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Office of the National Coordinator for Health IT

Proposed Rule Public Comment Template

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

Preface

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This document is meant to provide the public with a simple and organized way to submit comments on the proposed certification criteria and associated standards and implementation specifications, and respond to specific questions posed in the preamble of the proposed rule, which is published in the Federal Register at 79 FR 10880. While use of this document is entirely voluntary, commenters may find it helpful to use the document in lieu of or in addition to unstructured comments on the certification criteria and associated standards and implementation specifications, or to use it as an addendum to narrative cover pages.

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

The proposed rule proposes new, revised, and unchanged certification criteria that can be used to support the CMS Medicare and Medicaid EHR Incentive Programs. It also includes proposals and requests for public comment that offer insights into ONC's potential regulatory direction for the future. The proposed rule affects certification criteria only and does not impact meaningful use (MU) objectives and measures.

The following tables align with the presentation of the proposed certification criteria in the preamble of the proposed rule. The tables specify where the proposed 2015 Edition EHR certification criterion or criteria would be included in § 170.315. The tables also specify the MU objective that the proposed 2015 Edition EHR certification criterion or criteria and associated standards and implementation specifications support. The tables note the page(s) of the Federal Register where we discuss the certification criterion or criteria and whether we request specific comments on certain proposals in the preamble. Last, the tables provide a field for submitting public comments on the proposed criterion or criteria, including responses to specific questions or requests for comments posed in the preamble.

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

http://www.regulations.gov/#!submitComment;D=HHS-OS-2014-0002-0001

Proposed Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability

Updates and Regulatory Improvements

A. Proposed for 2015 Edition1 Certification Criteria

§ 170.315(a)(1) Computerized physician order entry - medications
MU Objective
Use computerized provider order entry (CPOE) for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines to create the first record of the order.
2015 Edition EHR Certification Criterion
(1)   Computerized provider order entry – medications. Enable a user to electronically record, change, and access medication orders.
Preamble FR Citation: 79 FR 10886   **Specific questions in preamble?** *No*
Public Comment Field:

§ 170.315(a)(2) Computerized physician order entry - laboratory
MU Objective
Use CPOE for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines to create the first record of the order.
2015 Edition EHR Certification Criterion

(2)   Computerized provider order entry – laboratory. (i) Enable a user to electronically record, change, and access laboratory orders.
       (ii) Ambulatory setting only. Enable a user to electronically create laboratory orders for electronic transmission:
       (A) With all the information for a test requisition as specified at 42 CFR 493.1241(c)(1) through (c)(8); and
       (B) In accordance with the standard specified at § 170.205(l)(1) and, at a minimum the version of the standard at § 170.207(c)(2).

Preamble FR Citation: 79 FR 10887   **Specific questions in preamble?** *No*
Public Comment Field:

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[1] This includes one proposed revision to the 2014 Edition certification criterion for transmission of syndromic surveillance information to public health agencies.

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10887	**Specific questions in preamble?** *No*

Public Comment Field:

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

MU Objective

Implement drug-drug and drug-allergy interaction checks.

2015 Edition EHR Certification Criterion

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

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

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

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

Preamble FR Citation: 79 FR 10887	**Specific questions in preamble?** *Yes*

Public Comment Field:

§ 170.315(a)(5) (Demographics)

MU Objective

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

2015 Edition EHR Certification Criterion

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

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

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

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

Preamble FR Citation: 79 FR 10888	**Specific questions in preamble?** *Yes*

Public Comment Field:

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

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

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

Preamble FR Citation: 79 FR 10889	Specific questions in preamble? *Yes*

Public Comment Field:

§ 170.315(a)(7) (Problem list)

MU Objective

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

2015 Edition EHR Certification Criterion

(7) Problem list. Enable a user to electronically record, change, and access a patient's active problem list:

    (i) Ambulatory setting. Over multiple encounters in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3); or

    (ii) Inpatient setting. For the duration of an entire hospitalization in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3).

Preamble FR Citation: 79 FR 10890	Specific questions in preamble? *No*

Public Comment Field:

§ 170.315(a)(8) (Medication list)

MU Objective

Maintain active medication list.

2015 Edition EHR Certification Criterion

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

    (i) Ambulatory setting. Over multiple encounters; or

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

Preamble FR Citation: 79 FR 10890	Specific questions in preamble? *No*

Public Comment Field:

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

MU Objective

Maintain active medication allergy list.

2015 Edition EHR Certification Criterion

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

     (i) Ambulatory setting. Over multiple encounters; or

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

Preamble FR Citation: 79 FR 10890	**Specific questions in preamble?** *No*

Public Comment Field:

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

MU Objective

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

2015 Edition EHR Certification Criteria

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

     (A) Problem list;

     (B) Medication list;

     (C) Medication allergy list;

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

     (E) Laboratory tests; and

     (F) Vital signs.

     (ii) Linked referential clinical decision support. (A) EHR technology must be able to:

     (1) Electronically identify for a user diagnostic and therapeutic reference information; or

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

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

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

     (B) EHR technology must enable interventions to be electronically triggered:

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

     (2) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received pursuant to paragraph (b)(1)(i)(B) of this section.

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

     (iv) Automatically and electronically interact. Interventions triggered in accordance with paragraphs (a)(10)(i) through (iii) of this section must automatically and electronically occur when a user is interacting with EHR technology.

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

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

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

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

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

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

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

(vi) Decision support – knowledge artifact. Electronically process clinical decision support knowledge artifacts in accordance with the standard specified at § 170.204(d).

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

Preamble FR Citation: 79 FR 10890	Specific questions in preamble? *Yes*

Public Comment Field:

§ 170.315(a)(11) (Electronic notes)

MU Objective

Record electronic notes in patient records.

2015 Edition EHR Certification Criterion

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

(i) Record, change, and access electronic notes; and

(ii) Search within and across electronic notes stored within EHR technology.

Preamble FR Citation: 79 FR 10891	Specific questions in preamble? *Yes*

Public Comment Field:

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

MU Objective

Implement drug formulary checks.

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10892	Specific questions in preamble? *Yes*

Public Comment Field:

§ 170.315(a)(13) (Smoking status)

MU Objective

Record smoking status for patients 13 years old or older.

2015 Edition EHR Certification Criteria

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

Preamble FR Citation: 79 FR 10892	**Specific questions in preamble?** *No*

Public Comment Field:

§ 170.315(a)(14) (Image results)

MU Objective

Imaging results and information are accessible through Certified EHR Technology.

2015 Edition EHR Certification Criterion

(14) Image results. Electronically indicate to a user the availability of a patient's images and narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable electronic access to such images and narrative interpretations.

Preamble FR Citation: 79 FR 10893	**Specific questions in preamble?** *No*

Public Comment Field:

§ 170.315(a)(15) (Family health history)

MU Objective

Record patient family health history as structured data.

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10893	**Specific questions in preamble?** *No*

Public Comment Field:

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

MU Objective

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

2015 Edition EHR Certification Criterion

(16) Patient list creation. Enable a user to electronically and dynamically select, sort, access, and create patient lists by: date and time; and based on each one and at least one combination of the following data:

    (i) Problems;

    (ii) Medications;

    (iii) Medication allergies;

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

    (v) Laboratory tests and values/results; and

    (vi) Ambulatory setting only. Patient communication preferences.

Preamble FR Citation: 79 FR 10893	Specific questions in preamble? *Yes*
Public Comment Field:	

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

    (i) In accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204(b)(1) or (3); and

    (ii) By any means other than using the standard specified in § 170.204(b).

Preamble FR Citation: **79 FR 10893**	Specific questions in preamble? *Yes*
Public Comment Field:	

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

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

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

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

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

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

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

Preamble FR Citation: 79 FR 10894	Specific questions in preamble? *No*
Public Comment Field:	

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

MU Objective

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

2015 Edition EHR Certification Criteria

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

Preamble FR Citation: 79 FR 10894	**Specific questions in preamble?** *No*

Public Comment Field:

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

MU Objective

N/A

2015 Edition EHR Certification Criteria

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

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

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

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

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

Preamble FR Citation: 79 FR 10894	**Specific questions in preamble?** *Yes*

Public Comment Field:

§ 170.315(b)(1) (Transitions of care)

MU Objective

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

2015 Edition EHR Certification Criteria

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

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

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

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

(iii) Display.

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

(B) Section views. Extract and allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary received and formatted in accordance with the standard adopted at §170.205(a)(3).

(iv) <u>Create</u>. (A) Enable a user to electronically create a transition of care/referral summary formatted according to the standard adopted at §170.205(a)(4) that includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):

(1) Encounter diagnoses. The standard specified in §170.207(i) or, at a minimum, the version of the standard specified §170.207(a)(3);

(2) <u>Immunizations</u>. The standard specified in §170.207(e)(2);

(3) Cognitive status;

(4) Functional status;

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

(6) Inpatient setting only. Discharge instructions; and

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

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

(1) Data. first name, last name, middle name (or middle initial in cases where only it exists/is used), suffix, date of birth, place of birth, maiden name, current address, historical address, phone number, and sex.

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

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

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

(5) Constraint. Represent current and historical address information, including the street address, city, state, zip code, according to the United States Postal Service format;

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

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

Preamble FR Citation: 79 FR 10896	Specific questions in preamble? *Yes*

Public Comment Field:

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

MU Objective

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

2015 Edition EHR Certification Criteria

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

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

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

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

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

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

    (1) <u>Medications</u>. At a minimum, the version of the standard specified in § 170.207(d)(2);

    (2) <u>Problems</u>. At a minimum, the version of the standard specified in § 170.207(a)(3);

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

Preamble FR Citation: 79 FR 10901	**Specific questions in preamble?** *Yes*

Public Comment Field:

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

MU Objective

Generate and transmit permissible prescriptions electronically (eRx).

2015 Edition EHR Certification Criterion

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

    (i) The standard specified in § 170.205(b)(2); and

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

Preamble FR Citation: 79 FR 10901	**Specific questions in preamble?** *No*

Public Comment Field:

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

MU Objective

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

2015 Edition EHR Certification Criteria

(4) Incorporate laboratory tests and values/results. (i) Receive results. (A) Ambulatory setting only. (1) Electronically receive and incorporate clinical laboratory tests and values/results in accordance with the standard specified in § 170.205(j)(2) and, at a minimum, the version of the standard specified in § 170.207(c)(2).

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

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

    (ii) Electronically display the test report information:

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

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

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

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

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

Preamble FR Citation: 79 FR 10901	**Specific questions in preamble?** *No*

Public Comment Field:

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

MU Objective

Provide structured electronic laboratory results to eligible professionals.

2015 Edition EHR Certification Criteria

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

    (i) That includes the information:

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

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

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

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

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

Preamble FR Citation: 79 FR 10901	**Specific questions in preamble?** *No*

Public Comment Field:

§ 170.315(b)(6) (Data portability)

MU Objective

N/A

2015 Edition EHR Certification Criterion

(6) Data portability. Enable a user to electronically create a set of export summaries for all patients in EHR technology formatted according to the standard adopted at § 170.205(a)(4) that represents the most current clinical information about each patient and includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):

    (i) Encounter diagnoses. The standard specified in § 170.207(i) or, at a minimum, the version of the standard at § 170.207(a)(3);

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

    (iii) Cognitive status;

    (iv) Functional status;

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

    (vi) Inpatient setting only. Discharge instructions; and

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

Preamble FR Citation: 79 FR 10902	**Specific questions in preamble?** *Yes*

Public Comment Field:

Clinical Quality Measures – Electronically Processing eMeasures

Preamble FR Citation: 79 FR 10902   **Specific questions in preamble?** *Yes*

Public Comment Field:

Clinical Quality Measures – Functions and Standards for CQM Certification

Preamble FR Citation: 79 FR 10903   **Specific questions in preamble?** *Yes*

Public Comment Field:

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

MU Objective

N/A

2015 Edition EHR Certification Criterion

(1) Clinical quality measures—capture and export.

(i) Capture. For each and every CQM for which the EHR technology is presented for certification, EHR technology must be able to electronically record all of the data identified in the standard specified at § 170.204(c) that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of "patient reason," "system reason," or "medical reason."

(ii) Export. EHR technology must be able to electronically export a data file formatted in accordance with the standards specified at § 170.205(h) that includes all of the data captured for each and every CQM to which EHR technology was certified under paragraph (c)(1)(i) of this section.

Preamble FR Citation: 79 FR 10903   **Specific questions in preamble?** *Yes*

Public Comment Field:

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

MU Objective

N/A

2015 Edition EHR Certification Criterion

(2) Clinical quality measures—import and calculate.

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

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

Preamble FR Citation: 79 FR 10903   **Specific questions in preamble?** *No*

Public Comment Field:

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

MU Objective

N/A

2015 Edition EHR Certification Criteria

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

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

(ii) That can be electronically accepted by CMS.

Preamble FR Citation: 79 FR 10903   **Specific questions in preamble?** *No*

Public Comment Field:

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

MU Objective

N/A

2015 Edition EHR Certification Criterion

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

(i) Practice site and address;

(ii) Tax Identification Number (TIN), National Provider Identifier (NPI), and TIN/PIN combination;

(iii) Diagnosis;

(iv) Primary and secondary health insurance, including identification of Medicare and Medicaid dual eligibles; and

(v) Demographics including age, sex, preferred language, education level, and socioeconomic status.

Preamble FR Citation: 79 FR 10903   **Specific questions in preamble?** *Yes*

Public Comment Field:

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

MU Objective

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

2015 Edition EHR Certification Criterion

(1) Authentication, access control, and authorization (i) Verify against a unique identifier(s) (e.g., username or number) that a person seeking access to electronic health information is the one claimed; and

(ii) Establish the type of access to electronic health information a user is permitted based on the unique identifier(s) provided in paragraph (d)(1)(i) of this section, and the actions the user is permitted to perform with the EHR technology.

Preamble FR Citation: 79 FR 10904   **Specific questions in preamble?** *Yes*

Public Comment Field:

The HITPC's policy recommendations are actionable, from a certification perspective, as the capability to require two forms of authentication can be tested functionally (for example, using the 800-63-2 LOA 3 functional specification). However, given the number of approaches that can be used in two-factor authentication for remote access and the fact that authentication technology is likely to advance over the next three years, the PSWG cannot recommend a specific set

of standards to use for this purpose. However, from a policy perspective, we would note that in today's environment, "remote access" may be difficult to define, as it is situational. For example, would EHR access using a mobile device within a hospital be considered "remote access?" We would suggest that "remote access" needs to be clearly defined in order to make this policy recommendation actionable.

We are not aware of any meaningful-use measures or other healthcare policy that would warrant a general requirement for a two-factor authentication capability. However, if the ONC decides to add such a requirement, the PSWG suggests that a product presenting proof of having passed a DEA audit of its two-factor authentication capability should be considered as having met the certification requirement for two-factor authentication for an EHR, but not necessarily for remote access. We would again note that this can only be tested functionally (see response above). The PSWG also observes that these two use cases (e-prescribing of controlled substances and remote access) highlight the need for healthcare engagement with the NSTIC program.

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

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

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

(ii) Default setting. EHR technology must be set by default to perform the capabilities specified in paragraph (d)(2)(i)(A) of this section and, where applicable, paragraph (d)(2)(i)(B).

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

(iv) Audit log protection. Actions and statuses recorded in accordance with paragraph (d)(2)(i) of this section must not be capable of being changed, overwritten, or deleted by the EHR technology.

(v) <u>Detection</u>. EHR technology must be able to detect whether the audit log has been altered.

Preamble FR Citation: 79 FR 10904	Specific questions in preamble? *Yes*

Public Comment Field:

The PSWG suggests no change from the 2014 Final Rule; the current criteria adequately function as a floor for meaningful use. Although the current certification criteria do not preclude the audit log from being disabled, they do require access controls restricting the capability to disable the audit log to a limited set of identified users (presumably those with audit-log administrative duties) and the capability to record the user ID, data, and time when the log was disabled. Since the proposed change would "prevent all users from disabling the audit log, the PSWG contends that prohibiting the disabling of the audit log would hamper security administrators from performing their functions properly.

Generally, this kind of action comes from concern that a system administrator would do something nefarious. A countermeasure is to audit the act of turning the audit log off and on; this capability is required in the current criteria. Furthermore, audit administrators are typically separate from other security administrators. Audit administration typically includes tuning (disabling) the list of audited or turning off positive authentication events while leaving negative authentication events enabled. Sometimes, the storage capacity required for the audit trail expands and can threaten continuing operations. While the PSWG does not suggest a regular practice of disabling the audit trail to manage storage, it does suggest that certification criteria should not thwart administrator's ability to perform their assigned functions.

§ 170.315(d)(3) (Audit report(s))

MU Objective

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

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10905	Specific questions in preamble? *Yes*

Public Comment Field:

ASTM E2147 was updated a year ago, and the PSWG is not aware of any need to define 'query' or any problems developers have encountered regarding query. Greater vendor input is needed to fully answer this question for the entire healthcare industry.   We recognize that there is confusion in the market in understanding the Security Audit Logging concept. We would suggest that a broader reference to ASTM E2147 might serve well to help clarify any misunderstandings. Specifically, we recommend expanding the references to include at least section 5, which explains Security Audit Logging and describes the kinds of events that should be recorded in the audit log. In addition, we recommend that Section 7 be referenced in its entirety rather than individually enumerating those parts of Section 7 that are not labeled "optional." Note that by citing all of Section 7, these provisions still would be treated as "optional."
With request to the question on whether a minimum audit baseline should be established for EHR technology, Section 7.6 of ASTM E2147 specifies the types of actions to be included in the audit trail and should cover any type of action taken within an enterprise, including transmitting a record within an enterprise, which would require a "copy." Transmissions to outside the enterprise are covered in Section 8, Disclosure Log Content, but Accounting of Disclosures currently is outside the scope of EHR certification so Section 8 should not be added at this time.
The PSWG believes it is quite feasible to certify EHR compliance with the ASTM E2147 audit log standard, and does not recommend ONC specify other actions in an updated standard for the 2017 Edition, or that ONC consider any additional standards.

§ 170.315(d)(4) (Amendments)

MU Objective

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

2015 Edition EHR Certification Criterion

(4) Amendments. Enable a user to electronically select the record affected by a patient's request for amendment and perform the capabilities specified in paragraphs (d)(4)(i) or (ii) of this section.

        (i) Accepted amendment. For an accepted amendment, append the amendment to the affected record or include a link that indicates the amendment's location.

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

Preamble FR Citation: 79 FR 10905	Specific questions in preamble? *No*

Public Comment Field:

The PSWG does not recommend changing this criterion.

§ 170.315(d)(5) (Automatic Log-Off)

MU Objective

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

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10905   **Specific questions in preamble?** *No*

Public Comment Field:

The PSWG does not recommend changing this criterion.

§ 170.315(d)(6) (Emergency access)

MU Objective

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

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10905   **Specific questions in preamble?** *No*

Public Comment Field:

The PSWG does not recommend changing this criterion.

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

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

(A) Electronic health information that is stored must be encrypted in accordance with the standard specified in § 170.210(a)(1).

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

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

Preamble FR Citation: 79 FR 10905   **Specific questions in preamble?** *No*

Public Comment Field:

The PSWG does not recommend changing this criterion.

§ 170.315(d)(8) (Integrity)

MU Objective

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

2015 Edition EHR Certification Criterion

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

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

Preamble FR Citation: 79 FR 10905	**Specific questions in preamble?** *No*

Public Comment Field:

The PSWG does not recommend changing this criterion.

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10905	**Specific questions in preamble?** *No*

Public Comment Field:

The PSWG does not wish to comment on this criterion as HHS OCR has not yet finalized guidance on Accounting of Disclosures under HIPAA, and agrees with ONC's recommendation to remove it as an "optional" requirement.

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

MU Objective

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

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

2015 Edition EHR Certification Criterion

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

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

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

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

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

(B) Download.

(1) Patients (and their authorized representatives) must be able to use EHR technology to electronically download an ambulatory summary or inpatient summary (as applicable to the EHR technology setting for which certification is requested) in only human readable format, in only the format specified in accordance to the standard adopted at § 170.205(a)(4), or in both formats.

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

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

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

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

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

(1) Enter a 3rd party destination of their choice to electronically transmit:

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

(ii) Inpatient setting only. Electronically transmit transition of care/referral summaries (as a result of a transition of care/referral) selected by the patient (or their authorized representative) in accordance with the standard specified in § 170.202(a).

(2) Accomplish a transmission of their ambulatory summary or inpatient summary through a method that conforms to the standard specified at §170.202(e) and that leads to such summary being processed by a service that has implemented the standard specified in §170.202(a).

(ii) Activity history log. (A) When electronic health information is viewed, downloaded, or transmitted to a third-party using the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section, the following information must be recorded and made accessible to the patient:

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

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

(3) The user who took the action; and

(4) The addressee to whom an ambulatory summary or inpatient summary was transmitted and whether that transmission was successful (or failed).

(B) EHR technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of this section if it is also certified to the certification criterion adopted at §170.315(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) is accessible by the patient.

Preamble FR Citation: 79 FR 10906	**Specific questions in preamble?** *Yes*

Public Comment Field:

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

MU Objective

Provide clinical summaries for patients for each office visit.

2015 Edition EHR Certification Criterion

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

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

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

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

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

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

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

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

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

Preamble FR Citation: 79 FR 10907	Specific questions in preamble? *Yes*

Public Comment Field:

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

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

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

Preamble FR Citation: 79 FR 10908	Specific questions in preamble? *No*

Public Comment Field:

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10908	Specific questions in preamble? *No*

Public Comment Field:

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

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

(ii) At a minimum, the version of the standard specified in § 170.207(e)(2).	
Preamble FR Citation: 79 FR 10908	**Specific questions in preamble?** *Yes*
Public Comment Field:	

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

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

MU Objective

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

Revised 2014 Edition EHR Certification Criterion
§ 170.314(f)(3) (Transmission to public health agencies – syndromic surveillance)

2015 Edition EHR Certification Criterion

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

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

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

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

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

Preamble FR Citation: 79 FR 10909	**Specific questions in preamble?** *Yes*
Public Comment Field:	

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

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

(ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2).

Preamble FR Citation: 79 FR 10910	**Specific questions in preamble?** *No*
Public Comment Field:	

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10910   **Specific questions in preamble?** *No*

Public Comment Field:

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

MU Objective

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

2015 Edition EHR Certification Criterion

(6) Ambulatory setting only—transmission to cancer registries. EHR technology must be able to electronically create cancer case information for electronic transmission in accordance with:

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

     (ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2).

Preamble FR Citation: 79 FR 10910   **Specific questions in preamble?** *No*

Public Comment Field:

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

MU Objective

N/A

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10911   **Specific questions in preamble?** *No*

Public Comment Field:

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

MU Objective

N/A

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10911   **Specific questions in preamble?** *No*

Public Comment Field:

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

MU Objective

N/A

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10911   **Specific questions in preamble?** *Yes*

Public Comment Field:

§ 170.315(g)(4) (Quality Management System)

MU Objective

N/A

2015 Edition EHR Certification Criterion

 (4) Quality management system. For each capability that an EHR technology includes and for which that capability's certification is sought, the use of a Quality Management System (QMS) in the development, testing, implementation and maintenance of that capability must be identified.

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

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

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

Preamble FR Citation: 79 FR 10911   **Specific questions in preamble?** *Yes*

Public Comment Field:

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

MU Objective

N/A

2015 Edition EHR Certification Criterion

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

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

Preamble FR Citation: 79 FR 10911	**Specific questions in preamble?** *Yes*

Public Comment Field:

§ 170.315(h)(1) (Transmit – Applicability Statement for Secure Health Transport)

MU Objective

N/A

2015 Edition EHR Certification Criterion

1) Transmit – Applicability Statement for Secure Health Transport. Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(a).

Preamble FR Citation: 79 FR 10914	**Specific questions in preamble?** *No*

Public Comment Field:

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

MU Objective

N/A

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10914	**Specific questions in preamble?** *No*

Public Comment Field:

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

MU Objective

N/A

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10914	**Specific questions in preamble?** *No*

Public Comment Field:

§ 170.315(h)(4) (Transmit – Applicability Statement for Secure Health Transport & Delivery Notification in Direct)
MU Objective
N/A
2015 Edition EHR Certification Criterion
(4) Transmit – Applicability Statement for Secure Health Transport & Delivery Notification in Direct. Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(d).
Preamble FR Citation: 79 FR 10914   **Specific questions in preamble?** *No*
Public Comment Field:

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

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

Non-MU EHR Technology Certification
Preamble FR Citation: 79 FR 10918   **Specific questions in preamble?** *Yes*
Public Comment Field:

ONC Regulations FAQ 28
Preamble FR Citation: 79 FR 10920   **Specific questions in preamble?** *No*
Public Comment Field:

Patient List Creation Certification Criteria
Preamble FR Citation: 79 FR 10920   **Specific questions in preamble?** *No*
Public Comment Field:

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

ONC Certification Mark (§ 170.523(k)(1))
Preamble FR Citation: 79 FR 10921   **Specific questions in preamble?** *No*
Public Comment Field:

Certification Packages for EHR Modules

Preamble FR Citation: 79 FR 10921   **Specific questions in preamble?** *Yes*

Public Comment Field:

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

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

Additional Patient Data Collection	
Preamble FR Citation: 79 FR 10922	**Specific questions in preamble?** *Yes*
Public Comment Field:	

Medication Allergy Coding	
Preamble FR Citation: 79 FR 10925	**Specific questions in preamble?** *Yes*
Public Comment Field:	

Certification Policy for EHR Modules and Privacy and Security Certification Criteria	
Preamble FR Citation: 79 FR 10925	**Specific questions in preamble?** *Yes*
Public Comment Field:	

We agree that having each EHR Module implement its own security solution (2011 approach) is not ideal; for strongest security protection, each EHR Module would use a common set of enterprise-wide security services. Path 2 of the HITSC's 2013 recommendation recognizes this ideal. The 2014 approach (certifying EHR Modules privacy and security only at the vendor's request) presents the risk that an end user could purchase a set of modules that would not provide the protection needed to counter risks present in that environment. However, we recognize that the privacy and security criteria are not equally applicable or useful to every criterion in each of the other functional areas (i.e., clinical, care coordination, clinical quality, patient engagement, public health, utilization) because each P&S criterion is designed to address specific risk conditions that may or may not be present.

We therefore recommend that ONC:
1. Revise each privacy and security criterion to specify the conditions under which it is applicable (similar to how the end-user device encryption criterion currently is written) AND
2. Allow each criterion to be met using one of the three paths the HITSC recommended in 2013.

This can be accomplished by modifying the wording of the criteria in the regulation to include the condition(s), or by providing the condition(s) as guidance. In either case, the condition(s) and paths would need to be incorporated into test procedure. If this approach is accepted, the PSWG would be happy to work with ONC to help with the implementation.

Example #1:
The current end-user device encryption criterion provides a good example of the proposed approach as worded in the regulation:
(7) End-user device encryption. Paragraph (d)(7)(i) or (ii) of this section must be met to satisfy this certification criterion. EHR technology that is designed to locally store electronic health information on end-user devices must encrypt the electronic health information stored on such devices after use of EHR technology on those devices stops.

Example #2:
Criterion, as currently worded:

Emergency Access: Permit an identified set of users to access electronic health information during an emergency.

Applicability Statement:
If the module allows human users access to electronic health information, and
If the module performs functions supporting the purpose of delivering patient care,
demonstrate how the module supports emergency access by an identified set of users.

Provider Directories

Preamble FR Citation: 79 FR 10926	Specific questions in preamble? *No*
Public Comment Field:	

Oral Liquid Medication Dosing

Preamble FR Citation: 79 FR 10926	Specific questions in preamble? *Yes*
Public Comment Field:	

Medication History

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

Blue Button +

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

PSWG encourages and supports further piloting, direction, and standards development for Blue Button + (BB+), but PSWG feels that at this point, prescribing specific standards that BB+ must use could potentially constrain the momentum surrounding its technological advancement.

2D Barcoding

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

Duplicate Patient Records

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

Disaster Preparedness

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

Public Comment Field:

PSWG believes that ONC's solicitation for comment on standards related to disaster preparedness is premature, as there are unresolved policy questions that must be answered prior to any attempt to determine standards EHRs should use to identify patients in disaster situations.

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

Preamble FR Citation: 79 FR 10929   **Specific questions in preamble?** *No*

Public Comment Field: