May 28, 2015

Karen DeSalvo, MD, MPH, MSc
National Coordinator
Office of the National Coordinator for Health IT
Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Dear Dr. DeSalvo,

On behalf of the Healthcare Information and Management Systems Society (HIMSS), thank you for the opportunity to develop written comments to the Office of the National Coordinator for Health Information Technology (ONC) in response to the Notice of Proposed Rulemaking (NPRM) on the 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications.

HIMSS is a cause-based, global enterprise producing health information technology (IT) thought leadership, education, events, market research and media services around the world. Founded in 1961, HIMSS encompasses more than 60,000 individuals, of which more than two-thirds work in healthcare provider, governmental and not-for-profit organizations across the globe, plus over 640 corporations and 400 not-for-profit partner organizations, that share this cause.

HIMSS appreciates the opportunity to work with our diverse membership to develop a coherent response to the 2015 edition certification criteria. Our organization looks forward to continuing to engage with ONC and the Centers for Medicare & Medicaid Services (CMS) as progress is made toward finalizing the 2015 edition certification criteria as well as the Meaningful Use Stage 3 NPRM also in its public comment period.

We remain firmly committed to and supportive of the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program and the meaningful use of EHRs. The Meaningful Use Program remains a critical tool for enabling healthcare transformation. Recent data from HIMSS Analytics affirms the positive impact that meaningful use is having on healthcare delivery. We have observed that over 70% of hospitals have made a positive progression in the advancement of their EHR capabilities over the last five years, and over 60% of ambulatory facilities have shown positive progression in just the last three years. This advancement confirms the impact across the community of improving the experience of care, enhancing patient engagement initiatives, better care coordination, and other benefits to our delivery system facilitated by the Meaningful Use Program.

Overall, HIMSS supports the principles included in the 2015 edition certification criteria. The key takeaways from our comments include the following ideas:

- **HIMSS recommends that ONC address the overall complexity of the 2015 Edition Certification Rule by reducing the total number of criterion, as well as the standards and functionalities included.**
HIMSS acknowledges ONC and the Centers for Medicare & Services (CMS) strived to reduce the complexity of the requirements for the 2015 edition certification criteria and Meaningful Use Stage 3 in their respective NPRMs for this cycle. However, given all the new requirements included in this NPRM, HIMSS asks ONC to reconsider the requirements needed for the 2015 edition certification criteria and consider approaches to minimize and simplify the options presented.

There are several instances in the draft regulation where it is unclear what is truly optional for the 2015 edition certification criteria. This includes requirements for Meaningful Use, 2015 Edition Base EHR Definition, as well as conditional criteria that apply to certification for particular functionalities. HIMSS strongly encourages ONC to clearly delineate what the essential 2015 requirements are to meet Meaningful Use, 2015 certification, and the Base EHR definition.

- **HIMSS cautiously supports ONC’s efforts to establish innovative certification and testing programs that utilize health IT**

Certification in support of a Learning Health System must be specific, carefully planned, focused on the areas that have the greatest impact on interoperability, and closely aligned with programmatic goals.

For new federal program-related health IT certification programs, HIMSS suggests that ONC or another agency establish the programmatic goals before commencing with any certification program associated with the effort. It is important that certification criteria be closely evaluated and aligned with the functionalities necessary to meet the goals of the program in question as we move beyond EHR-specific certification.

Overall, to achieve the greatest success, broad alignment and consolidation of current efforts will more rapidly ensure consistent adoption of standards and policies for health IT applications used across settings of care. Moreover, ONC should continue to work with established standards development organizations and voluntary consensus standards bodies (including IHE, Health Level-7 (HL7), Digital Imaging and Communications in Medicine (DICOM), CareQuality and others) to develop, harmonize and disseminate comprehensive standards and implementation guidance that provide the foundation for interoperability certification criteria.

In addition to advancing and aligning programs that test and certify that health IT systems conform to standards and interoperate with other data sources, it is essential that healthcare providers and users have the information and tools necessary to be smart purchasers of certified products. Widespread education and related service offerings that are an accessible part of the health IT ecosystem and articulate the benefits of using certified products will increase understanding of the system procurement and upgrade process, furthering the adoption of interoperable products in the marketplace.

It is also important to note that ONC has the opportunity to leverage complementary voluntary testing programs by qualified organizations for their ability to extend testing to emerging capabilities and specialty areas of healthcare.

- **HIMSS supports greater harmonization and alignment across the programs covered by certification.**

An underlying issue for health IT-related certification is the general complexity and multiple dimensions of harmonization and alignment required across federal programs. Any effort to address these issues would have
to encompass more than just measures being harmonized—it requires coordination of timelines for programs and proposed rules, as well as various incentives and disincentives.

Implementation timelines are a key component to ensure alignment of these programs. We strongly support the alignment and consolidation efforts, especially for quality measures; however, we urge ONC to take into account that those timelines may not necessarily coincide with the Meaningful Use Program. As we look at the certification criteria, HIMSS and other stakeholders must take into consideration the other programs and purposes for potential alignment. For example, with EHRs supporting clinical quality measures, the general timeline issues aren’t limited to meaningful use; ensuring measures are harmonized and program timelines are aligned are both critical factors.

- The level of adoption and maturity among standards is an important consideration when evaluating inclusions for certification programs.

Health IT Standards Committee member Dixie Baker and her colleagues published an article in May 2014 in JAMIA that discusses this evaluative approach for levels of standards adoption and maturity. Using this paradigm to identify implementation issues, barriers, and impacts to the end user workflow and/or use cases would make the health IT certification process more effective.

We look forward to the opportunity to meet with you and your team to discuss these issues in more depth. Please feel free to contact Jeff Coughlin, Senior Director of Federal & State Affairs, at 703.562.8824, or Eli Fleet, Director of Federal Affairs, at 703.562.8834, with questions or for more information.

Thank you for your consideration.

Sincerely,

Paul Kleeberg, MD, FAAFP, FHIMSS
Chief Medical Informatics Officer
Stratis Health
Chair, HIMSS Board of Directors

H. Stephen Lieber, CAE
President & CEO

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

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

Included in 2015 Edition Base EHR Definition?
Yes, as an alternative to § 170.315(a)(2) or (3)

Stage 3 MU Objective
Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.

2015 Edition Health IT Certification Criterion
(1) Computerized provider order entry – medications. Technology must enable a user to record, change, and access medication orders.

Preamble FR Citation: 80 FR 16814

Specific questions in preamble? Yes

Public Comment Field:
HIMSS supports the approach in the 2015 Edition to adopt three certification criteria for CPOE, as compared to a single criterion that would include combined functionality for all three clinical purposes. However, we question whether the additional data elements proposed for CPOE--secondary diagnosis codes; reason for order; and, comment fields entered by the ordering provider--are warranted at this time. HIMSS notes that CPOE is currently well understood through the 2014 certification criteria and appears to be functioning well from both the provider and developer perspective. Most of the criterion is applicable to Meaningful Use certification, but HIMSS cautions against the inclusion of these additional data elements without a compelling reason.

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

Included in 2015 Edition Base EHR Definition?
Yes, as an alternative to § 170.315(a)(1) or (3)

Stage 3 MU Objective
Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.

2015 Edition Health IT Certification Criterion
(2) Computerized provider order entry – laboratory.

(i) Technology must enable a user to record, change, and access laboratory orders.

(ii) Technology must be able to receive and incorporate a new or updated laboratory order compendium in accordance with the standard specified in § 170.205(l)(2) and, at a minimum, the version of the standard in § 170.207(c)(3).

(iii) Ambulatory setting only. Technology must enable a user to create laboratory orders for electronic transmission in accordance with the standard specified in § 170.205(l)(1) and, at a minimum, the version of the standard in § 170.207(c)(3).
§ 170.315(a)(2) Computerized provider order entry – laboratory

<table>
<thead>
<tr>
<th>Preamble FR Citation: 80 FR 16814</th>
<th>Specific questions in preamble? Yes</th>
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</table>

**Public Comment Field:**

HIMSS is concerned with some of the requirements in this criterion, as well as questioning the maturity of the proposed standard. We are concerned with the certification requirements, such as how this technology must be able to receive and incorporate a new or updated laboratory order compendium. Further, in an ambulatory setting, the technology must enable a user to create laboratory orders for electronic transmission. In addition, HIMSS is concerned about the maturity of HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders (LOI) from EHR, Draft Standard for Trial Use, Release 2 – US Realm (“Release 2”) and whether it has appropriate levels of adoption for inclusion in the 2015 certification criteria. HIMSS recommends that ONC provide a range of standards options for users rather than settle on one choice.

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

<table>
<thead>
<tr>
<th>Included in 2015 Edition Base EHR Definition?</th>
<th>Yes, as an alternative to § 170.315(a)(1) or (2)</th>
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</table>

**Stage 3 MU Objective**

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

**2015 Edition Health IT Certification Criterion**

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

<table>
<thead>
<tr>
<th>Preamble FR Citation: 80 FR 16815 (also see 80 FR 16814)</th>
<th>Specific questions in preamble? Yes</th>
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</table>

**Public Comment Field:**

HIMSS supports this criterion as described in the 2015 edition certification criteria rule.

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

<table>
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<tr>
<th>Included in 2015 Edition Base EHR Definition?</th>
<th>No</th>
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**Stage 3 MU Objective**

Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.
§ 170.315(a)(4) Drug-drug, drug-allergy interaction checks for CPOE

2015 Edition Health IT Certification Criterion
(4) Drug-drug, drug-allergy interaction checks for CPOE.
   (i) Interventions. Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically indicate to a user drug-drug and drug-allergy contraindications based on a patient’s medication list and medication allergy list.
   (ii) Adjustments.
      (A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.
      (B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.
   (iii) Interaction check response documentation.
      (A) Technology must be able to record at least one action taken and by whom in response to drug-drug or drug-allergy interaction checks.
      (B) Technology must be able to generate either a human readable display or human readable report of actions taken and by whom in response to drug-drug or drug-allergy interaction checks.

Preamble FR Citation: 80 FR 16815 Specific questions in preamble? Yes
Public Comment Field:
Drug-drug, and drug-allergy interaction checks for CPOE is currently a fairly well-defined area. HIMSS supports this criterion, but questions whether the additional requirements and capabilities proposed in the NPRM are warranted at this time.

§ 170.315(a)(5) Demographics

Included in 2015 Edition Base EHR Definition?
Yes

Stage 3 MU Objective
N/A

2015 Edition Health IT Certification Criterion
(5) Demographics.
   (i) Enable a user to record, change, and access patient demographic data including preferred language, sex, race, ethnicity, and date of birth.
      (A) Race and ethnicity.
         (1) Enable each one of a patient’s races to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify race.
         (2) Enable each one of a patient’s ethnicities to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify ethnicity.
         (3) Aggregate each one of the patient’s races and ethnicities recorded in accordance with paragraphs (a)(5)(i)(A)(1) and (2) of this section to the categories in the standard specified in § 170.207(f)(1).
      (B) Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g)(2) and whether a patient declines to specify a preferred language.
      (C) Enable sex to be recorded in accordance with the standard specified in § 170.207(n)(1).
   (ii) Inpatient setting only. Enable a user to record, change, and access the preliminary cause of death and date of death in the event of a mortality.

Preamble FR Citation: 80 FR 16816 Specific questions in preamble? No
§ 170.315(a)(5) Demographics

Public Comment Field:

HIMSS requests additional guidance from ONC on this criterion. Further, we have several questions as part of the demographics discussion. Overall, we would like to ensure that EHR usability is preserved for this criterion. For that reason, given the potentially significant changes in the NPRM, we are concerned that proposed changes for the race and ethnicities criterion could possibly lead to more code uncertainty for vendors and providers. We have several questions that need to be answered before any changes can be finalized, including: the level of detail needed to be available through dropdowns; how a health IT module would perform the aggregation of each one of a patient’s races and ethnicities; and, what the guardrails are for user interfaces under this criterion.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

(i) Vital signs. Enable a user to record, change, and access, at a minimum, a patient's height, weight, diastolic blood pressure, systolic blood pressure, heart rate, respiratory rate, temperature, oxygen saturation in arterial blood by pulse oximetry, body mass index [ratio], and mean blood pressure in accordance with the following (The patient’s height/length, weight, diastolic blood pressure, systolic blood pressure, heart rate, respiratory rate, temperature, oxygen saturation in arterial blood by pulse oximetry, body mass index [ratio], and mean blood pressure must be recorded in numerical values only.):

(A) The standard specified in § 170.207(k)(1) and with the associated applicable unit of measure for the vital sign in the standard specified in § 170.207(m)(1);

(B) Metadata. For each vital sign in paragraph (a)(6)(i) of this section, the technology must also record the following:

   [1] Date and time of vital sign measurement or end time of vital sign measurement;

   [2] The measuring- or authoring-type source of the vital sign measurement; and

   [3] Optional. Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g); and

(C) Metadata for oxygen saturation in arterial blood by pulse oximetry. For the oxygen saturation in arterial blood by pulse oximetry, the technology must enable a user to record, change, and access the patient’s inhaled oxygen concentration identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with LOINC® code 8478-0.
§ 170.315(a)(6) Vital signs, body mass index, and growth charts

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

(ii) Optional – Body mass index percentile per age and sex. Enable a user to record, change, and access a patient’s body mass index [percentile] per age and sex for patients two to twenty years of age in accordance with the following (The patient’s body mass index [percentile] per age and sex must be recorded in numerical values only.):

(A) Identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with LOINC® code 59576-9 and with the associated applicable unit of measure in the standard specified in § 170.207(m)(1); and

(B) Metadata. The technology must also record the following:

1. Date and time of vital sign measurement or end time of vital sign measurement;
2. The measuring or authoring-type source of the vital sign measurement;
3. The patient’s date of birth;
4. The patient’s sex in accordance with the standard specified in § 170.207(n)(1); and
5. Optional. Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g).

(iii) Optional – Weight for length per age and sex. Enable a user to record, change, and access a patient’s weight for length per age and sex for patients less than three years of age in accordance with the following (The patient’s weight for length per age and sex must be recorded in numerical values only.):

(A) Identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with the LOINC® code and with the associated applicable unit of measure in the standard specified in § 170.207(m)(1); and

(B) Metadata. The technology must record the following:

1. Date and time of vital sign measurement or end time of vital sign measurement;
2. The measuring or authoring-type source of the vital sign measurement;
3. The patient’s date of birth;
4. The patient’s sex in accordance with the standard specified in § 170.207(n)(1); and
5. Optional. Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g).

(iv) Optional – Head occipital-frontal circumference. Enable a user to record, change, and access a patient’s head occipital-frontal circumference for patients less than three years of age in accordance with the following (The patient’s head occipital-frontal circumference must be recorded in numerical values only.):

(A) Identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with LOINC® code 8287-5 and with the associated applicable unit of measure in the standard specified in § 170.207(m)(1); and

(B) Metadata. The technology must also record the following:

1. Date and time of vital sign measurement or end time of vital sign measurement;
2. The measuring or authoring-type source of the vital sign measurement;
3. The patient’s date of birth;
4. The patient’s age in accordance with the standard specified in § 170.207(n)(1); and
5. Optional. Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g).

(v) Optional – Calculate body mass index. Automatically calculate and display body mass index based on a patient’s height and weight.

(vi) Optional – Plot and display growth charts. Plot and display, upon request, growth charts for patients.

Preamble FR Citation: 80 FR 16817 Specific questions in preamble? Yes
§ 170.315(a)(6) Vital signs, body mass index, and growth charts

Public Comment Field:

HIMSS supports the idea of focusing certification for vital signs on a smaller core set that all providers would utilize and that aligns with the Common Clinical Data Set as well as is considered part of the Base EHR definition. If there are additional vital sign measures, they should be considered as optional certification criteria since they would only apply to a subset of clinicians.

In terms of the proposals around requiring a health IT module to enable a user to record vital signs with metadata, HIMSS questions whether metadata should be required when the data is calculated from different sources and comes in at different points in time.

We question the requirements around LOINC codes and ask for clarity around whether they are to be displayed, stored, or mapped. Moreover, HIMSS questions whether the idea of rolling up granular LOINC codes to more generic ones defeats the goal of semantic interoperability championed by ONC. If more granular LOINC codes are replaced by general LOINC codes, the level of specificity and context is lost along with any sort of guarantee of semantic meaning. HIMSS overwhelmingly supports the idea of allowing an EHR to record LOINC codes at the granular level chosen by the specific EHR technology.

§ 170.315(a)(7) Problem list

Included in 2015 Edition Base EHR Definition?
Yes

Stage 3 MU Objective
N/A

2015 Edition Health IT Certification Criterion
(7) Problem list. Enable a user to record, change, and access a patient’s active problem list:
   (i) Ambulatory setting. Over multiple encounters in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4); or
   (ii) Inpatient setting. For the duration of an entire hospitalization in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4).

Preamble FR Citation: 80 FR 16819 Specific questions in preamble? No

Public Comment Field:

HIMSS supports the revised problem list criterion as proposed in the NPRM.

§ 170.315(a)(8) Medication list

Included in 2015 Edition Base EHR Definition?
Yes

Stage 3 MU Objective
N/A

2015 Edition Health IT Certification Criterion
(8) Medication list. Enable a user to record, change, and access a patient’s active medication list as well as medication history:
   (i) Ambulatory setting. Over multiple encounters; or
   (ii) Inpatient setting. For the duration of an entire hospitalization.

Preamble FR Citation: 80 FR 16819 Specific questions in preamble? No

Public Comment Field:
### § 170.315(a)(9) Medication allergy list

<table>
<thead>
<tr>
<th>Included in 2015 Edition Base EHR Definition?</th>
<th>Yes</th>
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<tbody>
<tr>
<td>Stage 3 MU Objective</td>
<td>N/A</td>
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</table>
| 2015 Edition Health IT Certification Criterion | (9) Medication allergy list. Enable a user to record, change, and access a patient’s active medication allergy list as well as medication allergy history:  
  (i) Ambulatory setting. Over multiple encounters; or  
  (ii) Inpatient setting. For the duration of an entire hospitalization. |
| Preamble FR Citation: 80 FR 16820 | |
| Specific questions in preamble? | No |
| Public Comment Field: | HIMSS strongly endorses the idea of adding food allergies and environmental allergies to the medication allergy criterion. Most clinicians are already recording this information in their patient records, so adding these additional allergies to this certification criterion will ultimately benefit the patient. Overall, this is a patient safety issue and needs to be recognized as such. After all, food allergy is an increasing cause of morbidity and mortality in the US and is responsible for hundreds of preventable fatal outcomes each year. Additionally, a number of immunizations and other pharmaceuticals contain residues of edible substances. |

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

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<thead>
<tr>
<th>Included in 2015 Edition Base EHR Definition?</th>
<th>Yes</th>
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<tbody>
<tr>
<td>Stage 3 MU Objective</td>
<td>Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.</td>
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</tbody>
</table>
§ 170.315(a)(10) Clinical decision support

2015 Edition Health IT Certification Criterion

(10)  Clinical decision support.

   (i)  Evidence-based decision support interventions. Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data:

       (A) Problem list;
       (B) Medication list;
       (C) Medication allergy list;
       (D) At least one demographic specified in paragraph (a)(5)(i) of this section;
       (E) Laboratory tests; and
       (F) Vital signs.

   (ii)  Linked referential clinical decision support.

       (A) Technology must be able to identify for a user diagnostic and therapeutic reference information in accordance with the standard and implementation specifications at § 170.204(b)(3) or (4).

       (B) For paragraph (a)(10)(ii)(A) of this section, technology must be able to identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (a)(10)(i)(A), (B), and (D) of this section.

   (iii) Clinical decision support configuration.

       (A) Enable interventions and reference resources specified in paragraphs (a)(10)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role.

       (B) Technology must enable interventions to be:

              (1)  Based on the data referenced in paragraphs (a)(10)(i)(A) through (F) of this section.

              (2)  When a patient's medications, medication allergies, problems, and laboratory tests and values/results are incorporated from a transition of care/referral summary received and pursuant to paragraph (b)(2)(iii)(D) of this section.

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

   (iv)  CDS intervention interaction. Interventions provided to a user in paragraphs (a)(10)(i) through (iii) of this section must occur when a user is interacting with technology.

   (v)  Source attributes. Enable a user to review the attributes as indicated for all clinical decision support resources:

       (A)  For evidence-based decision support interventions under paragraph (a)(10)(i) of this section:

              (1)  Bibliographic citation of the intervention (clinical research/guideline);

              (2)  Developer of the intervention (translation from clinical research/guideline);

              (3)  Funding source of the intervention development technical implementation; and

              (4)  Release and, if applicable, revision date(s) of the intervention or reference source.

       (B)  For linked referential clinical decision support in paragraph (a)(10)(ii) of this section and drug-drug, drug-allergy interaction checks in paragraph (a)(4) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).

   (vi)  Intervention response documentation.

       (A) Technology must be able to record at least one action taken and by whom in response to clinical decision support interventions.

       (B) Technology must be able to generate either a human readable display or human readable report of actions taken and by whom in response to clinical decision support interventions.
### § 170.315(a)(10) Clinical decision support

**Public Comment Field:**

Given that there are many different types of clinical decision support (CDS) that sometimes are associated with a clinician taking an action but occasionally are purely informational, HIMSS notes that the specific requirements proposed in this criterion are not always broadly applicable every time CDS is utilized. Mandating a response from the provider when none is needed given the type of CDS being used (e.g. order sets) may serve to increase complexity and confusion among users of what the documented response should be when none is needed. HIMSS supports dropping these requirements from the 2015 certification criteria. Overall, we do not see the need for changes from the 2014 criteria.

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

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

No

**Stage 3 MU Objective**

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

**2015 Edition Health IT Certification Criterion**

(11) **Drug-formulary and preferred drug list checks.** Technology must either meet paragraph (a)(11)(i) or (ii) of this section.

(i) **Drug formulary checks.**

(A) Automatically check whether a drug formulary exists for a given patient and medication.

(B) Indicate for a user the last update of the drug formulary; and

(C) Receive and incorporate a formulary and benefit file in accordance with the standard specified in § 170.205(n)(1).

(ii) **Preferred drug list checks.**

(A) Automatically check whether a preferred drug list exists for a given patient and medication.

(B) Indicate for a user the last update of the preferred drug list.

**Preamble FR Citation:** 80 FR 16821

**Specific questions in preamble?** Yes

**Public Comment Field:**

HIMSS supports the use of the NCPDP Formulary and Benefit Standard v3.0 for this criterion. In addition, HIMSS notes that adding the idea of displaying the last formulary update to this certification criterion is problematic as that information is going to come from the pharmacy benefit provider and is not within the scope of the EHR. The Surescripts certification process addresses this issue and using that process for this functionality could allow for more streamlined testing of this criterion.

### § 170.315(a)(12) Smoking status

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

Yes

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

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

**Preamble FR Citation:** 80 FR 16822

**Specific questions in preamble?** No
§ 170.315(a)(12) Smoking status

Public Comment Field:

HIMSS notes a significant challenge associated with using the 2014 Release of SNOMED CT for recording, changing, and accessing the smoking status criterion. With over 100 smoking-related codes in SNOMED CT, questions remain about how to develop an appropriate EHR interface. We support the idea of optionality here—under our plan, the developer could design their systems to permit users to employ those of the broader set of SNOMED CT codes that are applicable to their users, but they would be required to at least use the 8 smoking status SNOMED CT codes from the 2014 edition. Even so, HIMSS is concerned with the mapping of the allowable SNOMED smoking codes in the CCDA. Providers consider these inadequate as they are missing certain relevant tobacco use criteria.

§ 170.315(a)(13) Image results

Included in 2015 Edition Base EHR Definition?
No

Stage 3 MU Objective
N/A

2015 Edition Health IT Certification Criterion
(13) Image results. Indicate to a user the availability of a patient’s images and narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable electronic access to such images and narrative interpretations.

Preamble FR Citation: 80 FR 16822 Specific questions in preamble? No

Public Comment Field:

HIMSS encourages ONC to explore the possibility of including an application program interface (API) with the image results. In addition, image results are often typically text so having access to the image itself would be helpful to the clinician. As the current requirements for this criterion do provide access to the image in addition to the report, overall, HIMSS recommends that the criterion remain unchanged.

§ 170.315(a)(14) Family health history

Included in 2015 Edition Base EHR Definition?
No, but proposed for the EHR Incentive Programs CEHRT definition

Stage 3 MU Objective
N/A

2015 Edition Health IT Certification Criterion
(14) Family health history. Enable a user to record, change, and access a patient’s family health history in accordance with the familial concepts or expressions included in, at a minimum, the version of the standard in § 170.207(a)(4).

Preamble FR Citation: 80 FR 16822 Specific questions in preamble? No

Public Comment Field:

HIMSS supports the approach taken by ONC with the two options for certification criteria for family health history. The two options provide flexibility to health IT developers and providers to develop, adopt, and implement technology that supports their clinical documentation needs, while still enabling interoperability. However, HIMSS recommends that ONC limit the possible standards options to the two described in the NPRM to facilitate interoperability.
### § 170.315(a)(15) Family health history – pedigree

**Included in 2015 Edition Base EHR Definition?**  
No, but proposed for the EHR Incentive Programs CEHRT definition as an alternative to § 170.315(a)(14).

**Stage 3 MU Objective**  
N/A

**2015 Edition Health IT Certification Criterion**

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

**Preamble FR Citation:** 80 FR 16822  
**Specific questions in preamble? No**

**Public Comment Field:**

HIMSS supports the approach taken by ONC with the two options for certification criteria for family health history. HIMSS recommends that ONC limit the possible standards options to the two described in the NPRM to facilitate interoperability.

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

**Included in 2015 Edition Base EHR Definition?**  
No

**Stage 3 MU Objective**  
N/A

**2015 Edition Health IT Certification Criterion**

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

**Preamble FR Citation:** 80 FR 16823  
**Specific questions in preamble? No**

**Public Comment Field:**

For patient list creation, HIMSS recommends that the criterion provide clinicians with the ability to sort the list many different ways, such as by name, location, or add/remove. This approach gives the clinician some flexibility in adapting to their regular clinical workflow.

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

**Included in 2015 Edition Base EHR Definition?**  
No
§ 170.315(a)(17) Patient-specific education resources

Stage 3 MU Objective
The EP, eligible hospital, or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability.

2015 Edition Health IT Certification Criterion
(17) Patient-specific education resources. Technology must be able to:
   (i) Identify patient-specific education resources based on data included in the patient's problem list and medication list in accordance with the standard (and implementation specifications) specified in § 170.204(b)(3) or (4); and
   (ii) Request that patient-specific education resources be identified in accordance with the standard in § 170.207(g)(2).

Preamble FR Citation: 80 FR 16823 Specific questions in preamble? No

Public Comment Field:
Although this 2015 certification criterion focuses solely on the use of Infobutton for patient-specific education resources, HIMSS is supportive of efforts by ONC and CMS that provide flexibility to clinicians to expand the criterion to the use of Infobutton as well as other means necessary. The kind of educational resources included in this criterion should be a function of what works for the provider in their care delivery setting.

HIMSS is supportive of the change in the 2015 criterion that no longer includes a requirement that health IT be capable of electronically identifying patient specific education resources based on “laboratory values/results.”

It is also important to note that that educational resources need to be tailored toward the patient’s health literacy, health IT literacy, and level of engagement. Moreover, since patients may need to communicate in languages other than English, the technology should be able to have the patient’s preferred language as a filter in the list, although we realize that the information will not necessarily be returned in the patient’s preferred language.

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

Included in 2015 Edition Base EHR Definition? No

Stage 3 MU Objective
N/A

2015 Edition Health IT Certification Criterion
(18) Electronic medication administration record.
   (i) In combination with an assistive technology that provides automated information on the “rights” specified in paragraphs (a)(18)(i)(A) through (E) of this section, enable a user to verify the following before administering medication(s):
      (A) Right patient. The patient to whom the medication is to be administered matches the medication to be administered.
      (B) Right medication. The medication to be administered matches the medication ordered for the patient.
      (C) Right dose. The dose of the medication to be administered matches the dose of the medication ordered for the patient.
      (D) Right route. The route of medication delivery matches the route specified in the medication order.
      (E) Right time. The time that the medication was ordered to be administered compared to the current time.
   (ii) Right documentation. Record the time and date in accordance with the standard specified in § 170.210(g), and user identification when a medication is administered.

Preamble FR Citation: 80 FR 16823 Specific questions in preamble? No
### § 170.315(a)(18) Electronic medication administration record

**Public Comment Field:**
HIMSS is supportive of this criterion, and offers one recommendation: the electronic medication administration record (eMAR) needs to be linked to a patient ID that is barcoded on their wristband or otherwise noted in their record. It is a significant patient safety tool in ensuring that the intended patient is receiving the right medications.

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

**Included in 2015 Edition Base EHR Definition?**
No, but proposed for the EHR Incentive Programs CEHRT definition

**Stage 3 MU Objective**
Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient’s care.

**2015 Edition Health IT Certification Criterion**
(19) **Patient health information capture.** Technology must be able to enable a user to:

- (i) Identify, record, and access patient health information documents;
- (ii) Reference and link to patient health information documents; and
- (iii) Record and access information directly shared by a patient.

**Preamble FR Citation:** 80 FR 16823

**Specific questions in preamble?** No

**Public Comment Field:**
HIMSS supports this certification criterion. We support the capability to store an advance directive and/or include more information about the advance directive, such as a link to the advance directive or instructions regarding where to find the advance directive or more information about it.

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

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

**Stage 3 MU Objective**
N/A

**2015 Edition Health IT Certification Criterion**
(20) **Implantable device list.**

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

**Preamble FR Citation:** 80 FR 16824

**Specific questions in preamble?** Yes
§ 170.315(a)(20) Implantable device list

Public Comment Field:

HIMSS is committed to advancing the implantable device list certification criterion and ensuring the availability of this information to facilitate the use of unique device identifiers to minimize device-related adverse events, enhance clinical decision-making for devices, and respond to recalls. Certification criteria focused on an implantable device list is an essential component of a patient safety program.

HIMSS is therefore supportive of section (i) of this criterion for inclusion in Base EHRs. However, we oppose the additional functionality proposed in (ii), (iii) and (iv). We urge ONC to make it optional for 2015 Edition certification and not a part of the Base EHR definition. It is premature to propose these additional EHR capabilities for Base EHR requirements as the process associated with this information will continue to evolve over the next five years. We understand that this information will be recorded by device manufacturers when devices are implanted, and that medical device manufacturers will perform the capabilities in (ii), (iii) and (iv). By making (ii), (iii) and (iv) optional, these capabilities can be adopted and implemented in specialty systems which would benefit during this timeframe as the process evolves.

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

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

We are furthermore concerned that without interoperability capabilities from the most likely sources (e.g., OR systems), accurate documentation is challenging to achieve.

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

Included in 2015 Edition Base EHR Definition?
No

Stage 3 MU Objective
N/A
§ 170.315(a)(21) Social, psychological, and behavioral data

2015 Edition Health IT Certification Criterion

(21) Social, psychological, and behavioral data. Enable a user to record, change, and access, at a minimum, one of the following patient social, psychological, and behavioral data.

   (i) Sexual orientation. Enable sexual orientation to be recorded in accordance with the standard specified in § 170.207(o)(1) and whether a patient declines to specify sexual orientation.

   (ii) Gender identity. Enable gender identity to be recorded in accordance with the standard specified in § 170.207(o)(2) and whether a patient declines to specify gender identity.

   (iii) Financial resource strain. Enable financial resource strain to be recorded in accordance with the standard specified in § 170.207(o)(3) and whether a patient declines to specify financial resource strain.

   (iv) Education. Enable education to be recorded in accordance with the standard specified in § 170.207(o)(4) and whether a patient declines to specify education.

   (v) Stress. Enable stress to be recorded in accordance with the standard specified in § 170.207(o)(5) and whether a patient declines to specify stress.

   (vi) Depression. Enable depression to be recorded in accordance with the standard specified in § 170.207(o)(6) and whether a patient declines to specify depression.

   (vii) Physical activity. Enable physical activity to be recorded in accordance with the standard specified in § 170.207(o)(7) and whether a patient declines to specify physical activity.

   (viii) Alcohol use. Enable alcohol use to be recorded in accordance with the standard specified in § 170.207(o)(8) and whether a patient declines to specify alcohol use.

   (ix) Social connection and isolation. Enable social connection and isolation to be recorded in accordance with the standard specified in § 170.207(o)(9) and whether a patient declines to specify social connection and isolation.

   (x) Exposure to violence (intimate partner violence). Enable exposure to violence (intimate partner violence) to be recorded in accordance with the standard specified in § 170.207(o)(10) and whether a patient declines to specify exposure to violence (intimate partner violence).

Preamble FR Citation: 80 FR 16826

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

Public Comment Field:

HIMSS is supportive of this criterion, but recommends that ONC conduct further study on best practices in this area and share that information across the community. Such action will ensure that providers have actionable steps that they can take to ensure the privacy and security of social, psychological, and behavioral data and that it can be exchanged. HIMSS observes how difficult it often is for is for a receiver of this information, like a primary care physician (PCP), to get this data. How a PCP incorporates Part 2 data is a challenge from a workflow as well as a technological basis. To help advance the field and this criterion, ONC should consider how to further study the following topics, such as non-redisclosure of information, clinician workflow, and how EHRs can digest Part 2 data in the legal and most appropriate way.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16830

Specific questions in preamble? Yes
§ 170.315(a)(22) Decision support – knowledge artifact

Public Comment Field:
In principle, HIMSS supports this criterion. The focus of our discussion on this item was on the portability of CDS, which many providers are not able to rigorously test. ONC putting forward this certification criterion should help providers who do not have the capability to test the portability of their clinical decision support.

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

Included in 2015 Edition Base EHR Definition?
No

Stage 3 MU Objective
N/A

2015 Edition Health IT Certification Criterion
(23) Decision support – service. Enable a user to send and receive electronic clinical guidance in accordance with the standard specified in § 170.204(e)(1).

Preamble FR Citation: 80 FR 16831
Specific questions in preamble? Yes

Public Comment Field:

§ 170.315(b)(1) Transitions of care

Included in 2015 Edition Base EHR Definition?
Yes

Stage 3 MU Objective
The EP, eligible hospital, or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of certified EHR technology.

2015 Edition Health IT Certification Criterion
(1) Transitions of care.
   (i) Send and receive via edge protocol. Technology must be able to:
      (A) Send transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(d); and
      (B) Receive transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(d) from a service that has implemented the standard specified in §170.202(a).
      (C) XDM processing. Receive and make available the contents of a XDM package formatted in accordance with the standard adopted in § 170.205(p)(1) if the technology is also being certified using an SMTP-based edge protocol.
   (ii) Validate and display.
      (A) Validate C-CDA conformance – system performance. Technology must demonstrate its ability to detect valid and invalid transition of care/referral summaries received and formatted in accordance with both of the standards specified in § 170.205(a)(3) and (4) This includes the ability to:
         (1) Parse each of the document types formatted according to the following document templates: CCD; Consultation Note; History and Physical; Progress Note; Care Plan; Transfer Summary; Referral Note, and Discharge Summary.
         (2) Detect errors in corresponding “document-templates,” “section-templates,” and “entry-templates,” including invalid vocabulary standards and codes not specified in either of the standards adopted in § 170.205(a)(3) and (4);
§ 170.315(b)(1) Transitions of care

| (3) | Identify valid document-templates and process the data elements required in the corresponding section-templates and entry-templates from either of the standards adopted in § 170.205(a)(3) and (4); |
| (4) | Correctly interpret empty sections and null combinations; and |
| (5) | Record errors encountered and allow for a user to be notified of or review the errors produced. |
| (B) | Technology must be able to display in human readable format the data included in transition of care/referral summaries received and formatted according to the standards specified in § 170.205(a)(3) and (4). |
| (C) | Section views. Allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary received and formatted in accordance with either of the standards adopted in § 170.205(a)(3) and (4). |

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

(iii) Create

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

(1) Formatted according to the standards adopted in § 170.205(a)(3);

(2) Formatted according to the standards adopted in § 170.205(a)(4); and

(3) Includes, at a minimum, the Common Clinical Data Set and the following data expressed, where applicable, according to the specified standard(s):

   (i) **Encounter diagnoses.** The standard specified in § 170.207(i) or, at a minimum, the version of the standard specified §170.207(a)(4);

   (ii) **Cognitive status;**

   (iii) **Functional status;**

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

   (v) **Inpatient setting only.** Discharge instructions.

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

(1) **Data.** first name, last name, maiden name, middle name (including middle initial), suffix, date of birth, place of birth, current address, historical address, phone number, and sex.

(2) **Constraint.** Represent last/family name according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0.

(3) **Constraint.** Represent suffix according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0 (JR, SR, I, II, III, IV, V, RN, MD, PHD, ESQ). If no suffix exists, the field should be entered as null.

(4) **Constraint.** Represent the year, month and date of birth are required fields while hour, minute and second should be optional fields. If hour, minute and second are provided then either time zone offset should be included unless place of birth (city, region, country) is provided; in latter local time is assumed. If date of birth is unknown, the field should be marked as null.

(5) **Constraint.** Represent phone number (home, business, cell) in the ITU format specified in ITU-T E.123 and ITU-T E.164. If multiple phone numbers are present, all should be included.

(6) **Constraint.** Represent sex in accordance with the standard adopted at § 170.207(n)(1).

**Preamble FR Citation:** 80 FR 16831  
**Specific questions in preamble?** Yes
§ 170.315(b)(1) Transitions of care

Public Comment Field:
HIMSS would like to reiterate its support from our comments on the 2015 interoperability Standards Advisory for the Consolidated-CDA R2.0 as the best available standard. Consolidated-CDA R 2.0 is a newer version than CCDA R1.1. It intentionally updates and reconciles issues reported from the use of R1.1. C-CDA R1.1 includes 9 document templates and about 70 section templates. C-CDA R2.0 includes 3 new document templates and some 30 new section templates. Both are Implementation Guides for use of the CDA R2 Standard to implement the document types included (also referred to as clinical notes).

However, many of our experts are concerned with the upgrade to CCDA Release 2.0 until such time that the compatibility issues have been addressed and can be managed. In particular, we are concerned that receipt of CCDA Release 2.0 documents by systems that are not able to support CCDA Release 2.0 fully will cause recipients to be unable to read even the human-readable sections. While it may not be feasible to consume and incorporate data from the CCDA in those scenarios, which would be acceptable as part of a transition period to adopt the new version, but throughout that process the human-readable sections must remain fully readable. HIMSS supports the criterion’s requirement that one be able to provide the human-readable content of the documents.

We also have concerns with the proposal to generate both C-CDA R1.1 and R2 documents to support the transition. A C-CDA R1.1 document will not be able to fully represent a C-CDA R2 document, and generating a C-CDA R2 document that only contains what a C-CDA R1.1 would represent is not useful. Furthermore, having to maintain multiple documents that are supposed to represent the same event will cause confusion with the users unless extraordinary steps are taken to “hide” the version of the document that is not used.

In addition, in terms of patient matching data quality, HIMSS recommends several points related to standardizing data formats for data demographic fields:
• Attributes. Rather than limit to such a small set of attributes, the list should be expanded to included address. In addition, specify that if a provider is sharing an attribute in the CDA format, that it should be shared in that format.
• Security. Given the increase in the number of demographic attributes that are shared there should be a specification for an appropriate encryption standard to protect the data while in transit.
• Data Quality. For example, the simplest measure of quality is the number of missing values that have a value. In addition, funds should be provided to study the issue of data quality or demographic data in greater detail.
• Date of Birth. The certification criteria could be read to disallow sending as much of the date of birth as is available. Instead, we recommend that senders send as much of the date of birth as available. For example, if day of birth is missing, the certification criteria specify senders should send year and month, if available.
• Administrative Gender. The certification criteria should point to applicable sections of the C-CDA implementation guide, rather than create new implementation guidance through regulation.

For name normalization, HIMSS recommends:
• Because the CAQH CORE implementation guide contains a large amount of information specific to ACS X12 documents, the certification criteria should point to the specific relevant sections of the CAQH CORE guide intended.
• The CAQH guide is specific to normalizing information on receipt, rather than on send. Because pre-normalization on send can lead to data loss (e.g., for receivers who may account for punctuation in matching rules), we recommend that ONC adopt these rules as best practice for receipt, rather than certification criteria on send.
• For send, we recommend that certification criteria clarify that Health IT systems should store last/family name distinct from suffix and populate for purposes of interoperability (for example, following C-CDA implementation guidance) accordingly.

Overall, internally valuating matching accuracy is urgently needed, though there is little information on this topic. If there is a lack of clarity on the issue, funding for further study of the issue should be allocated to allow good policy decisions be made. The continued evaluation of matching algorithms would allow organizations to continue adjusted the parameters on their matching software. Moreover, developing, promoting and disseminating best practices should be broken down further into two items. The issue of developing best practices can be conducted by ensuring that adequate research funds are available for the specific problems surrounding the issue of data quality and matching. The second point would be disseminating the best practices. Ways to further share lessons learned in this area should be explored.
### § 170.315(b)(2) Clinical information reconciliation and incorporation

**Included in 2015 Edition Base EHR Definition?**
No

**Stage 3 MU Objective**
The EP, eligible hospital, or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of certified EHR technology.

**2015 Edition Health IT Certification Criterion**
(2) Clinical information reconciliation and incorporation.

(i) General requirements. Paragraphs (b)(2)(ii) and (iii) of this section must be completed based on the receipt of a transition of care/referral summary formatted in accordance with the standard adopted in § 170.205(a)(3) as well as separately to the standard adopted in § 170.205(a)(4) using the Continuity of Care Document, Discharge Summary Document and Referral Summary document templates.

(ii) Correct patient. Upon receipt of a transition of care/referral summary formatted according to either of the standards adopted at § 170.205(a)(3) or (4), technology must be able to demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient.

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

- (A) Simultaneously display (i.e., in a single view) the data from at least two sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date;

- (B) Enable a user to create a single reconciled list of medications, medication allergies, or problems;

- (C) Enable a user to review and validate the accuracy of a final set of data; and

- (D) Upon a user's confirmation, automatically update the list, and incorporate the following data expressed according to the specified standard(s):

  1. Medications. At a minimum, the version of the standard specified in § 170.207(d)(3);
  2. Medication allergies. At a minimum, the version of the standard specified in § 170.207(d)(3); and
  3. Problems. At a minimum, the version of the standard specified in § 170.207(a)(4).

(iv) System verification. Based on the data reconciled and incorporated, the technology must be able to create a file formatted according to the standard adopted at § 170.205(a)(4) using the Continuity of Care Document template.

**Preamble FR Citation:** 80 FR 16835

**Specific questions in preamble?** No

**Public Comment Field:**
HIMSS supports this certification criterion as well as the addition of several data elements in the summary of care record that providers share with one another during transitions or referrals. For instance, HIMSS recommends that information on over-the-counter, drug samples, and nutraceuticals get included in the summary along with medications. Moreover, in addition to medication allergies, food and environmental allergies also need to be added. Overall, HIMSS wants to reiterate the importance of including this additional information in the summary of care record, and would posit that the burden is increased on providers that do not collect this information and share it with their colleagues during transitions or referrals.

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

**Included in 2015 Edition Base EHR Definition?**
No
§ 170.315(b)(3) Electronic prescribing

Stage 3 MU Objective
EPs must generate and transmit permissible prescriptions electronically, and eligible hospitals and CAHs must generate and transmit permissible discharge prescriptions electronically (eRx).

2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16835 Specific questions in preamble? Yes

Public Comment Field:
HIMSS recommends that ONC delete or separate many of the proposed new criteria that are not required to satisfy EHR Incentive Program objectives. We do not want the addition of several new criteria to adversely affect the ability of EHR developers to continue to provide certified software to providers who are actively engaged in electronic prescribing through utilization of current standards. For example, it is our understanding that change and cancel have very little uptake in the marketplace, while criteria for fill status notifications have even less use among Surescripts providers.

HIMSS recommends that the certification criterion add a field for the reason that a patient is taking a particular medication during the electronic prescribing process. Overall, pharmacists want to know why a patient is on a medication and having this information allows the pharmacist to help prepare the appropriate educational resources for the patient. In addition, HIMSS supports the proposal in this criterion to require a user to e-prescribe all medications in the metric unit standard only.
§ 170.315(b)(4) Incorporate laboratory tests and values/results

| Included in 2015 Edition Base EHR Definition? | No |
| Stage 3 MU Objective | N/A |

2015 Edition Health IT Certification Criterion

(4) **Incorporate laboratory tests and values/results.**

(i) **Receive results.**

(A) **Ambulatory setting only.**

(1) Receive and incorporate clinical laboratory tests and values/results in accordance with the standard specified in § 170.205(j)(2); and, at a minimum, the version of the standard specified in § 170.207(c)(3).

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

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

(ii) **Display the test report information:**

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

(B) Related to reference intervals or normal values as specified in 42 CFR 493.1291(d);

(C) For alerts and delays as specified in 42 CFR 493.1291(g) and (h); and

(D) For corrected reports as specified in 42 CFR 493.1291(k)(2).

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

Preamble FR Citation: 80 FR 16837

Specific questions in preamble? Yes

Public Comment Field:

HIMSS supports the proposal in the certification criterion for using LOINC as the vocabulary standard for laboratory orders.

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

| Included in 2015 Edition Base EHR Definition? | No |
| Stage 3 MU Objective | N/A |

2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16838

Specific questions in preamble? No

Public Comment Field:

For this certification criterion, HIMSS notes that there could be limitations associated with HL7 Version2.5.1 and setting up the connections for small practices can be costly. Therefore, we propose that the criterion not focus exclusively on 2.5.1. There are several studies that have used the Direct Project to transfer laboratory data, so HIMSS suggests incorporating an account with a health information service provider (HISP) via the Direct Project as part of the criterion.
§ 170.315(b)(6) Data portability

Included in 2015 Edition Base EHR Definition?
Yes

Stage 3 MU Objective
N/A

2015 Edition Health IT Certification Criterion

(6) Data portability.

(i) General requirements for export summary configuration. A user must be able to set the following configuration options when using technology to create an export summary or set of export summaries for patients whose information is stored in the technology. A user must be able to execute these capabilities at any time the user chooses and without subsequent developer assistance to operate.

(ii) Document creation configuration.

(A) Document-template types. A user must be able to configure the technology to create an export summary or export summaries formatted according to the standard adopted at § 170.205(a)(4) for any of the following document-template types.

(1) Generally applicable. CCD; Consultation Note; History and Physical; Progress Note; Care Plan; Transfer Summary; and Referral Note.

(2) Inpatient setting only. Discharge Summary.

(B) For any document-template selected the technology must be able to include, at a minimum, the Common Clinical Data Set and the following data expressed, where applicable, according to the specified standard(s):

(1) Encounter diagnoses. The standard specified in § 170.207(i) or, at a minimum, the version of the standard at § 170.207(a)(4);

(2) Cognitive status;

(3) Functional status;

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

(5) Inpatient setting only. Discharge instructions.

(C) Use of the “unstructured document” document-level template is prohibited for compliance with the standard adopted at § 170.205(a)(4).

(iii) Timeframe configuration. A user must be able to configure the technology to set the time period within which data would be used to create the export summary or summaries. This must include the ability to enter in a start and end date range as well as the ability to set a date at least three years into the past from the current date.

(iv) Event configuration. A user must be able to configure the technology to create an export summary or summaries based on the following user selected events:

(A) A relative date or time (e.g., the first of every month);

(B) A specific date or time (e.g., on 10/24/2015); and

(C) When a user signs a note or an order.

(v) Location configuration. A user must be able to configure and set the storage location to which the export summary or export summaries are intended to be saved.

Preamble FR Citation: 80 FR 16839
Specific questions in preamble? No
§ 170.315(b)(6) Data portability

Public Comment Field:
HIMSS supports patient data matching as a key tenet of this certification criterion and helping to ensure that each party has the same patient in mind. The NPRM proposes that the minimum data that a health module must be capable of including in an export summary are all the data represented in the common clinical data set; however, other settings of care may not have all that information.

As the intentions for certification go beyond EHRs, HIMSS recommends that ONC look at some contingencies to build into the certification criteria for those ancillary systems that don’t have all the data elements. Additional criteria may need to be established for the ancillary systems.

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

Included in 2015 Edition Base EHR Definition?
No

Stage 3 MU Objective
N/A

2015 Edition Health IT Certification Criterion
(7) Data segmentation for privacy – send. Technology must enable a user to create a summary record formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that is tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1).

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

Public Comment Field:
HIMSS believes there are many difficulties associated with this certification criterion. Further, HIMSS questions whether the community will ready to implement this for 2018.

In our Standards Advisory comments, HIMSS discussed how HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition, was the appropriate standard for data segmentation. However, we noted that although this is the best available standard, adoption has remained low. This may be related at least in part to the technical complexity of implementation, the limited participation of behavioral health in existing health information exchange implementations, and the challenges of policy implementations, particularly related to Part 2 data.

Moreover, on May 20, 2015, the Health IT Standards Committee (“HITSC”) Transport & Security Standards (“TSS”) Workgroup (“WG”) observed that, while data segmentation for privacy (“DS4P”) has been piloted and is beginning trial implementations in EHR products, there are resulting concerns that need to be addressed. While DS4P is important in that it enables data exchange where none had been possible, the HITSC TSS WG observed that DS4P is not ready to become a standard for certification. HIMSS supports this finding. At this time, HIMSS opposes DS4P becoming a standard for certification.

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

Included in 2015 Edition Base EHR Definition?
No

Stage 3 MU Objective
N/A
### § 170.315(b)(8) Data segmentation for privacy – receive

**2015 Edition Health IT Certification Criterion**

(8) **Data segmentation for privacy – receive.** Technology must enable a user to:

(i) Receive a summary record that is tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1);

(ii) Apply document-level tagging and sequester the document from other documents received; and

(iii) View the restricted document (or data), without incorporating the document (or data).

**Preamble FR Citation:** 80 FR 16842 (also see 80 FR 16840)  
**Specific questions in preamble?** No

**Public Comment Field:**

On May 20, 2015, the HITSC TSS WG observed that, while DS4P has been piloted and is beginning trial implementations in EHR products, there are resulting concerns that need to be addressed. HIMSS agrees with this observation. While DS4P is important in that it enables data exchange where none had been possible, the HITSC TSS WG also observed that DS4P is not ready to become a standard for certification. HIMSS supports this finding of the HITSC TSS WG and recommends against DS4P at this time becoming a standard for certification since it is not yet ready. Finally, the HITSC TSS WG recommends that ONC continue to support and encourage trial implementations of DS4P in EHR technology to help accelerate specification refinement and adoption. HIMSS agrees and supports this observation.

In addition, HIMSS supports the idea of less granular application levels of metadata in the Final Rule.

### § 170.315(b)(9) Care plan

**Included in 2015 Edition Base EHR Definition?**  
No

**Stage 3 MU Objective**  
N/A

**2015 Edition Health IT Certification Criterion**

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

**Preamble FR Citation:** 80 FR 16842  
**Specific questions in preamble?** Yes

**Public Comment Field:**

HIMSS asks for clarification here on what constitutes a care plan. During our discussions on this NPRM, there was significant confusion across the community. We request that the Final Rule clarify this point.

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

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

**Stage 3 MU Objective**  
N/A
### § 170.315(c)(1) Clinical quality measures – record and export

**2015 Edition Health IT Certification Criterion**

(1) **Clinical quality measures – record and export.**

(i) **Record.** For each and every CQM for which the technology is presented for certification, the technology must be able to record all of the data that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of “patient reason,” “system reason,” or “medical reason.”

(ii) **Export.** A user must be able to export a data file formatted in accordance with the standard specified at § 170.205(h) for one or multiple patients that includes all of the data captured for each and every CQM to which technology was certified under paragraph (c)(1)(i) of this section. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.

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<td>80 FR 16842</td>
<td>Yes</td>
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**Public Comment Field:**

HIMSS emphasizes that when evaluating this certification criterion there are two areas that need to be preserved: the meaning of the data in clinical quality measures (CQMs), and QRDA Category 1 as well as QRDA Category 3.

In terms of preserving meaning, providers could be using services to do the exporting of data that are outside the EHR. In an EHR when you have the data, there is a certain meaning. HIMSS wants to ensure that CQMs preserve the meaning of the data from the EHR. We see it as a significant opportunity--preserving the semantics of what measures mean.

In addition, QRDA Category 1 (patient level data) and QRDA Category 3 (de-identified data) both play significant roles in population health initiatives and need to be preserved. HIMSS emphasizes that these categories cannot be mixed. Each needs to be preserved.

This criterion also raises several questions. The NPRM proposes to require that a system user be able to export CQM data at any time the user chooses and without subsequent developer assistance to operate. HIMSS is concerned that the phrase “at any time the user chooses,” could ultimately limit technology choices and be unrealistic in some circumstances.

Rather than include that phrase, HIMSS asks ONC to focus on the transparency of what is being offered under this criterion rather than being restrictive of how it has to operate.

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

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

No, but proposed for the EHR Incentive Programs CEHRT definition

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

(2) **Clinical quality measures – import and calculate.**

(i) **Import.** Enable a user to import a data file in accordance with the standard specified at § 170.205(h) for one or multiple patients and use such data to perform the capability specified in paragraph (c)(2)(ii) of this section. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.

(ii) **Technology must be able to calculate each and every clinical quality measure for which it is presented for certification.**

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<td>80 FR 16843</td>
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§ 170.315(c)(2) Clinical quality measures – import and calculate

**Public Comment Field:**
HIMSS asks why ONC is no longer offering an exemption that would allow a Health IT Module presented for certification to all three CQM certification criteria to not have to demonstrate the data import capability. HIMSS was supportive of this exemption and would like to hear a compelling argument about why it was changed in the 2015 edition.

There is also confusion across the community about the notion of using QRDA Category 1 files for the purpose of importing test patients into an EHR. HIMSS notes that this functionality was not part of MU, it was a de facto requirement that has now moved into a permanent certification requirement. HIMSS would like clarification on this point.

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

**Included in 2015 Edition Base EHR Definition?**
No, but proposed for the EHR Incentive Programs CEHRT definition

**Stage 3 MU Objective**
N/A

**2015 Edition Health IT Certification Criterion**
(3) [Reserved]

**Preamble FR Citation:** 80 FR 16844
**Specific questions in preamble?** No

**Public Comment Field:**
HIMSS is strongly supportive of continued progress toward the alignment of measures and measurement processes. However, we caution that providers will have less time to evaluate and incorporate measures if they are published as part of the annual PQRS and/or hospital IQR program rulemakings. For the hospital IPPS rule this year, by not having key elements of quality measures which are dependent on data and capabilities that are required for EHRs and by not having a broad range of quality measures in MU, there is much less time available before quality measures become part of the regulatory process. Moreover, there is a lot less time for providers and vendors to respond.

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

**Included in 2015 Edition Base EHR Definition?**
No

**Stage 3 MU Objective**
N/A
§ 170.315(c)(4) Clinical quality measures – filter

2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16844 Specific questions in preamble? Yes

Public Comment Field:
HIMSS supports this certification criterion as a reasonable approach.

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

Included in 2015 Edition Base EHR Definition?
No, but a conditional certification requirement

Stage 3 MU Objective
N/A

2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16846 Specific questions in preamble? No
§ 170.315(d)(1) Authentication, access control, and authorization

Public Comment Field:
HIMSS supports the December 10, 2014 recommendations of the HITSC TSS WG in regard to supporting the development of OAUTH 2.0 for authorization and OpenID Connect for authentication. Also, in support of the HITSC TSS WG recommendations, HIMSS recommends that ONC continue to be informed by the National Strategy for Trusted Identities in Cyberspace (NSTIC) initiative, including in regard to the Trustmark pilot. The Trustmark framework being currently developed may be useful in the healthcare sector for the electronic communication of trust credentials between organizations with different trust frameworks (such as HIE-to-HIE) to facilitate data exchange. The NSTIC initiative may also help align direction in consumer identity-proofing, authentication, and the use of third-party credentials with the needs of the healthcare industry.

HIMSS observes that, in today’s electronic environment, login and other credentials to gain access to a system may be used by an unauthorized third party. There is a need in the industry for better means for authentication, access control, and authorization. However, the technology needs to be mature, cost-effective, and easy to implement. HIMSS members have observed that multifactor authentication has not been readily adopted in the industry, due to costs and burdensome implementation.

Nonetheless, HIMSS supports the December 10, 2014 recommendation of the HITSC TSS WG that, if passwords are used for user authentication, accept only passwords that meet the guessing entropy guidelines set forth in Appendix A of NIST 800-63-2.

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

Included in 2015 Edition Base EHR Definition?
No, but a conditional certification requirement

MU Objective
N/A

2015 Edition Health IT Certification Criterion
(2) Auditable events and tamper-resistance.
   (i) Record actions. Technology must be able to:
      (A) Record actions related to electronic health information in accordance with the standard specified in § 170.210(e)(1);
      (B) Record the audit log status (enabled or disabled) in accordance with the standard specified in § 170.210(e)(2) unless it cannot be disabled by any user; and
      (C) Record the encryption status (enabled or disabled) of electronic health information locally stored on end-user devices by technology in accordance with the standard specified in § 170.210(e)(3) unless the technology prevents electronic health information from being locally stored on end-user devices (see paragraph (d)(7) of this section).
   (ii) Default setting. Technology must be set by default to perform the capabilities specified in paragraph (d)(2)(i)(A) of this section and, where applicable, paragraph (d)(2)(i)(B) or (C) of this section, or both paragraphs (d)(2)(i)(B) and (C).
   (iii) When disabling the audit log is permitted. For each capability specified in paragraphs (d)(2)(i)(A) through (C) of this section that technology permits to be disabled, the ability to do so must be restricted to a limited set of users.
   (iv) Audit log protection. Actions and statuses recorded in accordance with paragraph (d)(2)(i) of this section must not be capable of being changed, overwritten, or deleted by the technology.
   (v) Detection. Technology must be able to detect whether the audit log has been altered.

Preamble FR Citation: 80 FR 16846  Specific questions in preamble? Yes
§ 170.315(d)(2) Auditable events and tamper-resistance

Public Comment Field:
HIMSS agrees with the HITSC TSS WG’s May 20, 2015 recommendation that all security-relevant events should be auditable. A change in user privileges is security-relevant and therefore auditable. Plus, HIMSS also agrees with the HITSC TSS WG recommendation to do the following:

– Add certification criterion stating that certified HIT should be capable of recording an audit trail of all security-relevant events
– Add NIST SP 800-92, sections 2.1.2 and 2.1.3, as standard for specification of auditable events, in addition to ASTM E2147-01.

HIMSS also agrees with the HITSC TSS WG’s observation that what to audit remains a risk management decision for the healthcare organization.

The HITSC TSS WG also recommended that there should be no change in the ability to disable the audit log and therefore recommends no change from the 2014 Final Rule. HIMSS agrees and supports the HITSC TSS WG recommendation regarding no change in the ability to disable the audit log and thus no change from the 2014 Final Rule.

§ 170.315(d)(3) Audit report(s)

Included in 2015 Edition Base EHR Definition?
No, but a conditional certification requirement

Stage 3 MU Objective
N/A

2015 Edition Health IT Certification Criterion
(3) Audit report(s) Enable a user to create an audit report for a specific time period and to sort entries in the audit log according to each of the data specified in the standards at § 170.210(e).

Preamble FR Citation: 80 FR 16847  Specific questions in preamble? No

Public Comment Field:
HIMSS suggests that there should be an electronic recording of an event when a user’s privileges are changed, as such an event may potentially be indicative of a compromised account, malware infection, or malicious insider activity. In addition, the audit log should contain the elements found in ASTM 2147.

§ 170.315(d)(4) Amendments

Included in 2015 Edition Base EHR Definition?
No, but a conditional certification requirement

Stage 3 MU Objective
N/A

2015 Edition Health IT Certification Criterion
(4) Amendments. Enable a user to select the record affected by a patient’s request for amendment and perform the capabilities specified in paragraph (d)(4)(i) or (ii) of this section.

(i) Accepted amendment. For an accepted amendment, append the amendment to the affected record or include a link that indicates the amendment’s location.
(ii) Denied amendment. For a denied amendment, at a minimum, append the request and denial of the request to the affected record or include a link that indicates this information’s location.

Preamble FR Citation: 80 FR 16847  Specific questions in preamble? No
§ 170.315(d)(4) Amendments

Public Comment Field:

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

Included in 2015 Edition Base EHR Definition?
No, but a conditional certification requirement

Stage 3 MU Objective
N/A

2015 Edition Health IT Certification Criterion
(5) Automatic access time-out.
   (i) Automatically stop user access to health information after a predetermined period of inactivity.
   (ii) Require user authentication in order to resume or regain the access that was stopped.

Preamble FR Citation: 80 FR 16847
Specific questions in preamble? Yes

Public Comment Field:
The HITSC TSS WG meeting of May 20, 2015 recommended that this certification criterion language be changed to the following: “Automatically terminate access to protected health information after a configurable period of inactivity, and reinitiate session upon re-authentication of the user.” HIMSS agrees and supports the recommendation of the HITSC TSS WG.

§ 170.315(d)(6) Emergency access

Included in 2015 Edition Base EHR Definition?
No, but a conditional certification requirement

Stage 3 MU Objective
N/A

2015 Edition Health IT Certification Criterion
(6) Emergency Access. Permit an identified set of users to access electronic health information during an emergency.

Preamble FR Citation: 80 FR 16847
Specific questions in preamble? No

Public Comment Field:

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

Included in 2015 Edition Base EHR Definition?
No, but a conditional certification requirement

Stage 3 MU Objective
N/A
### § 170.315(d)(7) End-user device encryption

**2015 Edition Health IT Certification Criterion**

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

(i) Technology that is designed to locally store electronic health information on end-user devices must encrypt the electronic health information stored on such devices after use of the technology on those devices stops.

(A) Electronic health information that is stored must be encrypted in accordance with the standard specified in § 170.210(a)(3);

(B) **Default setting.** Technology must be set by default to perform this capability and, unless this configuration cannot be disabled by any user, the ability to change the configuration must be restricted to a limited set of identified users.

(ii) Technology is designed to prevent electronic health information from being locally stored on end-user devices after use of the technology on those devices stops.

**Preamble FR Citation:** 80 FR 16847  
**Specific questions in preamble?** Yes

**Public Comment Field:**

The NPRM proposes to update the encryption standard to the October 2014 release of FIPS 140-2, Annex A. The HITSC TSS WG meeting of May 20, 2015 agreed with this proposal and suggests adding reference to FIPS 140-2, Annex A (which includes Guideline for Transport Layer Security (TLS)), to support proposed new certification criteria for “application access” for patient engagement and the Common Clinical Data Set. HIMSS agrees and supports the HITSC TSS WG recommendation.

HIMSS observes that, whether a user stores data on the end user device or whether a user stores data in the cloud and can access the data using the end user device, the data must be encrypted. Encryption should be for data at rest and in motion. There needs to be appropriate encryption key management and a strong encryption algorithm, as well as key life cycle management and key escrow recovery. ONC needs to provide guidance on who has or can access the keys: whether it is the end user, the vendor, others (such as to comply with a court order or court-ordered warrant, a subpoena or summons issued by a judicial officer, or a grand jury subpoena, to respond to an administrative request, such as an administrative subpoena or investigative demand or other written request from a law enforcement official, etc.), or a combination thereof.

### § 170.315(d)(8) Integrity

**Included in 2015 Edition Base EHR Definition?**  
No, but a conditional certification requirement

**Stage 3 MU Objective**  
N/A

**2015 Edition Health IT Certification Criterion**

(8) **Integrity.**

(i) Create a message digest in accordance with the standard specified in § 170.210(c).

(ii) Verify in accordance with the standard specified in § 170.210(c) upon receipt of electronically exchanged health information that such information has not been altered.

**Preamble FR Citation:** 80 FR 16847  
**Specific questions in preamble?** Yes

**Public Comment Field:**

HIMSS recommends that data integrity should be ensured for both data at rest and for data in motion. HIMSS supports SHA-2 and recommends that ONC replace SHA-1 with SHA-2 in the 2015 Edition, supporting the recommendation of the HITSC TSS WG of May 20, 2015.
§ 170.315(d)(9) Accounting of disclosures

Included in 2015 Edition Base EHR Definition?
No

Stage 3 MU Objective
N/A

2015 Edition Health IT Certification Criterion
(9) Accounting of disclosures. Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(d).

Preamble FR Citation: 80 FR 16848
Specific questions in preamble? No

Public Comment Field:
HIMSS observes that AOD takes much time and resources, since the tools are not available to efficiently perform an AOD request. HIMSS does not support implementation of the accounting of disclosures certification criterion.

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

Included in 2015 Edition Base EHR Definition?
No

Stage 3 MU Objectives
The EP, eligible hospital, or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability.

Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.
§ 170.315(e)(1) View, download, and transmit to a third party.

2015 Edition Health IT Certification Criterion

(1) View, download, and transmit to 3rd party.

(i) Patients (and their authorized representatives) must be able to use technology to view, download, and transmit their health information to a 3rd party in the manner specified below. Access to these capabilities must be online and through a secure channel that ensures all content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

(A) View. Patients (and their authorized representatives) must be able to use health IT to view in accordance with the standard adopted at § 170.204(a)(1), at a minimum, the following data:

(1) The Common Clinical Data Set (which should be in their English (i.e., non-coded) representation if they associate with a vocabulary/code set).

(2) Inpatient setting only. Provider's name and office contact information.

(3) Laboratory test report(s). Laboratory test report(s), including:

   (i) The information for a test report as specified all the data specified in 42 CFR 493.1291(c)(i) through (7);

   (ii) The information related to reference intervals or normal values as specified in 42 CFR 493.1291(d); and

   (iii) The information for corrected reports as specified in 42 CFR 493.1291(k)(2)

(B) Download.

(1) Patients (and their authorized representatives) must be able to use EHR technology to download an ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) in only human readable format, in only the format specified in accordance to the standard adopted at § 170.205(a)(4), or in both formats. The use of the “unstructured document” document-level template is prohibited for compliance with the standard adopted at § 170.205(a)(4).

(2) When downloaded according to the standard adopted at § 170.205(a)(4), the ambulatory summary or inpatient summary must include, at a minimum the following data (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set):

   (i) Ambulatory setting only. All of the data specified in paragraph (e)(1)(i)(A)(1), (2), (4), and (5) of this section.

   (ii) Inpatient setting only. All of the data specified in paragraphs (e)(1)(i)(A)(1), and (3) through (5) of this section.

(C) Transmit to third party. Patients (and their authorized representatives) must be able to:

(1) Transmit the ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) created in paragraph (e)(1)(i)(B)(2) of this section in accordance with at least one of the following.

   (i) The standard specified in § 170.202(a).

   (ii) Through a method that conforms to the standard specified at § 170.202(d) and leads to such summary being processed by a service that has implemented the standard specified in § 170.202(a).

(2) Inpatient setting only. Transmit transition of care/referral summaries (as a result of a transition of care (pursuant to the capability expressed in the certification criterion adopted at paragraph (b)(1) of this section).

   (i) The standard specified in § 170.202(a).

   (ii) Through a method that conforms to the standard specified at § 170.202(d) and leads to such summary being processed by a service that has implemented the standard specified in § 170.202(a).

(ii) Activity history log.

   (A) When electronic health information is viewed, downloaded, or transmitted to a third-party using the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section or when an application requests electronic health information using the capability specified at paragraph (e)(1)(iii) of this section, the following information must be recorded and made accessible to the patient:

   (1) The action(s) (i.e., view, download, transmission, API response) that occurred;

   (2) The date and time each action occurred in accordance with the standard specified at § 170.210(g);

   (3) The user who took the action; and

   (4) Where applicable, the addressee to whom an ambulatory summary or inpatient summary was transmitted.

   (B) Technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of this section if it is included in the certification criterion adopted at paragraph (b)(1) of this section.
§ 170.315(e)(1) View, download, and transmit to a third party

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

(i) Application access. Patients (and their authorized representatives) must be able to use an application that can interact with the following capabilities. Additionally, the following technical outcomes and conditions must be met through the demonstration of an application programming interface (API) that can respond to requests from other applications for data specified within the Common Clinical Data Set.

(A) Security. The API must include a means to establish a trusted connection with the application requesting patient data, including a means for the requesting application to register with the data source, be authorized to request data, and log all interactions between the application and the data source.

(B) Patient selection. The API must include a means for the application to query for an ID or other token of a patient’s record in order to subsequently execute data requests for that record in accordance with (e)(1)(iii)(C) of this section.

(C) Data requests, response scope, and return format. The API must enable and support both of the following data request interactions:

(1) Data-category request. The API must support syntax that allows it to respond to requests for each of the individual data categories specified in the Common Clinical Data Set and return the full set of data for that data category (according to the specified standards, where applicable) in either XML or JSON.

(2) All-request. The API must support syntax that allows it to respond to a request for all of the data categories specified in the Common Clinical Data Set at one time and return such data (according to the specified standards, where applicable) in a summary record formatted according to the standard adopted at §170.205(a)(4).

(D) Documentation. The API must include accompanying documentation that contains, at a minimum:

(1) API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

(2) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(E) Terms of use. The terms of use for the API must be provided, including, at a minimum, any associated developer policies and required developer agreements.

Preamble FR Citation: 80 FR 16848

Specific questions in preamble? Yes

Public Comment Field:

HIMSS urges ONC to continue to facilitate the development of OAUTH 2.0 for authorization, and OpenID Connect for authentication, and UMA (User Managed Access) an OAUTH profile.

In addition, HIMSS is concerned by the scope and loose definition of the API in this criterion since it could look different in every environment. Several questions arose during our review of the NPRM, including: what does it mean to have all the data in all the categories; what are the privacy and security provisions of the API? HIMSS would like to emphasize the importance of the integrity and management of the API and how the patient needs to be made aware of the potential risks under this approach. We also note that HIMSS supports using FHIR as the basis of the API, but not prematurely locking down FHIR or a particular version as the sole option. Based upon what we anticipate FHIR will become once it is a mature standard, what ONC has set out in the rule appears to be reasonably accomplished. That being said, we encourage ONC to follow the paradigm established by Dixie Baker and her colleagues for levels of standards adoption and maturity when considering what to finalize in this rule.

Moreover, HIMSS encourages ONC to explore the idea of developing guidance or support for patients to emphasize that it is their data, its importance, and to take steps to safeguard it. Ultimately, this effort would be to enable patients to be better custodians of their own data. If ONC was to advance this concept, it may want to consider giving providers the option to augment the information that the technology is required to display.
§ 170.315(e)(2) Secure messaging

Included in 2015 Edition Base EHR Definition?
No

Stage 3 MU Objective
Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient’s care.

2015 Edition Health IT Certification Criterion
(2) Secure messaging. Enable a user to send messages to, and receive messages from, a patient in a manner that ensures:
   (i) Both the patient (or authorized representative) and technology user are authenticated; and
   (ii) The message content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

Preamble FR Citation: 80 FR 16850  Specific questions in preamble? No

Public Comment Field:
HIMSS observes that secure messaging should encompass a variety of messaging—not just text-based messaging, but also incorporate other types of messaging, including but not limited to, audio and video content, and even digital photograph content (e.g., teledermatology). Otherwise, providers (and their patients) may resort to using consumer-grade or other solutions, which may be less secure.

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

Included in 2015 Edition Base EHR Definition?
No

Stage 3 MU Objective
The EP, eligible hospital, or CAH is in active engagement with a public health agency (PHA) or clinical data registry (CDR) to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

2015 Edition Health IT Certification Criterion
(1) Transmission to immunization registries.
   (i) Technology must be able to create immunization information for electronic transmission in accordance with:
      (A) The standard and applicable implementation specifications specified in § 170.205(e)(4);
      (B) At a minimum, the version of the standard specified in § 170.207(e)(3) for historical vaccines; and
      (C) At a minimum, the version of the standard specified in § 170.207(e)(4) for administered vaccines.
   (ii) Technology must enable a user to request, access, and display a patient’s evaluated immunization history and the immunization forecast from an immunization registry in accordance with the standard at § 170.205(e)(4).

Preamble FR Citation: 80 FR 16850  Specific questions in preamble? Yes

Public Comment Field:
HIMSS is generally supportive of this criterion, but raises the following key points: will registries be ready to implement receiving NDC numbers and supporting bidirectional exchange in the designated timeframe? HIMSS encourages ONC to ensure that the registries will be able to support these functionalities before finalizing this criterion. In addition, HIMSS asks whether NDC codes are the right ones to choose, or if CVX codes are more appropriate?

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

Included in 2015 Edition Base EHR Definition?
No
§ 170.315(f)(2) Transmission to public health agencies – syndromic surveillance

Stage 3 MU Objective
The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

2015 Edition Health IT Certification Criterion
(2) Transmission to public health agencies—syndromic surveillance.
   (i) Ambulatory setting only.
      (A) Technology must be able to create syndrome-based public health surveillance information for electronic transmission.
      (B) Optional. Technology must be able to create syndrome-based public health surveillance information for electronic transmission that contains the following data:
         (1) Patient demographics;
         (2) Provider specialty;
         (3) Provider address;
         (4) Problem list;
         (5) Vital signs;
         (6) Laboratory test values/results;
         (7) Procedures;
         (8) Medication list; and
         (9) Insurance.
   (ii) Inpatient setting only. Technology must be able to create syndrome-based public health surveillance information for electronic transmission in accordance with the standard (and applicable implementation specifications) specified in § 170.205(d)(4).

Preamble FR Citation: 80 FR 16853 Specific questions in preamble? No

Public Comment Field:
HIMSS echoes concerns regarding the overall perception that many public health agencies are not ready to accept much of the data that the criterion specifies for electronic health transmission.

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

Included in 2015 Edition Base EHR Definition? No

Stage 3 MU Objective
The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

2015 Edition Health IT Certification Criterion
(3) Transmission to public health agencies – reportable laboratory tests and values/results. Technology must be able to create reportable laboratory tests and values/results for electronic transmission in accordance with
   (i) The standard (and applicable implementation specifications) specified in § 170.205(g)(2); and
   (ii) At a minimum, the versions of the standards specified in § 170.207(a)(4) and (c)(3).

Preamble FR Citation: 80 FR 16853 Specific questions in preamble? No

Public Comment Field:
### § 170.315(f)(4) Transmission to cancer registries

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

No

**Stage 3 MU Objective**

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

**2015 Edition Health IT Certification Criterion**

(4) **Transmission to cancer registries.** Technology must be able to create cancer case information for electronic transmission in accordance with:

   (i) The standard (and applicable implementation specifications) specified in § 170.205(i)(2); and

   (ii) At a minimum, the versions of the standards specified in § 170.207(a)(4) and (c)(3).

**Preamble FR Citation:** 80 FR 16854

**Specific questions in preamble?** Yes

**Public Comment Field:**

HIMSS notes that this is a send requirement that doesn’t require that the cancer registry actually receives the information. We request that ONC explore whether most cancer registries can receive the information using these specified standards.

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

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

No

**Stage 3 MU Objective**

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

**2015 Edition Health IT Certification Criterion**

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

**Preamble FR Citation:** 80 FR 16855

**Specific questions in preamble?** Yes

**Public Comment Field:**

HIMSS recognizes the importance of case reporting to many core public health activities including outbreak management and the monitoring of disease trends. As specified earlier in our letter in general, we believe that some of the specific SDC standards associated with this item are very early in their development and should not be included in the final rule. We do believe, however, that the use of a CCDA, also identified in the NPRM can provide a foundation for the much needed case reporting functionality that is built on capabilities already certified in EHRs. SDC work associated with the IHE RDF standard also has a broader basis of implementation.

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

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

No

**Stage 3 MU Objective**

The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.
§ 170.315(f)(6) Transmission to public health agencies – antimicrobial use and resistance reporting

2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16855
Specific questions in preamble? No
Public Comment Field:
HIMSS reiterates its support for consistent reporting across all of the public health reporting criteria. As antimicrobials are drugs, we recommend that alignment of all public health reporting in standard vocabularies would make reporting easier.

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

Included in 2015 Edition Base EHR Definition?
No

Stage 3 MU Objective
The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16856
Specific questions in preamble? No
Public Comment Field:

§ 170.315(g)(1) Automated numerator recording

Included in 2015 Edition Base EHR Definition?
No, but proposed for the EHR Incentive Programs CEHRT definition

Stage 3 MU Objective
N/A

2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16856
Specific questions in preamble? No
Public Comment Field:
§ 170.315(g)(2) Automated measure calculation

<table>
<thead>
<tr>
<th>Included in 2015 Edition Base EHR Definition?</th>
<th>No, but proposed for the EHR Incentive Programs CEHRT definition</th>
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<tbody>
<tr>
<td>Stage 3 MU Objective</td>
<td>N/A</td>
</tr>
<tr>
<td>2015 Edition Health IT Certification Criterion</td>
<td></td>
</tr>
<tr>
<td>(2) Automated measure calculation. For each meaningful use objective with a percentage-based measure that is supported by a capability included in a technology, record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.</td>
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<tr>
<td>Preamble FR Citation: 80 FR 16856</td>
<td>Specific questions in preamble? No</td>
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</tbody>
</table>

Public Comment Field:
HiMSS supports the proposal to include the interpretation in FAQ 32. We support the EHR technology meeting the intent of the criterion by including the ability to support at least one method of calculation for the automated measure calculation as proposed. We appreciate the flexibility afforded by working with its providers to offer calculations based upon workflows available in their EHRs, and not requiring abilities to perform any method possible when CMS has granted open-ended flexibility. Even though the criterion is proposed as unchanged, we readily agree that testing to satisfy the measurement of objectives will require significant resources to develop the calculations for the proposed measures.

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

<table>
<thead>
<tr>
<th>Included in 2015 Edition Base EHR Definition?</th>
<th>No, but a conditional certification requirement</th>
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<tbody>
<tr>
<td>Stage 3 MU Objective</td>
<td>N/A</td>
</tr>
<tr>
<td>2015 Edition Health IT Certification Criterion</td>
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<tr>
<td>(3) Safety-enhanced design.</td>
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<tr>
<td>(i) User-centered design processes must be applied to each capability technology includes that is specified in the following certification criteria: paragraphs (a)(1) through (10) and (18), (20), (22), (23), and (b)(2) through (4) of this section.</td>
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<tr>
<td>(ii) The following information must be submitted on the user-centered design processed used:</td>
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<tr>
<td>(A) Name, description and citation (URL and/or publication citation) for an industry or federal government standard; or</td>
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<tr>
<td>(B) Name the process(es), provide an outline of the process(es), a short description of the process(es), and an explanation of the reason(s) why use of any of the existing user-centered design standards was impractical.</td>
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<tr>
<td>(iii) The following information/sections from NISTIR 7742 must be submitted for each capability to which user-centered design processes were applied:</td>
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<tr>
<td>(A) Name and version of the product; date and location of the test; test environment; description of the intended users; and total number of participants;</td>
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<tr>
<td>(B) Description of participants, including: sex; age; education; occupation/role; professional experience; computer experience; and product experience;</td>
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<tr>
<td>(C) Description of the user tasks that were tested and association of each task to corresponding certification criteria;</td>
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<tr>
<td>(D) List of the specific metrics captured during the testing, including: task success (%); task failures (%); task standard deviations (%); task performance time; and user satisfaction rating (based on a scale with 1 as very difficult and 5 as very easy);</td>
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<tr>
<td>(E) Test results for each task using metrics listed above in paragraphs (g)(3)(ii)(A) through (D) of this section;</td>
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<tr>
<td>(F) Results and data analysis narrative, including: major test finding; effectiveness; efficiency; satisfaction; and areas for improvement.</td>
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<tr>
<td>(iv) Submit test scenarios used in summative usability testing.</td>
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<tr>
<td>Preamble FR Citation: 80 FR 16856</td>
<td>Specific questions in preamble? Yes</td>
</tr>
</tbody>
</table>
§ 170.315(g)(3) Safety-enhanced design

Public Comment Field:
It would be useful, when discussing the make-up of both formative and summative testing groups, to consider utilizing standards for those processes currently defined in relevant literature and resources utilized by user experience professionals such as those found in NISTIR 7804. HIMSS highly encourages including formative testing for any new requirements or workflows or modules that get built in, as this can act as a risk management process before getting to summative testing. Regarding formative testing, it will be beneficial for certification bodies to be able to privately examine artifacts/evidence of formative testing as part of their certification process. Regarding summative testing, age and education should be included in the description of testing participants. HIMSS recommends including major findings and areas for improvement sections to the summative testing documentation. We are concerned about some of the metrics utilized in item D in this section. User satisfaction ratings are now based on non-standard surveying processes. We suggest highlighting an approach such as Jeff Sauro’s system usability scale (SUS).

§ 170.315(g)(4) Quality management system

Included in 2015 Edition Base EHR Definition?
No, but a mandatory certification requirement

Stage 3 MU Objective
N/A

2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16858
Specific questions in preamble? No

Public Comment Field:

§ 170.315(g)(5) Accessibility technology compatibility

Included in 2015 Edition Base EHR Definition?
No

Stage 3 MU Objective
N/A

2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16858
Specific questions in preamble? Yes
§ 170.315(g)(5) Accessibility technology compatibility

Public Comment Field:
User-facing capabilities such as, but not limited to, voice recognition technologies and visual aids (for those who may be visually disabled or impaired) should be offered to those who may need accessibility technology to access the CEHRT. Further, to the extent that the accessibility technology has to “store” data (e.g., voice commands), there needs to be a requirement in terms of how long such data are stored. In other words, if such data are stored indefinitely, there may a heightened chance for breach or other compromise.

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

Included in 2015 Edition Base EHR Definition?
No, but a conditional certification requirement

Stage 3 MU Objective
N/A

2015 Edition Health IT Certification Criterion

(6) Consolidated CDA creation performance. The following technical and performance outcomes must be demonstrated related to Consolidated CDA creation. The capabilities required under paragraphs (g)(6)(i) through (iii) of this section can be demonstrated in tandem and do not need to be individually addressed in isolation or sequentially.

(i) Reference C-CDA match. Upon the entry of clinical data consistent with the Common Clinical Data Set, the technology must be able to create a data file formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that matches a gold-standard, reference data file.

(ii) Document-template conformance. Upon the entry of clinical data consistent with the Common Clinical Data Set, the technology must be able to create a data file formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that demonstrates a valid implementation of each of the following document templates (as applicable to the adopted standard):

(A) Generally applicable. CCD; Consultation Note; History and Physical; Progress Note; Care Plan; Transfer Summary; and Referral Note.

(B) Inpatient setting only. Discharge Summary.

(iii) Vocabulary conformance. Upon the entry of clinical data consistent with the Common Clinical Data Set, the technology must be able to create a data file formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that demonstrates the required vocabulary standards (and value sets) are properly implemented.

Preamble FR Citation: 80 FR 16859

Specific questions in preamble? Yes

Public Comment Field:

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

Included in 2015 Edition Base EHR Definition?
Yes

Stage 3 MU Objectives

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

Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient’s care.
§ 170.315(g)(7) Application access to Common Clinical Data Set

2015 Edition Health IT Certification Criterion

(7) Application access to Common Clinical Data Set. The following technical outcomes and conditions must be met through the demonstration of an application programming interface (API) that can respond to requests from other applications for data specified within the Common Clinical Data Set.

(i) Security. The API must include a means to establish a trusted connection with the application requesting patient data, including a means for the requesting application to register with the data source, be authorized to request data, and log all interactions between the application and the data source.

(ii) Patient selection. The API must include a means for the application to query for an ID or other token of a patient’s record in order to subsequently execute data requests for that record in accordance with paragraph (g)(7)(iii) of this section.

(iii) Data requests, response scope, and return format. The API must enable and support both of the following data request interactions:

(A) Data-category request. The API must support syntax that allows it to respond to requests for each of the individual data categories specified in the Common Clinical Data Set and return the full set of data for that data category (according to the specified standards, where applicable) in either XML or JSON.

(B) All-request. The API must support syntax that allows it to respond to a request for all of the data categories specified in the Common Clinical Data Set at one time and return such data (according to the specified standards, where applicable) in a summary record formatted according to the standard adopted at § 170.205(a)(4).

(iv) Documentation. The API must include accompanying documentation that contains, at a minimum:

(A) API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

(B) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(v) Terms of use. The terms of use for the API must be provided, including, at a minimum, any associated developer policies and required developer agreements.

Preamble FR Citation: 80 FR 16860

Specific questions in preamble? Yes

Public Comment Field:
The API should be designed with security in mind. As an example, HIMSS asserts that if SSL/TLS is not properly implemented, it can leave the data wide open for compromise (e.g., Heartbleed). This can mean unauthorized access to information, theft of the information, tampering of the information in transit, etc.

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

Included in 2015 Edition Base EHR Definition? No, but a mandatory certification requirement

Stage 3 MU Objective

N/A
§ 170.315(g)(8) Accessibility - centered design

2015 Edition Health IT Certification Criterion

(8) Accessibility-centered design. For each capability that a Health IT Module includes and for which that capability’s certification is sought, the use of a health IT accessibility-centered design standard or law in the development, testing, implementation and maintenance of that capability must be identified.

(i) If a single accessibility-centered design standard or law was used for applicable capabilities, it would only need to be identified once.

(ii) If different accessibility-centered design standards and laws were applied to specific capabilities, each accessibility-centered design standard or law applied would need to be identified. This would include the application of an accessibility-centered design standard or law to some capabilities and none to others.

(iii) If no accessibility-centered design standard or law was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

Preamble FR Citation: 80 FR 16861
Specific questions in preamble? Yes

Public Comment Field:

§ 170.315(h)(1) Direct Project

Included in 2015 Edition Base EHR Definition? Yes

Stage 3 MU Objective
N/A

2015 Edition Health IT Certification Criterion

(1) Direct Project.

(i) Applicability Statement for Secure Health Transport. Technology must be able to send and receive health information in accordance with the standards specified in § 170.202(a).

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

Preamble FR Citation: 80 FR 16862
Specific questions in preamble? No

Public Comment Field:

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

Included in 2015 Edition Base EHR Definition? Yes, as an alternative to § 170.315(h)(1)

Stage 3 MU Objective
N/A

2015 Edition Health IT Certification Criterion

(2) Direct Project, Edge Protocol, and XDR/XDM. Technology must be able to send and receive health information in accordance with:

(i) The standards specified in § 170.202(a);

(ii) The standard specified in § 170.202(b); and

(iii) Both edge protocol methods specified by the standard in § 170.202(d).

Preamble FR Citation: 80 FR 16863 (also see 80 FR 16862)
Specific questions in preamble? No
### § 170.315(h)(2) Direct Project, Edge Protocol, and XDR/XDM

**Public Comment Field:**

HIMSS supports this proposal. Encryption needs to be in place.

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

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

No

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

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

**Preamble FR Citation:** 80 FR 16863  
**Specific questions in preamble?** No

**Public Comment Field:**

There is a need to have the option to use SOAP based transport and to have REST based transport. Either DIRECT, SOAP, or REST should be allowed.

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

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

No

**Stage 3 MU Objective**

N/A

**2015 Edition Health IT Certification Criterion**

(4) Healthcare provider directory – query request. In accordance with the standard specified in § 170.202(f)(1), technology must be able to make, at a minimum, the following queries to a directory and subsequently process the response returned:

- (i) Query for an individual provider;
- (ii) Query for an organizational provider;
- (iii) Query for both individual and organizational providers in a single query; and
- (iv) Query for relationships between individual and organizational providers.
- (v) Optional - federation. In accordance with the standard specified in § 170.202(f)(1), technology must be able to process federated responses.

**Preamble FR Citation:** 80 FR 16863  
**Specific questions in preamble?** No

**Public Comment Field:**

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

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

No
§ 170.315(h)(5) Healthcare Provider Directory – query response

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<tr>
<th>Stage 3 MU Objective</th>
<th>N/A</th>
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**2015 Edition Health IT Certification Criterion**

(5) Healthcare provider directory – query response. In accordance with the standard specified in § 170.202(f)(1), technology must be able to, at a minimum, respond to the following queries to a directory:

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

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

**Public Comment Field:**

<table>
<thead>
<tr>
<th>§ 170.315(i)(1) Electronic submission of medical documentation</th>
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Included in 2015 Edition Base EHR Definition?  
No

**Stage 3 MU Objective**  
N/A
§ 170.315(i)(1) Electronic submission of medical documentation

2015 Edition Health IT Certification Criterion
(1) Electronic submission of medical documentation.
   (i) Document templates. Health IT must be able to create electronic documents for transmission formatted according to the following standard and applicable implementation specifications adopted at § 170.205(a)(4) and (a)(5)(i). With respect to § 170.205(a)(5)(i):
      (A) Health IT must be able to create the following document types regardless of the setting for which it is designed: Diagnostic Imaging Report; Unstructured Document; Enhanced Operative Note Document; Enhanced Procedure Note Document; and Interval Document.
      (B) Ambulatory setting only. Health IT must be able to create an Enhanced Encounter Document.
      (C) Inpatient setting only. Health IT must be able to create an Enhanced Hospitalization Document.
   (ii) Digital signature.
      (A) Applying a digital signature. Technology must be able to apply a digital signature in accordance with the implementation specification adopted at § 170.205(a)(5)(ii) to a document formatted according to the following standard and applicable implementation specifications adopted at § 170.205(a)(4) and (a)(5)(i). It must also be able to demonstrate that it can support the method for delegation of right assertions.
         (1) The cryptographic module used as part of the technology must: be validated to meet or exceed FIPS 140-2 Level 1; include a digital signature system and hashing that are compliant with FIPS 186-2 and FIPS 180-2; and store the private key in a FIPS-140-2 Level 1 validated cryptographic module using a FIPS-approved encryption algorithm. This requirement may be satisfied through documentation only.
         (2) Technology must support multi-factor authentication that meets or exceeds Level 3 assurance as defined in NIST Special Publication 800-63-2.
         (3) After ten minutes of inactivity, technology must require the certificate holder to re-authenticate to access the private key.
         (4) If implemented as a software function, the system must clear the plain text private key from the system memory to prevent the unauthorized access to, or use of, the private key when the signing module is deactivated.
         (5) Technology must record time and date consistent with the standard adopted at § 170.210(g).
      (B) Validating a digital signature. Technology must be able validate a digital signature that has been applied to a document according to the implementation specification adopted at § 170.205(a)(5)(ii).
   (iii) Author of record level 1. Using the same system capabilities expressed in paragraph (i)(1)(iii), technology must be able to apply a digital signature according to the implementation specification adopted at § 170.205(a)(5)(iii) to sign single or bundles of documents a document formatted according to the following standard and applicable implementation specifications adopted at § 170.205(a)(4) and (a)(5)(i).
   (iv) Transactions. Using the same system capabilities expressed in paragraph (i)(1)(ii) of this section, technology must be able to apply a digital signature according to the implementation specification adopted at § 170.205(a)(5)(iv) to a transaction and include the signature as accompanying metadata in the signed transaction.

Preamble FR Citation: 80 FR 16864
Specific questions in preamble? No
Public Comment Field:
Pharmacogenomics Data – Request for Comment

Preamble FR Citation: 80 FR 16869
Specific questions in preamble? Yes

Public Comment Field:

Pharmacogenomics data would need special protections. How such data is integrated into the CEHRT needs to be discussed, developed, and piloted.

Base EHR Definitions

Preamble FR Citation: 80 FR 16870
Specific questions in preamble? No

Public Comment Field:

Certified EHR Technology Definition

Preamble FR Citation: 80 FR 16871
Specific questions in preamble? No

Public Comment Field:

Common Clinical Data Set Definition

Preamble FR Citation: 80 FR 16871
Specific questions in preamble? No

Public Comment Field:

Cross Referenced FDA Definitions

Preamble FR Citation: 80 FR 16872
Specific questions in preamble? No

Public Comment Field:

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

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

Specific questions in preamble? No

Public Comment Field:

HIMSS cautiously supports ONC’s efforts to establish innovative certification and testing programs that utilize health IT. Certification in support of a Learning Health System must be specific, carefully planned, focused on the areas that have the greatest impact on interoperability, and closely aligned with programmatic goals.

For new federal program-related health IT certification programs, HIMSS suggests that ONC or another agency establish its programmatic goals before commencing with any certification program associated with that effort. It is important that certification criteria are closely evaluated and aligned with the functionalities necessary to meet the goals of the program in question as we move beyond EHR-specific certification.

Health IT Modules

Specific questions in preamble? No

Public Comment Field:

“Removal” of Meaningful Use Measurement Certification Requirements

Specific questions in preamble? No

Public Comment Field:

Types of Care and Practice Settings

Specific questions in preamble? Yes

Public Comment Field:

Referencing the ONC Health IT Certification Program

Specific questions in preamble? No

Public Comment Field:

Privacy and Security

Specific questions in preamble? Yes
### Privacy and Security

**Public Comment Field:**
HIMSS agrees with the newly proposed approach for privacy and security certification as stated in this NPRM:

HIT Modules presented for certification will be certified against all of and only those security and privacy criteria identified as relevant to the functionality provided (e.g., clinical, care coordination) using either of two approaches:

- Technically demonstrate, or
- System documentation.

The HITSC TSS WG meeting of May 20, 2015 also agreed with this approach. As with the HITSC TSS WG, HIMSS recommends the adoption of additional privacy and security certification criteria:

- **Clinical Module:** add Integrity criterion
  - Involves transmissions (lab order compendium; formulary benefit file)
- **Care Coordination Module:** add Amendments criterion
  - Support patient requested amendments
- **Design and Performance Module, API criterion:** add (1) authentication, access control, and authorization; (2) Auditable events and tamper-resistance; and (8) Integrity

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

**Preamble FR Citation:** 80 FR 16876

**Specific questions in preamble?** No

**Public Comment Field:**

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

**Preamble FR Citation:** 80 FR 16876

**Specific questions in preamble?** Yes

**Public Comment Field:**

### Transparency and Disclosure Requirements

**Preamble FR Citation:** 80 FR 16880

**Specific questions in preamble?** No

**Public Comment Field:**

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

**Preamble FR Citation:** 80 FR 16883

**Specific questions in preamble?** Yes

**Public Comment Field:**
### Records Retention

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### Complaints Reporting

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### Adaptations and Updates of Certified Health IT

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

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If there are clear indications that certain health IT products are intentionally blocking information exchange, HIMSS would support implementing a health IT decertification process. Careful surveillance is an integral part of this overall certification effort. We would only support such action if there is a clear indication of wrongdoing.

HIMSS recommends that ONC review the EHR Association’s EHR [Developer Code of Conduct](#) as a reflection of the industry’s ongoing commitment to collaborate as trusted partners with all stakeholders. The Code of Conduct includes a section on interoperability and data portability that emphasizes the industry’s commitment to data following the patient. According to the code, EHR developers will enable their customers to exchange clinical information with other parties, including those using other EHR systems, through standards-based technology, to the greatest extent possible. In addition, they will use available, recognized, and nationally uniform standards to the greatest extent possible in developing interfaces. Also, as customers implement interfaces and work to achieve interoperability, they will share best practices with them about the safe deployment, implementation, and use of the supporting tools and technologies. Moreover, developers will work with their customers to facilitate the export of patient data if a customer chooses to move from one EHR to another, and, will enable, at a minimum, the export of one or more standards-based clinical summary formats such as CCD/CCDA (or the then-current equivalent) for all patients.

Overall, we would want any type of process to decertify health IT products to be completely credible, so we would ask for a public comment process to consider ideas and ensure that stakeholder input is incorporated into any final rule on this topic.

### Collections of Information – Paperwork Reduction Act

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