

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

**Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements**

**Comments from the Electronic Health Record Association (EHRA)**

The following comments are offered by the Electronic Health Record Association (EHRA), and developed through a collaborative process with input from representatives who work in a variety of EHR developer environments in an effort to provide a balanced perspective of large and small companies, those that serve enterprise and/or ambulatory environments, and those that provide broad EHR functionality as well as EHRs designed for specialty environments.

**Proposed Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements**

***A. Proposed for 2015 Edition<sup>1</sup> Certification Criteria***

**§ 170.315(a)(1) Computerized physician order entry - medications**

**MU Objective**

Use computerized provider order entry (CPOE) for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines to create the first record of the order.

**2015 Edition EHR Certification Criterion**

**(1) Computerized provider order entry – medications. Enable a user to electronically record, change, and access medication orders.**

**Preamble FR Citation: 79 FR 10886**

**Specific questions in preamble? No**

**Public Comment Field:**

EHRA supports the certification flexibility enabled<sup>1</sup> by separation of CPOE medication order entry criterion from other order entry criteria.

**§ 170.315(a)(2) Computerized physician order entry - laboratory**

**MU Objective**

Use CPOE for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines to create the first record of the order.

**2015 Edition EHR Certification Criterion**

**(2) Computerized provider order entry – laboratory.** (i) Enable a user to electronically record, change, and access laboratory orders.

(ii) Ambulatory setting only. Enable a user to electronically create laboratory orders for electronic transmission:

(A) With all the information for a test requisition as specified at 42 CFR 493.1241(c)(1) through (c)(8); and

(B) In accordance with the standard specified at § 170.205(l)(1) and, at a minimum the version of the standard at § 170.207(c)(2).

Preamble FR Citation: 79 FR 10887

Specific questions in preamble? *No*

**Public Comment Field:**

EHRA supports the certification flexibility enabled by separation of laboratory CPOE criterion from other order entry criteria. EHRA generally supports ONC working towards the goal for a standardized process for laboratory order submission utilizing LOINC codes. However, EHRA does not support the inclusion of LOINC for ordering prior to the 2017 Edition NPRM.

The EHRA strongly supports the advancement of interoperability across healthcare providers and service providers such as laboratories. In that context, the ability to consistently and unambiguously exchange laboratory orders is essential. However, we are concerned that the proposed implementation guide has not reached the level of maturity necessary to establish the use of this guide through rule making, even though the criteria are supposed to be voluntary. There are no known implementations of the guide, which is still subject to substantial changes that were known at the time of initial publication. We strongly suggest that ONC create an environment with providers, laboratories, and software vendors to properly test the guide in one or more operational settings before incorporating this guide in a future edition, after 2015.

Although we support the direction of this implementation guide and the need to provide support, we suggest that there should not be a requirement to replace current operational interfaces to adhere to this guide, particularly when they effectively communicate the required data set and are in operational use. We suggest flexibility regarding interface standards to accommodate mutually-acceptable interfaces between labs and providers. There is significant impact on providers to capture additional data, upgrade systems, and implement the certification changes. Rather, as new interfaces are established, existing interfaces should be considered the starting point for easing implementation as fewer implementation negotiations are required. Current EHRA surveys validate the significant problems surrounding deployment in general as far exceeding the challenges related to software development and certification difficulties. Many providers are forced to upgrade their EHRs without consideration as to whether their current interoperability already serves the desired outcome, so a change of interfaces just to adhere to an updated standard should not be required.

We reiterate that alignment must occur between EHR certification standards for lab ordering and lab receipt of orders for the process to be successful. We encourage alignment with CLIA to encourage laboratories to receive such standardized orders. However, we are concerned that the current references to CLIA, while applicable to a laboratory, do not apply “as-is” to a hospital or provider placing the orders. We suggest that the CLIA rules quoted are not necessary to be included in the new certification edition rules, consistent with the fact that CMS EHR Incentive Program rules are not included in the certification edition. Generally, the laboratory needs to establish the data they need, in line with these CLIA rules, for each orderable test to be performed in their laboratory. It is not up to the provider to guess what data the lab may need, which is what inclusion of these CLIA rules would imply. We suggest that the LOI IG, in combination with established processes for laboratories to communicate their test compendia, provides sufficient guidance to enable the ordering provider’s health IT to provide the necessary support.

The proposed language on the use of LOINC codes seems to imply the exclusive use of at least LOINC V2.40, without recognizing the substantial current dependence on non-LOINC local codes. Many laboratories require utilization of local codes for ordering, thus reducing the benefit of standardized codes. Estimates range from 30% to 80% coverage of LOINC codes for orderable tests depending on the provider setting and relevant tests. That range leaves a substantial gap that must be filled. Even then, we must recognize that code systems are dynamic in nature, constantly having to address new tests and results that are emerging.

In order to move towards standardized codes for ordering, a significant number of resources could be required to implement multiple interface changes to accommodate standardized ordering. While the use of standardized codes should be promoted, there always must be an opportunity to use localized codes during the multi-year transition to standardized codes. We suggest that the criterion indicate that LOINC 2.40 test codes are included when available for the test being ordered. This change will further enable transitions such that both LOINC and local codes can be communicated.

We agree with the increased flexibility that additional granularity offers for systems to focus on their target users. However, we seek clarification that, if a system was certified to the 2014 Edition for CPOE and opts to certify to only the CPOE-medication and CPOE-radiology/imaging for the 2015 Edition, the 2014 Edition certification for CPOE for laboratory remains in effect.

We request ONC to work with the laboratory community (i.e., through CLIA or CAP) to adopt lab-related criteria, including equivalent certification, to ensure that both communication partners are capable of communicating using the same standard.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 2 100-300 hrs "Revised" criterion	Adopt HL7 2.5.1 IG: 1,450 hrs LOINC 2.4 for lab orders: 1,140 hrs Lab orders include test requisition information: 1,100 hrs	The ONC estimate is significantly underestimated.  <i>Statistical comments:</i>  While LOINC 2.4 for lab orders and including test requisition information ended up with similar averages, the data was actually different.  Using LOINC was split with approximately half of respondents indicating it was a small project and half indicating a jumbo project.  In contrast, lab orders including test requisition information was reported as a large project by almost all estimators.

**§ 170.315(a)(3) (Computerized physician order entry – radiology/imaging)**

**MU Objective**

Use CPOE for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines to create the first record of the order.

**2015 Edition EHR Certification Criterion**

**(3) Computerized provider order entry – radiology/imaging.** Enable a user to electronically record, change, and access radiology and imaging orders.

Preamble FR Citation: 79 FR 10887

Specific questions in preamble? No

**Public Comment Field:**

EHRA supports the certification flexibility enabled by separation of the CPOE radiology/imaging order entry criterion from other order entry criteria.

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

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

**MU Objective**

Implement drug-drug and drug-allergy interaction checks.

**2015 Edition EHR Certification Criterion**

**(4) Drug-drug, drug-allergy interaction checks. (i) Interventions.** Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically and electronically 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.**

**Preamble FR Citation: 79 FR 10887**

**Specific questions in preamble? Yes**

**Public Comment Field:**

EHRA does not support the need for additional certification requirements to track health professionals' responses as described in the NPRM. EHRA believes that EHR technology currently available in the marketplace provides the functionality requested by providers and hospitals to assist in patient safety monitoring by capturing data on alert responses and overrides, while at the same time allowing workflow flexibility. EHR systems will continue to innovate as needed in the marketplace. CEHRT allows various system configuration settings, which can further complicate equivalent comparisons across systems when reviewing provider responses currently being tracked. The priorities for monitoring drug-drug interactions, as well as the specificity of what responses are deemed appropriate and tracked, are best accomplished through provider and hospital policies and procedures. EHRA discourages additional certification requirements without further understanding how such specific response tracking proposals put forth in this NPRM could provide additional benefits beyond current market functionality.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 2 100-300 hrs "Unchanged" criterion	Track user responses to DDI and DAI: 620 hrs *  Adjust DDI and DAI tracking configuration: 620 hrs *  Track when an adverse event occurs for an ignored check: 1,570 hrs *	The items for which ONC solicits public comment represent a significant development investment  *Estimates are for items that are not proposed but where public comment is solicited.

**§ 170.315(a)(5) (Demographics)**

**MU Objective**

Record the following demographics: preferred language; sex; race; ethnicity; date of birth; and for the inpatient setting only, date and preliminary cause of death in the event of mortality in the EH or CAH.

**§ 170.315(a)(5) (Demographics)**

**2015 Edition EHR Certification Criterion**

**(5) Demographics. (i) Enable a user to electronically record, change, and access patient demographic data including preferred language, sex, race, ethnicity, and date of birth.**

**(A) Enable race and ethnicity to be recorded in accordance with the standard specified in § 170.207(f) and whether a patient declines to specify race and/or ethnicity.**

**(B) Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g)(2) and whether a patient declines to specify a preferred language.**

**(ii) Inpatient setting only. Enable a user to electronically record, change, and access the preliminary cause of death and date of death in the event of mortality.**

**Preamble FR Citation: 79 FR 10888**

**Specific questions in preamble? Yes**

**Public Comment Field:**

EHRA supports interoperability and understands the value of preferred language standards utilized in the 2014 Edition. We appreciate ONC addressing issues that arose from the 2014 Edition preferred language standard by providing FAQs to assist us with information to make our products more usable within current certification standards. We believe this current approach utilizing FAQs is a workable solution for the time being and see no need for new standards prior to the 2017 NPRM. We believe the problems arising from selecting the 2014 Edition preferred language standard are representative of the challenges faced when writing regulations in pursuit of interoperability without benefit of user experience. The EHRA supports inclusion in the 2015 Edition NPRM of the omitted 2011 Edition capabilities regarding “enable a user to electronically record, change, and access the “date of death”. We understand the value of such information and note that we are unaware of any EHRA vendors who removed this capability regardless of omission from 2014 Edition certification.

ONC Estimate for Development (from pages 10933-10935 of the proposed rule)	Average EHRA Estimate for Development (gathered by surveying EHR developers)	Comments
Level 1 40-100 hrs “Revised” criterion	Adopt ISO 639-2 in full: 380 hrs Adopt ISO 693-3: 500 hrs Adopt RFC 5646: 400 hrs	The ONC estimate is significantly underestimated. The preferred language standard requiring the largest development effort is using ISO 639-3 (500 hrs/developer) and the language standard requiring the least development is adopting ISO 639-2 in full (380 hrs/developer).

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

**MU Objective**

**Record and chart changes in the following vital signs: height/length and weight (no age limit); blood pressure (ages 3 and over); calculate and display body mass index (BMI); and plot and display growth charts for patients 0-20 years, including BMI.**

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

2015 Edition EHR Certification Criterion

(6) Vital signs, body mass index, and growth charts. (i) Vital signs. Enable a user to electronically record, change, and access, at a minimum, a patient's height/length, weight, and blood pressure. Height/length, weight, and blood pressure must be recorded in numerical values only.

(ii) Calculate body mass index. Automatically calculate and electronically display body mass index based on a patient's height and weight.

(iii) Optional—Plot and display growth charts. Plot and electronically display, upon request, growth charts for patients.

Preamble FR Citation: 79 FR 10889

Specific questions in preamble? *Yes*

**Public Comment Field:**

Although we appreciate guidance regarding approaches to exchanging standardized data, we support a focus on normal standards and diffusion processes and believe that it is best left to EHR developers to determine the methodology to record and store data content in our products. Specifically, requiring emerging standards such as CIMI's models on actual capture and storage is inappropriate as many factors go into such modeling that go well beyond the scope and expertise of ONC and are not necessary to be the same across systems.

Given the choice between the two proposed options, EHRA supports the 2017 Edition proposed option 2 for exchange of vital sign data as opposed to option 1, which would require recording data in the aforementioned standards. We do not see added material value in the proposed metadata requirements regarding the context of how the vital signs were recorded. If such context is recorded, it should be left to EHR developers to determine the methodology to record and store data content in our products. We have concerns that vital signs standards do not align with value sets required for other functions, such as QRDA, quality measures, etc. We ask that all certification standards be aligned with other programs to prevent any certification misalignment.

ONC Estimate for Development (from pages 10933-10935 of the proposed rule)	Average EHRA Estimate for Development (gathered by surveying EHR developers)	Comments
Level 2 100-300 hrs "Unchanged" criterion	Native entry: 1,340 hrs* When data is transmitted: 1,456 hrs* Vitals metadata: 620 hrs* CIMI FHIR for vitals metadata: 1,140 hrs* *Estimates are for items that are not proposed but where public comment is solicited, including using LOINC, SNOMED, and UCUM for native entry of vitals, using LOINC, SNOMED, and UCUM for vitals when data is transmitted, collecting vitals metadata, and using CIMI FHIR for vitals metadata.	The items for which ONC solicits public comment represent a significant development investment.

### § 170.315(a)(7) (Problem list)

#### MU Objective

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

#### 2015 Edition EHR Certification Criterion

(7) Problem list. Enable a user to electronically 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)(3); 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)(3).

Preamble FR Citation: 79 FR 10890

Specific questions in preamble? *No*

#### Public Comment Field:

EHRA supports unchanged criterion.

### § 170.315(a)(8) (Medication list)

#### MU Objective

Maintain active medication list.

#### 2015 Edition EHR Certification Criterion

(8) Medication list. Enable a user to electronically 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: 79 FR 10890

Specific questions in preamble? *No*

#### Public Comment Field:

EHRA supports unchanged criterion.

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

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

**MU Objective**

Maintain active medication allergy list.

**2015 Edition EHR Certification Criterion**

(9) Medication allergy list. Enable a user to electronically record, change, and access a patient's active medication allergy list as well as medication allergy history:

(i) Ambulatory setting. Over multiple encounters; or

(ii) Inpatient setting. For the duration of an entire hospitalization.

Preamble FR Citation: 79 FR 10890

Specific questions in preamble? *No*

**Public Comment Field:**

EHRA supports unchanged criterion.

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

**MU Objective**

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

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

2015 Edition EHR Certification Criteria

(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) EHR technology must be able to:

- (1) Electronically identify for a user diagnostic and therapeutic reference information; or
- (2) Electronically identify for a user diagnostic and therapeutic reference information in accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204 (b)(1) or (3).

(B) For paragraph (a)(10)(ii)(A) of this section, EHR technology must be able to electronically 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) EHR technology must enable interventions to be electronically triggered:

- (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, and problems are incorporated from a transition of care/referral summary received pursuant to paragraph (b)(1)(i)(B) of this section.

(3) Ambulatory setting only. When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(4)(i)(A)(1) of this section.

(iv) Automatically and electronically interact. Interventions triggered in accordance with paragraphs (a)(10)(i) through (iii) of this section must automatically and electronically occur when a user is interacting with EHR 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) Decision support – knowledge artifact. Electronically process clinical decision support knowledge artifacts in accordance with the standard specified at § 170.204(d).

(vii) Decision support – service. Enable a user to electronically make an information request with patient data and receive in return electronic clinical guidance in accordance with the standard specified at § 170.204(e).

Preamble FR Citation: 79 FR 10890

Specific questions in preamble? Yes

Public Comment Field:

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

EHRA supports the clarification requirement that CDS utilizes at least one demographic criterion. EHRA supports the flexibility of the 2014 Edition implementation guides (IGs) for both URL and SOA InfoButton implementations and requests that both remain as implementation options for the 2015 Edition. We do not support removal of the URL IG. EHRA supports ONC specifying that the 2015 Edition does not require compliance with InfoButton for vital signs and medication allergies, as well as not requiring capabilities for laboratory values/results.

EHRA strongly opposes inclusion of HealtheDecisions implementations for knowledge artifacts or services for the 2015 Edition NPRM or 2017 Edition NPRM. We believe that these the standards are immature and should not be considered for certification until user experience proves that capabilities broadly exist to provide such services as specified in these criteria. We understand that HL7 is investigating a number of issues involving the receipt of the artifacts in the manner specified in this proposal and anticipate implementation changes. The magnitude of the implementation must be determined as well to better address our comments regarding suggested scope for future editions.

We also urge ONC to consider the work just launched in the Clinical Quality Framework initiative, and harmonize the work between both of these initiatives. Substantial efforts have just started to harmonize the CDS and CQM approach to yield a consistent representation of data across these two areas. Introducing standards that are known to change substantially and/or be replaced would create unnecessary re-work once the new standards emerge.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 2 100-300 hrs “Revised” criterion	Infobutton HL7 IG: SOA most recent version: 850 hrs Health eDecisions Use Case 1 – CDS knowledge artifact (simple case): 1,970 hrs Health eDecisions Use Case 1 – CDS knowledge artifact (complex case): 1,970 hrs Health eDecisions Use Case 2 – CDS support query: 1,910 hrs Map CDS knowledge artifact to data in EHR: 1,280 hrs	The ONC estimate is significantly underestimated.

**§ 170.315(a)(11) (Electronic notes)**

**MU Objective**

**Record electronic notes in patient records.**

**§ 170.315(a)(11) (Electronic notes)**

**2015 Edition EHR Certification Criterion**

**(11) Electronic notes. Enable a user to electronically:**

- (i) Record, change, and access electronic notes; and**
- (ii) Search within and across electronic notes stored within EHR technology.**

**Preamble FR Citation: 79 FR 10891**

**Specific questions in preamble? Yes**

**Public Comment Field:**

EHRA appreciates the intent of expansion of capabilities to search across notes, but EHRA members have not had significant levels of provider requests for such functionality nor seen any value to providers for such an expansion of functionality. We also suggest that provision of these types of application features is best handled between providers and their vendors, with no compelling reason for ONC to specify such functionality for certification. We therefore do not support additional functionality for this item to be required in the 2015 Edition NPRM or 2017 Edition NPRM. EHRA does not see additional benefits that outweigh associated development costs in consideration of the additional metadata requirements proposed to support data portability.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 1 40-100 hrs "Revised" criterion	Searching across one patient: 1,270 hrs Searching across all patients: 1,920 hrs Using HL7 R2 header metadata: 1,070 hrs	The ONC estimate is significantly underestimated.

**§ 170.315(a)(12) (Drug formulary checks)**

**MU Objective**

**Implement drug formulary checks.**

**2015 Edition EHR Certification Criterion**

**(12) Drug-formulary checks. EHR technology must automatically and electronically check whether a drug formulary (or preferred drug list) exists for a given patient and medication.**

**Preamble FR Citation: 79 FR 10892**

**Specific questions in preamble? Yes**

**§ 170.315(a)(12) (Drug formulary checks)**

**Public Comment Field:**

EHRA supports the proposal to include NCPDP Formulary and Benefit Standard V3 to support real-time benefit checks in e-prescribing criteria for the 2017 Edition NPRM, but as an optional capability. EHRA continues to support acceptance of current e-prescribing Surescripts certification as acceptable attestation for certification testing without additional testing requirements for vendors. Since this has not been considered feasible in previous certification rulemaking, EHRA suggests ONC and Surescripts collaborate to align standards requirements to assure no additional development is required for ONC certification in addition to satisfaction of Surescripts certification for equivalent standards.

At the same time, we caution that rolling this out too quickly by introducing these benefit checks into the provider workflows could create implementation challenges and costs for both EHR vendors and providers. We therefore suggest it be included in the 2017 Edition as an optional capability to allow time for sufficient experience through initial implementations.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 2 100-300 hrs "Unchanged" criterion	NCPDP 3.0: 620 hrs* NCPDP 4.0: 1,320 hrs* NCPDP Telecomm with F&B 3.0 or 4.0: 830 hrs*  *Estimates are for items that are not proposed but where public comment is solicited.	The items for which ONC solicits public comment represent a significant development investment.  <i>Statistical comments:</i>  <i>NCPDP 3.0 was estimated as tiny or small by a majority of estimators, with a minority of estimators indicating the project was jumbo.</i>

**§ 170.315(a)(13) (Smoking status)**

**MU Objective**

Record smoking status for patients 13 years old or older.

**2015 Edition EHR Certification Criteria**

(13) **Smoking status.** Enable a user to electronically record, change, and access the smoking status of a patient in accordance with the standard specified at § 170.207(h).

Preamble FR Citation: 79 FR 10892

Specific questions in preamble? *No*

**Public Comment Field:**

EHRA supports unchanged criterion.

**§ 170.315(a)(14) (Image results)**

**MU Objective**

Imaging results and information are accessible through Certified EHR Technology.

**2015 Edition EHR Certification Criterion**

(14) **Image results.** Electronically 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: 79 FR 10893

Specific questions in preamble? *No*

**Public Comment Field:**

EHRA supports unchanged criterion.

**§ 170.315(a)(15) (Family health history)****MU Objective**

Record patient family health history as structured data.

**2015 Edition EHR Certification Criterion**

(15) **Family health history.** Enable a user to electronically record, change, and access a patient's family health history according to the standard and implementation specification specified at § 170.205(m)(1).

Preamble FR Citation: 79 FR 10893

Specific questions in preamble? *No*

**Public Comment Field:**

EHRA discourages the use of the HL7 Pedigree Standard for the 2015 Edition or the 2017 Edition as the single standard. We support the flexibility of both SNOMED CT and HL7 Pedigree in 2015 Edition NPRM and 2017 Edition NPRM. Both standards have limitations as they currently exist and do not meet the current needs of many providers. We encourage further refinement before considering a single standard. We believe the goal should remain finding the best standard to utilize in support of interoperable exchange within the CCDA documents.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 2 100-300 hrs "Revised" criterion	1,510 hrs	The ONC estimate is significantly underestimated.

**§ 170.315(a)(16) (Patient list creation)****MU Objective**

Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care.

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

2015 Edition EHR Certification Criterion

(16) Patient list creation. Enable a user to electronically and 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: 79 FR 10893

Specific questions in preamble? Yes

Public Comment Field:

EHRA believes communication preference inclusions and appropriate preference selections are best addressed by the marketplace as we respond to provider requests. We do not support additional certification criteria for this criterion in the 2015 Edition or the 2017 Edition. Patient reminder content is currently not provided in multiple languages. EHRA does not support any proposals to require translation of patient reminders into the patient’s preferred language.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 2 100-300 hrs “Unchanged” criterion	Patient communication preferences for inpatient: 450 hrs* Minimum list of communication preferences: 320 hrs* Preferred language as filter: 740 hrs* Reminders provided according to preferred language and preferred communication method: 1,500 hrs* *Estimates are for items that are not proposed but where public comment is solicited.	The items for which ONC solicits public comment represent a significant development investment.

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

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

**MU Objective**

Use clinically relevant information from Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient.

**2015 Edition EHR Certification Criterion**

**(17) Patient-specific education resources.** EHR technology must be able to electronically identify for a user patient-specific education resources based on data included in the patient's problem list, medication list, and laboratory tests:

- (i) In accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204(b)(1) or (3); and
- (ii) By any means other than using the standard specified in § 170.204(b).

Preamble FR Citation: 79 FR 10893

Specific questions in preamble? Yes

**Public Comment Field:**

EHRA supports the flexibility of the 2014 Edition IGs for both URL and SOA Infobutton implementations and requests that both remain for 2015 Edition NPRM and the 2017 Edition NPRM. In terms of commenting on the three proposals to change certification for Infobutton, the EHRA desires to keep the current implementations in place for provider utilization and would readily support the flexibility afforded by option 3 to certify only Infobutton so long as CMS would permit the use of another method whether certified or not. Most EHRA vendors had alternate methods in place prior to the Infobutton standard implementation. Option 2 would be EHRA's second choice, and option 1 to maintain the current approach would be last. As stated previously, we believe our alternate patient education resources are a valuable asset to our provider customers and would like to maintain this ability.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 1 40-100 hrs "Revised" criterion	Infobutton HL7 IG: SOA most recent version: 1,560 hrs  Provide education in preferred language: 770 hrs*  *Estimates are for items that are not proposed but where public comment is solicited.	The ONC estimate is significantly underestimated.

**§ 170.315(a)(18) (Inpatient setting only – electronic medication administration record)**

**MU Objective**

Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR).

**§ 170.315(a)(18) (Inpatient setting only – electronic medication administration record)**

**2015 Edition EHR Certification Criterion**

**(18) Inpatient setting only—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 electronically verify the following before administering medication(s):

- (A) **Right patient.** The patient to whom the medication is to be administered matches the medication to be administered.
- (B) **Right medication.** The medication to be administered matches the medication ordered for the patient.
- (C) **Right dose.** The dose of the medication to be administered matches the dose of the medication ordered for the patient.
- (D) **Right route.** The route of medication delivery matches the route specified in the medication order.
- (E) **Right time.** The time that the medication was ordered to be administered compared to the current time.

(ii) **Right documentation.** Electronically 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: 79 FR 10894

Specific questions in preamble? *No*

**Public Comment Field:**

EHRA supports unchanged criterion.

**§ 170.315(a)(19) (Inpatient setting only – advance directives)**

**MU Objective**

Record whether a patient 65 years old or older has an advance directive.

**2015 Edition EHR Certification Criteria**

**(19) Inpatient setting only—advance directives.** Enable a user to electronically record whether a patient has an advance directive.

Preamble FR Citation: 79 FR 10894

Specific questions in preamble? *No*

**Public Comment Field:**

EHRA supports unchanged criterion.

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

**MU Objective**

N/A

§ 170.315(a)(20) (Implantable Device list)

2015 Edition EHR Certification Criteria

(20) Implantable device list. (i) Enable a user to electronically access and view a list of Unique Device Identifiers and other relevant information associated with a patient’s Implantable Device(s).

(ii) Enable a user to electronically record in a patient’s Implantable Device list the following information at the time the Device is implanted or removed:

(A) The Unique Device Identifier associated with the Implantable Device; and

(B) Other relevant information about the Implantable Device or procedure.

(iii) For each Unique Device Identifier in a patient’s Implantable Device list, allow a user to separately access and view electronically the Device Identifier and Production Identifier portions of the Unique Device Identifier.

Preamble FR Citation: 79 FR 10894

Specific questions in preamble? Yes

**Public Comment Field:**

The inclusion of these very complex and detailed criteria in EHR certification is premature for implementation for the 2015 NPRM. Much work remains to be completed by FDA to develop the GUDID device identification databases as proposed within this rule. The EHRA supports storing only the Unique Device Identifier (UDI) number as structured data in the EHR for the 2017 Edition NPRM. We do not support any additional requirements as proposed in this NPRM regarding additional data capture, minimum set of data elements, incorporation of GUDID device identification attributes, generating lists of patients, or reporting. The capture of the product identifier information could be problematic and should remain flexible, allowing either manual or electronic capture. The EHR could thus enable the identifying device number to be provided and exchanged within existing standardized documents. This information could be used by other systems to perform the functions associated with the proposed 2015 NPRM Edition criteria.

We do not believe these criteria have general relevance in the ambulatory setting and request removal of this criterion from ambulatory certification. In the hospital setting, we believe this information will at best be captured in surgical information systems and not within EHRs as workflows advance within the surgical setting. It is essential to understand the workflows associated with implantable devices in order to best determine how this information could appropriately be captured. It is our belief that EHRs are not readily available in these settings. We understand the issues around safety and identification of patients with implanted devices. In consideration for these points, we seek to identify how the EHR might best address these concerns.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 2 100-300 hrs “New” criterion	Enable user to electronically record, access, and view the UDI: 1,260 hrs  Parse UDI for device identifier and production identifier: 560 hrs  Automate retrieval of information from the GUDID: 980 hrs*  Include UDI in CCDA: 740 hrs  Generate list of patients with particular	The ONC estimate is significantly underestimated.  <i>Statistical comments:</i>  <i>Enabling a user to electronically record, access, and view UDI was estimated as small by approximately half of estimators, while approximately half of estimators indicated the project was jumbo, indicating variation across EHR</i>

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

	device: 380 hrs  *Estimates are for items that are not proposed but where public comment is solicited.	<i>developers. There was a similar split between small and large for automating retrieval from the GUDID.</i>
--	--	---

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

### MU Objective

The EP, EH, or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.

### 2015 Edition EHR Certification Criteria

(1) Transitions of care. (i) Send and receive via edge protocol. EHR technology must be able to electronically:

(A) Send transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(e) and that leads to such summaries being processed by a service that has implemented the standard specified in §170.202(a); and

(B) Receive transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(e) from a service that has implemented the standard specified in §170.202(a).

(ii) Receiving accuracy. EHR technology must meet or exceed the standard specified at §170.212(a)

(iii) Display.

(A) EHR technology must be able to electronically display in human readable format the data included in transition of care/referral summaries received and formatted according to any of the following standards (and applicable implementation specifications) specified in: §170.205(a)(1) through (4).

(B) Section views. Extract and 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 the standard adopted at §170.205(a)(3).

(iv) Create. (A) Enable a user to electronically create a transition of care/referral summary formatted according to the standard adopted at §170.205(a)(4) that includes, at a minimum, the Common MU 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 specified §170.207(a)(3);

(2) Immunizations. The standard specified in §170.207(e)(2);

(3) Cognitive status;

(4) Functional status;

(5) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information;

§ 170.315(b)(1) (Transitions of care)

(6) Inpatient setting only. Discharge instructions; and

(7) Unique Device Identifier(s) for a patient's implantable device(s).

(B) Patient matching data quality. EHR 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, middle name (or middle initial in cases where only it exists/is used), suffix, date of birth, place of birth, maiden name, 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 current and historical address information, including the street address, city, state, zip code, according to the United States Postal Service format;

(6) 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.

(7) Constraint. Represent sex according to the HL7 Version 3 ValueSet for Administrative Gender.

Preamble FR Citation: 79 FR 10896

Specific questions in preamble? Yes

**Public Comment Field:**

EHRA supports the separation of transport and content in principle, as well as the inclusion of "incorporation" in clinical reconciliation and incorporation criterion, and believe this is a much better fit into normal workflow within an EHR. However, we would like to note the following concerns:

*UDI*

The EHRA supports the capture of the UDI number (as a single field only) starting with the 2017 Edition. We also support inclusion of the UDI number in the CCDAs document at the same time. We do not believe these criteria have relevance in the ambulatory setting and request removal from ambulatory certification. We believe the additional information associated with the UDI is best supported by registries and not supported by workflows utilized within EHRs. We also suggest that, since multiple health IT modules beyond EHR modules are involved in the capture and communication of this data, ONC should focus on an effort to clearly define how to communicate this data beyond the CCDAs.

*Transport*

EHRA understands the transport issues that complicated the 2014 Edition certification. The EHRA agrees with ONC that the tight coupling of content and transport has caused substantial deployment challenges for providers and EHR developers alike. Although it could have been much better solved for the 2014 Edition, we support the flexibility afforded from the uncoupling of content and transport. However, we are concerned that the introduction of the edge protocol guidance document introduces ambiguity and

concern. We note that the original intent of the document was not to be included in regulations, thus it requires some work before it is used as such. The edge protocol flexibility as described in the guidance document will effectively require all exchange participants, including vendors and HISPs to support all protocols, since no single protocol is established as a minimum. We recommend that one of the protocols be identified as a minimum protocol that all must support, and allow for any other protocols (whether one of the remaining three or any one not documented in the edge protocol document) is permissible without requiring certification for those, nor allowing programs referencing the edition to disallow their use to be eligible for certain thresholds.

#### *Interoperability Compatibility*

We are very concerned that the 2015 Edition NPRM references a document that has not been published yet (i.e., HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.0) and is expected to have a different name once it is published to remain in sync with R1.1 (HL7 Implementation Guides for CDA Release 2: IHE Health Story Consolidation, DSTU Release 2 - US Realm). The absence of a complete document for review provides no opportunity to assess the full impact of this guide before the comment period opened, and at most a week or two before the comment period closes. We, therefore, consider this guide premature and inappropriate for use in the 2015 Edition, although it should be considered for the 2017 Edition. This approach will also avoid a serious interoperability compatibility issue where those who have not implemented the 2015 Edition cannot adequately process more current versions of CCDAs beyond V1.1. Having multiple active editions generally is not advisable for interoperability capabilities as senders and receivers should all be working with the same version to avoid interoperability conflicts. This is even more important as both senders and receivers, whether both are EHRs or other health IT (e.g., agencies, content providers, laboratories, etc.) begin to reference the edition.

#### *Performance*

We are extremely concerned about and oppose the proposals for Cross-Vendor Exchange. It is essential the CCDAs being used to demonstrate Cross-Vendor Exchange must be validated for accuracy at creation before being considered feasible for receipt. We also note concern that, even with such validation as failure to receive the CCDAs properly, it does not confirm that the problem is the receiving EHR. The failure to properly receive the CCDAs could be the responsibility of the sending EHR.

The proposal of 100-1000 CCDAs with 95% accuracy is impractical and could be quite time-consuming and expensive to implement, both in testing preparation prior to certification and during the certification testing process. If adopted, it is essential that vendors have access to a library of high quality CCDAs guaranteed to pass quality standards when created. Certification testing is expensive and the time required to test 25 CCDAs, much less 100 or 1000 could far exceed any value from such revised certification requirements. Our past experience with availability of properly functioning testing tools in a timely manner causes concern. In addition, we support pre-testing outside the ACB certification testing process. This ability would allow time for vendors to work together to resolve these issues in a more efficient process than during the certification testing. Vendors could validate results for a specified number of library documents and submit attestation documentation as permitted on other criteria. If this cannot be tested efficiently during the pre-testing or ACB certification testing process, we must find another acceptable process or remove this requirement entirely.

#### *Patient Matching*

With regards to patient matching proposals, we first point out that not all proposed data elements defined are currently captured by EHRs, with some captured by practice management or similar systems and imported into the EHR via interface, and if captured may not be in the constrained formats. We find it problematic and potentially a mistake to include such specificity in the 2015 Edition NPRM. It is premature to propose such significant demographics changes, which would likely lead to unexpected and negative consequences. Providers must understand the necessity of the data capture within the EHR and the potential consequences upon CCDAs validation. While knowing the majority of EHRs utilize various approaches, we question whether the cost associated with such imposing data sets and constraints is appropriate without further evaluation for the 2017 Edition NPRM as well. We also raise concerns about the effects this constrained data capture and potential effects on interfaces and additional systems utilizing current EHR data. If the data is captured, the EHR should be capable of exchange, but not without determining the effects on the connected

§ 170.315(b)(1) (Transitions of care)

systems.

With regard to the patient matching data transmission proposals, we must point out as above that not all data elements proposed are currently captured by EHRs, and if captured may not be in the constrained formats. We find it problematic and potentially a mistake to include such specificity in the 2015 Edition NPRM without further understanding the cost and benefits of this approach. We understand that a report was just issued for ONC on patient matching suggesting the fields included in the 2015 Edition NPRM, but suggest there has not been adequate time to fully evaluate that report and pilot test its recommendations.

Key considerations to determine the value of this approach:

- Ease of data collection – While some specified data is currently collected, other data, such as historical address information may or may not be retained in the EHR. There needs to be clarity whether such data has value to the provider, or whether alternative data that is already captured can serve equal or better purposes if the primary purpose is to improve on patient matching.
- Privacy and security – An essential principle is to send as little PHI as possible along with the document that is sufficient for the recipient to recognize the patient and have context for the content.
- Ability to match – Some studies have suggested that use of data like that proposed, without the use of part of or a whole unique identifier, does not increase the matching quality to desired levels, and thus does not substantially reduce the manual effort needed to correctly match incoming documents to the right patient to a level warranting implementation of this proposal, certainly in a 2015 time frame.

Taking these considerations into account, we suggest that the focus should be on establishing the minimum data set that in combination with a partial/complete unique identifier selected by the end users can yield high-quality matches and establish clear data capture and format standards for those. In the absence of that, providing any standards for the 2015 Edition has a high risk and high costs without meaningful benefits. We do think that ONC may have an important role in identifying best practices for data sets that can enhance matching accuracy for voluntary market testing and adoption.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 2 100-300 hrs “Revised” criterion	Decouple content and transport – EHRs use EDGE with IMAP4, POP3, SMTP, or IHE XDR: 1,380 hrs  Updated CCDA Release 2 from Sept 2013: 1,060 hrs  CCDA flexibility 95% performance standard: 1,510 hrs  Standardized patient matching data: 1,220 hrs	The ONC estimate is significantly underestimated.

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

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

**MU Objective**

The EP, EH, or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.

**2015 Edition EHR Certification Criteria**

(2) **Clinical information reconciliation and incorporation.** (i) **Correct patient.** Upon receipt of a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(4), EHR technology must be able to demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient.

(ii) **Reconciliation.** Enable a user to electronically reconcile the data that represent a patient's active medication, problem, and medication allergy list as follows. For each list type:

(A) Electronically and simultaneously display (i.e., in a single view) the data from at least two list 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 electronically 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)(2);

(2) **Problems.** At a minimum, the version of the standard specified in § 170.207(a)(3);

(3) **Medication allergies.** At a minimum, the version of the standard specified in § 170.207(d)(2).

Preamble FR Citation: 79 FR 10901

Specific questions in preamble? Yes

**Public Comment Field:**

EHRA supports gathering experience with the existing functionality before any consideration for expansion in the 2017 Edition NPRM. This certification requirement has little utilization currently and providers must learn to adopt the necessary workflows to derive benefits of current reconciliation/incorporation functionality not required for meaningful use. At most, support for a new CCDA version should be optional while the CCDA 1.1 remains required as long as providers may not use the 2015 Edition.

We also caution ONC to consider the current HIT Policy Committee Stage 3 proposals for functionality to reconcile additional information in the EHR. Ultimate CMS proposals for meaningful use should be aligned with ONC proposed certification functionality expansion. We believe this lack of experience with utilization also applies to any consideration of retention of outside/external data sources provenance as part of the incorporation process. Adding provenance would likely be a major "lift" in terms of database structure and workflow. We must have time for providers to adopt the technology before pursuing expansion.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 1	Retain outside data provenance after incorporation: 1,260 hrs*	The items for which ONC solicits public comment represent a significant

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

40-100 hrs "Revised" criterion	*Estimates are for items that are not proposed but where public comment is solicited.	development investment.
-----------------------------------	---	-------------------------

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

### MU Objective

Generate and transmit permissible prescriptions electronically (eRx).

### 2015 Edition EHR Certification Criterion

(3) **Electronic prescribing.** Enable a user to electronically create prescriptions and prescription-related information for electronic transmission in accordance with:

- (i) The standard specified in § 170.205(b)(2); and
- (ii) At a minimum, the version of the standard specified in § 170.207(d)(2).

Preamble FR Citation: 79 FR 10901

Specific questions in preamble? *No*

### Public Comment Field:

EHRA supports no change in the criterion. However, NCPDP issued a guidance document in August 2012 that should be considered for inclusion.

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

### MU Objective

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

### 2015 Edition EHR Certification Criteria

(4) **Incorporate laboratory tests and values/results.** (i) **Receive results.** (A) **Ambulatory setting only.** (1) Electronically 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)(2).

(2) Electronically display the tests and values/results received in human readable format.

(B) **Inpatient setting only.** Electronically receive clinical laboratory tests and values/results in a structured format and electronically display such tests and values/results in human readable format.

(ii) Electronically display the test report information:

(A) Specified in 42 CFR 493.1291 (a)(1) through (a)(3) and (c)(1) through (c)(7);

(B) Related to reference 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).

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

**(iii) Electronically attribute, associate, or link a laboratory test and value/result with a laboratory order or patient record.**

**Preamble FR Citation: 79 FR 10901**

**Specific questions in preamble? No**

**Public Comment Field:**

The EHRA supports adoption of the errata as they include a number of corrections that improve clarity of the guide. We also support not extending the LRI IG to the inpatient setting at this point.

However, we are concerned with the proposed inclusion of CLIA regulatory language that applies to laboratories, but does not extend appropriately to providers “as-is.” Specifically regarding, we note that the suggested CLIA regulatory requirements (e. g., alerts and delays as specified in 42 CFR 493.1291(g) and (h)) apply to laboratory behavior and should not be provider requirements. Language meant for laboratories should not be added to criteria intended for providers, and vice versa.

We believe that the LRI IG establishes the clear set of data that is relevant as part of a lab report, while the regulatory text referenced implies more data to be made available without specifying what that additional data would be. ONC should facilitate involvement of provider representation in the S&I Framework Laboratory Results initiative if there is a concern that not enough data is included. Such involvement would help validate the practical value of such data and makes any decisions more clear than the CLIA regulatory language provides to laboratories.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 1 40-100 hrs “Revised” criterion	Adopt HL7 2.5.1 S&I LRI R1: 680 hrs Display lab results according to CLIA: 860 hrs	The ONC estimate is significantly underestimated.

**§ 170.315(b)(5) (Inpatient setting only – transmission of electronic laboratory tests and values/results to ambulatory providers)**

**MU Objective**

**Provide structured electronic laboratory results to eligible professionals.**

**§ 170.315(b)(5) (Inpatient setting only – transmission of electronic laboratory tests and values/results to ambulatory providers)**

**2015 Edition EHR Certification Criteria**

**(5) Inpatient setting only—transmission of electronic laboratory tests and values/results to ambulatory providers. EHR technology must be able to electronically create laboratory test reports for electronic transmission:**

**(i) That includes the information:**

**(A) For a test report as specified in 42 CFR 493.1291 (a)(1) through (a)(3) and (c)(1) through (c)(7);**

**(B) Related to reference 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); and**

**(ii) In accordance with the standard specified in § 170.205(j)(2) and with laboratory tests expressed in accordance with, at a minimum, the version of the standard specified in § 170.207(c)(2).**

**Preamble FR Citation: 79 FR 10901**

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

**Public Comment Field:**

EHRA understands the current S&I proposals are heavily driven by laboratories without significant provider representation. We support encouraging more provider perspectives in the WG to help determine the essentials for making the functionality most useful to providers. We are concerned about the scope as the S&I framework seems to be moving beyond standards development fostering interoperability. Some recent proposals seem more focused on certification criteria than standards for interoperability, (e.g. (C) For alerts and delays as specified in 42 CFR 493.1291(g) and (h)). We question these specific requirements for EHRs to display information that would routinely be captured in laboratory systems and not EHRs. The EHR is capable of displaying values and flags, but the information included in this criterion exceeds typical information available in the EHR.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 1 40-100 hrs "Revised" criterion	Adopt HL7 2.5.1 S&I LRI R1 with errata: 500 hrs Include in test report more specific CLIA information: 1,370 hrs	The ONC estimate is significantly underestimated.

**§ 170.315(b)(6) (Data portability)**

**MU Objective**

**N/A**

## § 170.315(b)(6) (Data portability)

### 2015 Edition EHR Certification Criterion

(6) **Data portability.** Enable a user to electronically create a set of export summaries for all patients in EHR technology formatted according to the standard adopted at § 170.205(a)(4) that represents the most current clinical information about each patient and includes, at a minimum, the Common MU 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 at § 170.207(a)(3);

(ii) **Immunizations.** The standard specified in § 170.207(e)(2);

(iii) **Cognitive status;**

(iv) **Functional status;**

(v) **Ambulatory setting only.** The reason for referral; and referring or transitioning provider's name and office contact information;

(vi) **Inpatient setting only.** Discharge instructions; and

(vii) **Unique Device Identifier(s) for a patient's Implantable Device(s).**

Preamble FR Citation: 79 FR 10902

Specific questions in preamble? Yes

### Public Comment Field:

EHRA supports only inclusion of the UDI in the CCDA for the 2017 Edition NPRM. We believe the additional information associated with the UDI, as also proposed is best supported by registries and not supported by workflows utilized within EHRs.

The introduction of a new CCDA version creates an interoperability incompatibility issue as multiple Editions (2014 and 2015) can be deployed. Consequently, a system certified to the 2014 Edition cannot be assumed to be able to receive CCDA documents from a 2015 Edition certified system. We strongly advise against maintaining multiple active editions to avoid such interoperability incompatibilities, whether CCDA or any other data exchange with any receiver (e.g., laboratory, agencies, patients, etc.) EHRA does not support the updated version of the CCDA at this time and believes that the criteria for TOC and data portability should remain aligned on the same standard and IG.

EHRA opposes data portability expansion for the 2017 Edition NPRM. EHRA also does not support renaming certification criteria for data portability as "data migration." We believe data migration is a far more extensive undertaking than the current or proposed data portability criterion and not appropriate for standardization via certification. We believe it would be confusing to label such current or revised criteria as "data migration" when the focus is a summary or subset of information within the CCDA.

Noting this, we must continue to evaluate how the CCDA documents can best be used moving forward. We are concerned about the volume of documents and the length of time required including them for data portability all when the priority seems to be a summary of current information. Depending on the patient, the volume of documents could be immense. We also question the value of the current data portability criterion in the hospital setting. Overall, we propose that data portability remain focused on the minimum data set summary contained in the associated CCDA standard and to not further complicate the complexity by expanding the CCDA to accomplish true data migration which will tend to be highly situation-specific.

We are concerned with the inclusion of notes in portability requirements as there are multiple types of notes, many extending over

**§ 170.315(b)(6) (Data portability)**

a long period of time. It could be a difficult process to determine how to incorporate all note formats and options into current data portability expansion. EHRA also does not support for inclusion in the 2017 Edition NPRM proposals for a broader range of portability use cases. It is premature to suggest such functionality and question whether this level of migration capability should ever be considered as certified EHR functionality.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 1 40-100 hrs "Revised" criterion	Updated CCDA Release 2 from Sept 2013: 1,060 hrs Including UDI: 690 hrs Adding electronic notes: 910 hrs* Expanded time boundary for longitudinal data: 1,640 hrs* Header metadata for import/export: 1,210 hrs* Local access/query through an API: 1,740 hrs* Inter-organizational query: 1,500 hrs* Distributed multi-source access/query: 1,500 hrs* *Estimates are for items that are not proposed but where public comment is solicited.	The ONC estimate is significantly underestimated.

**Clinical Quality Measures – Electronically Processing eMeasures**

Preamble FR Citation: 79 FR 10902

Specific questions in preamble? Yes

**Public Comment Field:**

The EHRA generally supports the efforts to align standards for both CQMs and CDS through the newly launched Clinical Quality Framework (CQF initiative) of the Standards and Interoperability (S&I) framework. We also agree with the strategy to modularize components of the standards to help improve the ability to implement new versions of each standard independently. The EHRA also agrees that, at the very least, the HQMF should be improved, and generally would consider HQMF being replaced by another format that is more efficient than HQMF. As an association, we are also open to consideration of another format or alternative ideas that would improve the accuracy and efficiency of the implementation of an eMeasure. Some of our members have suggested JSON as an alternative standard and, in fact, have been using this standard in their eMeasure implementation process in order to streamline the incorporation of the HQMF.

At the same time, the EHRA feels strongly that some of the standards being proposed are not yet at a place of maturity or even basic implementation in the industry to make assessments about whether they would be appropriate or suitable for inclusion as a requirement for 2017 Edition certified EHR technology. For example, the HQMF Release 2 was only recently published by HL7; and since EHR vendors are still in the process of implementing the HQMF Release 1 requirement included in 2014 Edition EHR certification, it is difficult to assess or determine with any reliability the level of effort it would take to implement this new standard in a consistent manner. The CQF effort is, in fact, considering HQMF Release 2.1, which we do not feel is ready for consideration as it is still in active development by HL7. In addition, both subsequent versions of HQMF are not backwards compatible to previous versions, so we are concerned about the impact to both current customer implementations as well as to the process and tight timeframe for annual measures updates.

The EHRA is also concerned that the current timeline for Stage 3/2017 Edition certified software does not provide sufficient time to ensure that the critical improvements all stakeholders have undertaken for the CQM development, testing, and implementation process continue to advance, and are not compromised by rapidly changing standards and certification requirements that are not fully developed, tested, and piloted. The 2017 Edition of certified software would require full implementation by an EH by October 1, 2016. In order to accommodate the requisite 18 month timeframe that we have reiterated is necessary, a final rule, along with all supporting materials and tools including CQM specifications, must therefore be available no later than March, 2015, less than one year from now and well before the publication time projected by ONC. The inclusion of this framework in 2017 Edition certified software is therefore not feasible given this compressed timeline and the scope of the work required, including allowing adequate time for stakeholder input to the standards now under development, testing and piloting, and subsequent modifications to the standards. In addition, this timeline does not allow adequate time for ensuring that all associated processes, standards, and tools are fully addressed, such as re-engineering the measure authoring tool (MAT), the current CQM specifications, and development of new CQM specifications, along with new certification tools and processes.

The EHRA urges ONC not to include the proposed unified CDS/CQM standards in the requirements for 2017 CEHRT. Without thorough development and testing, the ability to accurately measure healthcare quality and outcomes along with the validity of the results may be compromised. As a result, rather than enhancing patient safety, implementation of clinical decision support and clinical quality measures intended to improve care may actually threaten it. These unintended consequences could become a potential barrier to the continued adoption of EHR technology and innovative payment and care delivery models. In addition, introducing standards that will require substantial revision and/or will potentially be replaced within a short period of time will create unnecessary re-work. We urge ONC and CMS to consider a more incremental approach to the eventual implementation and adoption of these standards, ensuring that each one has been fully tested and piloted prior to requiring adoption by all EHRs.

ONC also asked about possible ways to classify measures, along with the readiness of EHR technology to electronically “consume” the HQMF specification and map it to data found within the EHR. EHRA agrees that it could be possible to classify this data by identifying certain data elements, attributes, and logic that would be more difficult to implement, also taking into consideration provider workflows. For example, composite measures, or measures that look at longitudinal data over time, could be classified as high complexity. EHRA offers our assistance to work with ONC, CMS, and the measure developers to refine this capability.

In regard to the questions on the ability and readiness of EHR technology to store and incorporate an eCQM in HQMF R2 as well as to map the HQMF R2 standard to data within the EHR technology (including medications, laboratory, allergies information), EHRA is opposed to requiring this standard for 2017 for several reasons:

1. The HQMF generated by the measure authoring tool is often highly inefficient in its structure and logic. For example, one measure examines all patients to see if they are pregnant BEFORE determining which patients are male or female. As EHR developers, we often have to revise illogical and inefficient methods of traversing the large amounts of patient data found within EHRs in order to ensure that software design is as efficient as possible, and won't have a negative impact to system performance.
2. As we commented on previously in this response, HQMF R2 is immature as a standard and, to our understanding, does not support patient filtering. In addition, as mentioned previously, since the CQF S&I initiative is proposing HQMF R2.1, we need to standardize on one release AND ensure that release has been fully tested and piloted before requiring widespread use. HQMF is also inefficient at querying data.
3. The data needed to satisfy the measure is often not all found within one product/database, especially when requiring data from specialty departments such as surgery, imaging, or other areas likely to have their own specialty products in place.

### Clinical Quality Measures – Functions and Standards for CQM Certification

**Preamble FR Citation: 79 FR 10903**

**Specific questions in preamble? Yes**

EHRA is generally supportive of ONC and CMS working to include data elements as part of certification that may be leveraged for other quality reporting programs beyond the EHR Incentive Program. The difficulties with the past additions of data elements has not been the supplemental data elements themselves, but rather the difference between what EHR technology was required to demonstrate for the purposes of certification and these new requirements. EHRA strongly encourages ONC to work closely with the other agencies of HHS that may wish to leverage certification as a means to incorporate required data elements to determine which requirements are suitable or acceptable for certification.

In addition, it is important to remember that not all EHR technology serves providers who participate in each of the HHS quality programs; therefore it may be more appropriate to keep the software development that would be needed to support those programs separate and distinct from the software development required for certification. For example, an agency such as CMS could require that certain data elements be included in the QRDA's that are submitted as part of a new quality improvement program, but instead of requiring that those data elements be incorporated into ONC EHR certification, CMS could instead work closely with EHR vendors during the development of the requirements to determine which products would be impacted (e.g., what products are participating providers using), but also how those requirements can be refined in a way that facilitates development in a suitable timeframe for the program. At the same time, every effort should be made by the various HHS quality programs to rely on the criteria established for the EHR incentive program, which is not intended to be an end in itself, but rather a means to enable broad availability of roughly useful and applicable EHR functionality.

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

**MU Objective**

N/A

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

**2015 Edition EHR Certification Criterion**

**(1) Clinical quality measures—capture and export. (i) Capture.** For each and every CQM for which the EHR technology is presented for certification, EHR technology must be able to electronically record all of the data identified in the standard specified at § 170.204(c) 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.** EHR technology must be able to electronically export a data file formatted in accordance with the standards specified at § 170.205(h) that includes all of the data captured for each and every CQM to which EHR technology was certified under paragraph (c)(1)(i) of this section.

Preamble FR Citation: 79 FR 10903

Specific questions in preamble? Yes

**Public Comment Field:**

ONC has proposed the use of a QRDA category II format for submission in 2017. This requirement was introduced to allow access to patient level data that is not available through QRDA III. However, EHRA believes that this data is available now through a combination of QRDA III and I, not necessarily requiring QRDA II.

Furthermore, QRDA II has only passed a “for comment” HL7 ballot as part of the original QRDA DSTU and therefore cannot be recognized as even a DSTU. We, therefore, suggest that considering QRDA II for either the 2015 Edition or the 2017 Edition is premature.

We also note that at this time, QRDA I and III are not yet used widely, so we have not been able to address any potential problems that may occur when transmitting volumes of data using both these standards. We recommend that until the industry has been able to successfully implement and export both QRDA I and QRDA II formats for both EH and EP, and CMS has been able to successfully receive both formats, additional untested draft formats such as QRDA II should not be introduced.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 2 100-300 hrs “Unchanged” criterion	Store and incorporate eCQM using HQMF R2: 2,210 hrs* Map HQMF R2 to data in the EHR: 1,680 hrs* Support QRDA II: 1,650 hrs* Additional supplemental data elements: 1,120 hrs* *Estimates are for items that are not proposed but where public comment is solicited.	The items for which ONC solicits public comment represent a significant development investment.  <i>Note – estimators indicated that estimates for “Store and incorporate eCQM using HQMF” required higher estimates than were supported in our survey scale, so numbers given are likely under-estimated due to that limitation.</i>

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

**MU Objective**

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

N/A

**2015 Edition EHR Certification Criterion**

**(2) Clinical quality measures—import and calculate. (i) Import.** EHR technology must be able to electronically import a data file formatted in accordance with the standard specified at § 170.205(h) and use such data to perform the capability specified in paragraph (c)(2)(ii) of this section. EHR technology presented for certification to all three of the certification criteria adopted in paragraphs (c)(1) through (3) of this section is not required to meet paragraph (c)(2)(i).

(ii) Calculate. EHR technology must be able to electronically calculate each and every clinical quality measure for which it is presented for certification.

Preamble FR Citation: 79 FR 10903

Specific questions in preamble? *No*

**Public Comment Field:**

EHRA supports the proposal that this criterion remain unchanged in the 2015 certification requirements.

**§ 170.315(c)(3) (Clinical quality measures – electronic submission)**

**MU Objective**

N/A

**2015 Edition EHR Certification Criteria**

**(3) Clinical quality measures—electronic submission.** Enable a user to electronically create a data file for transmission of clinical quality measurement data:

(i) In accordance with the standards specified at § 170.205(h) and (k); and

(ii) That can be electronically accepted by CMS.

Preamble FR Citation: 79 FR 10903

Specific questions in preamble? *No*

**Public Comment Field:**

EHRA generally supports the proposal that this criterion remain unchanged in the 2015 certification requirements. However, we call attention to the statement in (3) (ii), “that can be electronically accepted by CMS.” EHRA has provided extensive documentation in letters to CMS and ONC about why this statement is inaccurate, therefore, we object to this clause since it is not currently feasible. CMS provides additional requirements in the additional implementation guides that they produce. It is also our understanding that CMS cannot accept a QRDA file that is generated according to the generic QRDA implementation guide to which vendors certify.

**§ 170.315(c)(4) (Clinical quality measures – patient population filtering)**

**MU Objective**

N/A

**2015 Edition EHR Certification Criterion**

**(4) Clinical quality measures – patient population filtering.** EHR technology must be able to record structured data for the purposes of being able to filter CQM results to create different patient population grouping by one or a combination of the

**§ 170.315(c)(4) (Clinical quality measures – patient population filtering)**

**following patient characteristics:**

- (i) Practice site and address;**
- (ii) Tax Identification Number (TIN), National Provider Identifier (NPI), and TIN/PIN combination;**
- (iii) Diagnosis;**
- (iv) Primary and secondary health insurance, including identification of Medicare and Medicaid dual eligibles; and**
- (v) Demographics including age, sex, preferred language, education level, and socioeconomic status.**

**Preamble FR Citation: 79 FR 10903**

**Specific questions in preamble? Yes**

**Public Comment Field:**

In their current form, the QRDA standards are capable of including the data components that would be necessary to filter CQMs by certain patient population characteristics, although there are not current standards for all of the suggested data elements in the proposal, which makes it difficult to standardize how this filtering could occur in a consistent manner. For example, while there are standard ways to represent metadata such as TIN and NPI, there are not standard ways to represent data elements such as education level and/or socioeconomic status. Even when looking at the data elements are collected in a standard way, it seems to be beyond the scope of EHR certification to require that all EHRs demonstrate this type of functionality. Additionally, there are very small numbers of cases where this type of detailed filtering would be required or, potentially, there are no known situations where providers would need to report specifically on some of these suggested filters. In addition, the ability to filter and/or complete additional analytics on clinical quality measure data may be seen as a proprietary offering by EHR companies and should not be included as part of EHR certification.

Also, these data elements seem to be focused on the ambulatory/EP segment, rather than the hospital/EH segment. As we stated previously in our response to “Clinical Quality Measures – Functions and Standards for CQM Certification”, we believe it would be more efficient if CMS and other relevant HHS agencies define the subset of all data required for patient filtering.

EHRA offers specific comments on the data elements listed in the proposed rule:

1. For the first three elements listed (practice site/address, TIN/PIN, and diagnosis), should allow null value in case of no entry.
2. Practice site and address – There is hidden complexity within this requirement. A physician practice could have multiple physician addresses that are all one clinic. Does CMS expect this data element to line up with their definitions of practice site?
3. TIN/PIN – Some providers may practice in multiple TINs. In addition, there are different levels of PIN numbers.
4. Diagnosis – When considering diagnosis, it is important to define which diagnosis (admitting, working, final, etc). 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., QRDA file only needs the data elements that qualify the patient for the CQM). An EHR would have to continue searching through the patient data to find this information, which subsequently would increase the size of the QRDAs. This is related to the "Goldilocks" concept discussed at the February 2014 Kaizen - the CQMs should determine the right size of the data.
5. Demographics - Education level – To our knowledge, there is no current standard or certification requirement for the education level, and a vocabulary must be named. This data element is also not generally captured today in an EHR. For these reasons, EHRA does not believe this is feasible for consideration in 2015.
6. Demographics - Socioeconomic status – Socioeconomic status includes a combination of different variables, including occupation, education (mentioned above), income, wealth, and place of residence. This data category needs additional definition, as well as standards defined. To our knowledge, there is no current standard or certification requirement for education level, and a vocabulary must be named. This is also not generally captured today in an EHR. For these reasons,

**§ 170.315(c)(4) (Clinical quality measures – patient population filtering)**

EHRA does not believe this is feasible for consideration in 2015.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 3 300-400 hrs “New” criterion	Patient population filtering: 1,580 hrs	The ONC estimate is significantly underestimated.

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

**MU Objective**

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

**2015 Edition EHR 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 EHR technology.

Preamble FR Citation: 79 FR 10904

Specific questions in preamble? Yes

**Public Comment Field:**

EHRA supports not duplicating the DEA certification processes for two-factor authentication required for electronic prescribing of controlled substances. We support the flexibility of adoption in the marketplace as determined by providers choosing to utilize EPCS and do not support inclusion of DEA certification or other two-factor authentication requirements for 2017 Edition NPRM. Not all providers prescribe controlled substances and so do not desire such authentication requirements or enhancements to their EHRs. More adoption must occur on the forefront of EPCS before additional requirements are practical, whether for EPCS or remote access.

Two-factor authentication is not a core EHR competency. The proposal for two-factor authentication at the application level fails to recognize organizational policies and technology implementations currently utilized as supporting needs in the marketplace for remote access. Currently, the majority of vendors provide remote access beyond the organization or compliance environment by requiring authentication connectivity via VPN, or some other comparable secured entry-point. We are, of course, concerned about authentication complexity involving remote access via cloud services or remote devices such as cellphones. However, we question why such requirements would be imposed on EHRs at this time. EHRA supports flexibility regarding secure remote access without regulatory imposition of a specific method.

Finally, the distinction between “remote access” and local access can set up a false dichotomy. Oftentimes, the internal network should not be considered secure, either because of large complex networks, “BYOD” policies, firewall holes, and un-patched systems. We point to the recent retail data breaches that occurred on retailers’ internal networks as examples. Rather than adopt a one-size-fits-all approach to remote access, we encourage a flexible approach that allows provider organizations to implement

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

security controls that are appropriate for them based on security risk analysis.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 2 100-300 hrs "Unchanged" criterion	Two factor authentication: 1,270 hrs* *Estimates are for items that are not proposed but where public comment is solicited.	The ONC estimate is significantly underestimated.

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

**MU Objective**

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

**2015 Edition EHR Certification Criterion**

**(2) Auditable events and tamper-resistance.** (i) **Record actions.** EHR technology must be able to:

(A) Record actions related to electronic health information in accordance with the standard specified in § 170.210(e)(1); and

(B) Record the encryption status (enabled or disabled) of electronic health information locally stored on end-user devices by EHR technology in accordance with the standard specified in § 170.210(e)(3) unless the EHR technology prevents electronic health information from being locally stored on end-user devices (see 170.314(d)(7) of this section).

(ii) **Default setting.** EHR 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).

(iii) **Prevent disabling.** EHR technology must prevent all users from being able to disable the capabilities specified in paragraphs (d)(2)(i)(A) and (B) of this section through the EHR technology.

(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 EHR technology.

(v) **Detection.** EHR technology must be able to detect whether the audit log has been altered.

Preamble FR Citation: 79 FR 10904

Specific questions in preamble? Yes

**Public Comment Field:**

EHRA supports identification of a baseline critical list of typical security auditable actions, such as additions, deletions, and changes that could not be disabled through the EHR technology as indicated in the specified standards for proposal in the 2017 Edition NPRM. In particular, we support the scope limitation that this disabling cannot occur through the EHR technology by regular EHR users. This provision should not preclude, however, a system administrator from disabling the audit trail for legitimate reasons (e.g., performance, stability, disaster recovery, system updates, etc.).

We emphasize that many technology vendors offer additional auditing parameters that may or may not be enabled by providers;

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

therefore, additional features may be disabled without affecting the baseline critical audit actions specified in (iii) Prevent Disabling. We support the ability to disable these additional audit actions beyond the baseline critical list as necessary by providers to maintain performance of their systems.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 1 40-100 hrs "Revised" criterion	Prevent disabling of audit log through EHR: 500 hrs	The ONC estimate is significantly underestimated.

**§ 170.315(d)(3) (Audit report(s))**

**MU Objective**

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

**2015 Edition EHR 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: 79 FR 10905

Specific questions in preamble? Yes

**Public Comment Field:**

EHRA supports the "query" action using current interpretations. We do not see the need for additional specificity and find the current standards to be up-to-date. EHRA supports the baseline set of actions including additions, deletions, and changes, and believes customer demands within the marketplace will determine the availability of further auditable actions. We do not support adding the act of "transmission" to current standards. We are, of course, cognizant of the fact that the HIPAA Omnibus Rule requirements should remain aligned with certification rules to maintain consistency essential to auditable events.

**§ 170.315(d)(4) (Amendments)**

**MU Objective**

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

**2015 Edition EHR Certification Criterion**

**(4) Amendments.** Enable a user to electronically select the record affected by a patient's request for amendment and perform the capabilities specified in paragraphs (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.

**§ 170.315(d)(4) (Amendments)**

(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: 79 FR 10905

Specific questions in preamble? *No*

**Public Comment Field:**

EHRA supports unchanged criterion.

**§ 170.315(d)(5) (Automatic Log-Off)**

**MU Objective**

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

**2015 Edition EHR Certification Criterion**

(5) Automatic log-off. Prevent a user from gaining further access to an electronic session after a predetermined time of inactivity.

Preamble FR Citation: 79 FR 10905

Specific questions in preamble? *No*

**Public Comment Field:**

EHRA supports unchanged criterion.

**§ 170.315(d)(6) (Emergency access)**

**MU Objective**

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

**2015 Edition EHR Certification Criterion**

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

Preamble FR Citation: 79 FR 10905

Specific questions in preamble? *No*

**Public Comment Field:**

EHRA supports unchanged criterion.

**§ 170.315(d)(7) (End-User Device Encryption)**

**MU Objective**

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

### § 170.315(d)(7) (End-User Device Encryption)

#### 2015 Edition EHR Certification Criterion

(7) End-user device encryption. Paragraph (d)(7)(i) or (ii) of this section must be met to satisfy this certification criterion.

(i) EHR 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 EHR 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)(1).

(B) Default setting. EHR 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) EHR technology is designed to prevent electronic health information from being locally stored on end-user devices after use of EHR technology on those devices stops.

Preamble FR Citation: 79 FR 10905

Specific questions in preamble? *No*

#### Public Comment Field:

EHRA supports unchanged criterion.

### § 170.315(d)(8) (Integrity)

#### MU Objective

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

#### 2015 Edition EHR 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: 79 FR 10905

Specific questions in preamble? *No*

#### Public Comment Field:

EHRA supports unchanged criterion.

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

#### MU Objective

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

#### 2015 Edition EHR 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: 79 FR 10905

Specific questions in preamble? *No*

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

### Public Comment Field:

EHRA supports unchanged criterion. However, we believe that removing the “optional” designation from this criterion may lead to confusion in the marketplace as to whether it is required or not. Thus, we support leaving an “optional” designation for this criterion. In addition, we continue to support that the Accounting of Disclosures criteria remain optional until the Accounting of Disclosures NPRM is finalized.

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

### MU Objective

#### EPs

Provide patients, and their authorized representatives, the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.

#### EHS and CAHs

Provide patients, and their authorized representative, the ability to view online, download, and transmit information about a hospital admission.

### 2015 Edition EHR Certification Criterion

(1) View, download, and transmit to 3rd party. (i) Patients (and their authorized representatives) must be able to use EHR 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 EHR technology to electronically view in accordance with the standard adopted at § 170.204(a)(2), at a minimum, the following data:

(1) The Common MU 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.

(B) Download.

(1) Patients (and their authorized representatives) must be able to use EHR technology to electronically download an ambulatory summary or inpatient summary (as applicable to the EHR technology 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.

(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):

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

**(i) Ambulatory setting only.** All of the data specified in paragraph (e)(1)(i)(A)(1) and (2) of this section and Unique Device Identifier(s) for a patient's implantable device(s).

**(ii) Inpatient setting only.** All of the data specified in paragraphs (e)(1)(i)(A)(1) and (3) of this section and Unique Device Identifier(s) for a patient's implantable device(s).

**(3) Inpatient setting only.** Patients (and their authorized representatives) must be able to electronically 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) Enter a 3<sup>rd</sup> party destination of their choice to electronically transmit:**

**(i) The ambulatory summary or inpatient summary (as applicable to the EHR technology setting for which certification is requested) created in paragraph (e)(1)(i)(B)(1) of this section in accordance with the standard specified in § 170.202(a).**

**(ii) Inpatient setting only.** Electronically 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 the standard specified in § 170.202(a).

**(2) Accomplish a transmission of their ambulatory summary or inpatient summary through a method that conforms to the standard specified at §170.202(e) and that 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, the following information must be recorded and made accessible to the patient:**

**(1) The action(s) (i.e., view, download, transmission) 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) The addressee to whom an ambulatory summary or inpatient summary was transmitted and whether that transmission was successful (or failed).**

**(B) EHR 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.**

Preamble FR Citation: 79 FR 10906

Specific questions in preamble? Yes

**Public Comment Field:**

EHRA does not support the proposed prescriptive language that a patient must be able to download an ambulatory or inpatient summary in only the human-readable format if they just want that, in only the CCDA format if they just want that, or in both formats if they want both. This revised criterion is overly prescriptive and not in synch with actual software development. Many vendors enable users to download the XML version and the style sheet together, since the style sheet is applied to the XML to provide the human-readable information. We believe most patients would find making a choice confusing and do not believe that patients

would benefit from this proposal.

The EHRA agrees with separating transport from content through use of the proposed IG for edge protocol. However, EHRA does not support the proposal for new CCDA standards in the 2015 Edition NPRM. We are very concerned that moving to CCDA 2.0 while CCDA 1.1 is supported in the 2014 Edition could lead to interoperability incompatibilities where a 2015 Edition provider is sending CCDA 2.0 documents to a 2014 Edition provider who cannot process that version. Maintaining multiple active editions, each using different versions of the same interoperability standard, is strongly discouraged. Until an adequate solution is identified to manage these interoperability incompatibility issues, we suggest that interoperability standards versions are not updated more frequently than every three (3) years to enable stable, orderly migrations. EHRA also supports inclusion of adequate time to consider user experience from actual implementations before updating to newer versions.

EHRA is also concerned that CCDA 2.0 is not appropriate to be referenced in the 2017 Edition and as such does not support inclusion in the 2017 Edition NPRM. HL7 ballot reconciliation is in process; however that process remains incomplete at this time (April 14, 2014). There are also a number of template issues that may not be part of the upcoming publication that addresses critical backwards compatibility issues with V1.1. Until these are resolved and published, EHRA does not support inclusion of the updated standard in the 2017 Edition NPRM.

The EHRA is concerned with ONC's statement regarding successful transmission with utilization of any Direct address through use of the new IG for Direct Edge Protocol. The EHR cannot guarantee that any Direct address specified for transmission is capable of reaching the endpoint. Each HISP has rules beyond the EHR's control specifying their exchange with other HISPs. It is our understanding that only Direct Trust/ENHAC-certified HISPs readily agree to exchange documents within their trust circle once the CCDA is exported from the EHR. Outside HISPs that are not Direct Trust/ENHAC-certified are not in the essential trust bundle and may or may not readily exchange information, thus some existing and working Direct addresses affiliated with non-certified HISPs could fail. We do not agree with the need for another transmission method for certification. EHRA believes the current scope is sufficient.

EHRA supports inclusion in the Activity History Log of the Direct address to which the summary was transmitted. For the reasons previously stated, the EHR may not have the transmission success information in a timely manner enable an update to the Activity History log. Receipt of this information is handled differently depending on the HISP.

EHRA supports current Level A adoption for 2017 Edition NRPM and continues to view AA as overly costly and burdensome. EHRA opposes hybrid A-AA standards. With regards to non-web application of WCAG, EHRA offers the following input.

- The use of different types of non-web applications, such as Android or iOS, affect design and testing plans.
- If using a browser on a mobile device, it may be possible to accommodate more areas of WCAG and test these accurately; however, the purpose of using a mobile device would to make it easier on the provider and therefore most EHR developers would develop a native application.
- Issues arise with WCAG standards, such as requiring a keyboard or a mouse since mobile devices are utilized as touch screens.
- Lastly, testing these items according to the test procedures outlined in the test script is impossible. Requirements to run the application through the WCAG accessibility checkers using a native application on non-web devices is not possible when these accessibility checkers are only programmed to check against web-based applications.

The EHRA supports allowing the market to determine the best approach for consideration of making any visit notes available to patients. We believe the market will drive adoption and do not support Open Notes for consideration in the 2017 Edition NPRM.

EHRA offers the following feedback regarding the inclusion of images. The EHRA has not received feedback suggesting patient requests for this information. Should this be considered for future proposals? The EHRA supports additional optional certification criteria for a patient-centric image exchange unrelated to VDT and outside the EHR. Much change is occurring in this area and future

consideration for images or non-text data such as ECGs warrants new proposed solutions. Considering the same granularity challenges that resulted in breaking up CPOE and separating transport from content, we strongly suggest that any imaging capabilities for VDT are separated. This approach will help further maturation of integrated imaging capabilities that do not yet have sufficient standards support to make it easy to integrate image viewing into VDT in parallel to other VDT capabilities.

The rationale for patients to receive diagnostic-quality images is unclear. While a patient could be the conveyor of images to their next provider, the extra bandwidth challenges for patients to support diagnostic-quality images seems unnecessary as minimum capabilities. Direct provider-to-provider exchange of such images when needed and use of shared image repositories, while providing patients with optional access to such images based on market-driven demands, seems sufficient to manage this.

We suggest separating images from other VDT capabilities as a first step towards determining if images should be viewable or downloadable but not required for transmission in future proposals. At most, EHRA suggests only consideration of viewable images at this time as we determine future market needs.

EHRA supports market-driven solutions over time as appropriate steps to determine whether cloud-based technology could allow for a link to accessible images. We do not support inclusion of such proposals in 2015 or 2017 NPRMs.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 2 100-300 hrs "Revised" criterion	Updated CCDA R2 from Sept 2013: 910 hrs Download human readable only, CCDA only, or both if desired: 380 hrs Decouple content and transport: 860 hrs Add UDI to CCDA: 380 hrs Add addressee of transmit and whether transmission was successful to activity history log: 680 hrs Adopt Level AA conformance with WCAG 2.0: 1,060 hrs Patients VDT DICOM images: 2,210 hrs* VDT for other data such as waveforms: 2,140 hrs* Support OpenNotes: 1,060hrs* *Estimates are for items that are not proposed but where public comment is solicited.	The ONC estimate is significantly underestimated. <i>Statistical comments:</i> Note – estimators indicated that estimates for "Patients VDT DICOM images" required higher estimates than were supported in our survey scale, so numbers given are likely under-estimated due to that limitation. Supporting OpenNotes was estimated as small by half of estimators and large or jumbo by half of estimators, indicating variation amongst EHR developers.

**§ 170.315(e)(2) (Ambulatory setting only – clinical summary)**

**MU Objective**

Provide clinical summaries for patients for each office visit.

**2015 Edition EHR Certification Criterion**

**(2) Ambulatory setting only—clinical summary. (i) Create.** Enable a user to create a clinical summary for a patient in human readable format and formatted according to the standards adopted at § 170.205(a)(4).

**(ii) Customization.** Enable a user to customize the data included in the clinical summary.

**(iii) Minimum data from which to select.** EHR technology must permit a user to select, at a minimum, the following data when creating a clinical summary:

**(A) Common MU Data Set** (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set);

**(B) Medications administered during the visit.** At a minimum, the version of the standard specified in § 170.207(d)(2);

**(C) Immunizations administered during the visit.** At a minimum, the version of the standard specified in § 170.207(e)(2);

**(D) Diagnostic tests pending and future scheduled tests.** At a minimum, the version of the standard specified in § 170.207(c)(2);

**(E) The provider’s name and office contact information; date and location of visit; reason for visit; clinical instructions; future appointments; referrals to other providers; and recommended patient decision aids; and**

**(F) Unique Device Identifier(s) for a patient’s Implantable Device(s).**

**Preamble FR Citation: 79 FR 10907**

**Specific questions in preamble? Yes**

**Public Comment Field:**

EHRA opposes the updated CCDA version (Draft Standard for Trial Use, Release 2.0) for the 2017 Edition NPRM. EHRA does not believe the UDI is appropriate for ambulatory providers and as such does not propose inclusion in the clinical summary for the 2017 Edition NPRM. EHRA is concerned about the use of LOINC associated with the ordering process as previously stated. We generally support standardization for interoperability; however, we are concerned about changes in both the ordering and interface connectivity associated with such standardization.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 1 40-100 hrs “Revised” criterion	CVX for immunizations: 550 hrs Updated CCDA R2 from Sept 2013: 860 hrs Include UDI in CCDA: 380 hrs Diagnostic tests pending and future scheduled tests use LOINC: 1,032 hrs EHRs limit data to just one visit: 470 hrs	The ONC estimate is significantly underestimated.

### § 170.315(e)(3) (Ambulatory setting only – secure messaging)

#### MU Objective

Use secure electronic messaging to communicate with patients on relevant health information.

#### 2015 Edition EHR Certification Criterion

(3) Ambulatory setting only—secure messaging. Enable a user to electronically send messages to, and receive messages from, a patient in a manner that ensures:

(i) Both the patient (or authorized representative) and EHR technology user are authenticated; and

(ii) The message content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

Preamble FR Citation: 79 FR 10908

Specific questions in preamble? *No*

#### Public Comment Field:

EHRA supports unchanged criterion.

### § 170.315(f)(1) (Immunization information)

#### MU Objective

Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

#### 2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10908

Specific questions in preamble? *No*

#### Public Comment Field:

EHRA supports unchanged criterion.

### § 170.315(f)(2) (Transmission to immunization registries)

#### MU Objective

Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

#### 2015 Edition EHR Certification Criterion

(2) Transmission to immunization registries. EHR technology must be able to electronically create immunization information for electronic transmission in accordance with:

(i) The standard and applicable implementation specifications specified in § 170.205(e)(4); and

(ii) At a minimum, the version of the standard specified in § 170.207(e)(2).

**Public Comment Field:**

EHRA does not support inclusion of bidirectional immunization information exchange in either the 2015 or 2017 Edition NPRMs. Our members are currently overwhelmed with the variety of differences among the state requirements often requiring individual interface development. We encourage consideration of hub approaches to exchange, which could make bidirectional exchange more feasible.

We therefore strongly encourage ONC to work with the various states to arrive at one standard for content and one minimum standard for transport, while enabling states to select the sub-set of data within the standard that is relevant to them, akin to the document type/section construct in CCDAs. We suggest development and piloting of such capabilities in advance of inclusion in certification criteria.

EHRA does not see the value in using NDC numbers as opposed to CVX codes for vaccines in the 2017 Edition NPRM. NDC numbers have traditionally created challenges, especially when NDC numbers get reissued for different items.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 1 40-100 hrs "Revised" criterion	Require HL7 2.5.1. IG R1.5: 1,040 hrs Bidirectional immunization data exchange: 1,380 hrs* NDC instead of CVX for historical immunizations: 1,210 hrs* NDC instead of CVX for immunization with NDC-like code for historical: 920 hrs* *Estimates are for items that are not proposed but where public comment is solicited.	The ONC estimate is significantly underestimated. The items for which ONC solicits public comment represent a significant development investment.

§ 170.314(f)(3) (Transmission to public health agencies – syndromic surveillance) and

§ 170.315(f)(3) (Transmission to public health agencies – syndromic surveillance)

**MU Objective**

**Capability to submit electronic syndromic surveillance data to public health agencies except where prohibited, and in accordance with applicable law and practice.**

**Revised 2014 Edition EHR Certification Criterion**

§ 170.314(f)(3) (Transmission to public health agencies – syndromic surveillance)

**2015 Edition EHR Certification Criterion**

§ 170.315(f)(3) (Transmission to public health agencies – syndromic surveillance)

**(3) Transmission to public health agencies – syndromic surveillance. EHR technology must be able to electronically create syndrome-based public health surveillance information for electronic transmission in accordance with:**

(i) Ambulatory setting only. (A) The standard specified in § 170.205(d)(2), (d)(5), or (k).

(B) Optional. The standard (and applicable implementation specifications) specified in § 170.205(d)(4).

(ii) Inpatient setting only. The standard (and applicable implementation specifications) specified in § 170.205(d)(4).

Preamble FR Citation: 79 FR 10909

Specific questions in preamble? Yes

**Public Comment Field:**

EHRA does not support the alternative syndromic surveillance criterion for ambulatory certification in the 2017 Edition NPRM. As stated, due to lack of clear demand, the EHRA agrees the inclusion of such alternative standards in the ambulatory certification is unwarranted. We have no experience with utilization of QRDA for this purpose, nor have we seen agencies utilizing other standards for receiving the syndromic surveillance data. EHRA believes it is premature to propose any alternative standards.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 2 100-300 hrs “Revised” criterion	QueryHealth for syndromic surveillance: 1,800 hrs QRDA III for syndromic surveillance in ambulatory: not estimated QRDA I for syndromic surveillance in ambulatory: 1,790 hrs* *Estimates are for items that are not proposed but where public comment is solicited.	The ONC estimate is significantly underestimated. The items for which ONC solicits public comment represent a significant development investment.

**§ 170.315(f)(4) (Inpatient setting only – Transmission of reportable laboratory tests and values/results)**

**MU Objective**

Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice.

**2015 Edition EHR Certification Criterion**

(4) Inpatient setting only—transmission of reportable laboratory tests and values/results. EHR technology must be able to electronically create reportable laboratory tests and values/results for electronic transmission in accordance with:

- (i) The standard (and applicable implementation specifications) specified in § 170.205(g)(2); and
- (ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2).

Preamble FR Citation: 79 FR 10910

Specific questions in preamble? *No*

**Public Comment Field:**

We are currently overwhelmed with the variety of differences among the state requirements often requiring individual interface development. We therefore strongly encourage ONC to work with the various states to arrive at one standard for content and one minimum standard for transport, while enabling states to select the sub-set of data within the standard that is relevant to them, akin to the document type/section construct in CCDA.

We suggest that upgrading the version of the standard in one active Edition (2015) while another Edition (2014) is still active as well can lead to interoperability incompatibilities. Therefore, we suggest either delaying the upgrade until the 2017 Edition, or maintaining the old version as mandatory and the new version as optional.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 1 40-100 hrs "Revised" criterion	HL7 2.5.1 IG ELR DSTU R2: 770 hrs	The ONC estimate is significantly underestimated.

### § 170.315(f)(5) (Ambulatory setting only – cancer case information)

**MU Objective**

Capability to identify and report cancer cases to a State cancer registry, except where prohibited, and in accordance with applicable law and practice.

**2015 Edition EHR Certification Criterion**

(5) Ambulatory setting only—cancer case information. Enable a user to electronically record, change, and access cancer case information.

Preamble FR Citation: 79 FR 10910

Specific questions in preamble? *No*

**Public Comment Field:**

EHRA supports unchanged criterion.

**§ 170.315(f)(6) (Ambulatory setting only – transmission to cancer registries)**

**MU Objective**

Capability to identify and report cancer cases to a State cancer registry, except where prohibited, and in accordance with applicable law and practice.

**2015 Edition EHR Certification Criterion**

**(6) Ambulatory setting only—transmission to cancer registries.** EHR technology must be able to electronically 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)(3) and (c)(2).

Preamble FR Citation: 79 FR 10910

Specific questions in preamble? *No*

**Public Comment Field:**

The EHRA does not support inclusion of information exchange with cancer registries in either the 2015 or 2017 Edition NPRMs. We are currently overwhelmed with the variety of differences among the state requirements often requiring individual interface development which must be addressed before engaging in bi-directional information exchange.

We therefore strongly encourage ONC to work with the various states to arrive at one standard for content and one minimum standard for transport, while enabling states to select the sub-set of data within the standard that is relevant to them, akin to the document type/section construct in CCDA.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 1 40-100 hrs "Revised" criterion	IG for ambulatory reporting to central cancer registries, HL7 CDA R1.1: 1,110 hrs	The ONC estimate is significantly underestimated.

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

**MU Objective**

N/A

**2015 Edition EHR Certification Criterion**

**(1) Automated numerator recording.** For each meaningful use objective with a percentage-based measure, EHR 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: 79 FR 10911

Specific questions in preamble? *No*

**Public Comment Field:**

EHRA supports unchanged criterion. We have other general comments on reporting requirements that are in (g)(2), so please consider our feedback there as well.

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

**MU Objective**

N/A

**2015 Edition EHR Certification Criterion**

**(2) Automated measure calculation.** For each meaningful use objective with a percentage-based measure that is supported by a capability included in an EHR technology, electronically record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.

Preamble FR Citation: 79 FR 10911

Specific questions in preamble? *No*

**Public Comment Field:**

We support the proposal that this criterion remain unchanged in the 2015 certification requirements.

Our experience as EHR developers has shown that measurement is one of the most time consuming development projects of all meaningful use work. EHR developers report that they need to invest more time on measuring a particular meaningful use objective than on developing the features for users to perform that objective. For this reason, we also consider this criterion to be one of the most inaccurately estimated (i.e., under-estimated) in ONC's assessments of the costs of complying with their rulemakings.

In addition, EHR developers have significant concerns that overly prescriptive requirements for measuring the use of the functionality tends to impose usability limitations. This outcome can happen even when the certification criterion for a particular functionality does not impose usability limitations. We suggest that closer attention be given in the 2017 Edition criteria to easing the impact of measure reporting on EHR usability.

Given our experience that (g)(2) or (g)(1) certification is both time consuming and problematic, we consider it appropriate that non-meaningful use modules would be certified only on functionality and not on measurement. We therefore appreciate this recognition of the burden associated with meaningful use measurement.

Finally, we call attention to the fact that (g)(2) and (g)(1) measurement can require functions that are otherwise unnecessary within the EHR, and that this should be remedied with revised test procedures permitting more flexibility. Two examples:

1. If an EHR has a drug formulary checking capability that is always on, it is not possible to demonstrate the automated measure calculation test procedure for e-prescribing, which requires showing the feature on and off. This situation means that an EHR must unnecessarily add the capability to turn off drug formulary checking only for certification, which is wasteful.
2. If an EHR only supports the ability for licensed users to enter orders, it is not possible to demonstrate the automated measure calculation test procedure for CPOE, which requires showing both CPOE and non-CPOE orders. Again, it is impractical that features need to be added to an EHR simply to satisfy the automated measure calculation requirements.

Given these and similar examples, we suggest that additional flexibility be given for software that does not permit certain workflows or configurations not required in the functional criterion, but that are included as part of the (g)(2) testing scenarios.

**§ 170.315(g)(3) (Safety-Enhanced Design)**

MU Objective

N/A

2015 Edition EHR Certification Criterion

(3) Safety-enhanced design. User-centered design processes must be applied to each capability an EHR technology includes that is specified in the following certification criteria: § 170.315(a)(1) through (4), (8) through (10), and (18) and (b)(2) and (3).

Preamble FR Citation: 79 FR 10911

Specific questions in preamble? Yes

**Public Comment Field:**

The EHRA supports the proposal to keep the 2014 Edition Safety Enhanced Design criteria as part of the 2015 Edition criteria; however, we would be interested in participating in future discussions with ONC on ways to modify this certification criterion without creating more prescriptive requirements. In general, the EHRA believes that market forces continue to drive system developers to higher levels of usability, and that regulation and certification criteria artificially narrow the focus of usability efforts in ways that are largely non-productive to developers or users. We support EHR developers having user-centered design (UCD) processes in place and discuss in our comments below our suggestions for focusing certification criteria around UCD processes as opposed to testing.

The 2014 Edition criteria for Safety Enhanced Design included prescriptive summative testing requirements that were difficult and time consuming to implement, and the EHRA has not seen customer interest in the results of those summative tests. It is even possible that completing these tests have had a negative impact on customers as time spent on completing and reporting on these tests meant less development time on areas of the EHR system that could have improved usability outside of EHR certification requirements. As such, we oppose expanding the scope of Safety-Enhanced Design to include additional certification criteria as this would only increase the level of effort required to conduct the prescriptive and time consuming summative tests that are currently part of the 2014 Edition.

One criteria included in the 2014 Edition was that all certified EHRs have to attest to having a user-centered design process. The EHRA supports this particular criterion but feels that additional prescriptive criteria that outline testing of systems designed using UCD processes is redundant and unnecessary. In general, conducting summative testing is part of having a UCD process but this process also includes other forms of testing that may be unique to the EHR developer. Although the EHRA supports EHR developers having UCD processes and understands that not all EHR developers are at a point where they have widely developed UCD processes, we agree with statements made by Raj Ratwani at the HIT Policy Committee "Implementation and Usability" hearing on July 23, 2013 in which he indicated that summative testing requirements under certification are unlikely to yield return on investment since the results of summative testing are not often seen in production systems until much later than the timeline seen for EHR certification. The EHRA would support further discussions with ONC to identify alternate ways to validate that an EHR developer is implementing a UCD process for potential inclusion in future certification rulemaking. The EHRA also supports private industry efforts to educate newer EHR organizations on UCD testing processes and feel that these efforts will likely yield better results for encouraging UCD processes in EHR development than additional regulation.

Although the EHRA supports EHR developers using formative testing as part of their UCD processes, we feel that formative usability tests in EHR certification criteria would not fit within the regulatory/certification framework since, almost by definition, formative usability tests are not performed on the system presented for certification. Formative usability tests are used to inform the finished product, not to validate it. Requiring formative usability tests could also lead to a codification of what an "appropriate" formative test method would be. Formative tests are wide, varied, and need to be deployed strategically and with flexibility. The EHRA also has concerns about including formative test results in the EHR certification criteria since the current regulations require that these test results be posted publically on the ONC Certified Health Product List. Since formative tests are conducted early in the development and design process, public results of formative testing or other forms of UCD research methods may be misinterpreted by EHR customers and may disclose early stage concepts before an EHR developer is able to implement it, potentially compromising competitive advantage.

Regarding the request for comment regarding requiring a minimum number of test subjects, the EHRA supports EHR developers using an applicable published guideline, such as Nielsen, NIST 7804, etc., for determining the appropriate sample size for user testing purposes. Additionally, ONC should be clear about whether this process should test the people who are actually supplying these data versus the eligible provider. In this regard, we encourage ONC to provide guidance to small and/or new EHR vendors to help accomplish the goals of user-centered design and SED testing. Guidance could suggest that types of individuals can participate in testing (users versus employees of the organization).

**§ 170.315(g)(4) (Quality Management System)****MU Objective****N/A**

**2015 Edition EHR Certification Criterion**

**(4) Quality management system.** For each capability that an EHR 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.

(i) If a single QMS was used for applicable capabilities, it would only need to be identified once.

(ii) If different QMS were applied to specific capabilities, each QMS applied would need to be identified. This would include the application of a QMS to some capabilities and none to others.

(iii) If no QMS was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

Preamble FR Citation: 79 FR 10911

Specific questions in preamble? Yes

**Public Comment Field:**

EHRA supports unchanged criterion.

**§ 170.315(g)(5) (Non-percentage-based measures report)**

**MU Objective**

N/A

**2015 Edition EHR Certification Criterion**

**(5) Non-percentage-based measures use report.** (i) For each capability included in EHR technology that is also associated with a meaningful use objective and measure that is not percentage-based (except for the capabilities specified in § 170.315(a)(12), (b)(1), and (d)) electronically record evidence that a user used or interacted with the capability and the date and time that such use or interaction occurred, in accordance with the standard specified at § 170.210(g).

(ii) Enable a user to electronically create a report of the information recorded as part of paragraph (g)(5)(i) of this section for the user's identified Medicare or Medicaid EHR reporting period.

Preamble FR Citation: 79 FR 10911

Specific questions in preamble? Yes

**Public Comment Field:**

We strongly oppose adding this item as a certification criterion in either 2015 or 2017 certification, and believe strongly that the same rationale that led ONC to not include this criterion in the 2014 Final Rule (i.e., it had been included in the 2014 *proposed rule*) still applies.

First, we note that this certification criterion is of very limited utility to users and primarily focused on satisfying meaningful use audits. Audits have been proceeding without this functionality for several years, so the features are non-essential. As EHR developers, we oppose adding features that are not requested by EHR users, not providing direct benefit to EHR users, not improving the efficiency of healthcare provision, and not improving patient care.

Second, we have significant concern that the need to measure activity within the EHR will actually result in limiting the available workflows to users, impeding flexibility currently offered to EHR users, and causing a perceptible decrease in the usability of EHRs directly attributable to this requirement.

Third, we note that information gathered in this type of report is not necessarily comparable across users of the same system or across systems.

Consider these general examples of the problematic nature of gathering this information:

- This approach limits users to only measured options. For example, measuring generation of a patient list by Dr. Jones versus by Dr. Jones' staff could be complex, and attempts to measure this could make it more complicated for Dr. Jones to use flexible arrangements with his staff allowing him to delegate efficiently. This is an example of a perceived usability concern due to measurement.
- Users are limited by measurement to only workflows foreseen and measured by their EHR developers, and flexibility and innovative use at the individual provider/site is inhibited.
- It is not always possible to be measured. Some determinations require human judgment. For example, different public health agencies have varying expectations for ongoing submission making it challenging to know within an EHR whether expectations are met.

Finally, we are concerned that this proposal makes EHRs a repository for information that isn't necessary for patient care or pertinent to EHR workflow. EHR developers do not consider this an appropriate use of EHRs or an appropriate area of focus for EHR development, and reiterate our opposition to the criterion. We have divided our more specific feedback on the burden and impracticality of this proposal by proposed criterion that would have a non-percentage based usage report.

Our first set of comments is on measuring usage of drug-drug, drug-allergy, and drug-formulary interventions:

- The data is not comparable across users systems because there are variations in configurations that change how frequently interventions are seen.
- Some providers write few/no prescriptions, and might have features enabled but not see interventions appear within a particular reporting period.
- Tracking is not as simple as having an "on/off" switch within the EHR, and the configuration is more complex and nuanced.
- EHR developers who track this type of information currently note that the data volumes can be very large, and that retention of large volumes of data over extended periods of time can have performance and hardware implications.

Overall, we do not think the cost imposed by this proposed requirement is offset by sufficient benefit.

Our second set of comments is on measuring usage of CDS interventions:

- The data is not comparable across users' systems because there are variations in configurations that change how frequently interventions are seen.
- Some providers might have interventions enabled but not see evidence of appearance if criteria for the intervention to appear are not met.
- Tracking is not as simple as having an "on/off" switch within the EHR and the configuration is more complex and nuanced.
- EHR developers who track this type of information currently note that the data volumes can be very large, and that retention of large volumes of data over extended periods of time can have performance and hardware implications.
- While it is possible to track when "active" interventions (such as a pop-up box) are seen and responded to, it is not always possible to track "passive" interventions. This could inadvertently encourage active interventions over passive, which would be inappropriate given that active interventions are not always the most usable option for each need.
- Attempts to limit users to only tracked intervention methods impose an artificial inflexibility on other CDS interventions that providers might desire to use. This limitation has negative usability implications also.

Overall, we do not think the cost imposed by this proposed requirement is justified by sufficient benefit.

Our third set of comments is on measuring immunization submission, syndromic surveillance submission, reportable labs submission, or cancer registry submission:

- It is possible that a user might be connected and submitting when appropriate but not have any submissions within a particular reporting period (e.g., didn't see any cases meeting syndromic criteria this quarter).
- Human judgment is required for what is "ongoing" submission when different recipients have differing expectations (e.g., real time, periodic load, etc.).
- Multiple transport methods and transmission methodologies introduce challenges.

Overall, we do not think the cost imposed by this proposed requirement is justified by sufficient benefit.

Our fourth set of comments is on measuring generation of a patient list:

- It could be artificially limiting to try to associate a particular list with a particular EP/EH (e.g., when EPs have staff who run reports for them).
- There are challenges with tracking reporting tools that might be outside the EHR, such as dashboards.
- We do not hear feedback from customers that saving off the list is difficult or insufficient and that further development is merited.
- When EHRs have generic query or reporting tools, it will be impossible or artificially limiting to recognize a "patient" list when the same tool could be used for lists of appointments or orders. Auditing of list generation might be unable to be distinguished from other information querying in a programmatic fashion.

Overall, we do not think the cost imposed by this proposed requirement is justified by sufficient benefit.

Our fifth set of comments is on testing with the NIST Randomizer and test EHR:

- If done in production systems, this will be audited and available, but we note that introducing test data into a production system is considered a data integrity issue by many healthcare organizations and should not be required by CMS or ONC.
- We do not hear feedback that saving the result email from the testing tool is insufficient and that further development is merited.

Overall, we do not think the cost imposed by this proposed requirement is justified by sufficient benefit.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 3	Option 1 - Record evidence each time the following are used (DDI or DAI, CDS,	The ONC estimate is significantly

<p>300-400 hrs</p> <p>“New” criterion</p>	<p>patient lists, transmission to immunization registries, transmission to syndromic surveillance, transmission of reportable labs, transmission to cancer registries): 7,000 hrs</p> <p>Option 2 - Record evidence of use at the beginning, during, and end of the reporting period for each of the following: (DDI or DAI, CDS, patient lists, transmission to immunization registries, transmission to syndromic surveillance, transmission of reportable labs, transmission to cancer registries): 7,000 hrs</p> <p>More detailed split:</p> <p>DDI/DAI: 920 hrs</p> <p>CDS: 1,150 hrs</p> <p>Pt list: 920 hrs</p> <p>Imm reg: 1,040 hrs</p> <p>Syn sur: 1,040 hrs</p> <p>Rep labs: 1,040 hrs</p> <p>Cancer reg: 920 hrs</p>	<p>underestimated.</p>
---	--	------------------------

<b>§ 170.315(h)(1) (Transmit – Applicability Statement for Secure Health Transport)</b>	
<p><b>MU Objective</b></p> <p>N/A</p>	
<p><b>2015 Edition EHR Certification Criterion</b></p> <p><b>1) <u>Transmit – Applicability Statement for Secure Health Transport</u>. Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(a).</b></p>	
<p><b>Preamble FR Citation: 79 FR 10914</b></p>	<p><b>Specific questions in preamble?</b> <i>No</i></p>

**Public Comment Field:**

EHRA is unclear as to the minimum transport standards proposed for certification and asks that the proposal be clarified on this point.

We agree with the general approach to separate content from transport. However, it is unclear from this approach which of the transport methods is intended to be supported by all, while others remain optional, including other transport methods not called out as criteria.

Generally, we suggest that an edition should only call out one minimum standard that everybody must adhere to, while leaving flexibility to the market to utilize other methods where they see fit, without compromising a provider's ability to meet certain program objectives where that program references this edition. Specifically, programs, such as the EHR Incentive Program, should not be allowed to require that their objectives can only be met using a certified transport method, but that any method is eligible.

Having one minimum certified transport capability will enable everybody to successfully connect with each other, yet allow for other, perhaps even more effective methods as well.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 1 40-100 hrs "New" criterion	470 hrs	

**§ 170.315(h)(2) (Transmit – Applicability Statement for Secure Health Transport & XDR/XDM for Direct Messaging)**

**MU Objective**

N/A

**2015 Edition EHR Certification Criterion**

**(2) Transmit – Applicability Statement for Secure Health Transport & XDR/XDM for Direct Messaging. Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(b).**

**Preamble FR Citation: 79 FR 10914**

**Specific questions in preamble? No**

**Public Comment Field:**

EHRA is unclear as to the minimum transport standards proposed for certification.

We agree with the general approach to separate content from transport.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 1 40-100 hrs "New" criterion	320 hrs	

**§ 170.315(h)(3) (Transmit – SOAP Transport and Security Specification & XDR/XDM for Direct Messaging)**

**MU Objective**

N/A

**2015 Edition EHR Certification Criterion**

**(3) Transmit – SOAP Transport and Security Specification & XDR/XDM for Direct Messaging. Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(c).**

**Preamble FR Citation: 79 FR 10914**

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

**Public Comment Field:**

EHRA is unclear as to the minimum transport standards proposed for certification.

We agree with the general approach to separate content from transport.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 1 40-100 hrs "New" criterion	320 hrs	

**§ 170.315(h)(4) (Transmit – Applicability Statement for Secure Health Transport & Delivery Notification in Direct)**

**MU Objective**

N/A

**2015 Edition EHR Certification Criterion**

**(4) Transmit – Applicability Statement for Secure Health Transport & Delivery Notification in Direct. Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(d).**

**Preamble FR Citation: 79 FR 10914**

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

**Public Comment Field:**

EHRA is unclear as to the minimum transport standards proposed for certification.

The EHRA understands and agrees with the concept of acknowledging receipt of the documentation by the intended recipient, or perhaps another provider reviewing the documentation in some circumstances. However, the proposed standards do not achieve that goal in any sort of complete fashion as it only enables measuring receipt in an in-box, therefore the value proposition remains limited.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
Level 2 100-300 hrs "New" criterion	1,070 hrs	The ONC estimate is significantly underestimated.

***B. Provisions of the Proposed Rule Affecting the ONC HIT Certification Program***

The following comment tables are meant to capture proposals relevant to the ONC HIT Program.

**Non-MU EHR Technology Certification**

**Preamble FR Citation: 79 FR 10918**

**Specific questions in preamble? Yes**

**Public Comment Field:**

EHRA is supportive of non-MU certification proposals to allow developers to submit non-MU modules without requirements for automated numerator or measure calculation certification requirements. EHRA also supports exclusion of the non-percentage based measures report from non-MU certification proposals. We believe the inclusion of non-MU certification is supportive of the expansion of interoperability among providers currently ineligible for the EHR Incentive Program. EHRA supports one category on the ONC CHPL that includes both MU and non-MU EHRs, since MU EHRs are capable of exceeding the proposed requirements for non-MU EHRs, thus allowing providers to choose either to satisfy their needs. We support a second ONC CHPL category for MU ONLY EHRs to enable meaningful users to easily determine EHRs to meet their specific needs.

We do not agree with the assertion that meeting the requirements for automated numerator or automated measure calculation reporting is a more significant burden only for small EHR technology developers. We find the process burdensome for all developers, as requirements for measurement often require additional functionality just for measure and exclusion calculations. This further complicates workflow and design requirements. When additional measurement requirements are added, much development work is often diverted from our primary goal of developing the best functionality to meet the objective. The substantial cost burden associated with the measurement development further complicates deployment and may result in less than optimal usability perceptions from providers. We encourage ONC to strive to simplify measure calculations and exclusions while strongly considering the effect the additional requirement imposes on software development. EHRA supports the pursuit of non-MU certification to improve the prospects for achieving interoperability across diverse care settings. We believe interoperability should remain the key focus for future certification criteria, and certification requirements should strive to include other care settings and specialties with the goal of improving care coordination. We have encountered many issues early in Stage 2 due to the lack of availability of interoperable trading partners in the marketplace. EHRA supports a simple approach to MU or non-MU testing,

allowing vendors seeking certification to select either type and perform the associated functionality.

We believe the approach utilized by ONC for Modular and Complete EHR certification to be understood by most providers, and believe a proposal for Modular certification-only would create more issues than it is proposed to resolve. From our perspective most of the confusion does not involve the certification designation of Modular or Complete EHR, but concerns the definition of “possession” of CEHRT as applied to individual components of a Complete EHR. ONC has specified that, in order to receive the benefits of Complete EHR certification, the provider cannot possess only “components” of the Complete EHRs since separate components of a Complete EHR do not derive their own certification status. We agree that separately sold components meant to connect to other EHR CEHRT benefits from Modular certification. However, many Complete EHR vendors do not develop EHRs in such a fashion. Complete EHRs are often combinations of applications that are purchased over time to build the EHR needed by the provider. These applications are often developed to work together and build off the Base EHR, thus satisfying all security requirements for certification. The vendor should retain the flexibility to certify and market their products as either a Complete EHR as a package of components requiring one certification or individual components with Modular certifications, or both per vendor preference.

We suggest that ONC evaluate the current definition of CEHRT to determine if it is possible to align requirements for possession of either Modular or Complete EHRs with the functionality necessary to accomplish the desired stage of meaningful use, thus eliminating the concern with offering Complete EHR certification. In addition, we have concerns regarding legal contracts that some of our members may have executed with providers that rely on the Complete her designation. We are uncertain of the consequences of this proposal on our contracts and our ability to provide customer assurance of functionality necessary to achieve meaningful use.

Overall, EHRA believes more confusion will result if ONC adopts the proposal to abolish Complete EHR certification. We are concerned that the perception will be such that all modules will easily plug and play with existing modules or Base EHRs, however combined. This could result in many costly implementations based upon perceived connectivity which does not exist. Many EHRs are developed in an integrated manner and accommodate other modules; however, not all EHRs are developed to work with any module combination. EHRs may rely upon integrated file structures preventing Complete EHR modules from being separated as Modular certification could require. EHRA is concerned that providers may not understand these nuances. Should ONC ultimately proceed with only Modular certifications, we reiterate that the marketing of our products and our explanation how our products meet marketplace needs must remain our prerogative in order to communicate the “completeness” of our products, regardless of certification.

## ONC Regulations FAQ 28

**Preamble FR Citation: 79 FR 10920**

**Specific questions in preamble? No**

### Public Comment Field:

Regarding FAQ #11-12-028-1 (<http://www.healthit.gov/policy-researchers-implementers/28-question-11-12-028>) EHRA continues to support Complete EHRs being certified for automated measure calculations (g)(2) as in the 2014 Edition. We also support the continued use of optional certification criteria for Complete EHRs.

EHRA has several concerns regarding the proposal for discontinuing Complete EHR certification. The flexibility to provide options within certification should remain. We have seen much meaningful use success by providers utilizing Complete EHRs and do not believe the industry would benefit from discontinuing this certification. The current environment enables all vendors to certify their products as they choose in accordance with how they market their products -- as Complete EHRs, Modules, or both. Some providers prefer to utilize Complete EHRs while some providers prefer to utilize modular EHRs. We believe many providers derive confidence from products certified as Complete EHRs to deliver all required objectives and measure calculations; however, the choice should be theirs to make.

Patient List Creation Certification Criteria	
Preamble FR Citation: 79 FR 10920	Specific questions in preamble? <i>No</i>
Public Comment Field: EHRA supports unchanged criterion.	

ISO/IEC 17065 (§ 170.503(b)(1))	
Preamble FR Citation: 79 FR 10920	Specific questions in preamble? <i>No</i>
Public Comment Field: No comment.	

ONC Certification Mark (§ 170.523(k)(1))	
Preamble FR Citation: 79 FR 10921	Specific questions in preamble? <i>No</i>
Public Comment Field: EHRA supports use of a single ONC certification mark.	

Certification Packages for EHR Modules	
Preamble FR Citation: 79 FR 10921	Specific questions in preamble? <i>Yes</i>
Public Comment Field: EHRA opposes the proposal for Care Coordination package and Patient Engagement Package as designations by ONC for the 2015 Edition or the 2017 Edition NPRM. We support individual vendor flexibility regarding how we market our products' functionality and how we differentiate or label our products. Many EHRs may already utilize such terminology as proposed, and EHRA does not support ONC suggesting such terminology based on specific criteria when such terminology may already be in use. Additional designations could be quite confusing and further complicate understanding the ONC CHPL. We believe it best for market demand and innovation to foster future development as care coordination and patient engagement functionality expands across care settings. EHRA does not support such restrictions imposed by ONC.	

### ***C. Other Topics for Consideration for the 2017 Edition Certification Criteria Rulemaking***

The following comment tables are meant to capture proposals relevant to the 2017 Edition of Certification Criteria. Please note that although we will consider the comments we receive on these issues as we develop proposals for future rulemaking, we do not plan to respond to those comments in the final rule for the 2015 Edition that we expect will follow this proposed rule.

**Additional Patient Data Collection**

**Preamble FR Citation: 79 FR 10922**

**Specific questions in preamble? Yes**

**Public Comment Field:**

EHRA reiterates our position that the overall goal of Stage 3 meaningful use should focus on enhanced interoperability, without expanded scope or additional functionality criteria, and opposes any additional functionality that does not accomplish this primary goal, or further increases the burdens that we and providers are experiencing with implementation of the expanded scope for 2014 Edition.

EHRA supports the previous single demographics criterion for 2014 Edition. We request that any additional data collection proposed become a separate certification criterion, thus enabling gap certification as we move forward.

EHRA is concerned about the collection and use of patient-generated data as proposed. We consider it appropriate to consider new data fields for EHR capture for interoperability purposes; however EHRA questions the intent associated with patient-generated data recording, change, and access. It is premature to propose that the patient would access the EHR data directly and allow direct patient data entry, or to propose to allow the patient to change data. Implementation of current functionality with patient portals presents significant learning opportunities which must be resolved without additional concerns for data integrity and security requirements. Perhaps allowing a patient to answer a questionnaire could be a starting point, or providing information such as preferred language, race, or ethnicity could be acceptable. EHRA has concerns about allowing a patient to enter this data or change demographics, especially fields such as DOB. EHRA suggests determining what new data fields are necessary for the 2017 Edition NPRM prior to including patient-generated data.

EHRA considers it appropriate to consider additional data fields for EHR capture for interoperability purposes. However, we are concerned with the intent and scope associated with the various data elements proposed. We are unclear if the intent is literally for patient-generated data recording, change, and access, or whether the intent is simply to potentially capture the additional data elements. EHRA believes it is premature to propose that the patient would access the EHR data directly and change fields such as DOB. Perhaps allowing a patient to answer a questionnaire could be a starting point, or providing information such as preferred language, race, or ethnicity could be acceptable.

Regarding additional data fields, EHRA believes the EHR market will continue drive which data elements most pertinent to their users, such as military service, veteran status, and occupation/industry codes. However, the EHRA is unfamiliar with the proposed standards. Any consideration for inclusion of these data elements or standards should be proposed as a separate criterion for the 2017 NPRM proposal. EHRA understands the privacy and security concerns with new certification criteria for capturing sexual orientation and gender identity. Collecting cognitive and functional information from a patient-generated questionnaire seems feasible for proposal in the 2017 Edition NPRM. However, we are not familiar with the proposed standards of ICF for categories of function or the use of LOINC or SNOMED CT for appropriate responses for capturing the proposed structured data fields.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
No estimates	Capture disability status using HS section 4302 survey: 1,160 hrs	
No estimates	Capture sexual orientation: 920 hrs	
No estimates	Capture gender identity: 920 hrs	
No estimates	Capture veteran status, dates of service, locales of service: 1,040 hrs	
No estimates	Capture occupation status using NOISH and ODH: 1,160 hrs	

## Medication Allergy Coding

Preamble FR Citation: 79 FR 10925

Specific questions in preamble? Yes

### Public Comment Field:

EHRA supports the criterion should remain unchanged for the 2017 Edition NPRM.

ONC Estimate for Development (from pages 10933-10935 of the proposed rule)	Average EHRA Estimate for Development (gathered by surveying EHR developers)	Comments
No estimates	Medication allergy coding: 1,120 hrs	

## Certification Policy for EHR Modules and Privacy and Security Certification Criteria

Preamble FR Citation: 79 FR 10925

Specific questions in preamble? Yes

### Public Comment Field:

In the preamble, ONC sought comment on four options for EHR Module certification for privacy and security criteria.

#### *Option 1 – Readopt the 2011 Edition approach*

EHRA does not agree this is the right approach at this time. The HIPAA Security Rule is not prescriptive on the implementation of security controls. Covered entities have the flexibility to implement best-in-class and surround solutions for their security. Whether or not these capabilities are included in the EHR should be driven by the market, not by certification. The 2011 method led to extra work and overhead with minimum added value.

#### *Option 2 – Maintain 2014 Edition approach*

We ask that ONC maintain the current approach to privacy and security certification for EHR modules. We feel this is the right approach to allow provider to select best-in-class modules when assembling their EHR solutions.

#### *Option 3 – Adopt HITSC recommendation*

Part (1) of the HITSC recommendation is the same as option 4. We believe it would be premature to implement Part (2) of their recommendation, as there are no standard service interfaces for a minimum set of privacy and security criteria. A requirement to support a plurality of interfaces for each privacy and security criteria may impose undue costs on EHR developers and lead to confusion among provider organizations on how to properly configure the interfaces. In addition, testing these interfaces during certification may prove challenging to govern and manage.

#### *Option 4 – Adopt a minimum set of P&S criteria*

We ask what value this would provide beyond the current HIPAA Privacy and Security standards. Provider organizations must currently meet the HIPAA Privacy & Security Rules which already outline a set of minimum security controls. Provider organizations have the flexibility to implement these controls in software such as an EHR, but also through surround solutions, infrastructure, physical controls, or policies and procedures.

## Provider Directories

Preamble FR Citation: 79 FR 10926

Specific questions in preamble? No

### Public Comment Field:

The EHRA agrees that substantial work is still required to successfully deploy Direct and directed communications, particularly involving the use of provider directories. While word-of-mouth raising of awareness of provider addresses will help somewhat, unlike the early e-mail days and lower level of privacy risks, it is essential that provider directories are well established to ensure secure exchange of data to the intended recipient.

We agree that substantial work is necessary to clarify implementation guidance and availability of reliable provider directories to enable providers to address communications to a specific provider regardless of transport method, as well as patient to confidently communicate with the provider of their choice.

While on the one hand it is important to make progress rapidly, we also must recognize that premature deployment of immature standards can result in substantial re-work and erode the confidence of the participants. MSPD, effectively HPDPlus plus further experience and abilities to querying multiple directories, is the right direction to progress, but just not ready for broad deployment by the 2017 Edition. A versioned release that can be used for pilot implementations is expected to be ready in the next couple of months, but that does not leave enough time to sufficiently mature by the time the 2017 Edition would be finalized.

Federating across slightly out-of-sync directories is very difficult. Therefore, we need to pilot across disparate implementations to gain the necessary experience and fine-tuning before this can be rolled out successfully. In the meantime, we suggest a focus on deployment of local HPDPlus and use of a manual approach for those addresses beyond local until MSPD is sufficiently mature to deploy. Such an approach would achieve the three queries outline locally, which would have the higher communication traffic, thus the most benefit in the short term.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
No estimates	Query a provider directory: 1,120 hrs	

## Oral Liquid Medication Dosing

Preamble FR Citation: 79 FR 10926

Specific questions in preamble? Yes

**Public Comment Field:**

EHRA does not support inclusion of this criterion in the 2017 Edition NPRM. EHRA is opposed to the prescriptive nature of these proposals regarding structured SIG requirements for providing the metric option or requiring recording in the metric standard only. EHRA supports the flexibility of converting a liquid dose to metric, if required, and proposes that any changes must be addressed by current e-prescribing standards without requirements for updated standards.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
No estimates	Metric standard for liquid oral meds: 920 hrs	

**Medication History****Preamble FR Citation: 79 FR 10927****Specific questions in preamble? Yes****Public Comment Field:**

EHRA has not seen substantial provider benefits from inclusion of medication history in current e-prescribing modules, and does not see added value derived from implementation of medication history beyond current e-prescribing solutions. The data received in current medication history e-prescribing implementations is available at no additional charge; however, the data received is of limited value. Implementation of medication history beyond e-prescribing modules requires collection of service fees to access the medication history provided by pharmacy data in functions such as medication reconciliation, thus making it even less desirable.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
No estimates	Medication history via pharmacy networks or repositories: 1,210 hrs	

**Blue Button +****Preamble FR Citation: 79 FR 10927****Specific questions in preamble? Yes**

**Public Comment Field:**

EHRA supports advancement of this initiative through market demands and does not support it for inclusion in the 2017 Edition NPRM. When the objective is more mature, EHRA suggests alignment between Blue Button+ functionality and VDT functionality to avoid duplication of certification criteria.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
No estimates	Blue Button+: 1,520 hrs.	

**2D Barcoding****Preamble FR Citation: 79 FR 10928****Specific questions in preamble? Yes****Public Comment Field:**

EHRA does not support inclusion of this criterion in the 2017 Edition NPRM. We anticipate that, as availability of 2D barcodes increase, we will see market demands increase and the functionality will be developed accordingly without the need for certification criteria.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
No estimates	2D bar coding: 1,740 hrs.	

**Duplicate Patient Records****Preamble FR Citation: 79 FR 10928****Specific questions in preamble? Yes****Public Comment Field:**

EHRA does not support inclusion of this criterion in the 2017 Edition NPRM. EHRA supports utilization of current vendor development for managing duplicate records as satisfactory to meet the provider demand in the marketplace. EHR developers have already designed the EMPI capabilities requested and implemented the functionality required by providers to address duplicate records. We strongly oppose proposals of a prescriptive nature that could require considerable redevelopment and considerable expense to providers to adopt new workflows. EHRA supports the continued flexibility afforded by our current approach as well as the longer term goals of various patient matching initiatives. Future initiatives will evolve and should be considered beyond 2017 Edition NPRM.

**Disaster Preparedness****Preamble FR Citation: 79 FR 10928****Specific questions in preamble? Yes**

**Public Comment Field:**

EHRA understands the importance of disaster preparedness and seeks to better understand what aspects of such preparedness could be improved utilizing EHRs beyond current capabilities. We are unfamiliar with accepted standards for temporary naming conventions. As such, current EHR technology has provided this capability to capture temporary names relying upon many different organizational policies in the marketplace.

EHRs currently rely on non- standard definitions to support the flexibility currently afforded to “face sheets” and “patient snapshots.” EHRA supports this flexibility and requests ONC to further clarify if such terms are envisioned by ONC to contain specific definitive concepts. EHRA also supports the flexibility afforded to produce documents in EHRs without the additional prescriptive requirements mentioned here for unique disaster document production. EHRA understands utilization of disaster preparedness tools in the hospital setting and questions the need for this additional functionality in the ambulatory setting.

EHRA supports continued use of the CCDAs as the primary standard document for sharing basic clinical information and discourages development of additional standard documents for disaster preparedness. Current EHR technology affords providers multiple options for capturing provision of care notations delivered during a disaster without the need for additional certification criteria. EHRA supports current capabilities for reporting requirements to public health agencies sufficient to track and trend emergency care management. EHRA supports utilization of standards and transport protocols in consideration of any future communication with public health specifically related to disasters if current standards are not sufficient.

<b>ONC Estimate for Development</b> (from pages 10933-10935 of the proposed rule)	<b>Average EHRA Estimate for Development</b> (gathered by surveying EHR developers)	<b>Comments</b>
No estimates	Bulk print information on groups by location: 1,740 hrs.	

**Certification of Other Types of HIT and for Other Health Care Settings**

**Preamble FR Citation: 79 FR 10929**

**Specific questions in preamble? No**

**Public Comment Field:**

EHRA does not support expansion certification to other types of health IT and other healthcare settings in the 2017 Edition NPRM. EHRA supports the advancement of interoperability as the main goal for the 2017 Edition NPRM. EHRA does not support inclusion of Children’s EHR Format or Practice Transformation criteria. We believe marketplace demand will allow vendors in these markets to further determine functional needs for the provision of care without the necessity of certification criteria.