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

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

A. Proposed for 2015 Edition[1] 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: **No Comment**	

§ 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: **FDB endorses efforts to increase adoption of CPOE. This electronic entry provides a means for clinical decision support at the point of ordering and within the order workflow.**	

[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:
No Comment

§ 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:
FDB endorses expansion of the clinical decision support for medications outside of the dispensing and administration arena. The ability to do drug/drug and drug/allergy at the point of ordering and prescribing provides additional assurance that appropriate medications are prescribed. Response tracking would allow for clinical review that could improve the specificity of clinical decision support that has the potential to decrease over alerting.
We would caution that tracking of responses must be done in an automated manner within the workflow and not require additional actions by the ordering healthcare provider. Codification of the actions would make the data computable and improve the ability to analyze the data
Rather than the technology enabling an authorized end-user administrator to simply modify the severity level of a drug-drug interaction, it would be more appropriate that the technology be required to enable an authorized end-user administrator to modify the "workflow interrupt" settings (i.e., hard stop, interrupt – may override, passive display, suppression) for a specific drug-drug interaction. For some systems, this is accomplished by the modification of the "severity level," knowing that an order entry system's display threshold may be constrained to drug-drug interactions with a severity level of "severe." Other systems may simply compile a specific drug-drug interaction subset for display in a particular setting; others may introduce an "alert display setting" independent of the severity level, to customize alert display behavior based upon variables such as setting, type of clinician and the activity (i.e., order entry, dispensing, administration, surveillance).

§ 170.315(a)(5) (Demographics)

MU Objective

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

§ 170.315(a)(5) (Demographics)

2015 Edition EHR Certification Criterion

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

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

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

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

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

Public Comment Field:

No Comment

§ 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:

No Comment

§ 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*

§ 170.315(a)(7) (Problem list)

Public Comment Field:

FDB believes that maintenance of and access to a comprehensive, accurate and up-to-date problem list is critical to the safety of the patient and for the provision of clinical decision support

§ 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:

FDB believes that maintenance of and access to a comprehensive, accurate and up-to-date medication list is critical to the safety of the patient and for the provision of clinical decision support

§ 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*

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

MU Objective

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

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

2015 Edition EHR Certification Criteria

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

(A) Problem list;

(B) Medication list;

(C) Medication allergy list;

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

(E) Laboratory tests; and

(F) Vital signs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Public Comment Field:

FDB endorses expansion of clinical decision support beyond drug/drug and drug/allergy contraindications and the targeting of high priority health conditions. We will always be required to make decisions on the use of limited resources. Identifying and targeting those conditions that can have the largest impact on improving public health makes sense clinically and economically.

§ 170.315(a)(11) (Electronic notes)

§ 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:

No Comment

§ 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:

The use of the NCPDP Formulary Standard could be used at the level of RxNorm to cut down on the size of the files currently required by using the NDC. The NDC defines a packaged product while RxNorm defines a drug product at the level of product, dosage form, strength and strength unit of measure. One RxNorm may represent one, tens, or hundreds of NDCs. This would dramatically reduce the size of formulary files. FDB endorse the use of the NCPDP Formulary and Benefit Standard v 3.0.

In response to the comments regarding real-time access to an individual patients specific coverage parameters prescribers could use the NCPDP telecommunications Standard D.0 to have access to the same information available to the dispensing pharmacy. The NCPDP Telecommunication standard could be used for real-time access to patient level claims adjudication information that would allow a prescriber to know with great reliability the patients out of pocket costs. Consideration must be given to the effort, cost and time this would require. An inquiry and adjudication of that inquiry would produce a result, the prescriber or agent would then have to make a decision to proceed with prescribing or choose an alternative drug and repeat the process. These changes would take time and effort for implementation and cost would be incurred in software development and possibly with transaction fees. The value derived from having this level of information before prescribing could help improve adherence to the drug regimen and improve patient satisfaction.

§ 170.315(a)(13) (Smoking status)

§ 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: **No Comment**	

§ 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: **No Comment**	

§ 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: **No Comment**	

§ 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:

Providing reminders to patients is a valuable tool to improve patient outcomes. Patients should have access to pertinent health information while an inpatient. Providing notification information to a patient in their preferred communication medium should be required, as long as the choices are limited and reasonable. Preferred language is a difficult problem to solve. First we must be able to provide the information in a manner that is understandable to a lay person. Translation into multiple languages would be so expensive as to possibly outweigh the benefit. However, a single language alternative, very possibly Spanish would make sense and though costly, provide value for the investment.

§ 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:

No Comment

§ 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:

FDB endorses expansion of the use of electronic medication administration records as critical to a patient's safety. The question is not to the value of an eMAR, but as to whether additional benefit would be found using assistive technologies. Technologies that include access to clinical decision support at the point of administration would serve as an additional quality check in the process of drug administration. Some alerts, such as a running 24 hour aggregate acetaminophen dose are very appropriate to be triggered with the eMAR. The key would be to assure that any alerts that have already been observed and adjudicated are not producing additional alerts at the bed side. Without this capability additional CDS at this point would be disruptive and result in over alerting and would not be of benefit to the patient or the healthcare provider

§ 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:

No Comment

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

MU Objective

N/A

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

2015 Edition EHR Certification Criteria

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

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

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

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

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

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

Public Comment Field:

FDB endorses the inclusion of a Unique Device Identifier in the EHR for implanted devices. It is critical to patient safety that the device is accurately listed and actionable electronically.

§ 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.

§ 170.315(b)(1) (Transitions of care)

2015 Edition EHR Certification Criteria

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

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

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

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

(iii) Display.

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

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

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

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

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

(3) Cognitive status;

(4) Functional status;

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

(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:

No Comment

§ 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

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

should perform medication reconciliation.

2015 Edition EHR Certification Criteria

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

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

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

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

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

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

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

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

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

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

Public Comment Field:

No Comment

§ 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:

FDB endorses expansion of e prescribing and the inclusion of the RxNorm drug identifier within those electronic prescriptions. Use of RxNorm codes will provide a means for additional quality controls for drug identification. Its inclusion, when available, promotes interoperable transfer of medication information. When available RxNorm should be used instead of, not in addition to a representative NDC. It should be noted that there will be cases when an RxNorm code will not be available and at that time a representative NDC could be used.

§ 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:

No Comment

§ 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:

No Comment

§ 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: **No Comment**	

Clinical Quality Measures – Electronically Processing eMeasures	
Preamble FR Citation: 79 FR 10902	**Specific questions in preamble?** *Yes*
Public Comment Field: **No Comment**	

Clinical Quality Measures – Functions and Standards for CQM Certification	
Preamble FR Citation: 79 FR 10903	**Specific questions in preamble?** *Yes*
Public Comment Field: **No Comment**	

§ 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*

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

Public Comment Field:

No Comment

§ 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:

No Comment

§ 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:

No Comment

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

No Comment

§ 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:

No Comment

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

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

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

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

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

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

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

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

Public Comment Field:

No Comment

§ 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:

No Comment

§ 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:

No Comment

§ 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:

No Comment

§ 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:

No Comment

§ 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:

No Comment

§ 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:

No Comment

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

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

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

Public Comment Field:

No Comment

§ 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

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

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:

No Comment

§ 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:

No Comment

§ 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:

No Comment

§ 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:

No Comment

§ 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:

FDB supports exchange of health immunization data in a bidirectional manner. We cannot comment on the maturity of this effort.

FDB does not support the use of NDC codes for vaccination reporting. This level of packaged product specificity is unnecessary and could be burdensome.

FDB believes the industry has adapted well to 2014 CEHRT immunization registry reporting vocabulary requirements of CVX; companion use of MVX enables manufacturer reporting. We applaud continued CDC distribution of authoritative cross-walks from NDC to CVX. In the absence of evidence that demonstrates functional deficiencies in the use of CVX/MVX for immunization registry reporting, FDB recommends that CVX not be replaced by NDC.

§ 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:

No Comment

§ 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:

No Comment

§ 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:

No Comment

§ 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:

No Comment

§ 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:

No Comment

§ 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:

No Comment

§ 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:

No Comment

§ 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:

No Comment

§ 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:

No Comment

§ 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:

No Comment

§ 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:

No Comment

§ 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: **No Comment**

§ 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: **No Comment**	

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: **No Comment**	

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

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

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

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

Certification Packages for EHR Modules	
Preamble FR Citation: 79 FR 10921	**Specific questions in preamble?** *Yes*
Public Comment Field: **No Comment**	

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: **No Comment**	

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

Public Comment Field: General allergy types can be coded using the RxNorm vocabulary that we have adopted in our rules. However, for coding medication allergies, RxNorm is not specific enough to distinguish allergies to particular ingredients in drugs nor is it specific enough for coding food-drug allergies. Allergic reaction symptoms and DDI reactions can be coded using the SNOMED CT vocabulary also adopted in our rules, but there is no specific reaction value set and using general problem value sets do not allow for identification of the allergy's cause. No formal reaction list has been defined in the C–CDA or through the work done by the Health Information Technology Standards Panel. In the HITPC's meaningful use Stage 3 Request for Comment, stakeholders commented that other vocabulary and value sets could be leveraged to address these gaps. These include:

- The FDA Unique Ingredient Identifier (UNII) system which can be used to identify unique ingredients in drugs, biologics, food, and devices;
- The VA National Drug File— Reference Terminology (NDF–RT) vocabulary which has been mapped to RxNorm and may be a good standard for describing allergies to classes of drugs such as penicillin.

Additionally, CDC has developed a value set for Vaccine Reaction and Adverse Events that is available but not currently assigned to drug and general allergic reactions. The HITPC has indicated that EHR systems should provide functionality to code medication allergies, including the related drug family for reactions. Currently, we require that CEHRT base CDS interventions on certain data (including medication allergies) but this list does not specifically include DDI reactions. Given these issues, we solicit comment on:

(1) The adoption of additional vocabularies to code medication allergies to drug ingredients, allergic reaction symptoms, and DDI reactions (e.g., UNII, NDF–RT);
(2) Whether we should adopt the CDC Vaccine Reaction and Adverse Event value set;
(3) The value of using specific reaction value sets versus general problem value sets;
(4) Whether CDS interventions should be based on DDI reactions.

Response:

FDB believes that the RxNorm vocabulary consistently demonstrates the specificity required to serve the interoperable medication allergen exchange needs for ingredients, multiple-ingredient drug names and brand names. NDF-RT handles most of the class-based medication allergens required for interoperable exchange; however, selection of the most appropriate NDF-RT value can be quite daunting for implementers. NDF-RT could be made more useful for the interoperable exchange of medication allergen classes if a smaller subset of applicable concepts was to be maintained and published by a Standards Development Organization. Interoperable exchange of food and environmental agents could be supported with SNOMED-CT substance concepts or for the most part, with FDA UNII. The problem presented with the use of so many vocabularies in the context of interoperable exchange of coded allergy or intolerance substances (i.e., RxNorm, NDF-RT, SNOMED-CT, FDA UNII) is that it becomes an implementation challenge to technology providers. When translating a user-interface based allergen, it is quite difficult to know which code system to use when an allergen term spans multiple vocabularies. No matter what the source of the allergy/intolerance vocabulary term, FDB recommends that ONC simply support the interoperable exchange of the RXCUI (the RxNorm Concept Unique Identifier assigned to the vocabulary concept when incorporated into RxNorm) and the vocabulary term's description within required HL7 C-CDA and QRDA in lieu of the source vocabulary's assigned code. In other words, interoperable exchange of medications, foods and environmental agents could be simplified significantly by using a single code system (i.e., RXCUI) for reporting the allergen/intolerance substance.

Regarding the use of structured vocabularies for the interoperable exchange of an allergy or adverse drug event's "reaction," we believe that SNOMED CT "clinical findings" are more than adequate for this purpose. We support the collection and redistribution of SNOMED CT based reaction "starter sets" for this purpose. We believe the CDC Adverse Reaction Code value set, which is SNOMED CT based, is a nice starting point, but would advise that reaction interoperable exchange be constrained to this value set, as it only includes 15 members.

We are a bit confused by the inclusion of "DDI Reactions" (Drug-Drug Interaction Reactions) in this topic. We do believe that a role for Drug-Drug Interaction potential clinical consequence expression as a "clinical finding" is appropriate, but don't believe it should be addressed within the general discussion topic for the documentation and interoperable exchange of an allergy or intolerance "reaction" itself. In the long term, we believe that codified Drug-Drug Interaction clinical consequences could be tied to advanced rules that trigger risk notification to a clinician when programmatic manifestations of the clinical consequence are detected in the clinical record (e.g., vital signs, lab results, co-morbidities). At this time, we believe certification criteria requiring Drug-Drug Interaction Reaction codification is premature; as such rules are in their infancy.

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: **No Comment**	

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

Oral Liquid Medication Dosing	
Preamble FR Citation: 79 FR 10926	**Specific questions in preamble?** *Yes*

Public Comment Field: **Our strategic goal is to provide more granular descriptions of prescriptions to allow for CDS, identify patient safety issues (such as excessive acetaminophen in combination medications), and reduce dosing confusion. For example, the U.S. currently uses the English measurement system standard (e.g., teaspoons) rather than the metric standard (e.g., milliliters (mL)) for prescribing liquid oral medications. The medication dose is determined in part by the patient's weight. The metric standard (mL) offers more precision in medication dose, which can decrease preventable adverse drug events. Dosing errors are the most common medication error in pediatrics. The American Academy of Pediatrics (AAP) supports the use of the metric standard (mL) for eprescribing. AAP supports modification of both dosing guidelines and dose-screening parameters to support dosing for every indication that warrants modified dosing regimens. The Food and Drug Administration has provided a draft guidance that supports metric units for labeling prescription medications. And, the National Council for Prescription Drug Programs supports mL dosing in retail dispensing.**

We understand that e-prescribing functionality can present standard dosing formula to use the patient's weight to: Calculate a dose; convert the dose to a volume for liquids; and present the dose in a format that is least likely to be confusing to a prescriber, pharmacist, nurse, or patient. Sophisticated e-prescribing functionality has been said to use individual dose limits, compared to weight- or body surface area-based normal values. Given the clinical need and stakeholder support for reducing preventable adverse events resulting from dosing errors in e-prescribing, we solicit comment on whether we should adopt a certification criterion (or establish a requirement within a certification criterion) for EHR technology to use the metric standard for prescribing oral liquid medications or to solve the problem more generally using a structured Sig standard. Potential (non-mutually exclusive) options for certification include, but are not limited to:

- **Require EHR technology to use a structure Sig with explicit dosing units, frequency, and number of units;**
- **Require EHR technology to provide the metric standard as one option to record liquid medication doses;**
- **Require EHR technology to record liquid medication doses in the metric standard only; and**
- **Require EHR technology to be able to accurately convert a liquid dose to the metric standard. For this last option, we are also soliciting comment on minimum/maximum dosing checks for dose conversion.**

We also solicit comment on EHR readiness to implement the metric standard for prescribing oral liquid medications, the effect on existing vocabulary standards for units of measurement (e.g., UCUM), and implications on the structured Sig format for e-prescribing.

Response:

The use of a structured SIG is a laudable goal, but current methods for standard sig are cumbersome and difficult to implement. The requirements should limit the use to sigs that are uncomplicated, for example 'one tablet twice daily'.

Liquid dosage should be supplied in metric units only to prevent errors and confusion on dose. EHR technology should not be required to convert liquid doses to metric units; the prescriber should use metrics when providing the dose and not rely on conversion to metrics.

Though we agree that use of the metric standard for prescribing the volume of an oral liquid is much more appropriate than the use of the English measurement system. EHR technology providers could most certainly support this best practice goal by preferentially providing volume-based dosage units of measure for oral liquid medications that are metric-based. However, as long as clinicians may continue to prescribe oral liquids in terms of English measurement units of measure, it seems unreasonable to forbid EHR technology providers from use of "teaspoons" or "tablespoons" when demanded by the clinician.

We would also like to note that information provided by the patient or caregiver may use volumes described by teaspoons and tablespoons and the likelihood of this occurring must be considered.

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

Public Comment Field: In the 2014 Edition, we adopted the NCPDP SCRIPT 10.6 standard for eprescribing (170.314(b)(3)). SCRIPT 10.6 supports a medication history source feature that provides where the history was obtained and the identity of the source, as well as consolidates histories from different sources. We solicit comments on whether we should propose a 2017 Edition certification criterion focused on medication history capabilities. We encourage commenters to address the specific information/specific capabilities that should be provided, standards recommended to support this capability, and which existing certification criterion/criteria could include this capability (e.g., medication reconciliation, medication list, eprescribing) if it were not a stand-alone certification criterion.

Response:

FDB supports actions that would provide access to medication history. This information would be of value at transition of care and whenever medication reconciliation is performed. The use of NCPDP RxHistoryRequest and RxHistory Response would provide valuable information to healthcare providers seeking to accurately develop a medication list. Other sources of medication history should also be considered. This information should not be used to populate a medication list without confirmation by the patient, caregiver or healthcare professional.

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Preamble FR Citation: 79 FR 10927	**Specific questions in preamble?** *Yes*
Public Comment Field: **No Comment**	

2D Barcoding	
Preamble FR Citation: 79 FR 10928	**Specific questions in preamble?** *Yes*
Public Comment Field: **No Comment**	

Duplicate Patient Records	
Preamble FR Citation: 79 FR 10928	**Specific questions in preamble?** *Yes*
Public Comment Field: **No Comment**	

Disaster Preparedness	
Preamble FR Citation: 79 FR 10928	**Specific questions in preamble?** *Yes*
Public Comment Field: **No Comment**	

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: **No Comment**	