. We are concerned that these requirements might add unnecessary steps to the order entry process.

EHRA does not support the additional criteria in (ii) and (iii) for inclusion in CPOE laboratory order entry. Criteria related to transmission requirements should be separated from order entry requirements. The additional criteria and standards should be considered optional criteria, as these additional functions are not required to satisfy CPOE laboratory order entry and require significant development for features which will be underutilized by providers.

EHRA does not recommend including standards for lab compendia in certification. The standard is premature to be included in certification; we are unaware of any laboratories that produce compendia in the named standard, or labs who receive orders as proposed. As we have seen in the past, proposing additional criteria for functionality that is beyond the scope of program requirements results in features that are underutilized. Requiring development based on these immature standards has served no purpose to further the adoption of these functions and standards by labs. Until the standards are mature, EHRA is concerned that they will not adequately address the need for efficiency that seems to be implicated by such inclusion in the criteria.

We are concerned that the proposed implementation guides are not yet published. While the expectation is that these will be published in the next 2-3 months, there will not have been sufficient implementation experience to ensure the implementation guides are unambiguous and that the implementations have achieved the intended improvements. None of those essential initial experiences will be reflected in the proposed implementation guides.

We also suggest that the Lab Orders Interface implementation guide should have a higher priority and focus than the Test Compendium. Generally, incorporating test compendium data into an ordering system has not been widely explored, while ordering lab tests is much more common. We, therefore, suggest that as part of making support for the Lab Orders implementation guide optional, further support of the Test Compendium should be optional as well.

We note that while the Laboratory Orders R1 guide is published, this guide cannot be used as an alternative as it is incomplete and not sufficiently synchronized with the Laboratory Results guide already published, nor the one that is about to be published.

Finally, we note that the proposed implementation guide can accommodate the secondary diagnosis code as support for diagnosis information is required (although it is not specific to always send a secondary diagnosis, nor would it be appropriate to require at all times multiple diagnosis codes). However, currently the reason for the study is not a required field, thus would not be tested. We suggest that this issue be resolved with HL7 whether to require support for

that capability as part of the next version of the implementation guide rather than through regulation that modifies the implementation guide.

**§ 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:**

EHRA supports the adoption of three separate criteria for purposes of testing and certification of CPOE for order entry of medications, lab, and diagnostic imaging orders. This change provides appropriate flexibility to developers whose products focus on one type of orders.

EHRA appreciates inclusion of CPOE imaging order entry as gap eligible criterion. Gap certification provides important testing efficiencies.

EHRA does not support adding any additional data field requirements such as secondary diagnosis codes, reason for order, or comment fields as requirements for CPOE order entry. We do not support any additional field requirements for use as measures of completeness of orders for calculating CPOE thresholds. We are concerned that these requirements might add unnecessary steps to the order entry process.

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

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

No

**Stage 3 MU Objective**

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



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

**2015 Edition Health IT Certification Criterion**

**(4) Drug-drug, drug-allergy interaction checks for CPOE.**

- (i) Interventions. Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list.
- (ii) Adjustments.
  - (A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.
  - (B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.
- (iii) Interaction check response documentation.
  - (A) Technology must be able to record at least one action taken and by whom in response to drug-drug or drug-allergy interaction checks.
  - (B) Technology must be able to generate either a human readable display or human readable report of actions taken and by whom in response to drug-drug or drug-allergy interaction checks.

**Preamble FR Citation:** 80 FR 16815

**Specific questions in preamble?** Yes

**Public Comment Field:**

EHRA does not support the proposed criteria (iii) for documenting actions taken in response to drug-drug (DD) and drug allergy (DA) interaction warnings.

Instead of the proposed changes, EHRA requests the criterion remain gap eligible for the 2015 Edition.

EHRA supports both the ability to adjust severity levels as well as any requirements for response documentation be left up to providers' discretion and not mandated by certification. If ONC chooses to keep the proposed criteria, we do not see significant advantages to capture actions for a subset of interactions rather than all interactions. We are unaware of a subset deemed appropriate across all databases that could be used universally to identify the highest patient safety concerns. However, we do note that it is not feasible to track provider reactions to passive decision support. Features such as highlighting of a patient's allergies might help providers pay attention to key information, but it is not possible to programmatically associate whether a provider saw highlighted information with the action or lack of action that might be taken on a particular medication order. If distinguishing between this type of decision support is what was intended by only tracking a subset of interactions, then we are in support of the proposal.

ONC requested comment on several additional areas related to interaction checking. EHRA does not support additional certification requirements beyond current 2014 Edition requirements for DD/DA interaction checking associated with CPOE, nor the inclusion of additional checking requirements such as med list or allergy list, or requirements for capturing additional provider actions mandated through certification. EHRA believes systems are currently capable of providing warnings throughout and allowing providers to best determine their use without the need for inclusion in certification.

**§ 170.315(a)(5) Demographics**

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

Yes

**Stage 3 MU Objective**

N/A

## § 170.315(a)(5) Demographics

### 2015 Edition Health IT Certification Criterion

#### (5) Demographics.

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

Preamble FR Citation: 80 FR 16816

Specific questions in preamble? *No*

#### Public Comment Field:

##### Preliminary Cause of Death

EHRA thinks it is reasonable to include the preliminary cause of death for inpatient settings in the 2015 Edition. As previously noted, EHRs have not removed this feature since it was required in the 2011 Edition.

##### Race, Ethnicity, and Preferred Language

We have several concerns with both the required standards and the implementation guidance related to race and ethnicity and preferred language, and propose that 2014 Edition standards remain adequate for the majority of providers. ONC should retain the 2014 Edition standards for these items.

We are unaware of significant problems among providers using the current race, ethnicity, and preferred language standards that would justify the significant changes introduced by the proposed standards, which have extensive granularity. The overwhelming majority of providers are satisfied with the current race and ethnicity codes. We understand the granularity of the newly proposed codes might benefit a small group of providers, but we question the potential burden on usability and workflow redesign for the majority of providers.

In addition to the complexity introduced by the requirement to aggregate the information, and the potential inclusion of such large amounts of data in the user interface display, we are concerned that interpretations of the ONC implementation guidance flexibility could adversely affect testing and certification decisions. We suggest that less ambiguity is essential to determining what is expected in testing to support any changes in the existing standards.

EHRA proposes that each vendor determine a default list of the standards for race and ethnicity, and preferred language that serve most of their providers, and provide directions to allow the flexibility to the providers who wish to customize the default if necessary. We agree that 900 codes in a drop down list is unrealistic, and prefer that implementation guidance beyond what is required for certification be left to the vendors' discretion. We are concerned that preamble language might be interpreted subjectively during certification testing. If it is intended to be flexible, caution will be necessary that it is preserved flexibly during the testing process.

We are concerned with potential testing approaches to assess support for all race and ethnicity values considering the large number of potential values defined in § 170.207(f)(2). We suggest that testing for all values is not practical, and that software developers should be allowed to choose relevant values and demonstrate mapping to the OMB values.

We seek clarification of the potential changes to the standard referenced in § 170.207(f)(2). We note that the proposed § 170.207(f)(2) standard in the NPRM is not listed in the proposed Standards Advisory. We suggest that these be synchronized upon finalizing both the rule and advisory.

We are concerned with the complexities of §170.207(g)(2), particularly when referenced without explicit mention of the registry that recognizes language codes formatted according to the proposed standard. We are concerned that language codes will be constructed without using the already available and approved registry entries. Additionally, we are concerned that the proposed approach requires substantial changes as codes change from three characters to two characters where we just included three-character codes. Furthermore, the proposed standard pre-coordinates sign language vs. spoken languages without clearly distinguishing the two forms of language. A more appropriate distinction would have been introduced using a clear tag indicating whether the language is spoken, written, or signed, as done with script that can clearly distinguish between Braille and other scripts. We suggest continuing with the current use of the three-character 639-3 codes and suggest that these are able to be captured for the purpose of indicating whether the language is spoken, written, and/or signed.

**Sex**

We are concerned with referencing the § 170.207(n)(1) standard, considering that CCDA, HL7 V2, HL7 FHIR, NCPDP, and X12 all use different value sets. We suggest that health only be required to support encoding according to the respective standards that represent the proposed criteria.

**§ 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<sup>®</sup> code 8478-0.
- (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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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 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

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

### Public Comment Field:

#### Basic and Expanded Vitals

We encourage a base list of vital signs which aligns with the Common Clinical Dataset and believe this essential set of vital signs should be considered part of a Base EHR. Other vitals should be separated to a different criterion. EHRA proposes that the additional data elements oxygen saturation and mean blood pressure should be proposed as separate optional criteria, as they are specific to certain providers and device monitoring and not relevant to all providers.

#### Blood Pressure

We are supportive of systolic and diastolic blood pressure recorded as discrete values, though we are concerned that the ONC language might be overly prescriptive as to how this is captured by clinicians.

#### Capture

We do not understand the implications of requirements to capture natively the data elements without requiring mapping. EHRA is concerned that certification seems to specify how vendors store data in EHRs. We seek clarification as to why ONC would go into such explicit detail regarding data storage. It is our experience that providers are far more concerned about the usability and workflow associated with data entry and display, and not data storage in the EHR. Certification and adoption of standards should be focused on interoperability purposes and not prescribe EHR database storage.

#### LOINC

EHRA seeks clarification regarding the LOINC coding specified in regards to the display requirements for the codes as attributes. ONC should clarify that there is no expectation to display LOINC codes, simply to be able to associate the codes internally with the data for purposes of exporting the data via CCD documents?

We also seek clarification of the meaning of semantically and syntactically identical data being exchanged. Per the proposal, ONC requests the ability to roll up granular LOINC codes to more generic LOINC codes. We find this contradictory to being semantically consistent, as previously proposed. We question how doing this would guarantee semantic meaning when the level of specificity and context is lost when more granular LOINC codes are replaced with more generic LOINC codes. We believe it best to allow EHRs to record LOINC codes at the granular level chosen by each EHR developer. Further, we are concerned about quality measure value set applicability, and how that might be accomplished in the future to guarantee semantic specificity if such data is ever expected to be incorporated. We are unfamiliar with how such could be determined and how it affects the validity of the information. It is our experience that very few providers would incorporate vital signs recorded by other providers into their EHRs, but would record new vital signs based upon their patient encounters.

## Record, Change, and Access

EHRA is also concerned with the criteria specification to record, change and access to all vital signs in (i). Vital measures such as BMI and mean blood pressure are calculations and not created at the users' discretion to record or change. We suggest removal of metadata associated with all calculated values. This metadata might be recorded at different times and there is no single piece of metadata (e.g., when only a weight is changed for BMI), yet the calculated value changes as a result. We suggest that only measures that are appropriately recorded and changed are relevant to such metadata requirements. EHRA questions why (v) Calculate BMI is listed as an optional criterion when BMI is included in (i).

## Expanded Vitals

Pulse oximetry and other such items are very specific to certain specialties and do not apply to all providers. We believe the word "arterial" should be removed from the requirement "oxygen saturation in arterial blood by pulse oximetry", as this is incorrect since pulse oximetry measures oxygen saturation in capillary blood. Mean blood pressure is often associated with data from automated devices and not routinely captured by all providers so should not apply to base vital signs capture.

## UCUM

We have significant concern over the specification of use of UCUM units. We understand UCUM does not allow mixing of measurements and, as such, the data collected in various methods, such as height in feet and inches would present problems. We seek clarity on what data must be presented with UCUM units.

EHRA supports all remaining criteria as optional. The metadata for any vital sign that is calculated in (i)(B) should be removed, as well as metadata associated with (ii)(B) and (iii)(B). This is not appropriate for calculations. Metadata associated with (iv)(B) is reasonable to propose. Please remove (v) as this is included in (i). We support (vi) as optional.

We wish to note that the expanded use of LOINC for the proposed vital signs further makes the U.S. different from many other countries that rely on SNOMED. Convergence between SNOMED and LOINC in this area remains critical. We believe that the proposed approach in general will help accomplish the stated goal of ensuring that the vital signs data entered into a health IT system is semantically and syntactically identical to the information coming out of the system and being exchanged.

We suggest that it is appropriate to include a standard for the source of the vital sign measurement, in particular using SNOMED for that encoding.

We suggest changing the weight LOINC code from 3141-9 (body weight measured) to the more generic 29463-7 (body weight) to enable consistent collection of measure and unit of measure as done for the other vital signs.

### § 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:

EHRA supports attestation provided by the vendor regarding incorporating the new standard as adequate to demonstrate compliance with a previously certified product as an alternative to product demonstration.

### § 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:

EHRA supports the ONC proposal for the unchanged criterion.

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

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

Yes

#### Stage 3 MU Objective

N/A

#### 2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16820

Specific questions in preamble? *No*

#### Public Comment Field:

EHRA supports the ONC proposal for the unchanged criterion.

## § 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.

### 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:

In general, EHRA does not support additional certification requirements that are not necessary for providers to satisfy objectives of the EHR Incentive Program regarding intervention response documentation. It is our experience that providers would prefer EHR developers to spend time enhancing features that they desire vs. adding functionality that complicates their workflows. Specifically for this item, EHRA is concerned about the requirement to record intervention response documentation within the various configurations available to support clinical decision support (CDS). Many different types of CDS exist in both active and passive presentations. Passive forms of clinical decision support, such as highlighting information in a display, are not possible to programmatically associate with particular user actions. Even some active interventions are more challenging to associate with user actions than others. It is not practical to require active alerts and documentation of response without significant redesign and disruption to workflow. The EHR cannot determine in many circumstances what action the provider chose without specific provider input, even for active presentations or alerts. Many CDS alerts are capable of prompting the provider to supply missing information or take an action. However, as currently designed, they might not require or capture a definitive response. The provider simply might take an action outside the alert, such as placing a new order or discontinuing an order as recommended.

In summary, we are very concerned about disruption to provider workflows and related usability issues that might be unintended consequences of this certification expectation. EHRA recommends removing the proposed changes to CDS, or at most making them separate certification criteria beyond the current CDS requirements with specific guidance regarding specific types of interventions that could easily capture the response without significant disruption to provider workflow. As intervention tracking is prioritized, we consider drug interaction tracking a higher priority and technically simpler than tracking responses to the broad range of clinical decision support tools.

## § 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

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

**Public Comment Field:**

EHRA supports the use of NCPDP Formulary & Benefit 3.0.

However, the requirement for the EHR to display the last formulary update is beyond scope for the EHR to display as that is controlled by the pharmacy benefit provider and not the EHR. Surescripts certification also defines requirements for display of this information during their certification process.

EHRA requests that attestation from Surescripts certification be validated as meeting this criterion without the need for additional testing.

For preferred drug lists in the hospital setting, the determination of formulary update information is not within scope for the EHR developer to control or indicate. Many hospitals may have policies regarding formularies and drug substitutions, and many formularies are also updated on a daily basis due to drug shortages, availability of new medications, etc.

**§ 170.315(a)(12) Smoking status**

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

Yes

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

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

**Preamble FR Citation:** 80 FR 16822

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

### § 170.315(a)(12) Smoking status

#### Public Comment Field:

We are concerned that the proposal to record, change, and access smoking status in any of the available codes for smoking status in, at a minimum, the September 2014 Release of the U.S. Edition of SNOMED CT will present unjustified complications, as more than 100 codes are potentially available. The choice of which codes are available in the EHR beyond the eight codes required for 2014 Edition should remain at the discretion of the EHR developer. In the spirit of flexibility, the EHR developer should be given the option to expand these choices. However, the EHR developer should not be required to support additional codes during testing.

EHRA is concerned with the mapping of the allowable SNOMED smoking statuses to the eight smoking codes in the CCDAs. Providers consider these eight inadequate as they are missing certain relevant tobacco use. EHRA urges ONC to work with SDOs to enable exchange of any of the SNOMED codes while establishing a full mapping to reportable smoking status categories.

EHRA seeks clarification that one does not need to support entry of all the SNOMED smoking statuses, rather just those applicable to the provider community being supported. We agree that any smoking statuses received in an interoperable document with appropriate coding should be displayed to a user.

### § 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:

EHRA supports the ONC proposal for the unchanged criterion.

### § 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:

We request the ability to provide attestation for the updated standard associated with (a)(14) as adequate to criterion satisfaction for a previously certified product as an alternative to demonstration testing.

### § 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:

EHRA suggests that this standard is only listed in the Standards Advisory until such time that wider adoption and applicability has been demonstrated. Support of the pedigree options should be based upon vendor discretion for providing functionality related to provider needs in their market. EHRA indicated in its response to the original 2015 Edition NPRM in April 2014 that it would not be appropriate to use the pedigree as the only standard. EHRA specifically notes that the standard has limitations as it currently exists and does not meet the current needs of many providers. Specific concerns include:

- Uptake of the pedigree standard remains limited.
- The W3C XML schema language cannot represent all constraints expressed in the base specifications referenced in the implementation guide.
- Guidance on interactions and appropriate methods is insufficient, thus potentially leading to inconsistent implementations.

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

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

No

#### Stage 3 MU Objective

N/A

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

### 2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16823

Specific questions in preamble? *No*

#### Public Comment Field:

EHRA supports the ONC proposal for this unchanged criterion.

## § 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:

EHRA supports the capability to enable patient education through the use of the Infobutton, and to not have to certify to an alternate means. At the same time, as indicated in our comments to CMS, we do not believe that the only patient education that should count for meaningful use is provision through the Infobutton.

EHRA supports the removal of lab value/results from the requirements for providing education resources.

EHRA is also concerned about the perception that patient-specific resources will be returned in the patient's preferred language using the value set of ISO 639-1 codes with the new preferred language standard. We wish to clarify that the certification requirement is only the ability to request education in a patient's language without regard to whether or not the information will be returned in the preferred language.

Please see our comments on the use of RFC 5646 (§170.207(g)(2)) in the demographics criterion.

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

### Included in 2015 Edition Base EHR Definition?

No

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

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

(18) Electronic medication administration record.

- (i) In combination with an assistive technology that provides automated information on the “rights” specified in paragraphs (a)(18)(i)(A) through (E) of this section, enable a user to verify the following before administering medication(s):
  - (A) Right patient. The patient to whom the medication is to be administered matches the medication to be administered.
  - (B) Right medication. The medication to be administered matches the medication ordered for the patient.
  - (C) Right dose. The dose of the medication to be administered matches the dose of the medication ordered for the patient.
  - (D) Right route. The route of medication delivery matches the route specified in the medication order.
  - (E) Right time. The time that the medication was ordered to be administered compared to the current time.
- (ii) Right documentation. Record the time and date in accordance with the standard specified in § 170.210(g), and user identification when a medication is administered.

**Preamble FR Citation:** 80 FR 16823

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

**Public Comment Field:**

EHRA supports the ONC proposal for this unchanged criterion.

**§ 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*

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

### Public Comment Field:

EHRA supports inclusion of (i) the ability to identify, record, and access documents, as well as (ii) the ability to reference and link to documents as this relates to advanced directives and birth plans documents. We have concerns specifically with the requirement to embed links to external documents, sites, or systems that are not under the control of the CEHRT. This requirement creates the security risk of potentially injecting a wide range of malware into the EHR system and the provider's network. This requirement also creates an element in the patient's chart that cannot be protected from alteration or deletion, and cannot be audited to track and record access.

EHRA requests removal of (iii) ("record and access information directly shared by a patient") from this criterion. The ability to record and access information directly shared by a patient in (iii) should be a separate optional criterion if remaining in the 2015 Edition. It is unclear exactly what is being proposed to capture, but the implications potentially far exceed the capture of patient health information documents shared by a patient. Broadening the scope adds considerable possibilities to record electronic data without the standards or specificity needed to be able to record and access information as proposed directly from a mobile device. Certification to such a broad statement poses high risk to be varyingly interpreted by certification testing labs and by providers forming expectations of what CEHRT can do.

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

### Included in 2015 Edition Base EHR Definition?

Yes

### Stage 3 MU Objective

N/A

### 2015 Edition Health IT Certification Criterion

(20) Implantable device list.

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

Preamble FR Citation: 80 FR 16824

Specific questions in preamble? Yes

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

**Public Comment Field:**

EHRA recommends postponing introduction of this criterion until the multiple different identifier formats are harmonized.

We understand that there is a discussion with FDA to establish a canonical format that harmonizes the four unique device identifier (UDI) formats currently in place, and others that may emerge. This effort should be completed before requiring health IT to capture UDI information.

At most, EHRA is supportive of section (1) to include UDI information in the sense that the EHR is capable of recording a list of implantable devices as free text information and that associated UDI's are added as structured data as they are known.

We do not support the additional functionality proposed in (ii), (iii) and (iv) and request that it is either removed or at most, remains as optional for 2015 Edition certification. It is premature to propose these additional EHR capabilities for Base EHR requirements as the process associated with this information will continue to evolve over the next five years. This information will be recorded by device manufactures when devices are implanted, and medical device manufacturers will perform the capabilities in (ii), (iii) and (iv). These capabilities will be adopted and implemented in specialty systems that would benefit during this timeframe until such time as it will be feasible to require for EHRs.

We are concerned with the immaturity of the implementation guidance to support the necessary data exchange to optimize capture and documentation of implantable devices. Specifically as it relates to the implicit use of the CCDA to communicate this documentation, we are concerned that the CCDA guide does not provide sufficient guidance as to how to document implantable devices, thus leading to variant, incompatible implementations. Example of ambiguities include:

- The current value sets to associate procedures with equipment usage does not clearly distinguish between implantable devices vs. other devices used in the procedure.
- It is unclear how to document procedure information when the source of the documentation (e.g., not the original clinicians who implanted the device) does not have full or correct data.

We are furthermore concerned that without interoperability capabilities from the most likely sources (e.g., OR systems) accurate documentation is challenging to achieve and suggest postponing introduction of this criterion until CCDA guidance and interoperability guidance between source systems and EHRs is available.

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

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

No

**Stage 3 MU Objective**

N/A



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

### 2015 Edition Health IT Certification Criterion

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

**Preamble FR Citation:** 80 FR 16826

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

#### Public Comment Field:

EHRA suggests separating these criteria, creating more flexibility for the industry.

We are concerned and uncertain with the use case of these criteria since the focus here seems to be creating more lists and data collection without specified use of such data. Since the collection of these social, psychological, and behavioral data is sensitive, clear use cases within the health IT ecosystem will be needed to drive implementation.

The EHRA is also concerned with the maturity of these standards and suggests more time to be fully vetted and normalized. For example, in the proposed rule, ONC question-answer sets suggests patients should have an opportunity to refuse to answer, but it is unclear if the refusal should be for the entirety of the question-answer set or per question. Careful review of the proposed assessments is necessary prior to implementation.

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

### Included in 2015 Edition Base EHR Definition?

No

### Stage 3 MU Objective

N/A

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

**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:**

EHRA suggests removing this criterion from the 2015 Edition. We do not recommend use of the HealtheDecisions standards proposed for clinical decision support knowledge artifacts or services for the purpose of appropriate use criteria (AUC); these standards are immature and not ready for widespread implementation as described in our feedback on those criteria. However, we urge ONC to work closely with CMS to ensure that CMS adopts a standard for AUC services and knowledge artifacts that are consistent with the choices made for clinical decision support (CDS). In our view, the HealtheDecisions standards proposed in the 2015 Edition are not appropriate for either. Such functionality should not be driven by certification.

The EHRA would also like to highlight that HHS will have milestones later this year and next year to release the appropriate definitions and services for imaging AUCs, and the EHRA would like to ensure alignment with this and other government programs. The current proposed standards are not appropriate for adoption for AUC.

EHRA is concerned that the proposed standard has not sufficiently progressed nor been utilized such that by the time the CQF project is complete, substantial re-work will be required. We suggest that while the proposed standard is appropriate to be listed in the Standards Advisory, as it is the best available, we wait for conclusion and sufficient maturation of the standards resulting from the CQF project before incorporating these standards into a certification edition. We urge ONC to work with CMS to appropriately incent providers and software developers to establish pilots and initial deployments to ensure the standards address the intended objectives and are sufficiently mature. Without production experience, there is too much risk to move forward.

**§ 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

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

#### Public Comment Field:

EHRA suggests removing this criterion from the 2015 Edition. We do not recommend use of the HealtheDecisions standards proposed for clinical decision support knowledge artifacts or services for the purpose of appropriate use criteria (AUC); these standards are immature and not ready for widespread implementation as described in our feedback on those criteria. However, we urge ONC to work closely with CMS to ensure that CMS adopts a standard for AUC services and knowledge artifacts that are consistent with the choices made for clinical decision support (CDS). In our view, the HealtheDecisions standards proposed in the 2015 Edition are not appropriate for either. Such functionality should not be driven by certification.

The EHRA would also like to highlight that HHS will have milestones later this year and next year to release the appropriate definitions and services for imaging AUCs, and the EHRA would like to ensure alignment with this and other government programs. The current proposed standards are not appropriate for adoption for AUC.

We are concerned that the proposed standard has not sufficiently progressed nor been utilized such that by the time the CQF project is completed, substantial re-work will be required. We suggest that, while the proposed standard is appropriate to be listed in the Standards Advisory, as it is the best available, we wait for conclusion and sufficient maturation of the standards resulting from the CQF project before incorporating these standards into a certification edition. We urge ONC to work with CMS to appropriately incent providers and software developers to establish pilots and initial deployments to ensure the standards address the intended objectives and are sufficiently mature. Without production experience, there is too much risk to move forward.

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

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

Yes

#### Stage 3 MU Objective

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

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

### 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 CCD A 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)
  - (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).

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

Preamble FR Citation: 80 FR 16831

Specific questions in preamble? Yes

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

### Public Comment Field:

EHRA is concerned that the proposed state of this criterion takes away from the original intent to create modularity in the transitions of care (TOC) create, transmit and receive criteria. EHRA suggests reorientation of this criterion to again create modularity between the creation, transmission, and receipt of TOC documents criteria.

EHRA asks for clarity around validation and display, since it would be unrealistic for EHRs to accept every single code that comes into the system. How exactly does ONC expect to test for this criterion? The EHRA does not believe testing and certification of health IT to create summary records formatted to CCD Release 2.0 without the ability to meet the requirements of the Common Clinical Data Set is a useful test for health IT. It is furthermore concerned that it seems only the CCD document type counts towards the CMS objectives/measures as that is the only one that can satisfy the criterion's requirement to always include the Common Clinical Data Set. Rather the perspective should be to enable sending the right-sized document that supports the specific transition of care, thus may not include the full common clinical data set.

We are concerned with the proposed upgrade to CCD Release 2.0 until compatibility issues are addressed. In particular, we are concerned that receipt of CCD Release 2.0 documents by systems that are not able to fully support CCD Release 2.0 fully will cause recipients to continue to use the document as they have been accustomed to.

- Not all systems receiving CCDs can render the human readable sections. EHRA supports the criterion language to ensure systems conform to the underlying CDA standards that require this capability at all times.
- Reconciliation of problems, medications, medication allergies may be interrupted due to changes in vocabulary that are not yet recognized.
- Use of data for quality measures may be interrupted due to changes in vocabulary.

Supplemental cutover guidance for R 2.0 or in R2.1 is a prerequisite to successful implementation. Until that is available, we should encourage initial CCD Release 2.0 adoption in limited settings to further drive out ambiguities and improve on its maturity. We note that hundreds of updates were processed with CCD Release 1.1 and, while the hope is that this experience will not repeat for CCD Release 2.0, we must anticipate a substantial number of necessary updates.

We do not support any suggestions to generate both CCD R1.1 and R2 documents to support the transition. A CCD R1.1 document will not be able to fully represent a CCD R2 document, and generating a CCD R2 document that only contains what a CCD R1.1 would represent is not useful and raises patient safety concerns as the two documents do not necessarily match. Furthermore, having to maintain multiple documents that are supposed to represent the same event will cause confusion with the users unless extraordinary steps are taken to "hide" the version of the document that is not used.

We suggest that the certification rule should only focus on the version health IT needs to be able to generate, as the consuming health IT will clearly have to continue to support older versions. Members of HL7 (several from EHRA) are actively pursuing creation of a CCD 2.1 Release through a fast evolution in HL7 that might be expected to produce a document in the July or August timeframe. This project, if accepted by HL7 would generate an edition of CCD based on the 2.0 release, but that enabled backwards compatibility between 2.1 and 1.1. An appropriately crafted CCD 2.1 could then be readily be interpreted by a system designed to support only CCD 1.1. This would allow asynchronous bilateral cutover without requiring production and proliferation of multiple documents for the same patient containing different levels of information for the same activity, as was proposed in the NPRM. The EHRA would strongly prefer this approach instead of adopting CCD 2.0.

We refer to the notes on Implantable Devices regarding the uncertainty how to consistently document an implantable devices list in the CCD.

We suggest that the provenance standard is not ready for deployment. The proposed standard is not yet published, and is still in ballot reconciliation. It is also not yet in the Standards Advisory. Rather, we recommend we wait for maturation. To that end, we urge ONC to work with CMS to encourage a small group of providers and software developers to implement and exercise the standard first before its deployment is widely mandated.

We are concerned with the guidance on the existing and additional data to collect and communicate to support patient matching.

- Whatever guidance is provided, it should not be limited to CCDA, but any data exchange.
- We are concerned that adding new fields is increasing the burden to collect such data, while there is no clear evidence the additional data substantially improves on the quality of the match.
- Unless unique, strong patient identifiers (or part thereof) are included in the guidance, with standardized formats, and improved workflows to validate potential matches at the time of patient presentation, inclusion of additional fields will require additional development but not the intended results.

EHRA suggests sending the granular SNOMED codes for smoking status, not just one of the eight to which it is mapped. As we also indicate under the smoking status criterion (§ 170.315(a)(12)), EHR technology should not be required to support all of the full SNOMED values for documentation. This should be based on the specific types of providers supported by the EHR. However, EHRs must be able to display the values as communicated through a document or transaction.

EHRA supports XDM processing on receipt of an XDM package formatted in accordance with the standard adopted in § 170.205(p)(1). We suggest that the processing on receipt relies on the metadata conveyed by the XDM package be aligned with the general metadata specified in the S&I Framework DAF Appendix B.

#### **§ 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 template.

Preamble FR Citation: 80 FR 16835

Specific questions in preamble? *No*

#### Public Comment Field:

EHRA is concerned with the modularity of this criterion. Although creation and reconciliation are two different criteria, the current requirement within this criterion would inadvertently require both the creation and reconciliation to meet these standards that could cause confusion and challenges. EHRA proposes the reconciliation process and creation process should be split into separate criteria.

See also our comments on CCDA Release 2.0 and patient matching earlier in our response.

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

### Included in 2015 Edition Base EHR Definition?

No

### Stage 3 MU Objective

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



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

### 2015 Edition Health IT Certification Criterion

(3) Electronic prescribing.

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

**Preamble FR Citation:** 80 FR 16835

**Specific questions in preamble?** Yes

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

#### Public Comment Field:

EHRA is concerned that the addition of several new requirements could adversely affect the ability of EHR developers to continue to provide certified software to providers who are actively engaged in electronic prescribing through utilization of current standards. EHRA recommends that ONC delete or separate many of the proposed new requirements that are not required to satisfy EHR Incentive program objectives.

It is our understanding that “change” and “cancel” have very little uptake in the marketplace, while criteria for fill status notifications have even less among Surescripts providers. Currently, only about 1% of the pharmacies in the Surescripts directory support “cancel” or “change” transactions. And there is no current adoption of fill status. While we believe that the pharmacy industry does generally wish to support these transactions, and would do so if the EHRs were supportive, industry-wide adoption will take time and require both sides of the transactions to adopt the standards. If these transactions are to remain in the final rule, we encourage ONC to explore every alternative at its disposal to help drive adoption on the pharmacy side as well.

Medication history has been fairly well adopted; however, any utilization of medication history outside the ambulatory e-prescribing setting requires an additional certification and additional payment for utilization in the acute setting for Surescripts Acute Medication History. With regard to medication history utilizing NCPDP SCRIPT standards, we agree that medication history during a prescribing event presents valuable information to providers that may positively influence prescribing decisions. We urge, however, flexibility in the use of standards to request and receive medication history from an external source. For example, Surescripts offers HL7-based medication history and NCPDP SCRIPT 10.6 medication history. Many EHRs support additional means of retrieving medication history that provides more robust structured data and increased probability of successfully receiving medication history for a patient. These methods include, but are not limited to, HL7--based medication history, proprietary third party integration, and direct connection with third party payers.

EHRA encourages removal from 2015 Edition certification of the structured sig requirements completely, in addition to the other proposed revisions. EHRA does not support the additional structured sig prescribing instructions due to immaturity of the standard and its potential impact until more testing confirms its ability to provide benefits in the marketplace. We encourage removal of all criteria associated with structured sigs until such time as more evidence for functional improvements is derived. The NCPDP SCRIPT 10.6 standard has several well-documented barriers to structured sig adoption, most notably the 140 character limitation for a free text sig. We disagree with the pilot analysis provided by ONC, and consider the 10.6 standard for structured sig support to be incomplete and immature for widespread industry adoption – both for CEHRT and receiving pharmacy systems. Given the state of industry adoption on the pharmacy side, it is imperative that an e-prescription with a structured sig match the free text sig field required by NCPDP SCRIPT 10.6. Full support of structured sig proposes significant challenges that will hamper user adoption without correction of these barriers in more recent versions of NCPDP SCRIPT.

The expanded scope will require much development and certification with intermediaries and as such should not be lumped into one criterion, but should be separate criteria to enable adoption in the marketplace.

EHRA does support the NCPDP conventions for decimal requirements; however, we believe this functionality exists currently without certification mandates.

Considering the variances in the 2014 Edition between Surescripts testing and certification testing, EHRA strongly suggests alignment of these tests to ensure one test can satisfy both ONC's and Surescripts requirements.

<b>§ 170.315(b)(4) Incorporate laboratory tests and values/results</b>	
<b>Included in 2015 Edition Base EHR Definition?</b>	
No	
<b>Stage 3 MU Objective</b>	
N/A	
<b>2015 Edition Health IT Certification Criterion</b>	
(4) <u>Incorporate laboratory tests and values/results.</u>	
(i) <u>Receive results.</u>	
(A) <u>Ambulatory setting only.</u>	
(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) <u>Inpatient setting only.</u> Receive clinical laboratory tests and values/results in a structured format and display such tests and values/results in human readable format.	
(ii) <u>Display</u> 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) <u>Attribute</u> , associate, or link a laboratory test and value/result with a laboratory order or patient record.	
<b>Preamble FR Citation:</b> 80 FR 16837	<b>Specific questions in preamble?</b> Yes
<b>Public Comment Field:</b>	
<p>As indicated in other criteria, EHRA is concerned with the maturity of the not-yet-published lab results implementation guide. While it has made substantial improvements and enhanced clarity, it also introduces new and enhanced capabilities (e.g., acknowledgement process and micro-biology reporting structure) that have not been tested in production environments that should be a pre-requisite before requiring it as the next version of the national standard. EHRA urges ONC to work with CMS to promote pilot implementation to validate the guide and incorporate this version in the next iteration.</p> <p>Considering the progress made on the first version of the EHR-S Functional Requirements guide that seeks to clarify lab results recipients' responsibilities in particular, the guide is not ready for national adoption. We suggest this guide first be completed and then tested in production environments to ensure the guidance is practical.</p>	

<b>§ 170.315(b)(5) Transmission of laboratory test reports</b>	
<b>Included in 2015 Edition Base EHR Definition?</b>	
No	
<b>Stage 3 MU Objective</b>	
N/A	

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

### 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:

See comments regarding the maturity of the lab results implementation guide in § 170.315(b)(4).

## § 170.315(b)(6) Data portability

### Included in 2015 Edition Base EHR Definition?

Yes

### Stage 3 MU Objective

N/A

### 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*

### § 170.315(b)(6) Data portability

#### Public Comment Field:

The EHRA suggests removal of the requirements related to event configuration. We do not understand how such requirements would satisfy the use case needs for data portability, as data portability utilization is not expected to be a frequently occurring event. EHRA suggests that the criterion be prioritized so the actual need and use of the criterion matches the functionality. As proposed, this criterion seems to be attempting to satisfy basic database requirements and not true data portability for implementation of new systems. Would vendors be required to create “all “of those listed, or “any” when only certain uses apply to inpatient settings and not ambulatory? The EHRA is also concerned that the current proposed criteria could be exceedingly burdensome for software developers without adding sufficient value for the provider. We suggest rewording of the certification criteria to focus on the prioritized basic functionality required and not detailed guidelines as proposed.

EHRA supports the ability to enable data portability using CCDA documents. However, EHRA suggests that the ability to generate documents specifically to support data portability should focus on the CCDA CCD document type. While other document types would have been generated over the course of patient care and should be able to be exchanged as part of interoperability, it is not appropriate to specifically generate those document types just for data portability as they typically require clinician composition. Furthermore, it would be inappropriate to require those document types to include all data of the common clinical data set. Consequently, the criterion should focus the document creation component on CCDA CCD only.

EHRA seeks clarification whether the timeframe configuration is relative to the actual time of the event (e.g., admission date on encounter) or when it was entered in the system.

### § 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).

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

**Specific questions in preamble?** No

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

**Public Comment Field:**

EHRA suggests that the data segmentation for privacy standards have not been sufficiently matured to include in this certification edition.

In general, we support the use of data segmentation and the inclusion of sensitive medical data into the interoperability process. However, the existing standards and proposed regulation are too immature and untested as it stands today. We believe that if this proposal is adopted “as is”, there is significant risk of accidental disclosures and that more clarity is needed to record the patient’s consent to transmit as well as processes to ensure a provider that the receiving system is capable of honoring the segmentation tags and to what level, document, section, or element.

EHRA suggest that standards associated with criteria that are not in support of the EHR Incentive Program should be held to the same level of maturity as those in support of the EHR Incentive Program. The 2015 Edition should not be used as a mechanism to mature any standards, rather propagate standards that have a proven record to support the use case being addressed.

In case this criterion is still included, we strongly urge specific reference to Level 1 that is discussed in the pre-amble in the actual rule language to ensure clarity on which part of the standard is applicable. We believe that there still remains too much variance within this subset to be recognized for use now – i.e., the vocabulary is not universally understood and although some concepts are well-defined, others are completely un-usable. There is a mix of codes that are just flags with other codes that are demands (obligations). This approach makes it unclear as to what should be done with them either on the publication side or the use side. Ultimately, even this subset of DS4P requires further implementation guidance or profiling. We recommend that the Advisory includes no more than the DS4P subset refined by the IHE IT Infrastructure Technical Framework Volume 4 – National Extensions – Section 3.1 Data Segmentation for Privacy (DS4P) ([http://www.ihe.net/uploadedFiles/Documents/ITI/IHE\\_ITI\\_TF\\_Vol4.pdf](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol4.pdf)), noting that piloting is insufficient.

**§ 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

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

See comments on § 170.315(b)(7).

In general, we support the use of DS4P and the inclusion of sensitive medical data into the interoperability process. However, the existing standards and proposed regulation is too immature and untested as it stands today. Specifically, there needs to a better understanding of the impact of sequestering these documents, and what access and auditing controls CEHRT would be required to support in order to prevent a user from incorporating specific data elements into the chart. This also raises the question of how useful these documents are to a provider in supporting clinical decisions if they are not allowed to incorporate elements of the document into the chart, orders, and billing.

**§ 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:**

In response to the question regarding whether to impose additional constraints on implementation guides through rule-making, we strongly urge ONC not to impose additional constraints through rulemaking. Rather, such constraints should be addressed through an updated or new implementation guide.

We suggest that this document type has not yet been widely used and requires further maturation before including in a certification edition. Such maturation process would also enable clarification as to whether the implementation guide should be updated before it can be more widely used, as well as determining whether the suggested sections should be fully optional, always present, or supported only when needed.

**§ 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



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

### Public Comment Field:

The EHRA agrees with renaming this criterion to CQM, record and export, and including this as part of the “base” definition.

Regarding the proposal to allow a system user to export CQM data at any time the user chooses, and without subsequent developer assistance, we provide the following comments:

- The phrase “without subsequent developer assistance” requires some additional clarification and comment. There may be reasons why assistance is needed from the developer (e.g., if this is provided as a service to users, or if there may be optimal times to export large amounts of data in order to ensure that there are no performance issues that could impact other system users).
- There should be clarification regarding the specific use case, including the objective and specifying the definition of a “system user”. We suggest this should be limited to only those users who have been provided specific administrative privileges.
- We recommend that this specific capability be considered “optional”.

Regarding the versions of QRDA or the QRDA-like standards that should be adopted for this certification criterion, the ERHA reiterates past comments regarding the work being done in the Clinical Quality Framework (CQF) Initiative. We generally support the efforts to align standards for both eCQMs and clinical decision support (CDS) through the CQF Initiative, and agree with the strategy to modularize components of the standards to help improve the ability to implement new versions of each standard independently. We agree that these efforts will lead to improving the implementation and use of both the eCQMs and related CDS.

However, while EHRA supports the overall direction of FHIR for expressing quality reports, whether RESTful service-based or using other appropriate technologies, EHRA does not consider the industry ready to adopt the QUICK FHIR-based DSTU. Premature inclusion could disrupt the critical improvements and progress already made with the CQMs. There have been no pilots to date using these developing standards with eCQMs, as well as insufficient implementation experience, including lack of robust testing of the anticipated standards, and these standards continue to evolve rapidly. To arrive at the earliest possible opportunity to implement these emerging standards, EHRA encourages ONC and CMS to establish pilots and limited deployments to support such maturation and determine the return on investment of moving to a new standard.

Therefore, the EHRA recommends the adoption of the second option, HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture (QRDA), DSTU Release 2 (July 2012) and the September 2014 Errata. EHRA also supports adoption of any further standards errata before the final rule is issued, as they typically do not contain scope changes.

## § 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

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

**2015 Edition Health IT Certification Criterion**

(2) Clinical quality measures – import and calculate.

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

**Preamble FR Citation:** 80 FR 16843

**Specific questions in preamble?** Yes

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

### Public Comment Field:

Regarding the proposal to require a system user to be able to import CQM data at any time the user chooses and without subsequent health IT developer assistance to operate, and to no longer include an exemption to the data import capability if a health IT module was certified to for all three original certification criteria, the EHRA has several comments and recommendations:

- We recommend that import and calculate be separated into two distinct certification criteria. The import criterion is more closely aligned with data warehouse and analytics systems. The ability to demonstrate import has no direct connection to demonstrating the ability to calculate in a source EHR system.
- We are concerned that requiring every certified health IT system to import CQM data using a standard such as QRDA forces EHR developers to structure their EHRs based on this requirement. Some vendors may de-couple their EHR from an analytics repository that also calculates and reports the measures. Some providers may choose to use another product for analytics and quality measurement. Not every EHR should act as a repository to import CQM measure data. This is especially important as we move towards patient-centered, longitudinal outcome-based measures that are not provider-centric and cross settings of care and health IT products (e.g., LTPAC, etc.).

Regarding ONC's proposal that testing include import of a larger number of test records compared to testing for the 2014 Edition and automatically de-duplicate them for accurate CQM calculation, we provide the following recommendations:

- We suggest that the focus of the test data be on more coverage of measure algorithms and populations. For example, currently the test data utilizes one simple path to meet the measure and one simple path to fail the measure, with nothing regarding any of the exclusion or exception logic as part of the algorithm. And the test patients cover only a small percentage of the algorithms (e.g., if the numerator has five different clusters of "or" logic to meet the numerator, the current test data would only follow one of the five paths).
- Therefore, when increasing the "size" of the test data, we recommend that ONC focus on increasing the quality and value of the data to the testing process, and not just on large volumes of data that add little value.
- We also recommend caution when thinking about the definition of duplication.
- The EHRA would be happy to review and comment on specific samples of test data prior to finalizing the data, in order to assure that we are not creating similar problems to those encountered previously. We also suggest that a pilot of the new data and certification process would be beneficial to all stakeholders.

Regarding the version of the QRDA standards that should be adopted, we reiterate the comments made above in § 170.315(c)(1), and recommend the adoption of the second option, HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture (QRDA), DSTU Release 2 (July 2012) and the September 2014 Errata, as well as any additional standards errata that is adopted before the final rule is released.

## 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

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

**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:**

EHRA is concerned that ONC proposes to include certification criteria for the reporting of CQMs in or with the IPPS rule related to the Hospital IQR program, as well as the upcoming PFS rule in the PQRS program requirements. EHRA strongly suggests including this criterion in the 2015 Edition, recognizing that other programs may point to it, and some already are. EHRA is concerned that the current approach of including certification criteria directly into other program rules will quickly result in health IT requirements that are scattered across many programs.

We are also concerned that this timeline may not give adequate time for development, testing, and implementation. We would like to note that the release date of the PFS rule does not leave enough time for changes to CQM reporting beyond very minor modifications. If the PFS rule is released in October, there are at most three months to analyze the requirements, develop the changes necessary, test those changes, and make them available to customers to implement by January 1. This is simply not sufficient time for EHRs and providers to be fully capable of consuming modifications. EHRA has consistently stated that 18 months from the release of new requirements to the expected implementation date is needed.

At the same time, EHRA appreciates that ONC indicated a criterion as “reserved” that is expected to be addressed specifically for CMS payment programs, and did not include it in the certification edition until that program actually proposes the need for that capability.

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

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

No

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

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

**Preamble FR Citation:** 80 FR 16844

**Specific questions in preamble?** Yes

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

### Public Comment Field:

EHRA is concerned about the alignment of required data elements across ONC and CMS programs, including these proposed data to filter CQM results. The ONC 2015 Edition certification NPRM proposes an updated Common Clinical Data Set as well as this set of data elements. The Inpatient Prospective Payment System (IPPS) NPRM proposes the use of a set of “Core Clinical Data Elements” for use with quality measures. These data sets lack alignment of definition and vocabulary standards across similar data elements (e.g., birth date, age at admission, gender (sex), and vital signs). Alignment of data elements is essential both to furthering interoperability and to streamlining the implementation of new measures and their specifications. We strongly urge that this alignment be included in the final requirements of these related standards.

EHRA also offers specific comments on the proposed data elements listed here:

- TIN – Consideration should be given to the fact that some providers may practice in multiple TINs. In addition, there are different levels of TIN/PIN numbers.
- NPI – We support this data element and criterion.
- Provider type – We agree that the Healthcare Provider Taxonomy Code set seems to be the only code set in use for classifying provider types. We are concerned that providers can select multiple codes in the NPI system, and may choose one that reflects their overall practice, not their individual specialty. Therefore, this code set may have very low reliability. Additional research should be done before finalizing this data element as required.
- Patient Insurance – We agree that the proposed Payer Typology code set is in use today for administrative transactions.
- Patient Age – We support this data element and criterion, and urge alignment of this criterion across all other related requirements.
- Patient sex – We support this data element and criterion, and urge alignment of this criterion across all other related requirements.
- Patient race and ethnicity – We refer ONC to the comments and concerns EHRA makes on the newly proposed requirements on these data elements in the section on the certification criterion for § 170.315(a)(5).
- Patient Problem list data – The EHRA has raised issues previously around the source, timeliness, and clinical fidelity of the problem lists in EHRs. When considering the problem list, is it intended that the patient’s entire problem list is included with the CQM data? Historically, providers have relied on the more accurate codes entered by the medical records professionals when calculating manually-abstracted or claims-based quality measures. We are concerned regarding the initial input and ongoing maintenance of problem lists to ensure accuracy, for example:
  - Accurate assignment of ordinality (principal, secondary, etc.) and cardinality to procedures and diagnoses/problems by the provider in the EHR. Measure authors have algorithms that depend upon the use of these concepts
  - Typically, when considering CQM data, it is important to define *which* diagnosis (e.g., admitting, working, final, etc.) is to be used to calculate the measure. This must be further defined in order to ensure the correct data is being captured.
  - This criterion also seems to rule out using the “smoking gun” criteria (i.e., the QRDA file only needs the data elements that qualify the patient for the CQM).
  - In the ambulatory setting, the provider relies on the diagnoses and procedure information entered in to the EHR to feed the billing system and ensure accurate billing. Mapping of terms from SNOMED to ICD and/or CPT is typically done when SNOMED is implemented, but introduces issues with variability depending on the accuracy of the cross-mapping.

- Practice site address – We are concerned that there is hidden complexity within this requirement. A physician practice could have multiple physician addresses that are all one clinic. Physicians may practice at multiple practice sites, and individual patients may be seen at multiple practice sites. Therefore, this requirement seems to conflict with the goal of patient-centered outcomes. We are concerned with how this data element will be expected to line up with a physician practice definition of practice site, as well as the clinical usefulness of filtering CQM data by address.

### § 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:

EHRA supports this unchanged 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

#### 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*



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

#### Public Comment Field:

The NPRM states under 170.315(d)(2) (Auditable events and tamper-resistance) that, “Section 7.7 requires that the audit log record when patient data is accessed. So, while not explicitly referenced in section 7.6., the action of “access” or viewing of a patient’s information is also required to be recorded for certification.”

ONC differentiates access from query, which is explicitly called out in section 7.6.

In response to ONC’s request for comments on additional audit events for “logging emergency access”, we agree that emergency access is already being audited and no additional changes are needed to report on these events.

### § 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:

EHRA supports this unchanged 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*

#### Public Comment Field:

EHRA supports this unchanged criterion.

<b>§ 170.315(d)(5) Automatic access time-out</b>	
<b>Included in 2015 Edition Base EHR Definition?</b>	No, but a conditional certification requirement
<b>Stage 3 MU Objective</b>	N/A
<b>2015 Edition Health IT Certification Criterion</b>	(5) <u>Automatic access time-out.</u> (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.
<b>Preamble FR Citation:</b> 80 FR 16847	<b>Specific questions in preamble?</b> Yes
<b>Public Comment Field:</b> EHRA supports this unchanged criterion.	

<b>§ 170.315(d)(6) Emergency access</b>	
<b>Included in 2015 Edition Base EHR Definition?</b>	No, but a conditional certification requirement
<b>Stage 3 MU Objective</b>	N/A
<b>2015 Edition Health IT Certification Criterion</b>	(6) <u>Emergency Access.</u> Permit an identified set of users to access electronic health information during an emergency.
<b>Preamble FR Citation:</b> 80 FR 16847	<b>Specific questions in preamble?</b> No
<b>Public Comment Field:</b> EHRA supports this unchanged criterion.	

<b>§ 170.315(d)(7) End-user device encryption</b>	
<b>Included in 2015 Edition Base EHR Definition?</b>	No, but a conditional certification requirement
<b>Stage 3 MU Objective</b>	N/A
<b>2015 Edition Health IT Certification Criterion</b>	(7) <u>End-user device encryption.</u> 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) <u>Default setting.</u> 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.
<b>Preamble FR Citation:</b> 80 FR 16847	<b>Specific questions in preamble?</b> Yes

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

**Public Comment Field:**

EHRA supports this unchanged 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:**

We agree with ONC that a 2018 adoption of SHA-2 is reasonable.

### § 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:**

EHRA supports this unchanged 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

- (iii) 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

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

### Public Comment Field:

EHRA wishes to re-iterate the concerns raised in the Transitions of Care criterion about adopting CCDAs Release 2.0 at this point when backwards compatibility is not fully addressed.

Successful API implementation will require work from standards developers, EHR and other health IT developers, application developers, as well as the users of all of these applications.

We appreciate the direction indicated in the 2015 Edition toward future adoption of FHIR as the expected standard for application access to the CCDS. There is ongoing work to develop FHIR profiles to ensure consistent adoption of this standard across the industry. Further work will continue to be necessary in this area. Requiring implementation of FHIR prior to the development of standard profiles will result in inconsistent and inefficient custom adoption across the industry, which does not achieve our goals. Certification requirements will be most successful when they include only data services for which there are defined profiles. EHRA appreciates that ONC is not prematurely requiring a FHIR version, and supporting the use of APIs that are widely used among health IT developers and their customers.

Security of information will be a key area of focus. Proposed API security standards should match the same level of security applied to other data in transit.

Providers will need sufficient time to prepare to offer database access through APIs to patient applications. They will need to consider their capacity, database availability, agreements with application developers, appropriate practices for security and appropriate authorization of access to information.

At the same time, an area where consistency can already be promoted is the use of document queries that should be recognized (e.g., the use of XDS, XCA, and XCPD). While not utilizing data element-based queries, these widely available document exchange capabilities should be recognized, particularly considering that documents are here to stay in one form or another (e.g., CCDAs on V3 or on FHIR).

## § 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:
- (iii) Both the patient (or authorized representative) and technology user are authenticated; and
  - (iv) 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:

EHRA is supportive of the unchanged 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:

While EHRA supports the general movement toward enabling two-way query capabilities, we remain concerned that the variations among states still require substantial effort to accommodate differences. EHRA, therefore, urges ONC to work with the states to support a single implementation guide before establishing a single federal standard that in practice is not widely used.

We do not support an immunization history reconciliation added to the criteria, as validation is not guaranteed.

EHRA also wants to encourage ONC to establish a registry with the states creating an inventory of what each agency is capable of supporting and/or planning to support.

EHRA suggests that registries should also be encouraged to submit to the same testing as the sending systems to ensure consistency of data transmission end-to-end.

EHRA suggests not replacing CVX with NDC, but allowing the use of both to allow needed flexibility based on current usage.

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

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

No

#### Stage 3 MU Objective

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

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

### 2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16853

Specific questions in preamble? *No*

#### Public Comment Field:

EHRA remains concerned that variations among states still require substantial effort by software developers to accommodate such differences. EHRA, therefore, continues to urge ONC to work with the states to arrive at support for a single implementation guide before establishing a single federal standard that in practice is not widely used. Until such time, EHRA remains concerned that the effort toward a single standard is not justified. EHRA suggests that until at least 75% of states are committed to the use of a common standard within the timeline of the 2015 Edition, this criterion should not list a particular standard that must be supported, but rather reference the respective standards required by the states and maintain support for the national standard as optional. While this is not an optimal situation, considering the states' autonomy in this space, EHRA does not see an alternative.

EHRA also wants to encourage ONC to establish a registry with the states to create an inventory of what each agency is capable of supporting and/or is planning to support.

EHRA suggests that agencies should also be encouraged to submit to the same testing as the sending systems to ensure consistency of transmission end-to-end.

## § 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.



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

**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:**

EHRA suggests that agencies should also be encouraged to submit to the same testing as the sending systems to ensure consistency of data transmission end-to-end.

**§ 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*

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

#### Public Comment Field:

Considering the many variations in registries and reporting requirements, EHRA is very concerned that the proposed standard will not satisfy most registries. Considering that the EHR Incentive Program appears not to be limiting the providers and registries to use the proposed standard, EHRA is concerned that many more formats will be required and it is unclear how much the proposed standard will be used. EHRA suggests that ONC works with the registries and CMS to arrive at a single standard that covers the superset of data that can be filtered as part of the configuration of a specific registry.

As a library evolves, vendors can determine which one(s) they need to certify against to support specific registries with which their providers interact.

EHRA wishes to clarify that without such an approach, certification does not represent production ready interoperability due to those variations. Rather, we suggest that either the states must agree to a common format, or certification to a single format is dropped and replaced with certification by states. The expectations would then be clear.

EHRA also wants to encourage ONC to establish a central registry, with the registries creating an inventory of what each registry is capable of supporting and/or is planning to support.

EHRA suggests that registries should also be encouraged to submit to the same testing as the sending systems to ensure consistency of data transmission end-to-end.

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

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

No

#### Stage 3 MU Objective

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

#### 2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16855

Specific questions in preamble? Yes

#### Public Comment Field:

While EHRA has no concerns with the IHE profile proposed in § 1170.205(q)(1), other than the general issues of state inconsistencies, we do have a concern with FHIR SDC DSTU version as it is too premature and requires more piloting and initial deployments before it can be adopted as a national standard.

EHRA suggests that agencies should also be encouraged to submit to the same testing as the sending systems to ensure consistency of data transmission end-to-end.

**§ 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:**

EHRA understands the goal of providing additional flexibility for providers trying to meet the requirements for the MU program. However, we are very concerned with the expectations that every available option will be available and implemented within the necessary timeframe. The volume of choices creates a significant burden on software developers and potentially increases costs.

EHRA wants to reiterate our concerns with state variations that this criterion does not recognize. EHRA suggests that, unless at least 75% of agencies are committed to adopt this standard, the standard should become an optional capability to support the EHR Incentive Program, using state issued standards as an alternative.

EHRA suggests that agencies should also be encouraged to submit to the same testing as the sending systems to ensure consistency of data transmission end-to-end.

**§ 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

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

**Public Comment Field:**

EHRA understands the flexibility intended to providers trying to satisfy the requirements of the MU program. However, we are concerned about the potential impact on product development. EHRA suggests a starting point with more defined and more finite possibilities. Although much of the data for this criterion are generally supported in current provider workflows, there will be many additional data elements that must be captured to satisfy various program requirements. As has already been experienced, adding or requiring many data elements that are not typical in the workflow may compromise and complicate workflows when such data must be captured or used to complete the survey. In order to better fulfill this capability, we suggest a limited code set of information that could be proposed and adopted by the multitude of surveys. Without a limited code set, we are concerned the providers will have unrealistic expectations that an EHR certified for this criterion will satisfy the needs of any healthcare survey that they choose for participation. As more and more development is required to create these “one-off” surveys, costs are likely to rise.

EHRA suggests that agencies should also be encouraged to submit to the same testing as the sending systems to ensure consistency of data transmission end-to-end.

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

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

No, but proposed for the EHR Incentive Programs CEHRT definition

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

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

**Preamble FR Citation:** 80 FR 16856

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

**Public Comment Field:**

EHRA is supportive of these unchanged criteria.

**§ 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*

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

### Public Comment Field:

We support the EHR technology meeting the intent of the criterion by including the ability to support at least one method of calculation for the automated measure calculation as proposed. The EHRA appreciates the flexibility afforded by working with its providers to offer calculations based upon workflows available in their EHRs, and not requiring abilities to perform any method possible when CMS has granted open-ended flexibility.

Even though the criterion is proposed as unchanged, we note that testing to satisfy the measurement of objectives will require significant resources to develop the calculations for the proposed measures.

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

### Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

### Stage 3 MU Objective

N/A

### 2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16856

Specific questions in preamble? Yes

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

### Public Comment Field:

While the EHRA and its members support and encourage thorough, frequent, and iterative usability testing, we question whether the user-centered design criterion, introduced in 2014 certification, has indeed achieved the goals that ONC intended in that regulation. In our experience, the materials we submitted for certification were:

- Too specific for the intended audience; and
- Of little use or interest to our current and potential users.

While many of our member organizations were asked to provide demos and site references, we were unaware of any requests for our summative testing results for certification. We note that, in general, the time and resources spent on one summative test for certification could produce approximately ten formative tests performed early in the design cycle, with an eye toward rapid iteration and improvement.

While we will continue to test our designs, practice user-centered design, learn from our users in the field, and share techniques and success stories among our membership regardless of regulation, we ask ONC and the physician community to carefully consider the requirements of usability regulation and the extent to which they have proven to serve the stated purpose. More specifically, we ask that ONC not proceed as proposed with an expansion of the approach taken for the 2014 edition.

### ***NISTIR 7742 Submission Requirements***

We support ONC's effort to spell out in further detail the reporting rules put forward in the 2014 Edition "safety-enhanced design" criterion and in the NISTIR 7742 "Customized Common Industry format Template for Electronic Health Record Usability Testing." Listing each required data element in the criterion itself communicates the expectations more effectively, will lead to more standardized reports, will increase access to the information, and will reduce uncertainty on the side of EHR developers. While the EHRA continues to have concerns with the requirement for public reporting of Major Finding and Areas for Improvements, information that is intended to inform the developer directly, we are pleased ONC responded to our previous request for greater clarity.

### ***Number of Test Participants***

We also applaud ONC for recommending, but not requiring, the number of participants per user cohort. We believe that while 15 participants is a statistically solid sample size, recommending but not requiring this number is a valid approach. It does not impose undue bias to smaller vendors and newer product vendors who may not have access to larger user populations. We agree that summative testing should be conducted with actual end users, and that this cohort should not include employees of the vendor company.

We agree with ONC in not requiring a fixed number of participants. In some cases, a specific numerical target can be difficult to achieve for new products, where the user base is still small for statistically smaller user cohorts (certain clinical or administrative specialists) or when observations are lost due to reasons outside of the control of the vendor. Often long distances must be traveled to collect data and it would create an undue time and financial burden to re-collect data simply to sample a few more data points. Instead, we support the guidance of NISTIR 7804<sup>1</sup>, which emphasizes that the tester can include justification for the number of participants, allowing for developers to reference more recent findings (usability.gov<sup>2</sup>, for example, also states that a test with five users "lets you find almost as many usability problems as you'd find using many more test participants").

<sup>1</sup> [http://www.nist.gov/healthcare/usability/upload/EUP\\_WERB\\_Version\\_2\\_23\\_12-Final-2.pdf](http://www.nist.gov/healthcare/usability/upload/EUP_WERB_Version_2_23_12-Final-2.pdf)

<sup>2</sup> <http://www.usability.gov/how-to-and-tools/methods/recruiting-usability-test-participants.html>, retrieved 2015

### ***New Requirements and Compliance Guidance***

We are pleased to note that the ONC has included several ISO standards recommended by the EHRA in our previous comments into their recommended list of standards for vendor-applied UCD:

- ISO 9241-11
- ISO/IEC 62366
- ISO 9241-210

We also applaud the ONC for continuing to allow vendors to define and document their own standards, based on industry standards, as large organizations often have to use a more integrative approach when organizing across departments.

### ***Request for Comment on Summative and Formative Testing***

While we continue to believe that formative testing is a more timely and efficient way to improve the usability and safety of developed projects than summative testing, we do not believe that standardized reporting of such formative methods would be useful. Depending on the size and type of enhancement, many different formative methods exist, and it would produce an undue burden to the vendor to have to adhere to a standard format in conducting and reporting such research. Similarly, it would produce an undue burden to reviewers to try to understand and compare such research methods and results. So, while we agree that vendors should continue to report their UCD process and attest to it, reporting and interpreting the details of these formative efforts would be burdensome, ineffective for comparative efforts, and would be unlikely to achieve the goal of more usable systems.

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

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

No, but a mandatory certification requirement

##### **Stage 3 MU Objective**

N/A

##### **2015 Edition Health IT Certification Criterion**

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

**Preamble FR Citation:** 80 FR 16858

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

##### **Public Comment Field:**

EHRA generally supports the ONC proposal, but we request clarification regarding the proposal to map each QMS to specific capabilities. In some cases, the QMS utilized across the criteria may itself be a combination of principles from different QMS approaches. In this case, the combined QMS approach could be applicable to all capabilities and specific QMS components would not be separated and applied to specific criteria. EHRA recommends that the identification of the combined QMS approach satisfies the criteria by being identified once and not dissected into individual QMS components for specific capabilities.

### § 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:

We recognize and agree that widespread use of EHR technology can lead to safer and healthier patients, and we, with ONC, will continue to advance accessibility in our software to support that goal. Given the development costs associated with this item and its lack of linkage to a specific CMS program requirement, we appreciate that ONC made this criterion “available” rather than part of the base or otherwise required. We do continue to have concerns as indicated elsewhere with the large number of “available” certification criteria and the potential for resulting costs and market uncertainty.

### § 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 CCD data 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



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

The EHRA requests clarification regarding the proposal to validate the CCDA.

First, there is some confusion as to what is meant by a “Gold Standard.” Is this a single document or several documents that will need to be tested during certification? Is there a threshold for performance? We understand that several documents will be available for testing prior to the actual certification testing. Will these documents all meet the Gold Standard such that any issue identified during the vendor’s testing can be relied upon solely as that particular vendor’s problem? If not, how will vendors work together to identify and solve problems as they arise prior to certification testing? We question the capability of such testing to guarantee the success that seems to be implied, given the optionality that exists in CCDA documents. Documents are not only transmitted from EHRs to providers, but are often transmitted directly to health information exchanges and others. We seek clarification of any potential impact outside EHR-to-EHR testing as proposed.

EHRA suggests that, if CCDA Release 2.0 is adopted, there is no need to support CCDA Release 1.1 for this criterion, as one should only generate CCDA Release 2.0 moving forward, and only need to be able to display/consume earlier versions.

EHRA is concerned that not all health IT may support creation of all proposed document types, while EHRA recognizes that supporting document types beyond CCD will help address the concerns of initially receiving too much data as part of certain TOCs. EHRA suggests requiring support for at least CCDA CCD and three out of the remaining six plus CCDA CCD, with market forces will drive adoption of others as needed. To ensure that the additional document types are indeed created to the specifications, it would behoove vendors, but not be required of them, to certify the additional document types to then be listed on Certified Health Product List (CHPL) as certified to this criterion.

EHRA is concerned that the current phrasing implies a “preview” at the time of creation. Our concern is that this approach means that a user must generate such a “preview” every time, rather than as desired. Depending on placement in the workflow and the vocabularies used by the provider, this may not be the right time to do such “preview”. And a “preview” later in the workflow may not be efficient or effective either. EHRA is also concerned that “upon the entry” will be taken literally and only allowed to be done while the user finishes creating/composing the document. However, between a user creating a document and the CCDA being sent, additional vocabulary mapping steps may need to be applied. Therefore, EHRA suggests that “upon the entry” be replaced with “before sending”.

Finally, we need to recognize that providers can extend vocabularies, and consequently may need to use free text in the absence of available vocabulary codes. EHRA suggests that the vocabulary subject to these criteria is for certification testing only, while surveillance must recognize the presence of non-coded data.

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

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

Yes

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

### Stage 3 MU Objectives

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

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

### 2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16860

Specific questions in preamble? Yes

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

### Public Comment Field:

Successful API implementation will require work from standards developers, EHR and other HIT developers, application developers, as well as the users of all of these applications.

We appreciate the direction indicated in the 2015 Edition toward future adoption of FHIR as the expected standard for application access to the CCDS. There is ongoing work to develop FHIR profiles to ensure consistent adoption of this standard across the industry. Further work will continue to be necessary in this area. Requiring implementation of FHIR prior to the development of standard profiles will result in inconsistent and inefficient custom adoption across the industry, which does not achieve our goals. Certification requirements will be most successful when they include only data services for which there are defined profiles. EHRA appreciates that ONC is not prematurely requiring a FHIR version, and supporting the use of APIs that are widely used among health IT developers and their customers

Security of information will be a key area of focus. Proposed API security standards should match the same level of security applied to other data in transit.

In reference to the "terms of use" (TOU), we request that ONC address the intended uses and scope. There are different levels of terms of use, one for developers consuming a service's API, and another for a patient using an application or device that accesses the API as their agent.

At a patient level, most users today ignore the terms of service notices due to the complexity and legal language, thus any TOU that is presented to a patient needs to be short, simple, and clear. There also needs to be some clarity if it is ONC's intent that the TOU would replace, include, or overlap with the HIPAA privacy policy that practices are required to give to their patients.

**§ 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

**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:**

We recognize and agree that widespread use of EHR technology can lead to safer and healthier patients, and we, with ONC, will continue to advance accessibility in our software to support that goal. Given the development costs associated with this item, and the early stage of applicable standards, we agree that options (ii) and (iii), to identify the absence of application of ACD, should be permitted as proposed.

**§ 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:**

We agree with continuation of this criterion as unchanged and eligible for gap certification.

EHRA urges ONC to work with SDOs to identify an “owner” of the Direct Project to incorporate updates to the implementation guides that reduce ambiguities and variations that impede interoperability. Additionally, development of robust testing tools is essential to further limit the variations in interpretation.

EHRA urges ONC to encourage health information service providers (HISPs) to support both (h)(1) and (h)(2) to ensure that varying EHR technology choices do not yield an inability to connect.

**§ 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:**

EHRA urges ONC to work with SDOs to identify an “owner” of the Direct Project to incorporate updates to the implementation guides that reduce ambiguities and variations that impede interoperability. Additionally, development of robust testing tools is essential to further limit the variations in interpretation.

EHRA urges ONC to encourage health information service providers (HISPs) to support both (h)(1) and (h)(2).

**§ 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:**

We agree with continuation of this criterion as unchanged, “available,” and eligible for gap certification.

**§ 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:**

EHRA understands that the final text of the proposed standard is due to be published this summer. While we support the direction and need to promulgate this standard, national deployment without sufficient early testing unnecessarily rushes rollout and increases risks of excessive costs for inefficiencies and re-work. We therefore appreciate that this criterion is indicated as “available”, but still have concerns about its readiness for inclusion in the 2015 edition.

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

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

No

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

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

**Preamble FR Citation:** 80 FR 16864

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

**Public Comment Field:**

EHRA understands that the final text of the proposed standard is due to be published this summer. While we support the direction and need to promulgate this standard, national deployment without sufficient early testing unnecessarily rushes rollout and increases risks of excessive costs for inefficiencies and re-work. We, therefore, appreciate that this criterion is indicated as “available” but still have concerns about its readiness for inclusion in the 2015 edition.

## § 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 to validate a digital signature that has been applied to a document according to the implementation specification adopted at § 170.205(a)(5)(ii).
- (iii) Author of record level 1. Using the same system capabilities expressed in paragraph (i)(1)(ii), technology must be able to apply a digital signature according to the implementation specification adopted at § 170.205(a)(5)(iii) to sign single or bundles of documents a document formatted according to the following standard and applicable implementation specifications adopted at § 170.205(a)(4) and (a)(5)(i).
- (iv) Transactions. Using the same system capabilities expressed in paragraph (i)(1)(ii) of this section, technology must be able to apply a digital signature according to the implementation specification adopted at § 170.205(a)(5)(iv) to a transaction and include the signature as accompanying metadata in the signed transaction.

Preamble FR Citation: 80 FR 16864

Specific questions in preamble? No

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

**Public Comment Field:**

This proposal exemplifies the EHRA’s major concerns in general with inclusion of certification criteria that exceed capabilities required to satisfy MU or other specified CMS programs. We are opposed to such expansion, and certainly the scope of expansion proposed for the 2015 Edition. Given the scope across a wide variety of criteria in this proposed rule, it becomes very complicated to attempt to prioritize development opportunities that best serve the needs of our providers. These providers depend on their EHRs to satisfy their needs under current regulations. However, they depend on their vendors to satisfy their individual requests for enhancements that they believe are most useful in their workflows to support more efficient clinical practice. In consideration of such preferences, we support the marketplace driving diverse requirements rather than ONC including them in certification. We are also concerned that such a broad range of criteria that could be adopted by other programs would require prioritization and actually interfere with meeting the development requirements in a timely manner. We are also very concerned that adoption of these criteria by other programs must be given the same timelines for consideration as any criteria associated with MU. In addition, the possibility of requiring such criteria also potentially expands the data entry and editing associated with supporting such documentation, further disrupting workflows and potentially increasing costs.

It is unclear whether this criterion is intended to replace the pending claims attachment standards. If it is, that should be clarified with an indication of upcoming rules referencing this criterion. If it is not, then it is unclear how these relate.

EHRA also notes that the clinical documents for payers guide has not gone back to ballot, so it is not ready for inclusion in the 2015 Edition.

**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:**

We are supportive of as much gap eligibility as possible, consistent with the MU and other identified program needs. We ask that other criteria be considered for eligibility by keeping the requirements for the 2014 Edition, where they are sufficient to meet applicable MU objectives and measures, while making any additional functionality optional. Vital signs serve as an excellent example where the criterion has been expanded and the expansion should be considered separate from the base criteria.

**Pharmacogenomics Data – Request for Comment**

**Preamble FR Citation:** 80 FR 16869

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



## Pharmacogenomics Data – Request for Comment

### Public Comment Field:

EHRA discourages inclusion of pharmacogenomics data at this time. Without proper assessment of the true effect on desired outcomes, more studies are essential as proof of effectiveness and value for inclusion of such data. As with other datasets, we support identification and adoption of criteria that are associated with the use of mature standards for such data capture and representation. We are concerned with the level of staffing or services from third party suppliers that may be required to support inclusion of such a criterion. Further requirements to staff or hire such expertise by vendors can also increase the costs associated with such criterion being a part of an EHR, while the utilization and benefit may be derived by very few providers. EHRA is also concerned with the requirements for privacy and security and for inclusion of such information at this time, and considers it essential that proper standards are in place when such a criterion is proposed.

EHRA is more generally concerned with extending the scope of the 2015 Edition with these functional requirements, rather than proposing specific interoperability capabilities that support these emerging capabilities. The proposed functional requirements have every opportunity to be driven by market forces and innovation. As interoperability capabilities mature, future iterations should address the necessary standards and guidance that support exchange of the necessary data across providers.

## Base EHR Definitions

Preamble FR Citation: 80 FR 16870

Specific questions in preamble? *No*

### Public Comment Field:

EHRA proposes the Base EHR definition should only include criteria associated with satisfaction of the MU Program requirements. As proposed, the Base EHR definition includes functionality that is not required to satisfy MU, and may be potentially used only by a limited number of providers. This broad approach has the potential to increase costs to all providers. For example, we recommend removal of UDI requirements from the definition, or at minimum, narrowing the scope of the UDI requirements included in Base, per our specific UDI comments. We also recommend that any criterion proposed as Base be explicitly spelled out as its own criterion and should not include additional functionality requirements within another criterion. It should be transparent to the user regarding the complete list of requirements necessary for the Base EHR. Such an example would be vital signs. The requirement to satisfy the common clinical dataset includes the ability to record additional data that is not explicitly defined in Base EHR requirements. Such requirements should be obvious to the provider seeking an EHR.

Finally, we suggest that the definition of a base EHR accommodate use of some modules that are part of the 2014 Edition and other modules that are part of the 2015 Edition. This will give providers flexibility as they upgrade to 2015 Edition and begin to achieve Stage 3.

## Certified EHR Technology Definition

Preamble FR Citation: 80 FR 16871

Specific questions in preamble? *No*

## Certified EHR Technology Definition

### Public Comment Field:

EHRA agrees that CMS should assume responsibility for definition of CEHRT but we have concerns with the possibility of additional criteria being adopted in the CEHRT definition to accommodate additional program requirements beyond MU. It is essential that any change to the CEHRT definition adhere to the requirements for adequate development timelines so that providers participating in other CMS programs have the assurance that vendors will be able to develop and certify additional criteria in a timely manner. Although ONC will not be defining CEHRT, we respectfully request that ONC work closely with other organizations to align any changes to the definition or adoption of proposed criteria for inclusion in programs beyond MU, especially in terms of providing guidance regarding when it is reasonable to expect that providers would have certain functionality identified as “available” in their EHRs and ready for use. We are concerned about the effects on the ability to meet unknown timelines and unknown requirements as the scope of certification potentially expands beyond MU. The potential to redirect development resources to support the needs of a few should be carefully considered in light of the untoward effects on providing functional and certified software in the current marketplace.

Finally, we suggest that the definition of CEHRT accommodate use of some modules that are part of the 2014 Edition and other modules that are part of the 2015 Edition. This will give providers flexibility as they upgrade to 2015 Edition and begin to achieve Stage 3.

## Common Clinical Data Set Definition

Preamble FR Citation: 80 FR 16871

Specific questions in preamble? *No*

### Public Comment Field:

EHRA is supportive of using a definition that encompasses several data elements into the clinical common dataset definition, as was done previously with the MU Data Set. EHRA is supportive of updating the definition with updated standards and code sets. We recommend removal of UDIs from the data set until more progress has been made with medical device identifier manufacturers and more utilization can reasonably be expected by providers participating in current programs. We believe the need for such data is primarily among specialty practices. We reiterate our suggestion that some data elements that are proposed for the 2015 Edition should also be broken into additional optional criteria to reflect inclusion in the common clinical data set for the essential elements, and not as an expanded list such as required in the current proposal. As we have previously stated, we encourage the 2014 Edition definition as the base for mandatory vital sign inclusion, while making all additions to (a)(6)(i) optional.

## Cross Referenced FDA Definitions

Preamble FR Citation: 80 FR 16872

Specific questions in preamble? *No*

### Public Comment Field:

EHRA is supportive of the proposed definitions.

## ***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.

<b>Subpart E – ONC Health IT Certification Program</b>	
<b>Preamble FR Citation:</b> 80 FR 16873	<b>Specific questions in preamble?</b> <i>No</i>
<b>Public Comment Field:</b> EHRA is supportive of using the terminology health IT.	

<b>Health IT Modules</b>	
<b>Preamble FR Citation:</b> 80 FR 16873	<b>Specific questions in preamble?</b> <i>No</i>
<b>Public Comment Field:</b> EHRA is supportive of this criterion.	

<b>“Removal” of Meaningful Use Measurement Certification Requirements</b>	
<b>Preamble FR Citation:</b> 80 FR 16873	<b>Specific questions in preamble?</b> <i>No</i>
<b>Public Comment Field:</b> EHRA is supportive of this criterion.	

<b>Types of Care and Practice Settings</b>	
<b>Preamble FR Citation:</b> 80 FR 16873	<b>Specific questions in preamble?</b> <i>Yes</i>
<b>Public Comment Field:</b> The market should determine the composition of these products because it will do a better job at getting providers the products that meet their needs. <ul style="list-style-type: none"><li>• Certification is not the place for these kinds of proposals.</li><li>• Certification should not attempt to address patient assessments that are already clearly defined by regulatory agencies that utilize the information, and implemented in EHRs that serve these providers. These assessments should not be added to the already complicated and expanding scope of certification criteria.</li></ul>	

<b>Referencing the ONC Health IT Certification Program</b>	
<b>Preamble FR Citation:</b> 80 FR 16874	<b>Specific questions in preamble?</b> <i>No</i>

## Referencing the ONC Health IT Certification Program

### Public Comment Field:

We are concerned about the timeframe and timeliness of referencing these requirements across other programs. We encourage ONC to leverage its authority to offer assurance, and provide associated specific guidance, that other government and private sector programs that might reference ONC 2015 Edition certification criteria, whether required for MU or “available”, understand the necessary timelines for development and certification of any referenced criteria. A minimum of 18 months is required between reference to inclusion of any criterion included in the 2015 Edition as essential to any program beyond MU and its intended implementation and use.

## Privacy and Security

Preamble FR Citation: 80 FR 16875

Specific questions in preamble? *Yes*

### Public Comment Field:

We support the ONC proposal to adopt a limited applicability approach under which ONC would establish a limited set of privacy and security functionality that every health IT module would be required to address in order to be certified.

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

Preamble FR Citation: 80 FR 16876

Specific questions in preamble? *No*

### 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*

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

### **Public Comment Field:**

EHRA is unaware of any surveillance program in the field randomized surveillance as proposed and cannot offer guidance on any best practices that would minimize the burden and associated costs.

We share the same concern over costs associated with administrative and remote on-site surveillance. We anticipate provider concern over rising EHR-associated costs due to the burden of such surveillance, as well as concern regarding provider reluctance to participate in such programs.

We are supportive of inclusion of vendors in the process to determine why the EHR is perceived to be non-compliant in the case of complaints and reactive surveillance. Most EHR companies have processes in effect through their quality management programs to address concerns and provide solutions without the disruption of the proposed process.

It is our experience that current certification requirements are validated during the testing process with an established workflow often considered by the vendor as their optimal workflow, although additional workflows and many options are available to providers during software implementation to best determine how the software will be utilized in their specific environments.

The EHRA is concerned that additional and previously non-demonstrated workflows may be seen in the field and may not be considered as demonstrating compliance to the tested product, when in fact they represent the flexibility essential to providers to use EHRs to best meet their needs and achieve desired outcomes.

The EHRA is also concerned that providers may have chosen workflows that do not support the flexibility intended in vendor best-practices, and as such may not meet the desired outcomes. In these cases, EHRs may be judged during the surveillance process as non-conformant and requiring corrective action, when in fact the vendor has no control over such implementations.

EHRA has general concern over not having any insight into how providers use the certified EHR technology in every instance. Even though we may design the EHR in a particular way, providers may use it in a different way that may or may not achieve the desired outcome.

EHRA is concerned that the flexibility afforded to the ONC ACB creates the possibility that different methods of performing the surveillance may be used. We are concerned that the process will not be completely standardized and consistent. If a vendor uses more than one ACB, issues could arise simply from inconsistent ACB processes.

EHRA is concerned with the proposal that these corrective action plans will be made publically available. Only corrective action plans where the vendor is conclusively determined to be at fault following due process should be publically available. We are concerned that posting surveillance results without identification of fault could be prematurely perceived as negative without clear interpretation of the results. EHRA is concerned that such surveillance may potentially create negative outcomes between vendor and customer.

EHRA suggests taking time to learn about the process used for 2014 Edition certification before expanding across the board to randomized surveillance. Taking the time to address non-compliance in a shared experience could serve to highlight additional opportunities for improvement. This should be a learning process that is mutually participatory to achieve the desired outcome. The 2014 Edition could serve as a learning period.

We are uncertain what randomized surveillance will accomplish, and at what costs.

EHRA has concerns regarding the ability to maintain obligations regarding protected health information (PHI) and business associate agreements when ONC ACBs are granted access to provider systems in the field.

Providers may be reluctant to grant ACBs access to their systems, and ACBs have no authority of to force such access.

## Transparency and Disclosure Requirements

Preamble FR Citation: 80 FR 16880

Specific questions in preamble? *No*

### Public Comment Field:

EHRA is concerned with the broad scope proposed for transparency and disclosure requirements regarding limitations and additional types of costs imposed beyond the MU program. Determining the costs for unknowns is not feasible. We do not believe examples cited in the NPRM are typical and widespread and, as such, find the additional proposals burdensome and likely to severely constrain needed flexibility in products, services, and marketing development. EHRA recommends continuation of current “would pay” requirements a reasonable method based upon actual usage and one that is far more predictable and likely to be useful than what ONC has proposed.

- We consider it especially problematic that we are expected to disclose costs that a user may pay or encounter based on “potential conditions” under which a user may use certified technology. We are only capable of identifying the cost associated with use of the systems as intended and do not consider it reasonable to assume the extent to which the health IT developer has knowledge of every potential use of the products outside the MU program. Specifying the “potentials” to be determined is not possible. The predictable use is far more accurate. A good example is when a provider chooses to implement multiple combinations of systems to achieve their goals. Predicting costs in ranges as specified, when not knowing the “potential” differences, the number of users, and many other factors is not possible and is not much of an improvement over a potential requirement to disclose specific prices.
- We question why ONC would specify requirements for any other reason outside use for MU. We are supportive of transparency for MU as applied in the 2014 Edition, but anything outside that cannot be predicted even for a single EHR where every component is certified as a health IT module. Obviously, the more modules the provider requires, more costs will be incurred, but each circumstance will be different.
- We are very concerned with and strongly oppose the proposal for a voluntary public attestation “pledge” to provide information to other persons who request such information. Under such a proposal, the pledge is, in fact, quite mandatory and far beyond the scope of certification to mandate business policy. EHRA is concerned that such mandatory proposals have far reaching negative consequences on legitimate business protections and flexibility, and requests withdrawal in the Final Rule.
- EHRA agrees that specific prices are not to be disclosed. We do not believe accurate estimates based upon levels of costs can be determined with the use of health IT modules or should be subject to government mandated disclosure. In the proposed example, transaction fees and circumstances for use are called out. However, the broad scope of the proposal to provide sufficient detail given the provider’s circumstances assumes the vendor knows this information. In reality, we believe any estimates based upon such arbitrary information would not derive the proposed benefits.
- Overall, we believe that market forces, along with appropriate application of current, in-force transparency requirements, will be provide the greatest benefit with the lowest cost and disruption.

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

Preamble FR Citation: 80 FR 16883

Specific questions in preamble? *Yes*

#### Public Comment Field:

EHRA is generally supportive of the data elements required for the CHPL. However, we have a concern related to the surveillance and corrective action plan posting policy for publishing of quarterly surveillance results. We reiterate that only action plans that are truly related to vendor discrepancies should be posted after clear determination that there was lack of conformance to meet the criterion with the certified product.

### Records Retention

Preamble FR Citation: 80 FR 16885

Specific questions in preamble? *No*

#### Public Comment Field:

EHRA is supportive of six year proposal for records retention.

### Complaints Reporting

Preamble FR Citation: 80 FR 16885

Specific questions in preamble? *No*

#### Public Comment Field:

EHRA is concerned that the described process adds certification cost without value.

### Adaptations and Updates of Certified Health IT

Preamble FR Citation: 80 FR 16885

Specific questions in preamble? *Yes*

#### Public Comment Field:

Monthly reports could be very burdensome. We recommend quarterly reporting as the maximum requirement. If monthly updates are maintained, these should be limited to software changes that could materially affect the integrity of the certification. We could make user changes that have nothing to do with under certified functionality or only affect it in a minor way. This proposal is too broad. Please clarify whether this is beyond what is currently required.

### “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:

- Decertification should not be based on business practices, but rather, a possible result to software not meeting functionality requirements of a certification criterion.
- EHRA agrees that more guidance is required to define specifics related to business practices across all customers that could compromise certification. EHRA agrees with ONC’s assessment that such practices must be clearly defined in future guidance before given the authority to decertify a product that could unfairly punish a broad range of providers who were not affected but such isolated occurrences.
- Criteria for decertification should be completely measurable regarding failure of certified product to perform the functionality required to pass the certification criteria.
- In any usage, decertification should be a last resort after other opportunities to cure the problem have failed and only for material variances form certification requirements.

## 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:

See below

## ONC 2015 Edition: EHRA Development Estimates

May 2015

Responses were from the EHR developers responsible for 45% of EP attestations to date and 70% of EH attestations to date.

EHRA development estimates include research, planning and design, development, testing, usability testing, documentation, release, and certification effort. Implementation effort is not included. The estimates presume that the EHR has already been certified against 2014 criteria.

Criterion	ONC Estimate for Development	Average EHRA Estimate for Development (gathered by surveying EHR developers)	ONC average estimate/EHRA average estimate (%)
(a)(2) CPOE-labs	1000-2000 hrs	Update to HL7 2.5.1 IG LOI from EHR DSTU R2 and update to LOINC v 2.50: 1200 hrs  <i>Comments:</i>  <i>Estimates had an unusual split with approximately half of respondents indicating the project was small and half indicating it was very large.</i>  <b>Total: 1200 hrs</b>	125%



Criterion	ONC Estimate for Development	Average EHRA Estimate for Development (gathered by surveying EHR developers)	ONC average estimate/EHRA average estimate (%)
(a)(4) drug interactions	400-800 hrs	Track user responses to DDI and DAI: 480 hrs Generate display or report of actions: 610 hrs <b>Total: 1090 hrs</b>	55%
(a)(5) demographics	500-1000 hrs	Record sex using HL7 V3 administrative gender: 450 hrs Record race and ethnicity using CDC PHIN VADS: 620 hrs Aggregate those races and ethnicities to OMB standard: 560 hrs Preferred language using IEFTR RFC 5646: 510 hrs <b>Total: 2140 hrs</b>	31%
(a)(6) vitals	614-922 hrs	Blood pressure, height, weight (measured), heart rate, respiratory rate, body temperature, oxygen saturation, BMI and mean blood pressure using LOINC, SNOMED, and UCUM for native entry, collecting metadata: 5550 hrs BMI for youth, weight for length using LOINC, SNOMED, and UCUM for native entry, collecting metadata: 1240 hrs <b>Total: 6790 hrs</b>	11%
(a)(10) CDS	600-1200 hrs	Update Infobutton to SOA R1IG or URL-based R4 IG: 600 hrs Request patient education based on preferred language: 600 hrs Record user responses: 610 hrs Generate report or display of actions: 550 hrs <b>Total: 2350 hrs</b>	38%
(a)(11) drug formulary	310-620 hrs	Receive and incorporate a formulary and benefit file according to NCPDP 3.0: 930 hrs Check whether a preferred drug lists exists for a given patient and medication including the time last updated: 570 hrs <b>Total: 1500 hrs</b>	31%
(a)(12) smoking status	100-200 hrs	Use all codes in SNOMED Sept 2014 release: 410 hrs Map to previous 7 codes: 430 hrs <b>Total: 840 hrs</b>	18%
(a)(15) family history pedigree	500-1200 hrs	<b>Total: 1220 hrs</b>	70%
(a)(17) patient education	600-1200 hrs	Update Infobutton to SOA R1 IG or URL-based Release 4 IG: 630 hrs Request patient ed based on preferred language: 550 hrs <b>Total: 1180 hrs</b>	76%
(a)(19) patient health information capture	500-1000 hrs	Record, store, link to, label, and access health information documents (advance directives, birth plans): 1030 hrs <b>Total: 1030 hrs</b>	73%
(a)(20) UDI	1000-1700 hrs	Record, change, and access a patient's implantable device list: 1200 hrs Parse device identifier, batch/lot number, expiration date, production date, serial number from the UDI: 1280 hrs Retrieve the device description from the GUDID: 1020 hrs <b>Total: 3490 hrs</b>	39%

Criterion	ONC Estimate for Development	Average EHRA Estimate for Development (gathered by surveying EHR developers)	ONC average estimate/EHRA average estimate (%)
(a)(21) social, psychological, and behavioral health data	235-480 hrs	Capture financial resource strain with LOINC: 960 hrs Capture educational attainment with LOINC: 960 hrs Capture stress with LOINC: 960 hrs Capture depression (PHQ-2) with LOINC: 960 hrs Capture physical activity (SAMHSA) with LOINC: 960 hrs Capture alcohol use (AUDIT-C) with LOINC: 960 hrs Capture social connection and isolation (NHANES III) with LOINC: 960 hrs Capture exposure to violence - intimate partner violence (HARK 4Q) with LOINC: 960 hrs Record, change, and access sexual orientation according to SNOMED and HL7 V3: 960 hrs Record, change, and access gender identity according to SNOMED and HL7 V3: 1210 hrs Record, change, and access patient's employment status and primary activities (volunteer work) Record, change, and access patient's current I/O, linked to one another and with time stamp including start date: 920 hrs Record, change, and access patient's usual I/O, linked to one another and with time stamp, including start year and duration: 1050 hrs Record, change, and access patient's history of occupation with a time and date stamp for when the history was collected: 990 hrs <b>Total: 13,810 hrs</b>	3%
(a)(22) decision support knowledge artifact	394-788 hrs	HeD use case 1 R1.2: 1730 hrs <b>Total: 1730 hrs</b>	34%
(a)(23) decision support service	229-458 hrs	HeD use case 2 March 2014 DSTU R1.1: 1700 hrs <b>Total: 1700 hrs</b>	20%
(b)(1) TOC	1550-3100 hrs	Update CCDA to R2: 1560 hrs Send 2 documents for bilateral cutover between 1.1 and 2.0: 1020 hrs Identify invalid CCDAs: 1420 hrs Accept and process XDM packages: 1200 hrs Updated Common Clinical Data Set: 1170 hrs Use patient matching data for exchange: 1590 hrs CDA Release 2: Data provenance R2 DSTU: 1560 hrs <b>Total: 9520 hrs</b>	24%
(b)(2) clinical information reconciliation	600-1200 hrs	Enhanced testing: 1010 hrs <b>Total: 1010 hrs</b>	89%
(b)(3) eRx	1050-2100 hrs	Use NCPDP Script V 10.6 additional segments (change Rx, cancel Rx, refill Rx, fill status, med history): 1460 hrs structured sigs: 1450 hrs limit e-prescribing to metric: 710 hrs <b>Total: 3620 hrs</b>	44%

Criterion	ONC Estimate for Development	Average EHRA Estimate for Development (gathered by surveying EHR developers)	ONC average estimate/EHRA average estimate (%)
(b)(4) incorporate lab results	313-626 hrs	LRI R2: 970 hrs More specific requirements for electronic display of lab reports: 980 hrs <b>Total: 1950 hrs</b>	24%
(b)(5) lab results to ambulatory providers	360-720 hrs	LRI R2 and LOINC v 2.50: 1030 hrs <b>Total: 1030 hrs</b>	52%
(b)(6) data portability	800-1200 hrs	Configure export summaries for one or more patients for specific time range: 1240 hrs Configure export summaries based on selected user events: 1060 hrs Set storage location: 740 hrs <b>Total: 3040 hrs</b>	33%
(b)(7) DS4P - send	450-900 hrs	Document level tagging (level 1) in conformance with DS4P IG: 1370 hrs <b>Total: 1370 hrs</b>	49%
(b)(8) DS4P - receive	450-900 hrs	Recognize and view privacy metadata tags in conformance with DS4P IG: 1740 hrs <b>Total: 1740 hrs</b>	39%
(b)(9) care plan	300-500 hrs	Record, change, access, create, and receive care plan with document template in CCDA R2: 1370 hrs <b>Total: 1370 hrs</b>	29%
(c)(1) CQM – record and export	200-500 hrs	QRDA RD export: 1270 hrs <b>Total: 1270 hrs</b>	28%
(c)(2) CQM – import and calculate	0-200 hrs	Import CQM data using QRDA and de-duplicate records: 1460 hrs <b>Total: 1460 hrs</b>	7%
(c)(4) CQM - filter	316-632 hrs	Filter individual patient level and aggregate level CQM results by TIN, NPI, provider type, patient insurance, patient age, patient sex, patient race and ethnicity, patient problem list, practice site address: 1720 hrs <b>Total: 1720 hrs</b>	28%
(e)(1) VDT	1000-2000 hrs	Update CCDA to R2: 1180 hrs Updated Common Clinical Data Set: 1000 hrs Make available diagnostic imaging reports: 840 hrs Application access to common clinical data set with documentation and TOU: 1270 hrs Add addressee to activity history log: 530 hrs Provide patient lab test reports with info for CLIA: 840 hrs WCAG 2.0 Level AA: 1050 hrs <b>Total: 6700 hrs</b>	22%
(f)(1) immunization transmission	680-1360 hrs	HL7 V2.5.1 IG R1.5: 970 hrs Use NDC and CVX: 940 hrs Receive and display immunization history and forecast: 1640 hrs <b>Total: 3550 hrs</b>	29%

Criterion	ONC Estimate for Development	Average EHRA Estimate for Development (gathered by surveying EHR developers)	ONC average estimate/EHRA average estimate (%)
(f)(2) syndromic surveillance	480-960 hrs	PHIN R2.0: 950 hrs <b>Total: 950 hrs</b>	76%
(f)(3) reportable lab results	520-1040 hrs	Update IG to R2 DSTU R1.1, use updated SNOMED and LOINC versions: 970 hrs <b>Total: 970 hrs</b>	80%
(f)(4) cancer transmission	500-1000 hrs	Use IG R1, use updated SNOMED and LOINC versions: 1070 hrs <b>Total: 1070 hrs</b>	70%
(f)(5) case reporting	500-1000 hrs	Create case reporting information with IHE QRPHTFS, Structured Data Capture, Trial Imp: 1700 hrs <b>Total: 1700 hrs</b>	44%
(f)(6) antimicrobial use and resistance	500-1000 hrs	HL7 R2 Level 3: HAI Reports R1 (HAI IG): 1570 hrs <b>Total: 1570 hrs</b>	48%
(f)(7) health care surveys	500-1000 hrs	NHCS R1 DSTU: 1500 hrs <b>Total: 1500 hrs</b>	50%
(g)(1) automated numerator calculation	400-800 hrs	ANR for objective 2: 850 hrs ANR for objective 4: 1000 hrs ANR for objective 5: 1080 hrs ANR for objective 6: 1080 hrs ANR for objective 7: 1080 hrs <b>Total: 5080 hrs</b>	12%
(g)(2) automated measure calculation	600-1200 hrs	AMR for objective 2: 800 hrs AMR for objective 4: 910 hrs AMR for objective 5: 1110 hrs AMR for objective 6: 1170 hrs AMR for objective 7: 1170 hrs <b>Total: 5170 hrs</b>	17%
(g)(3) safety enhanced design	300-600 hrs	Summative testing for 17 criteria: 1710 hrs <b>Total: 1710 hrs</b>	26%
(g)(5) accessibility technology compatibility	800-1400 hrs	Demonstrate compatibility with accessibility technology for text-to-speech: 1760 hrs <b>Total: 1760 hrs</b>  <i>Comment:</i> <i>1/3 of respondents indicated they did not have information to even estimate the impact.</i>	63%
(g)(6) CCDA creation performance	400-1000 hrs	1760 hrs <b>Total: 1760 hrs</b>	40%

Criterion	ONC Estimate for Development	Average EHRA Estimate for Development (gathered by surveying EHR developers)	ONC average estimate/EHRA average estimate (%)
(g)(7) API	500-1000 hrs	Application access to common clinical data set with documentation and TOU: 1720 hrs <b>Total: 1720 hrs</b>	44%
(g)(8) accessibility-centered design	50-100 hrs	<b>Total: 1360 hrs</b>	6%
(h)(4) HPD query request	120-240 hrs	Query a directory using the IHE HPD profile: 1600 hrs <b>Total: 1600 hrs</b>	11%
(h)(5) HPD query response	120-240 hrs	Response to queries using the IHE HPD profile: 1590 hrs <b>Total: 1590 hrs</b>	11%
(j)(1) esMD	1000-2000 hrs	Support the creation of a document in accordance with HL7 CDA R2: Additional CDA R2 Templates - Clinical Documents for payers Set 1 R1 and CDP1 IG: 1520 hrs Support the use of digital signatures embedded in CCCDA R2.0 and CDP1 IG documents using DSDR IG: 1640 hrs Support creation and transmission of external digital signatures per Author of Record Level I IG: 1560 hrs Support creation and transmission of digital signatures for data integrity and non-repudiation authenticity (provider profiles authentication): 1260 hrs <b>Total: 5980 hrs</b>	25%