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

A. Proposed for 2015 Edition Certification Criteria

§ 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:

Mayo Clinic supports the proposal to view alert history and provider decisions. This is key functionality missing from the EHR and would be welcome. We have several examples of care team members wishing to know what the response to an alert was upstream in the care cycle for a patient and why it was responded to a specific way. For example, if a DAI and DDI were presented to an ordering physician, it is common for the pharmacy to wish to know why he decided to override the alert. Similarly for nursing staff, since they administer the medication, they spend a lot of time trying to double check before administering in the absence of information. As to who can view the alert history, it may be necessary for EHR vendors to implement new security classes to control the viewing of information related to CDS alerts, but this will likely be a subset within generalized security controls already in place. Adjustment of the tracking configuration should not be done by the care team as this really falls into the same best practice governance that we have for CDS in general. The tracking granularity should be possible to the lowest level but it would be up to institutional governance what level to set it to. In addition, Mayo Clinic recommends that other types of clinical conflicts are tracked and viewable as well such as drug/lab, drug/diagnosis, lab/indications, CDS interventions, etc.

§ 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:

Mayo Clinic supports the collection of the demographics stated in the objective. Of the proposed options for Preferred Language, Mayo Clinic recommends ISO 639-3 as the minimum standard. As indicated in the proposed rule, adopting ISO 639-2 in full does not support the use of Cantonese or sign language among other languages contained in Mayo's preferred language value set.

Additionally, the Language Code in the CDA R2.0 normative standard was fixed to RFC 3066. As the coding strength was defined as "Coded, No Extensions" or CNE, no implementation guide can change this binding. This can be seen in the CDA Hierarchical Description (Excel Spreadsheet) found in the ANSII approved HL7 Clinical Document Architecture, Release 2.0 specification. Therefore, technically RFC 4646 and RFC 5646 should not be specified on top of an IG based on CDA R2.0.

§ 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) <u>Vital signs, body mass index, and growth charts</u>**.** (i) <u>Vital signs</u>**.** 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) <u>Calculate body mass index</u>**.** Automatically calculate and electronically display body mass index based on a patient's height and weight.

    (iii) <u>Optional—Plot and display growth charts</u>**.** Plot and electronically display, upon request, growth charts for patients.

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

Public Comment Field:

Mayo Clinic supports the adoption of LOINC for observations, SNOMED CT for qualitative results and Unified Code for Units of Measure (UCUM) to represent units of measure. Additionally, to facilitate interoperability, Mayo Clinic recommends a value set of pre-coordinated units of measure be developed and incorporated into the requirements.

With regard to the question about granularity with CIMI and FHIR, here is an example of how FHIR could be used. Please see http://www.hl7.org/implement/standards/fhir/observation-example-f201-bmi.xml.html for proposed representation and suggested SNOMED and LOINC codes.

§ 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*

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

Public Comment Field:

Mayo Clinic supports the proposal relative to the scope of data that should be passed to the knowledge provider (e.g. Micromedex etc.) at this juncture. However, further refinement of what ONC, EHR vendors and knowledge content providers is anticipated for scoping the domains of basic EHR functionality, CDS and knowledge delivery. For example one can easily see the Infobutton standard evolving into the domain space of Clinical Decision Support Services with enough data element extensions to it. We would agree, however, that the SOA standard for Infobutton is the appropriate data interchange standard to move to. The robustness of the Infobutton standard is enhanced by this especially when the implementation architecture includes the Infobutton Manager.

Mayo Clinic seeks clarification regarding the "HL7 IG: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release August 1, 2013" as to whether or not the continued use of "The URL-Based Implementations of the Context-aware Information Retrieval (Infobutton) Domain, Release 4" will be allowed. Clarification would be useful and continued support of the URL solution is desirable.

Mayo Clinic supports incorporating the Health eDecisions (HeD) recommendations as this will provide beneficial functionality. However, the HeD standard version cited in the proposed rule has several areas that are not fully defined at this point and would prevent the automated consumption of the CDS Knowledge Artifacts ready for electronic processing as is. Furthermore, EHR vendor implementations vary a great deal with respect to where the semantic layer boundaries are in the implementation of computable rules. Although the HeD model is correct and desirable in this respect, it is likely that the current EHR state of the art will need to retool the CDS approach, and this may be unattainable over a three year period. With respect to CDS Services and the ability of the EHR to utilize them, Mayo Clinic sees this as a strategic and natural direction that should be taken as one option to provide decision support from within the workflow of the certified EHR. There is a tipping point at which the data artifacts required to call the CDS service are of the size and complexity that would drive an institution to use CDS integrated within the EHR.

In addition, testing and certification of CDS Knowledge Artifacts should focus on preventive care interventions and immunizations. With regard to the feasibility to make an information request, send patient data, and receive CDS guidance in near real-time, Mayo Clinic has concerns with the viability of reliable real-time guidance functionality. There will be instances where the data complexity and response performance required will be such that CDS services are not possible. One of the reasons for this, and something that we have had experience with, is the number of layers within the communication stream to a CDS service which can add a delta time increments to 'conversation' that an EHR workflow and CDS service must have in order to provide guidance to the provider. Furthermore, if the CDS service is remote to the institution using it and these layers have anything less than six sigma reliability, what should be done to ensure patient safety when the layers break down?

It is feasible to develop knowledge artifacts; however, Mayo Clinic sees a couple of issues with this: 1) having the specific patient data to execute them accurately, 2) the long term maintenance. In addition, the key is to harmonize the schema for knowledge artifacts and the patient data model implemented within EHR technology. If they are divergent to a large degree, then the ability to consume the knowledge artifacts without highly skilled IT intervention is lost. At this point, only simple knowledge artifacts should be incorporated into the criteria until the domain has matured.

Mayo Clinic has concerns about the ability to store and auto-configure a CDS knowledge artifact in the EHR because, although it would be beneficial, the long-term maintenance is problematic. However, Mayo Clinic strongly supports the ability to map the CDS knowledge artifact standard to data within the EHR to provide development of CDS rules.

§ 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:

Mayo Clinic supports the goals proposed for electronic notes because they will provide value to those navigating multiple notes for a patient or a number of patients. However, an important concern is adding text-searchable functionality because it would create a rather large performance issue. At one of the Mayo Clinic sites, there is a means for text-searching notes for individual providers; this is performed using an off-box replicated database. Mayo Clinic has not attempted to use this function for notes from all providers because of the performance issues it would cause. To require this through a standard CEHRT could "bring the system to its knees" so to speak. Mayo Clinic suggests that, in order to implement this functionality, vendors provide the functionality in such a way it does not allow performance issues.

With regard to Opennotes, Mayo Clinic supports the proposal to use Opennotes as described.

§ 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:

Mayo Clinic seeks explanation regarding the use of a related person's identifiers within the Pedigree model. Additional clear guidance may be required as there may be issues related to HIPAA and the proper isolation of the related person's PHI within a given patient's medical record. What identifiers are to be allowed when constructing a Family History using the Pedigree model?

§ 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:

Mayo Clinic seeks clarification regarding the "HL7 IG: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release August 1, 2013" as to whether or not the continued use of "The URL-Based Implementations of the Context-aware Information Retrieval (Infobutton) Domain, Release 4" will be allowed. Clarification would be useful and continued support of the URL solution is desirable.

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§ 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:

Mayo Clinic strongly supports the proposal for an implantable device list to ensure patient safety. Standardizing this data in the EHR supports reusability so that it is both reportable and can be used for patient care alerts. Efforts are currently underway at Mayo Clinic to implement an implantable device list.

Furthermore, Mayo Clinic supports the proposed minimum set of data elements for each UDI and strongly encourages the adoption of accepting UDI data using bar code scanning with automatic UDI documentation. Mayo Clinic also recommends device information be discrete for reuse purposes, including clinical decision support rules.

§ 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) <u>Transitions of care</u>. (i) <u>Send and receive via edge protocol</u>. 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) <u>Receiving accuracy</u>. EHR technology must meet or exceed the standard specified at §170.212(a)

(iii) <u>Display</u>.

(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) <u>Section views</u>. 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):

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

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

(<u>3</u>) Cognitive status;

(<u>4</u>) Functional status;

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

(<u>6</u>) <u>Inpatient setting only</u>. Discharge instructions; and

(<u>7</u>) Unique Device Identifier(s) for a patient's implantable device(s).

(B) <u>Patient matching data quality</u>. 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:

(<u>1</u>) <u>Data</u>. 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.

(<u>2</u>) <u>Constraint</u>. 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.

(<u>3</u>) <u>Constraint</u>. 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.

(<u>4</u>) <u>Constraint</u>. 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.

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

(<u>6</u>) <u>Constraint</u>. 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.

(<u>7</u>) <u>Constraint</u>. 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:

Mayo Clinic supports the proposed standardized data. However, telephone numbers will need to use the prefix in order to be conformant. Phone numbers in CDA R2.0 documents, are defined with TEL data types, which require that the representations be modeled as URL references. As such, a prefix "tel:" must occur prior to the number representation. Referencing the HL7 RIM on which the CDA R2.0 standard is based:

2.16.1 Telephone and FAX Numbers

§ 170.315(b)(1) (Transitions of care)

Telephone and FAX Numbers. There is no special data type for telephone numbers. Telephone numbers are telecommunication addresses and are specified as a URL. Voice telephone URLs begin with "tel:" and fax URLs begin with "fax:".

The telephone number URL is defined in the Internet RFC 2806 [http://www.ietf.org/rfc/rfc2806.txt] URLs for Telephone Calls. For example, "tel:+1(317)630-7960" is a phone number, and "fax:+49(30)8101-724" is a FAX number. The global absolute telephone numbers starting with the "+" and country code are preferred. Separator characters serve as decoration but have no meaning for the telephone number, thus "tel:+13176307960" and "fax:+49308101724" are the same telephone and FAX numbers as the previous respective examples.

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

MU Objective

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

2015 Edition EHR Certification Criteria

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

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

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

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

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

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

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

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

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

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

Public Comment Field:

Mayo Clinic supports correctly matching a health record to the appropriate patient and the proposed automation of this process with user review and validation to ensure accuracy.

§ 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:

Mayo Clinic supports the proposal to include header metadata with electronic notes. As EHR systems typically store clinical documents within a document repository, the question of supporting the export of Clinical Documents using a standard header (CDA R2.0) might be entertained.

Clinical Quality Measures – Electronically Processing eMeasures

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

Public Comment Field:

Mayo Clinic supports the recommendations as documented.

Clinical Quality Measures – Functions and Standards for CQM Certification

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

Public Comment Field:

Mayo Clinic supports the recommendations as documented.

§ 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:

Mayo Clinic supports the recommendations as documented.

§ 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:

Mayo Clinic supports the recommendations as documented.

§ 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:

Mayo Clinic supports the recommendations as documented.

§ 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:

Mayo Clinic supports the recommendations as documented.

§ 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:

Mayo Clinic supports two-factor authentication for specific use cases. E-prescribing controlled substances and remote provider access to EHR technology are two higher-risk propositions, and Mayo Clinic agrees that two-factor authentication is warranted for these use cases. However, organizations such as Mayo Clinic frequently implement and manage their remote access services at the network infrastructure level. Adoption of the proposed rule will make EHR-specific remote access metrics collection and reporting problematic. Mayo Clinic recommends authentication by specifying two of the three: object, secret or biometric. Two secrets, such as a password plus answering a question are not strong enough.

§ 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:

Mayo Clinic agrees disabling activity logs undermines the effectiveness of the audit control; therefore, EHR technology should prohibit this. The most common argument against activity logging is storing the volumes of generated data. However, this is a cost of doing business. Mayo Clinic does not foresee unintended consequences of disallowing users from disabling activity logs, nor can we cite examples that would justify allowing users to do so.

Organizations such as Mayo Clinic frequently employ audit log collation, translation and reduction tools across multiple systems and applications to holistically monitor and respond to security-relevant events within their electronic environments. Naturally, it is at this level where analysis, metrics generation and reporting occur rather than at the EHR technology level. This should be considered for follow-up measures.

§ 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:

Mayo Clinic supports a minimum baseline set of auditable actions. "Additions, deletions and changes," when combined with the Section 7.7 requirement to log accesses (viewing), is risk-appropriate for medical information. Mayo Clinic agrees copy, print and query actions in the audit baseline should not be included for the stated reasons.

As an alternative standard to ASTM E2147, Mayo Clinic suggests the DoD 5220.22M National Industrial Security Program Operating Manual which specifies safeguards for classified information possessed by defense contractors. Classified information is handled on a need-to-know basis like medical information, and the document provides good plain-English controls guidance. Section 6 Paragraph 8-602a(1)(c) on audit capability specifies audit records shall record "successful and unsuccessful accesses to security-relevant objects and directories, including creation, open, close, modification, and deletion." This section contains other pertinent guidance that has stood the test of time as well.

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

MU Objective

<u>EPs</u>

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.

<u>EHs and CAHs</u>

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) <u>View, download, and transmit to 3rd party</u>. (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) <u>View</u>. 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:

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

(<u>2</u>) <u>Ambulatory setting only</u>. Provider's name and office contact information.

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

(B) <u>Download</u>.

(<u>1</u>) 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.

(<u>2</u>) 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):

(<u>i</u>) <u>Ambulatory setting only</u>. 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).

(<u>ii</u>) <u>Inpatient setting only</u>. 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).

(<u>3</u>) <u>Inpatient setting only</u>. 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) <u>Transmit to third party</u>. Patients (and their authorized representatives) must be able to:

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

(<u>i</u>) 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).

(<u>ii</u>) <u>Inpatient setting only</u>. 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).

(<u>2</u>) 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) <u>Activity history log</u>. (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:

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

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

(<u>3</u>) The user who took the action; and

(<u>4</u>) 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.

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

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

Public Comment Field:

Mayo Clinic seeks guidance on managing non-text data, embedded or referenced images within C-CDA documents. There is currently a lack of support and guidance in the industry on how to manage embedded images for various results of waveforms, or images in healthcare that might need to be shared, excluding radiology/ultrasound images which are assumed to be managed via DICOM standards.

Additionally, Mayo Clinic has seen an increased usage of PDF by vendors as a means to transfer information and reports to other systems. A specific example was a recent upgrade to a vendor-supplied laboratory system in which a PDF report feed replaced a discrete feed. Using a PDF exclusively limits the ability for institutions to use the contents of the report data thus inhibiting research and other activities. Mayo Clinic supports the continued use of discrete data as a data transport mechanism in Meaningful Use standards.

§ 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:

Mayo Clinic supports the proposal to use LOINC to represent all pending diagnostic tests and futures scheduled tests. Mayo Clinic is currently engaged in a Standards and Interoperability Initiative focused on developing a set of commonly ordered tests. However, at this time laboratory orders have not been adequately defined. Therefore, due to the lack of maturity for the implementation of laboratory orders in LOINC, Mayo Clinic recommends this criterion be deferred to 2017.

§ 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.

15 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:

Mayo Clinic supports the ability to receive vaccination data from external sources but does not support applying data from an outside source programmatically in real-time. It is important to review and have a process for integrating the information from different sources. Vetting the data ensures accuracy and avoids a vaccination history open to over or under vaccination. Mayo Clinic recommends immunization data be sent as discrete and coded data to enable consolidation from more than one source.

Mayo Clinic supports using NDC as the primary identifier. However, none of the three coding systems (CPT, CVX, NDC) used by registries is sufficient by itself. For example, CPT reflects the age range of the patient but it is not a clinical code set; CVX is a clinical code set, expandable when new vaccines arrive, but it is challenging to match the appropriate vaccine with the proper CVX code if the drug manufacturer doesn't include the CVX in the package insert; NDC is more granular than either CPT or CVX but it doesn't differentiate between pediatric vs. adult doses the way CVX does, and as cited in the proposed rule, it cannot be used exclusively in historical records. Another advantage of NDC is the ease of incorporating them into the barcode workflow, work that is already underway. Therefore, Mayo Clinic favors linking all three code sets and making all three mandatory for the highest level of data confidence. The Lot Number is currently optional but should also be mandatory for all administered vaccines.

Mayo Clinic suggests a national database be developed that contains the following list of data elements. Linking this data would provide registries and EHR vendors a single official source that would streamline processing and error checking for all parties involved.
- NDC (Sale & Use)
- CVX
- CPT (Billing & IIS)
- ICD9 (Billing & IIS)
- ICD10 (Billing & IIS)
- SNOMED CT
- Long Name
- Short Name
- RxNorm
- Age Range
- Market Enter Date
- Market Exit Date
- VIS IDs
- MVX
- Minimum Day Dose Interval
- Gender
- Dose
- Units
- Route
- Type
- Group
- Category
- Storage
- Package Insert Link
- Series Max Doses
- Brand Name
- Latex, Thimerosal, Diluent, Preservative Flags
- How Supplied
- ACIP Abbreviation

§ 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:

Mayo Clinic supports the recommendations as documented.

§ 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:

Mayo Clinic supports the decision to exclude Stage 1 Drug Formulary, Stage 2 Transition of Care Testing, and Stage 1 & 2 Privacy and Security from the certification criterion; however, Mayo Clinic suggests MU compliance could be improved and administrative burden reduced by relaxing requirements in the following ways.
1) Only require usage reports for three of the six approved non-percentage-based measures.
2) Allow sites to choose which three non-percentage-based measures they wish to implement reports for.
3) Revise the regulatory text to read, "Require the EHR technology to record evidence of use during the reporting period for no fewer than three of the six approved non-percentage-based measures." If further specificity is needed, CMS should provide examples of qualifying evidence of use for each of the six approved non-percentage-based measures.

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

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

Public Comment Field:

Mayo Clinic supports the 2017 proposal for collection of additional patient demographics including sexual orientation and gender identity, military service, and occupation to ensure inclusivity and health equity to all patient populations.

For this additional demographic data collection, Mayo Clinic supports offering patients the option to not disclose this information. Mayo Clinic prefers the language, "decline to answer" and recommends that this language be consistent when collected (both "declined to provide" and "decline to answer" were referenced in the proposed rule).

Sexual Orientation and Gender Identity

Mayo Clinic strongly agrees with the proposed rule to include sexual orientation and gender identity (SOGI) as additional demographic data capture in the 2017 Edition Certified EHR Technology. Mayo Clinic is currently piloting data capture of SOGI.

Mayo Clinic echoes The Fenway Institute's response to the ONC and agrees the SNOMED CT concepts in the proposed rule do not accurately reflect patient identities. Mayo Clinic supports The Fenway Institute's approach in following the question and answer sequence below:

Sexual orientation:
Do you think of yourself as:
- Lesbian, gay or homosexual
- Straight or heterosexual
- Bisexual
- Something else, please describe:_____
- Don't know

Gender identity:
What is your current gender identity? (Check all that apply)
- Male
- Female
- Female-to-Male (FTM)/Transgender Male/Trans Man
- Male-to-Female (MTF)/Transgender Female/Trans Woman
- Genderqueer, neither exclusively male nor female
- Additional Gender Category/(or Other), please specify _____
- Decline to answer

Birth Sex Assignment:
What sex were you assigned at birth on your original birth certificate? (Check one)
- Male
- Female
- Other
- Decline to answer

Preferred gender pronoun:
- He/Him
- She/Her
- Something else (Specify:_____)

Preferred name: (Specify:_____)

Military Service

Mayo Clinic supports gathering military service information in order to provide effective care to military service members. Capturing the locale of service would assist providers in knowing possible conditions which should be screened. However, limiting service locale to recent deployment could undermine the knowledge of past service exposures such as Agent Orange exposure in Vietnam; therefore, Mayo Clinic recommends no time limitation on military service data capture nor do we believe it necessary to require collection of service start date and date of separation. Mayo Clinic supports military service members from the U.S. Public Health Service and the National Oceanographic and Atmospheric Administration be included in addition to patients who have served in the military other than for the U.S.

Additionally, after reviewing the C-CDA R2.0 specification, it is possible that the Social History section could support this data; however, it would at a minimum require the development of informative guidance on how to construct a conformant entry. Modeling requirements cannot be determined until the actual data elements or components of military service are specifically defined.

Disability Information and Accommodation Requests

While Mayo Clinic supports the collection of disability information, we believe more work is needed to define the criterion before including it in EHR certification. For healthcare organizations to provide patient-centered care that meets patients' unique needs, identifying disability accommodations is essential. The EHR is an optimal location for this information as it provides a consistent location, standardized language, and an efficient method for sharing the information across providers. Below are additional suggestions and recommendations for integrating disability status in the EHR.

1. As noted in the proposed rule, patients' disability status should be modifiable within the EHR as disability status can change over time. EHRs should have the capability of logging and storing these changes. This would allow healthcare organizations to track the quality of care they are providing patients with disabilities and control for changes in patients' disability status.

2. While the proposed American Community Survey (ACS) questions were rigorously developed, the questions were not designed for the healthcare setting.[1] Consequently, it is questionable whether they will yield informative data for healthcare organizations. Unfortunately, to date there are no available standards for documenting disability in the healthcare environment for the purpose of identifying accommodations. Researchers at Mayo Clinic are currently conducting the first study to develop evidenced-based disability status questions that will yield actionable data for healthcare organizations. Below are preliminary results that demonstrate the critical need for additional research on this topic.

   a. Preliminary results indicate that over 20% of patients we surveyed were uncomfortable with non-medical staff collecting disability status information, and 12% of participants had concerns that the information could be used to discriminate against persons with disabilities. This highlights the essential need for further research to ensure that proposed disability status questions are not only evidence-based but do not harm the patient or the patient's relationship with his/her provider.

   b. In our current survey, we asked patients an open ended question about their need for disability assistance and accommodations within the healthcare environment. Participants gave widely varying answers which yielded vague and not actionable data. As a result, we recommend the development of the option for closed ended question for disability accommodations.

In conclusion, we support the proposed rule for EHRs to include the capabilities to document disability status and needed accommodations. Unfortunately, at this time there is insufficient evidence for disability and accommodation questions that will yield informative and actionable data that will not cause harm. Development of standard disability status questions and methods to collect the questions will advance patient-centered care and ultimately improve the quality of care provided to patients with disabilities.

1. Morris MA, Hasnain-Wynia R. A Research Agenda for Documenting Disability Status within Healthcare Organizations to Address Disparities in Care. *J Healthc Qual.* Mar 2014;36(2):7-13.

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

Public Comment Field:

Mayo Clinic seeks guidance on the ability to identify an appropriate Provider Directory entry. This is indeed a desirable capability in support of the direct transport solution. However, there are operational issues that may confound the use of these capabilities. The selection of a specific provider over her associated organization may be site dependent. Some organizations may wish that referrals to their hospital be submitted to an organizational direct address, others may direct referrals to the physicians with practice privileges. How will simply supporting extended directory services support these various use cases?