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Office of the National Coordinator for Health IT
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Submitted electronically via www.regulations.gov

Re: 0991-AB93; Proposed 2015 Edition Electronic Health Record (EHR) Certification Criteria, 2015 Edition Base EHR Definition, and ONC Health IT Certification Program Modifications

Dear Dr. DeSalvo,

athenahealth, Inc. ("athenahealth") appreciates the opportunity to provide comments on the Proposed 2015 Edition Electronic Health Record (EHR) Certification Criteria, 2015 Edition Base EHR Definition, and ONC Health IT Certification Program Modifications Proposed Rule ("Proposed Rule").

As you know athenahealth provides electronic health record ("EHR"), practice management, care coordination, patient communication, data analytics, and related services to physician practices, working with a network of more than 60,000 healthcare professionals who serve over 60 million patients in all 50 states. We envision and work to establish a nationwide health information backbone that makes healthcare work as it should by connecting patients and care providers with the information they need to seek and provide high-quality, cost-effective, efficient care. All of our providers access our services on the same instance of continuously-updated, cloud-based software. Our clients' successes, exemplified by a Meaningful Use ("MU") attestation rate more than double the national average, underscore the very real potential of health IT to improve care delivery and patient outcomes while increasing efficiency and reducing systemic costs.

General Remarks

We have significant concerns about the Proposed Rule. Our specific suggestions and criticisms are set forth in detail below, but many of our observations can be boiled down thematically to the refrain that has been heard from across the stakeholder spectrum as the MU program has progressed slowly through its stages: As it has evolved from the initial, paradigm-shifting adoption of digital technologies that it created initially into progressively more granular and bureaucratic stages of implementation, the program has failed to produce truly "meaningful" improvements in patient care. Although we have enabled our clients to "succeed" at the MU game to a degree far beyond the industry norm, those same clients routinely report that the requirements of the program have turned them into "professional box-checkers," distracted from patient care by MU requirements that improve neither care nor efficiency and too often adversely impact both. As you know, we have in the past vociferously disagreed with

others in our industry as they called for slower implementation timelines and lower performance bars. We continue to oppose such efforts and believe that federal policy should force vendors and providers to reach higher—but in ways that leverage modern information technology to measurably improve patient care. We agree with much of our industry, however, on the assertion that the MU program forces our developers to devote a disproportionate share of time and resources to compliance with the ONC Health IT Certification Program rather than development to meet client requests and improve patient care.

The Center for Medicare and Medicaid Services ("CMS") made progress towards addressing those criticisms in its Electronic Health Record Incentive Program—Stage 3 Proposed Rule. The result was a simplified proposed rule that will enable providers and their vendors to focus resources on a few key areas of CEHRT use that will have the greatest benefit to patient care. We urge the Office of the National Coordinator for Health IT ("ONC") to follow suit.

Certification criteria that are not linked to an MU measure should not be included in the final Rule. ONC's role should be to designate the functionality that CEHRT must have to enable a provider to meet the requirements of the MU program. Respectfully, ONC should not be in the business of designing an EHR through regulation. We suggest that ONC focus its attention on the certification criteria that are needed to promote interoperable exchange of health information and meaningful use of CEHRT, as defined by CMS. Functionality that is not explicitly tied to either of those objectives should be left to EHR vendors to retain and/or develop based on the needs of and in consultation with their provider customers.

We appreciate that ONC attempted to align with CMS in incorporating greater flexibility in the Proposed Rule. A less prescriptive Certification Program—one that focuses on outcomes and lets the market determine means—will foster greater innovation in health IT.

ONC has done a wonderful job over the years in partnering with and listening to stakeholders. We hope that the agency returns to that approach to produce a more focused final Rule. Vendor and provider resources are limited; certification criteria should promote high-priority areas that will transform the MU program into a foundational element for the successful reform of our healthcare system.

Specific Comments

With the above context in mind, we provide the following specific comments on the proposed Stage 3 certification criteria:

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: We the support the retention of this criterion, and the intention of leaving it unchanged from the previous edition.

§ 170.315(a)(2) Computerized provider order entry – laboratory
Included in 2015 Edition Base EHR Definition? Yes, as an alternative to § 170.315(a)(1) or (3)
Stage 3 MU Objective Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.
2015 Edition Health IT Certification Criterion (2) Computerized provider order entry – laboratory. (i) Technology must enable a user to record, change, and access laboratory orders. (ii) Technology must be able to receive and incorporate a new or updated laboratory order compendium in accordance with the standard specified in § 170.205(l)(2) and, at a minimum, the version of the standard in § 170.207(c)(3). (iii) Ambulatory setting only. Technology must enable a user to create laboratory orders for electronic transmission in accordance with the standard specified in § 170.205(l)(1) and, at a minimum, the version of the standard in § 170.207(c)(3).
Preamble FR Citation: 80 FR 16814 **Specific questions in preamble?** *Yes*

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

Public Comment Field:

Although we believe the longer term adoption of the S&I Framework Laboratory Orders (LOI) Release 2 is a positive step for the industry, we have concerns over requiring this standard in its current state. Release 1 has now been out for two years though no one—other than the pilot program—uses it. The proposed rule would mandate the use of Release 2 of LOI specification that has not come out yet and may not be market-ready for industry-wide adoption. We agree with the direction of using standards-based data exchange across the industry, but we caution ONC about its implementation where EHRs are held to the "official standard" but that official standard is not enforced on other side of the transaction (as was the case with the NCPDP standard for electronic prescribing) which resulted in EHRs having to build separate copy of the standard for the purposes of certification only. Consistency across the industry is paramount for true interoperation.

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

Included in 2015 Edition Base EHR Definition?

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

Stage 3 MU Objective

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

2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16815 (also see 80 FR 16814) **Specific questions in preamble?** *Yes*

Public Comment Field:

We support the retention of this criterion, as well as the intention of leaving it unchanged from the previous edition.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

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

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

2015 Edition Health IT Certification Criterion

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

(i) Interventions. Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list.

(ii) Adjustments.

(A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.

(B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.

(iii) Interaction check response documentation.

(A) Technology must be able to record at least one action taken and by whom in response to drug-drug or drug-allergy interaction checks.

(B) Technology must be able to generate either a human readable display or human readable report of actions taken and by whom in response to drug-drug or drug-allergy interaction checks.

Preamble FR Citation: 80 FR 16815 **Specific questions in preamble?** *Yes*

Public Comment Field:

The drug-drug, drug-allergy interaction checks for CPOE are simultaneously overly-prescriptive and not well-defined. We recommend the following changes to avoid unnecessary burden on providers and lack of clarity in the regulations.

(1) While it is clear that these interaction checks should be fired during CPOE, we caution against trying to be overly prescriptive in the workflow by requiring "extra clicks" solely for the purposes of audit tracking. The categories—"declined, ignored and overrode"—mean the same thing when trying to capture the user's action. It is important to simplify these areas, especially when an EHR is incapable of making a distinction and would have to revert to requiring clinicians to interrupt their workflow to record these distinctions. We are not concerned with the burden to develop this functionality, but are concerned with burden placed on clinical users which does not benefit patient care and only helps in the auditing process.

(2) In recording user actions for drug-drug, drug-allergy interactions, we suggest limiting this to "severe" interactions as it will otherwise impact the user experience and contribute to alert fatigue. It is important to note that many EHRs will be dependent on drug database vendors to provide the severity of a particular interaction. "Severe" should also be the only category that is auditable.

(3) If any comment field is added, we suggest making it optional as in most EHRs there is already another field used for this purpose. Making this field optional would allow providers to avoid extra work that does not benefit patient care, but only helps in the auditing process.

(4) The proposed rule also solicited feedback on whether an EHR should be able to track when an adverse event occurs. Often there is no way for the EHR to capture this as adverse events frequently occur outside of the patient-provider experience in the ambulatory setting.

§ 170.315(a)(5) Demographics

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

§ 170.315(a)(5) Demographics

2015 Edition Health IT Certification Criterion

(5) Demographics.

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

(A) Race and ethnicity.

(1) Enable each one of a patient's races to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify race.

(2) Enable each one of a patient's ethnicities to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify ethnicity.

(3) Aggregate each one of the patient's races and ethnicities recorded in accordance with paragraphs (a)(5)(i)(A)(1) and (2) of this section to the categories in the standard specified in § 170.207(f)(1).

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

(C) Enable sex to be recorded in accordance with the standard specified in § 170.207(n)(1).

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

Preamble FR Citation: 80 FR 16816 **Specific questions in preamble?** *No*

Public Comment Field:

We support the changes in demographics criteria though we caution against changing "preferred language" standards again and remind ONC that each change in a standard requires a significant time and infrastructure investment as well as data backfills to meet the new standard. We request that the value in changing such categories always be weighed against the time and infrastructure investments expended in updating them.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

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

2015 Edition Health IT Certification Criterion

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

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

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

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

(1) Date and time of vital sign measurement or end time of vital sign measurement;

(2) The measuring- or authoring-type source of the vital sign measurement; and

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

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

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

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

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

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

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

(1) Date and time of vital sign measurement or end time of vital sign measurement;

(2) The measuring or authoring-type source of the vital sign measurement;

(3) The patient's date of birth;

(4) The patient's sex in accordance with the standard specified in § 170.207(n)(1); and

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

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

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

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

(1) Date and time of vital sign measurement or end time of vital sign measurement;

(2) The measuring- or authoring-type source of the vital sign measurement;

(3) The patient's date of birth;

(4) The patient's sex in accordance with the standard specified in § 170.207(n)(1); and

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

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

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

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

(1) Date and time of vital sign measurement or end time of vital sign measurement;

(2) The measuring or authoring-type source of the vital sign measurement;

(3) The patient's date of birth;

(4) The patient's age in accordance with the standard specified in § 170.207(n)(1); and

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

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

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

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

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

Public Comment Field:

We support the uniform standard for entering and exchanging LOINC values and accompanying metadata, but we recommend that ONC not dictate how health IT platforms store the data. We also support the criterion on vitals in UCUM measure conversion, but again reiterate that health IT platforms should be able to store the data in their own way while still meeting these standards for the purposes of data exchange.

§ 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:

We support the retention of this criterion, as well as the intention of leaving it unchanged from the previous edition.

§ 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:

We support the retention of this criterion, as well as the intention of leaving it unchanged from the previous edition

§ 170.315(a)(9) Medication allergy list

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

§ 170.315(a)(9) Medication allergy list	
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:	
We support the retention of this criterion, as well as the intention of leaving it unchanged from the previous edition	

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

§ 170.315(a)(10) Clinical decision support

2015 Edition Health IT Certification Criterion

(10) Clinical decision support.

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

(A) Problem list;

(B) Medication list;

(C) Medication allergy list;

(D) At least one demographic specified in paragraph (a)(5)(i) of this section;

(E) Laboratory tests; and

(F) Vital signs.

(ii) Linked referential clinical decision support.

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

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

(iii) Clinical decision support configuration.

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

(B) Technology must enable interventions to be:

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

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

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

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

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

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

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

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

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

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

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

(vi) Intervention response documentation.

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

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

Preamble FR Citation: 80 FR 16820 **Specific questions in preamble?** *Yes*

§ 170.315(a)(10) Clinical decision support

Public Comment Field:

We applaud ONC's efforts to promote evidence-based clinical guidance. Though as with many of our comments, we want to ensure flexibility in the regulations to achieve the stated aims of the criterion. We recommend that health IT platforms be permitted to use tools other than Infobutton—as different CDS may accomplish the same goals. For example, we already have integrations with other CDS through FHIR and don't want to be constrained by Infobutton.

§ 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:

We support the required use of NCPDP Formulary and Benefit Standard v3.0 but agree that version 4.0 is still too unstable We also recommend use of the NCPDP TELECOM standard which allows us to do a patient level formulary checking. This would be a "new standard" for CPOE, but it is a well-established standard in the pharmacy world.

§ 170.315(a)(12) Smoking status

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

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

Public Comment Field:

We support the retention of this criterion, as well as the intention of leaving it unchanged from the previous edition

§ 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:	
We support the retention of this criterion, as well as the intention of leaving it unchanged from the previous edition.	

§ 170.315(a)(14) Family health history	
Included in 2015 Edition Base EHR Definition?	
No, but proposed for the EHR Incentive Programs CEHRT definition	
Stage 3 MU Objective	
N/A	
2015 Edition Health IT Certification Criterion	
(14) Family health history. Enable a user to record, change, and access a patient's family health history in accordance with the familial concepts or expressions included in, at a minimum, the version of the standard in § 170.207(a)(4).	
Preamble FR Citation: 80 FR 16822	**Specific questions in preamble?** *No*
Public Comment Field:	
We urge ONC to continue to use the SNOMED standard for both criteria without mandating a transition to HL7 Pedigree for the creation and incorporation of a patient's family health history as the transitional costs would not outweigh the value in care quality.	

§ 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:	
We reiterate our comments from the previous section § 170.315(a)(14) Family health history.	

§ 170.315(a)(16) Patient list creation

§ 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:

We support the retention of this criterion, as well as the intention of leaving it unchanged from the previous edition.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

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

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 the InfoButton is a tremendous tool for patient-specific education resources, EHRs have included patient education for quite some time. We—and other vendors—have designed user-friendly and effective workflows for our providers to provide education. Mandating this standard will only cause confusion and challenges for the provider. We support displaying information for the patient using InfoButton, but requiring only InfoButton for a provider to satisfy meaningful use is overly prescriptive without a benefit to care. Furthermore, if we were to implement this requirement, InfoButton only lets someone see information. There is no way to convert this information into a format that we can present to a patient on the portal.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(18) Electronic medication administration record.

(i) In combination with an assistive technology that provides automated information on the "rights" specified in paragraphs (a)(18)(i)(A) through (E) of this section, enable a user to verify the following before administering medication(s):

(A) Right patient. The patient to whom the medication is to be administered matches the medication to be administered.

(B) Right medication. The medication to be administered matches the medication ordered for the patient.

(C) Right dose. The dose of the medication to be administered matches the dose of the medication ordered for the patient.

(D) Right route. The route of medication delivery matches the route specified in the medication order.

(E) Right time. The time that the medication was ordered to be administered compared to the current time.

(ii) Right documentation. Record the time and date in accordance with the standard specified in § 170.210(g), and user identification when a medication is administered.

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

Public Comment Field:

We support the retention of this criterion, as well as the intention of leaving it unchanged from the previous edition.

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

Included in 2015 Edition Base EHR Definition?

No, but proposed for the EHR Incentive Programs CEHRT definition

Stage 3 MU Objective

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

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:

We support the new proposed criterion for patient health information capture via "safe" formats (e.g., pdf).

§ 170.315(a)(20) Implantable device list

Included in 2015 Edition Base EHR Definition?

Yes

§ 170.315(a)(20) Implantable device list

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(20) Implantable device list.

(i) Enable a user to record, change, and access, a list of Unique Device Identifiers associated with a patient's Implantable Device(s).

(ii) Parse the following data elements from a Unique Device Identifier:

(A) Device Identifier;

(B) Batch/lot number;

(C) Expiration date;

(D) Production date; and

(E) Serial number.

(iii) Retrieve the "Device Description" attribute associated with a Unique Device Identifier in the Global Unique Device Identification Database.

(iv) For each Unique Device Identifier in a patient's list of implantable devices, enable a user to access the following:

(A) The parsed data elements specified under paragraph (a)(20)(ii) of this section that are associated with the UDI; and

(B) The retrieved data element specified under paragraph (a)(20)(iii) of this section.

Preamble FR Citation: 80 FR 16824 **Specific questions in preamble?** *Yes*

Public Comment Field:

We support the new proposed criterion for an implantable device list.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

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

2015 Edition Health IT Certification Criterion

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

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

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

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

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

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

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

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

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

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

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

Preamble FR Citation: 80 FR 16826

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

Public Comment Field:

We support the new criteria for social, psychological and behavioral data on sexual orientation and gender identity. However, we recommend that ONC not mandate changes for work information, industry and occupational data as the value of this information will be limited and only adds administrative work for the providers to collect research data points that, while interesting, do not benefit care quality.

§ 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:

We are concerned with the requirement to use one standard for the sending and receiving of clinical decision support knowledge artifacts as this mandate limits flexibility to achieve the end goal without a clear purpose.

§ 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:

Although the HeD standard would enable tremendous sending and extracting of data across platforms, this task creates considerable work. Unless CDS vendors are building this functionality now, we recommend that EHR vendors not be required to build this simply to achieve certification. This measure should focus on supporting the use of CDS, not the specific transmission transaction.

§ 170.315(b)(1) Transitions of care

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

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

2015 Edition Health IT Certification Criterion

(1) Transitions of care.

(i) Send and receive via edge protocol. Technology must be able to:

(A) Send transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(d); and

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

(C) XDM processing. Receive and make available the contents of a XDM package formatted in accordance with the standard adopted in § 170.205(p)(1) if the technology is also being certified using an SMTP-based edge protocol.

(ii) Validate and display.

(A) Validate C-CDA conformance – system performance. Technology must demonstrate its ability to detect valid and invalid transition of care/referral summaries received and formatted in accordance with both of the standards specified in § 170.205(a)(3) and (4) This includes the ability to:

(1) Parse each of the document types formatted according to the following document templates: CCD;

Consultation Note; History and Physical; Progress Note; Care Plan; Transfer Summary; Referral Note, and Discharge Summary.

(2) Detect errors in corresponding "document-templates," "section-templates," and "entry-templates," including invalid vocabulary standards and codes not specified in either of the standards adopted in § 170.205(a)(3) and (4);

(3) Identify valid document-templates and process the data elements required in the corresponding section-templates and entry-templates from either of the standards adopted in § 170.205(a)(3) and (4);

(4) Correctly interpret empty sections and null combinations; and

(5) Record errors encountered and allow for a user to be notified of or review the errors produced.

(B) Technology must be able to display in human readable format the data included in transition of care/referral summaries received and formatted according to the standards specified in § 170.205(a)(3) and (4).

(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:

Echoing previous points in our comments, we recommend that ONC add clarity and flexibility to the transitions of care criterion. We suggest the following:

(1) It is both burdensome and unnecessary for vendors to be able to create both versions of the CCDA. Supporting two versions with different code set requirements will lead to confusion and obstacles to interoperability. Instead we recommend the certification criterion require that we generate either version (but not both), but have the ability to receive both versions as it is the receiving side that may encounter either version.

(2) More clarity is needed around error handling: ONC should either decide to be less prescriptive in this measure or should provide more specific error scenarios and standard messages so that everyone handles the same errors in a consistent manner.

(3) We suggest that the extraction of metaData from the XDM message creates unnecessary burden and this data instead be taken from the CCDA, which provides more consistency when there is only a CCDA inside the XDM.

(4) To provide more clarity, we recommend that for DOBs, if the time is provided, the time zone should also be required as issues may arise in inferring the time zone from a city name, state or zip code.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

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

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

2015 Edition Health IT Certification Criterion

(2) Clinical information reconciliation and incorporation.

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

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

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

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

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

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

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

(1) Medications. At a minimum, the version of the standard specified in § 170.207(d)(3);

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

(3) Problems. At a minimum, the version of the standard specified in § 170.207(a)(4).

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

Preamble FR Citation: 80 FR 16835 **Specific questions in preamble?** *No*

Public Comment Field:

We would support this criterion if it remains unchanged. However, in response to the proposed changes, we note that it is not a valid testing technique to incorporate/reconcile the information into the chart and then require the EHR to create an outgoing CCDA with the same information. For medication mappings there is not always one-to-one mapping between the RxNorm code and an EHR drug database vendor's medication ID concept. So if the RxNorm is reconciled into the EHR, it is not guaranteed that the same RxNorm code would be generated back out as the first choice based on the drug database vendor's medication ID mapping to RxNorm.

§ 170.315(b)(3) Electronic prescribing

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

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

§ 170.315(b)(3) Electronic prescribing

2015 Edition Health IT Certification Criterion

(3) Electronic prescribing.

(i) Enable a user to prescribe, send, and respond to prescription-related transactions for electronic transmission in accordance with the standard specified at § 170.205(b)(2), and, at a minimum, the version of the standard specified in § 170.207(d)(3), as follows:
- (A) Create new prescriptions (NEWRX);
- (B) Change prescriptions (RXCHG, CHGRES);
- (C) Cancel prescriptions (CANRX, CANRES);
- (D) Refill prescriptions (REFREQ, REFRES);
- (E) Receive fill status notifications (RXFILL); and
- (F) Request and receive medication history information (RXHREQ, RXHRES).

(ii) Enable a user to enter, receive, and transmit structured and codified prescribing instructions for the transactions listed in paragraph (b)(3)(i) of this section for electronic transmission in accordance with the standard specified at § 170.205(b)(2) and, at a minimum, for at least the following component composites:
- (A) Repeating Sig;
- (B) Code System;
- (C) Sig Free Text String;
- (D) Dose;
- (E) Dose Calculation;
- (F) Vehicle;
- (G) Route of Administration;
- (H) Site of Administration;
- (I) Sig Timing;
- (J) Duration;
- (K) Maximum Dose Restriction;
- (L) Indication; and
- (M) Stop.

(iii) Technology must limit a user's ability to prescribe all medications in only the metric standard.

(iv) Technology must always insert leading zeroes before the decimal point for amounts less than one and must not allow trailing zeroes after a decimal point when a user prescribes medications.

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

§ 170.315(b)(3) Electronic prescribing

Public Comment Field:

We are very supportive of many of the changes in the electronic prescribing section, particularly from patient safety and medical adherence perspectives.

(i) We also agree that the new message types could greatly benefit care. However, while the RXFILL transactions exist today, pharmacies do not send messages. Once again EHRs are forced to certify the capability even when pharmacies are not sending anything.

(ii) We agree with the direction of adopting the Structured and Codified SIG. We recommend that the additional components and attributes be optional as they would not be necessary for the majority of prescribing use cases.

(iii) We recommend that ONC not mandate metric units for data entry as we try to give our providers the flexibility to prescribe how they want with the system doing the conversion to metric if necessary. While metric units for volumetric dosing are best practices according to patient safety literature, we note that occasionally, our users want to dose in other units and can do so with unstructured sigs. Furthermore, we get our options for units from FDB and they seem to limit most options for metric units. They are not under the regulation of CMS or ONC, and it would be ill-advised for us to attempt to create metric conversion mappings for these cases on our own.

(iv) We are supportive if this change is limited to display in the user interface and on transmission but it should not be mandated to store it that way in the database

§ 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*

§ 170.315(b)(4) Incorporate laboratory tests and values/results
Public Comment Field:
We support the changes in this section, but reiterate our point in e-prescribing that unless the other side of the transaction is required to comply to this standard as well EHR vendors will spending money, time, and opportunity cost building to certification without a real-world application.

§ 170.315(b)(5) Transmission of laboratory test reports	
Included in 2015 Edition Base EHR Definition?	
No	
Stage 3 MU Objective	
N/A	
2015 Edition Health IT Certification Criterion	
(5) Transmission of laboratory test reports. Technology must be able to electronically create laboratory test reports for electronic transmission in accordance with the standard specified in in § 170.205(j)(2) and, at a minimum, the version of the standard specified in § 170.207(c)(3).	
Preamble FR Citation: 80 FR 16838	**Specific questions in preamble?** *No*
Public Comment Field:	
We support the new proposed criterion for the transmission of laboratory test reports.	

§ 170.315(b)(6) Data portability
Included in 2015 Edition Base EHR Definition?
Yes
Stage 3 MU Objective
N/A

§ 170.315(b)(6) Data portability

2015 Edition Health IT Certification Criterion

(6) Data portability.

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

(ii) Document creation configuration.

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

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

(2) Inpatient setting only. Discharge Summary.

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

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

(2) Cognitive status;

(3) Functional status;

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

(5) Inpatient setting only. Discharge instructions.

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

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

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

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

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

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

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

Preamble FR Citation: 80 FR 16839 **Specific questions in preamble?** *No*

§ 170.315(b)(6) Data portability

Public Comment Field:

Overall, we are supportive of this measure and agree that users should be able to create a bulk export of the common clinical data set in CCDA format for a given set of patients. However, we caution ONC from implementing overly prescriptive requirements and where it is necessary to do so, we ask for simplicity and clarity for the providers.

Attempts to customize document types, the content within the document, and the triggers used to produce each document create unnecessary complexity and will lead to roadblocks to the overarching goal of interoperability. Additionally, we believe that without explicitly requiring EHRs to have the capability to bulk import a set of CCDAs, the measure will fall short of its intended outcomes.

We cannot assume all users will have a deep, technical knowledge of the CCDA standard. For this reason, we are making a number of recommendations to simplify the user experience with the goal of ensuring each data set is generated as expected.

(1) The proposed rule has minimum data requirements for a Health IT Module to be capable of including in different types of export summaries. We recommend that this measure require a single document with a specific set of data elements. If this function is user-facing, it should be made simple and intuitive. We don't expect providers to understand the differences between these document types. We recommend a single document standard required for certification. This eliminates potential confusion in the marketplace when documents are exchanged.

(2) We recommend removing the requirement for a user to enter a start and end date range for a given summary. This creates an unnecessary risk of a provider accidently excluding or including certain clinical data. Many data elements in the CCDA contain multiple associated dates. For example, a problem has a date recorded, a date started, and possibly a date completed the multiple dates associated with medications can be even more complex. On top of that, some of these dates are automatically recorded which drives the complexity of this requirement too high to be confident in creating expected outcomes.

(3)Part of this measure would require a user to be able to configure the technology to create an export summary based on some user-selected events. We recommend that the trigger for this function be accessible to a user, but not associated with any other clinical occurrence. In order to successfully transition EHRs, users should have easy access to a transparently defined set of data. Associating triggers and filters with clinical events goes beyond the scope of enabling data portability.

(4) Defining a storage location—where the exported CCDAs should be stored—is out of scope for the EHR certification. PHI storage is already explicitly defined by HIPAA, and given the variability in each system's architecture, requiring EHRs to configure and set a location presents unnecessary risk.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

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

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:

On this measure, we recommend that ONC focus on the sending side of the data exchange. This rule would create an unrealistic workflow where providers would be required to obtain patient permission each time the patient's information moves, an untenable option because patients are not always available for such requests. We feel that the capabilities that allow providers to redact certain information before sending should be sufficient to these most common use cases.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

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

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

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

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

Public Comment Field:

We support the end-goal that this measure is trying to achieve, but it would place significant burden on providers while simultaneously foraying into an area of high complexity with minimal benefits. The provider would need to disclose and restrict documents based on the receiver (e.g., is HIV status acceptable to disclose to an obstetrician, but not to a dermatologist?). The receiver would need to process the metadata and verify the patient's consent before a redisclosure, placing tremendous work on the providers in this process. We believe this implementation actually would have the opposite effect from the stated goals and would essentially stop the data exchange between HIPAA covered entities. It gets even more complicated with the incorporation of exchanged data. For example, is the data you already had acceptable to exchange if someone else sent you the same data and it was tagged as private?

§ 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).

§ 170.315(b)(9) Care plan	
Preamble FR Citation: 80 FR 16842	**Specific questions in preamble?** *Yes*
Public Comment Field: We support the new proposed criterion for care plans.	

§ 170.315(c)(1) Clinical quality measures – record and export
Included in 2015 Edition Base EHR Definition? Yes
Stage 3 MU Objective N/A
2015 Edition Health IT Certification Criterion (1) Clinical quality measures – record and export. (i) Record. For each and every CQM for which the technology is presented for certification, the technology must be able to record all of the data that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of "patient reason," "system reason," or "medical reason." (ii) Export. A user must be able to export a data file formatted in accordance with the standard specified at § 170.205(h) for one or multiple patients that includes all of the data captured for each and every CQM to which technology was certified under paragraph (c)(1)(i) of this section. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.
Preamble FR Citation: 80 FR 16842 **Specific questions in preamble?** *Yes*

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

Public Comment Field:

This measure requires EHRs to give front end users the ability to generate their own QRDA files. As the primary purpose of QRDA file generation is submission to programs such as PQRS, we support and agree with this requirement when limited to this use case. We support allowing users to generate QRDA Category III files without the need for developer intervention. This empowers practices to submit for sponsored programs on their own while reducing financial burden and dependence on external companies such as data submission vendors. However, we would stress that any organization receiving such files should use the same standard of QRDA in order to ensure successful receipt of data.

While we agree with giving users the ability to generate Category III files, we do not support the requirement for generating patient level Category I files using any standard of QRDA. Again, as the primary purpose of QRDA is program submission, QRDA Category III provides a far more manageable way to do so. The burden of generating and submitting individual patient files is immense even for small practices and would create substantial work that could be avoided through Category III files.

Finally if the aim of this criterion is not for submission and rather for the sharing of information between EHR systems, we also do not support the use of QRDA for this end. The value of sending patient level QRDA files lies in sharing CQM information between systems, which entails the sharing of clinical data. Currently, the majority of data in a QRDA file would be redundant with data shared through other standards already in existence (C-CDA) with only incremental additions. Rather than require an additional file format to be supported, we support enhancing existing standards to include additional types of data.

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

Included in 2015 Edition Base EHR Definition?

No, but proposed for the EHR Incentive Programs CEHRT definition

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(2) Clinical quality measures – import and calculate.

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

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

Preamble FR Citation: 80 FR 16843 **Specific questions in preamble?** *Yes*

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

Public Comment Field:

Given the above criteria to export files for CQM calculation, we agree that if vendors are required to export files then they should be required to allow the import of them as well. However, the calculation of imported files creates immense difficulties for both vendors and providers and is inherently different from the importation itself. We recommend dividing these two components into separate criteria. Furthermore, we recommend making the requirement to calculate CQM satisfaction optional as it will be more useful for specific types of Health IT products.

To clarify, a software product dedicated to data analytics would find value in being able to calculate satisfaction from raw QRDA data. However, an EHR that uses patient's health data stored within its system for calculations would be forced into two difficult options. Either build a calculation engine made specifically to read QRDA files or integrate this data into the patient's chart. The first option requires vendors to spend resources building a requirement not valuable for patient care, while the second creates new areas of difficulty in interoperability and data reconciliation. In order to share this patient data between systems for CQM calculation, we recommend the use of existing standards such as C-CDA rather than requiring additional ones. Especially when much of the clinical data included in both standards is identical.

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:

We support the new requirements for clinical quality measures—report.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

§ 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:

We would like to express concern over the concept of filtering by practice site address. Patients are often being seen by multiple providers and those providers may conduct office visits in multiple location, and therefore it is difficult to link a patient to a single address.

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

Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16846 **Specific questions in preamble?** *No*

Public Comment Field:

We support the retention of this criterion, as well as the intention of leaving it unchanged from the previous edition.

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

Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

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

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*

Public Comment Field:

We agree with this section's mandate for logging increased privilege changes and emergency access to patient information. We also support the requirement for EHRs to track who viewed a patient's PHI, but caution ONC against requiring the EHR to record which data was accessed in a patient's chart though. Modern EHR design has many different data elements presented in a cohesive design with most common data represented on multiple screens. Requiring distinct auditing for viewing individual data elements would create an overwhelming task without corresponding benefit.

§ 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:

We support the retention of this criterion, as well as the intention of leaving it unchanged from the previous edition.

§ 170.315(d)(4) Amendments
Included in 2015 Edition Base EHR Definition? No, but a conditional certification requirement
Stage 3 MU Objective N/A
2015 Edition Health IT Certification Criterion (4) Amendments. Enable a user to select the record affected by a patient's request for amendment and perform the capabilities specified in paragraph (d)(4)(i) or (ii) of this section. (i) Accepted amendment. For an accepted amendment, append the amendment to the affected record or include a link that indicates the amendment's location. (ii) Denied amendment. For a denied amendment, at a minimum, append the request and denial of the request to the affected record or include a link that indicates this information's location.
Preamble FR Citation: 80 FR 16847 **Specific questions in preamble?** *No*
Public Comment Field: We support the retention of this criterion, as well as the intention of leaving it unchanged from the previous edition.

§ 170.315(d)(5) Automatic access time-out
Included in 2015 Edition Base EHR Definition? No, but a conditional certification requirement
Stage 3 MU Objective N/A
2015 Edition Health IT Certification Criterion (5) Automatic access time-out. (i) Automatically stop user access to health information after a predetermined period of inactivity. (ii) Require user authentication in order to resume or regain the access that was stopped.
Preamble FR Citation: 80 FR 16847 **Specific questions in preamble?** *Yes*
Public Comment Field: We support the retention of this criterion, as well as the intention of leaving it unchanged from the previous edition.

§ 170.315(d)(6) Emergency access
Included in 2015 Edition Base EHR Definition? No, but a conditional certification requirement
Stage 3 MU Objective N/A
2015 Edition Health IT Certification Criterion (6) Emergency Access. Permit an identified set of users to access electronic health information during an emergency.
Preamble FR Citation: 80 FR 16847 **Specific questions in preamble?** *No*
Public Comment Field: We support the retention of this criterion, as well as the intention of leaving it unchanged from the previous edition.

§ 170.315(d)(7) End-user device encryption
Included in 2015 Edition Base EHR Definition? No, but a conditional certification requirement
Stage 3 MU Objective N/A
2015 Edition Health IT Certification Criterion (7) End-user device encryption. Paragraph (d)(7)(i) or (ii) of this section must be met to satisfy this certification criterion. (i) Technology that is designed to locally store electronic health information on end-user devices must encrypt the electronic health information stored on such devices after use of the technology on those devices stops. (A) Electronic health information that is stored must be encrypted in accordance with the standard specified in § 170.210(a)(3); (B) Default setting. Technology must be set by default to perform this capability and, unless this configuration cannot be disabled by any user, the ability to change the configuration must be restricted to a limited set of identified users. (ii) Technology is designed to prevent electronic health information from being locally stored on end-user devices after use of the technology on those devices stops.
Preamble FR Citation: 80 FR 16847 **Specific questions in preamble?** *Yes*
Public Comment Field: We support the proposed changes for the end-user device encryption.

§ 170.315(d)(8) Integrity
Included in 2015 Edition Base EHR Definition? No, but a conditional certification requirement
Stage 3 MU Objective N/A
2015 Edition Health IT Certification Criterion (8) Integrity. (i) Create a message digest in accordance with the standard specified in § 170.210(c). (ii) Verify in accordance with the standard specified in § 170.210(c) upon receipt of electronically exchanged health information that such information has not been altered.
Preamble FR Citation: 80 FR 16847 **Specific questions in preamble?** *Yes*
Public Comment Field: We agree with the proposed rule's deprecation of SHA1-1 and that aligning this change with a 2017 start is most appropriate. We would ask that ONC not require recertification in 2015.

§ 170.315(d)(9) Accounting of disclosures
Included in 2015 Edition Base EHR Definition? No
Stage 3 MU Objective N/A

§ 170.315(d)(9) Accounting of disclosures	
2015 Edition Health IT Certification Criterion	
(9) Accounting of disclosures. Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(d).	
Preamble FR Citation: 80 FR 16848	**Specific questions in preamble?** *No*
Public Comment Field:	
We support the retention of this criterion, as well as the intention of leaving it unchanged from the previous edition.	

§ 170.315(e)(1) View, download, and transmit to a third party
Included in 2015 Edition Base EHR Definition?
No
Stage 3 MU Objectives
The EP, eligible hospital, or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability. Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.

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

2015 Edition Health IT Certification Criterion

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

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

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

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

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

(3) Inpatient setting only. Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization.

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

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

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

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

(5) Diagnostic image report(s).

(B) Download.

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

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

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

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

(3) Inpatient setting only. Patients (and their authorized representatives) must be able to download transition of care/referral summaries that were created as a result of a transition of care (pursuant to the capability expressed in the certification criterion adopted at paragraph (b)(1) of this section).

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

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

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

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

(2) Inpatient setting only. Transmit transition of care/referral summaries (as a result of a transition of care/referral) selected by the patient (or their authorized representative) in accordance with at least one of the following:

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

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

(ii) Activity history log.

§ 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*

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

Public Comment Field:

For this measure, we would reiterate that the government should set required outcomes and allow the market to innovate around the means to achieve those outcomes. However, if ONC plans to mandate a standard here, more clarity is needed for developers to follow it. A standard is necessary to implement this goal or everyone will create their own version and the industry will be no closer to interoperation.

Additionally, we provide comments on the following:

(1) If there is an API requirement, we would recommend that FHIR DSTU2 be used for clinical fields.

(2) We propose that instead of specifying custom search criteria, ONC should specify a profile that contains search specification to certify against (e.g., DAF).

(3) Under this API requirement, ONC should specify a security layer to be used for an API with a non-web application so that all parties are authenticating the same way, such as SMART OAuth 2.0.

(4) More clarity is needed for the requirements on diagnostic image reports—if this is not a part of the ambulatory summary, how does this report get downloaded? This requirement would be confusing to patients as they would be expecting to see everything as a part of the ambulatory summary.

(5) The proposed rule explicitly excludes unstructured data for labs and image results. The majority of labs are structured data, but the minority of image results are. We can include metadata, but not the actual image interpretation text which is typically received via fax. It is possible to embed a PDF in an unstructured CCDA wrapper, but ONC explicitly excludes the use of the unstructured type. It is unreasonable to take image only labs (scanned documents) and convert them to a text format. We advocate for more electronic exchange of lab results instead of requiring EHRs responsible for cleaning up different formats.

§ 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:

We support the retention of this criterion, as well as the intention of leaving it unchanged from the previous edition.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

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

2015 Edition Health IT Certification Criterion

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

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

Public Comment Field:

We reiterate our overarching comments for the proposed rule that if ONC proposes to mandate standards, more clarity is needed to achieve their intended aim. We recommend that ONC mandate a specific version of NDC. Otherwise, different versions will create issues where EHRs map to a code set, but the registry maps to a different code value for the same vaccine. Any combination of standards or versions will cause mapping interpretation problems, especially on a state-by-state registry basis.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

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

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

2015 Edition Health IT Certification Criterion

(2) Transmission to public health agencies—syndromic surveillance.

(i) Ambulatory setting only.

(A) Technology must be able to create syndrome-based public health surveillance information for electronic transmission.

(B) Optional. Technology must be able to create syndrome-based public health surveillance information for electronic transmission that contains the following data:

(1) Patient demographics;
(2) Provider specialty;
(3) Provider address;
(4) Problem list;
(5) Vital signs;
(6) Laboratory test values/results;
(7) Procedures;
(8) Medication list; and
(9) Insurance.

(ii) Inpatient setting only. Technology must be able to create syndrome-based public health surveillance information for electronic transmission in accordance with the standard (and applicable implementation specifications) specified in § 170.205(d)(4).

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

Public Comment Field:

We support the changes in the public health agencies—syndromic surveillance measure.

§ 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:

We ask ONC for greater clarity around this proposed measure. We note that laboratory results do not contain diagnoses so SNOMED would not be used in the laboratory result. Unless ONC mandated a specific version, a version of LOINC would need to be incorporated, and where two entities are using different versions, the transmission should include the version currently used.

§ 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:

We ask ONC to use consistency throughout the proposed rule as the CCDA 2.0 standard is already used for a few other measures and could also be used here. Where possible, ONC should simplify and be consistent in mandating standards. This criterion has an issue similar to electronic prescribing where the version required for certification is not what is used by the CDC in the real world so EHRs are forced to create and support both.

§ 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:

We ask for greater clarity on this measure and would recommend that ONC not include it in the final rule until the uncertainty is alleviated. We have some questions about the case reporting measure: What is the use case for this? Who will use this and what is the end user intended to do with the URL? What is the trigger for this transmission and do subsequent triggers need to pass back the URL? Additionally we reiterate our concern with requiring clinicians to perform additional data entry solely for the purposes of research, which takes time away from patient care.

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

Included in 2015 Edition Base EHR Definition?

No

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

Stage 3 MU Objective

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

2015 Edition Health IT Certification Criterion

(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:

Echoing our comments from the transmission to cancer registry measure, ONC should avoid using formats specific to each measure or the proposed rule will transform clinicians into data entry clerks, adding tremendous administrative burdens to a practice and drawing attention away from patient care. We recommend the use of the CCDA standard here as well to maintain consistency and encourage simplification throughout the proposed rule.

§ 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:

Echoing our comments from the transmission to cancer registry and antimicrobial use and resistance reporting criteria, ONC should avoid using formats specific to each measure or the proposed rule will transform clinicians into data entry clerks, adding tremendous administrative burdens to a practice and drawing attention away from patient care.

The CMS Meaningful Use program has recognized the overwhelming burden on providers to perform data entry that does not directly support patient care. We applaud this direction, but note that unless providers are required to follow certain steps, they will not perform them. Therefore, criteria like this compel EHR vendors to build new functionalities simply for certification that will not be used in the real world. This draws attention away from building functionality that our client base is actually requesting.

§ 170.315(g)(1) Automated numerator recording

Included in 2015 Edition Base EHR Definition?

No, but proposed for the EHR Incentive Programs CEHRT definition

§ 170.315(g)(1) Automated numerator recording
Stage 3 MU Objective
N/A
2015 Edition Health IT Certification Criterion
(1) Automated numerator recording. For each meaningful use objective with a percentage-based measure, technology must be able to create a report or file that enables a user to review the patients or actions that would make the patient or action eligible to be included in the measure's numerator. The information in the report or file created must be of sufficient detail such that it enables a user to match those patients or actions to meet the measure's denominator limitations when necessary to generate an accurate percentage.
Preamble FR Citation: 80 FR 16856 **Specific questions in preamble?** *No*
Public Comment Field:
We support the retention of this criterion, as well as the intention of leaving it unchanged from the previous edition

§ 170.315(g)(2) Automated measure calculation
Included in 2015 Edition Base EHR Definition?
No, but proposed for the EHR Incentive Programs CEHRT definition
Stage 3 MU Objective
N/A
2015 Edition Health IT Certification Criterion
(2) Automated measure calculation. For each meaningful use objective with a percentage-based measure that is supported by a capability included in a technology, record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.
Preamble FR Citation: 80 FR 16856 **Specific questions in preamble?** *No*
Public Comment Field:
We support the retention of this criterion, as well as the intention of leaving it unchanged from the previous edition

§ 170.315(g)(3) Safety-enhanced design
Included in 2015 Edition Base EHR Definition?
No, but a conditional certification requirement
Stage 3 MU Objective
N/A

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

2015 Edition Health IT Certification Criterion

(3) Safety-enhanced design.

(i) User-centered design processes must be applied to each capability technology includes that is specified in the following certification criteria: paragraphs (a)(1) through (10) and (18), (20), (22), (23), and (b)(2) through (4) of this section.

(ii) The following information must be submitted on the user-centered design processed used:

(A) Name, description and citation (URL and/or publication citation) for an industry or federal government standard; or

(B) Name the process(es), provide an outline of the process(es), a short description of the process(es), and an explanation of the reason(s) why use of any of the existing user-centered design standards was impractical.

(iii) The following information/sections from NISTIR 7742 must be submitted for each capability to which user-centered design processes were applied:

(A) Name and version of the product; date and location of the test; test environment; description of the intended users; and total number of participants;

(B) Description of participants, including: sex; age; education; occupation/role; professional experience; computer experience; and product experience;

(C) Description of the user tasks that were tested and association of each task to corresponding certification criteria;

(D) List of the specific metrics captured during the testing, including; task success (%); task failures (%); task standard deviations (%); task performance time; and user satisfaction rating (based on a scale with 1 as very difficult and 5 as very easy);

(E) Test results for each task using metrics listed above in paragraphs (g)(3)(ii)(A) through (D) of this section;

(F) Results and data analysis narrative, including: major test finding; effectiveness; efficiency; satisfaction; and areas for improvement.

(iv) Submit test scenarios used in summative usability testing.

Preamble FR Citation: 80 FR 16856 **Specific questions in preamble?** *Yes*

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

Public Comment Field:

We applaud the ONC's continued concern that EHRs reduce the risk of use error through following a UCD process. As we have stated before, we do not believe that Summative testing is a substitute for a UCD or that it promotes a usable or safe EHR user experience. This is primarily because Summative testing measures the end result of product development, after the opportunity to address usability issues has passed.

Summative testing is designed for comparison– of different products or different versions of the same product. For these comparisons to be valid, the testing must be done in a repeatable manner--same tasks, same data, same kinds of users, same moderation, same measurements. As different vendors use different tasks, moderation, and so on, the results of summative tests are not comparable; yet publishing them, especially in the same NIST template, implies that they are comparable, which is highly misleading to those seeking to purchase a truly usable product.

Further, Summative testing is expensive, which effectively favors established vendors, pricing new players out of the market.

The Stage 3 proposed changes to the Safety-Enhanced Design requirements actually exacerbate this unfair cost to small vendors by adding additional criteria for testing. We recommend trimming this list, not expanding it, to focus on particular user tasks that pose the most risk for patients.

We would agree that 15 participants per user group does allow for smaller confidence intervals for comparisons--if the proposed summative tests were actually comparable. As they are not, we do not see the point of enforcing a minimum. Instead, the ONC should focus on ensuring that all certifying bodies apply requirements for passing equitably across all vendors.

Also, the proposed changes distinguish physicians, nurse practitioners, and physician assistants as separate user groups. For the purposes of the tasks, these three groups of ordering providers can all belong to the same user group. They have the same goals, same tasks, and the same variety of technical experience. The proposed rule changes, by requiring 15 of each, is unnecessarily adding to the cost of completing the summative test--again pricing new entrants out of the EHR market and stifling innovation.

In lieu of summative testing, we support two additions to the UCD Process document in the safety-enhanced design measure: (1) reporting of the UCD activities that supported the development of the criteria covered in the safety-enhanced requirement, including formative usability testing; and (2) reporting the safety processes that are part of the UCD process.

§ 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

§ 170.315(g)(4) Quality management system

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:

We are supportive of the changes in the quality management system measure, but feel strongly that ONC should avoid prescribing quality standards to private industry.

§ 170.315(g)(5) Accessibility technology compatibility

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16858 **Specific questions in preamble?** *Yes*

Public Comment Field:

We echo our overall sentiments that ONC should weigh the burden of a measure against the intended benefit. In this case, accessibility technology certainly provides necessary benefits to a diverse patient market, but we believe this offers little value for the complex roles and responsibilities of staff in a medical practice. We would ask for more clarity on use-cases and particular diseases this would benefit. Otherwise, it is not reasonable for health IT platforms to design a product to accommodate all when it adds very little benefit at a significant cost.

§ 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

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

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:

We recommend that ONC provide more clarity and simplify several aspects of this measure:

(1) In document template conformance section, the proposed rule would require CCDA 1.1 and 2.0, which is not realistic for a sender to choose between two standards as a clinician would not want to choose. We recommend the measure require both versions inbound, but not outbound.

(2) We appreciate much of the vocabulary conformance language as it should alleviate some of the issues we have seen in the past when the structure of the document is sound but the content contained within it is inconsistent across the industry.

(3) We recommend a crisper definition of “receive”—is ONC proposing “incorporate” or “receive and display”? If ONC has decided to be stricter on a content side, the industry needs testing tools to support the validation of this content, which would require building and testing faster iterations.

(4) The proposed rule must be clearer on the timeframe for the data included in this measure. For example, if someone has a lifetime of vitals, this makes the document so big that no one would read it. We ask for clarity on how long to include historical data for each data section as it is not relevant to include longitudinal data and it is important to maximize the usefulness of the information.

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

Included in 2015 Edition Base EHR Definition?

Yes

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

Stage 3 MU Objectives

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

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

2015 Edition Health IT Certification Criterion

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

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

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

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

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

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

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

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

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

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

Preamble FR Citation: 80 FR 16860 **Specific questions in preamble?** *Yes*

Public Comment Field:

We reiterate our earlier comments that to foster an open ecosystem , an API standard is necessary. We would recommend using FHIR. Furthermore, we do not agree with a custom search criteria, but instead advocate for a "FHIR profile" that can define supported search capabilities.

We do not agree with adding any additional API capabilities listed in the proposed rule.

We recommend limiting the scope of the C-CDA creation capability within this certification criterion to focus solely on the creation of a CCD document template based on the C-CDA Release 2.0.

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

Included in 2015 Edition Base EHR Definition?

No, but a mandatory certification requirement

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

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

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

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

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

Public Comment Field:

We reiterate our comments from the Accessibility Technology Compatibility criterion

§ 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:

Overall, we support certification on the ability to send via a single transport protocol, but we agree that all that systems should be able to receive on the Edge Protocol. We would ask that ONC avoid requiring EHRs to send via more than one standard, though they should be able to receive others.

§ 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)

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

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

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

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

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

Preamble FR Citation: 80 FR 16863 (also see 80 FR 16862) **Specific questions in preamble?** *No*

Public Comment Field:

We reiterate our comments from the Direct Project criterion.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

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

Public Comment Field:

We reiterate our comments from the Direct Project criterion.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

(i) Query for an individual provider;

(ii) Query for an organizational provider;

(iii) Query for both individual and organizational providers in a single query; and

(iv) Query for relationships between individual and organizational providers.

(v) Optional - federation. In accordance with the standard specified in § 170.202(f)(1), technology must be able to process federated responses.

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

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

Public Comment Field:

The scope of certification should not extend beyond message transport and protocol. Requiring the use of specific architecture, such as LDAP, is overly prescriptive and adds no additional value to care.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

(i) Query for an individual provider;

(ii) Query for an organizational provider;

(iii) Query for both individual and organizational providers in a single query; and

(iv) Query for relationships between individual and organizational providers.

(v) Optional - federation. In accordance with the standard specified in § 170.202(f)(1), technology must be able to federate queries to other directories.

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

Public Comment Field:

We reiterate our comments from the healthcare provider directory—query request section.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

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

2015 Edition Health IT Certification Criterion

(1) Electronic submission of medical documentation.

(i) Document templates. Health IT must be able to create electronic documents for transmission formatted according to the following standard and applicable implementation specifications adopted at § 170.205(a)(4) and (a)(5)(i). With respect to § 170.205(a)(5)(i):

(A) Health IT must be able to create the following document types regardless of the setting for which it is designed: Diagnostic Imaging Report; Unstructured Document; Enhanced Operative Note Document; Enhanced Procedure Note Document; and Interval Document.

(B) Ambulatory setting only. Health IT must be able to create an Enhanced Encounter Document.

(C) Inpatient setting only. Health IT must be able to create an Enhanced Hospitalization Document.

(ii) Digital signature.

(A) Applying a digital signature. Technology must be able to apply a digital signature in accordance with the implementation specification adopted at § 170.205(a)(5)(ii) to a document formatted according to the following standard and applicable implementation specifications adopted at § 170.205(a)(4) and (a)(5)(i). It must also be able to demonstrate that it can support the method for delegation of right assertions.

(1) The cryptographic module used as part of the technology must: be validated to meet or exceed FIPS 140-2 Level 1; include a digital signature system and hashing that are compliant with FIPS 186-2 and FIPS 180-2; and store the private key in a FIPS-140-2 Level 1 validated cryptographic module using a FIPS-approved encryption algorithm. This requirement may be satisfied through documentation only.

(2) Technology must support multi-factor authentication that meets or exceeds Level 3 assurance as defined in NIST Special Publication 800-63-2.

(3) After ten minutes of inactivity, technology must require the certificate holder to re-authenticate to access the private key.

(4) If implemented as a software function, the system must clear the plain text private key from the system memory to prevent the unauthorized access to, or use of, the private key when the signing module is deactivated.

(5) Technology must record time and date consistent with the standard adopted at § 170.210(g).

(B) Validating a digital signature. Technology must be able validate a digital signature that has been applied to a document according to the implementation specification adopted at § 170.205(a)(5)(ii).

(iii) Author of record level 1. Using the same system capabilities expressed in paragraph (i)(1)(ii), technology must be able to apply a digital signature according to the implementation specification adopted at § 170.205(a)(5)(iii) to sign single or bundles of documents a document formatted according to the following standard and applicable implementation specifications adopted at § 170.205(a)(4) and (a)(5)(i).

(iv) Transactions. Using the same system capabilities expressed in paragraph (i)(1)(ii) of this section, technology must be able to apply a digital signature according to the implementation specification adopted at § 170.205(a)(5)(iv) to a transaction and include the signature as accompanying metadata in the signed transaction.

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

Public Comment Field:

We support the intention of this measure, but we would need more information and clarity around the standards, security requirements, and use cases. Additionally, we have concerns about the readiness of the industry for this requirement. If FDB does not have the data yet, then EHRs should not be forced to build this functionality for the sake of certification when there is yet to be real-world application.

Conclusion

We appreciate ONC's engagement of the public to inform the 2015 Edition Standards and Certification criteria. athenahealth continues to welcome the opportunity to provide feedback and participate in the transformation of health care.

Sincerely,

Dan Haley
Vice President
Government and Regulatory Affairs