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National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Suite 729D
200 Independence Avenue, SW
Washington, DC 20201

RE: RIN 0991–AB92; Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements; Proposed Rule

Dear Dr. DeSalvo:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to provide our comments on the Version 2015 Certification Proposed Rule. Well-developed technologies in the hands of properly trained physicians can help drive improvements and efficiencies in patient care. The Health Information Technology for Economic and Clinical Health Act (HITECH), which established both the Meaningful Use (MU) program and the certification process, has radically increased the adoption of electronic health records (EHRs). The most recent data (2013) from the National Center for Health Statistics find that, since the start of the MU program, EHR adoption (including basic EHRs that do not meet MU requirements) has increased by approximately 27 percent.

Yet, despite this increase, there are significant obstacles that threaten physicians' ability to deliver better care when using certified EHRs. The AMA remains concerned that the MU program requirements are overly rigid, and that the certification process is not focused on ensuring interoperable and usable systems. According to our own analysis of the most recent Centers for Medicare & Medicaid Services (CMS) MU data, approximately 20 percent of eligible professionals have dropped out of the program, a figure we expect to rise once all the data for 2013 are tabulated. The AMA firmly believes these barriers must be removed in order to continue leveraging the use of EHRs and other health information technology (HIT). We therefore recommend the following suggestions to improve the EHR certification process:

I. Need to Chart a New Course

First, the AMA fully appreciates the magnitude of developing an entirely new program as large as MU and the EHR certification process. We also appreciate the significant hours devoted to this effort by the U.S. Department of Health and Human Services (HHS) and the Office of the National Coordinator (ONC), as well as countless other stakeholders. Yet, after three years, there are strong indications that the program's direction must be changed.

The AMA is hearing significant complaints from physicians from across the country who are not only deeply disappointed with the certified product they purchased, but also feel they were misguided. This palpable frustration was documented in a recent RAND report sponsored by the AMA that was commissioned to study factors affecting physician professional satisfaction and implications for patient care, health systems, and health policy.[1] This study found that EHRs led to significant physician frustration because the systems lack usability, require time-consuming data entry, and are more costly than originally projected. Furthermore, there is evidence that many of the MU requirements may not lead to better care. According to a recent article in the *Journal of the American Medical Association* (*JAMA)*, a study at Brigham and Women's Hospital concluded that, "[d]espite hope that achieving meaningful use improves quality, we found that meaningful users did not consistently provide higher quality care." [2]

The AMA is committed to working to help find solutions to these challenges. In particular, we believe that certified EHR technology (CEHRT) on the market today is not working well for physicians in part because the MU program's overly prescriptive, and numerous requirements limit the time and resources many vendors have to improve technology so that it can truly enhance care.

Currently, EHR certification is seen as a high-water mark since vendors are not required to continually test and update their software once approved. The AMA believes that poor EHR usability is partially an outcropping of this certification process, which allows products to be developed, tested, and certified in computer labs that do not reflect true use environments. We believe that testing is a key component of ensuring properly performing technology, usability, and patient safety. Testing early and often in the development of EHRs and utilizing impartial practicing physicians should be strongly encouraged by ONC.

Furthermore, ONC should ensure that testing reports posted on the Certified Health IT Product List (CHPL) are clear of technical jargon and are easily understood by the consumer. ONC should also require vendors to perform scenario-based testing prior to certification to ensure the exception handling capabilities of their products. A method for post-certification testing should also be established, allowing for ONC certification to be used as a base-line benchmark. Although not required, EHR vendors should have the opportunity to continually test their products—post-certification—and receive de-identified testing reports comparing their products to other high scoring EHR technologies.

The AMA firmly believes that the MU program and certification process must be substantially overhauled so physicians can leverage technology to help ensure improvements in health care delivery. We specifically encourage ONC to focus on more comprehensive testing along with greater transparency of these results.

II. Looking to the Future

Many of the problems we are seeing today with EHRs are rooted in certification requirements that include rigid and overly complex MU mandates (e.g., create a problem list, document smoking cessation and

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[1] The RAND Corporation with Sponsorship by the American Medical Association. Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy. October 2013. Available at http://www.rand.org/content/dam/rand/pubs/research_reports/RR400/RR439/RAND_RR439.pdf.

[2] Lipika Samal, MD, MPH, et al. Letter to the *JAMA Internal Medicine*, April 14, 2014, http://archinte.jamanetwork.com/article.aspx?articleid=1860495.

blood pressure). We believe that the certification process should be redesigned to focus instead on the product's ability to handle data and how it is leveraged to provide value to physicians. EHRs and other health technologies can promote a future health care system that ensures data migration, interoperability, and a more coordinated care system. To achieve this, we believe several changes are necessary to bring about a higher performing health care system:

- **Interoperability:** The AMA believes that the future state of EHRs and other HIT are ripe with potential, but interoperability must be a key focus to improve data sharing and care coordination. The recent JASON report funded by the Agency for Healthcare Research and Quality concisely described the current state of interoperability, finding "[a]t present, large-scale interoperability amounts to little more than replacing fax machines with the electronic delivery of page-formatted medical records."[3] If we are to move away from this approach, the certification process must be keenly focused on achieving true interoperability that is deployed in a fashion that requires minimal user intervention. **We believe ONC should focus less on what specific data are exchanged, and more on identifying and coordinating the standards needed to exchange information.**

- **Data Synthesis:** The AMA encourages a certification model that is data synthesis driven rather than one that is focused on data collection. Physicians believe and expect that EHRs will be more than a mere reporting tool and will facilitate gathering, organizing, and transferring health information. An EHR focused on data synthesis would provide tools to facilitate a physician's workflow, such as technology that remembers the physician's preferences and provides choices in how data are presented. Sophisticated data analytics and decision support tools that can be customized to meet the needs of unique patient populations are needed. While some EHR vendors are capable of developing this capability, it is more likely that EHRs will require integration with third party applications to achieve this goal.

- **Emerging Technologies:** We believe more focus is needed on emerging technologies that can facilitate interoperability and support modularity in EHR technology, like Application Program Interfaces (APIs) and Fast Healthcare Interoperability Resources (FHIR). Use of APIs has the potential to unlock the data and facilitate better exchange by allowing disparate systems to speak with one another, a concept that is well-supported in the aforementioned JASON report. We urge ONC to consider how best to highlight these other technologies and their potential uses.

The AMA recognizes that developing and deploying new technologies takes time. The course that is chartered now for EHRs will have a significant impact on the future state of this technology and will become even more important as physicians move towards outcomes based models of care, where data sharing will not only be a necessity but will have to be done in a seamless manner that does not require significant reengineering. We therefore encourage ONC to consider ways to improve certification now and consider how certification can facilitate future health care models.

[3] *A Robust Health Data Infrastructure,* Agency for Healthcare Research and Quality, Publication No. 14-0041-EF April 2014, prepared by JASON, The Mitre Corporation. http://healthit.gov/sites/default/files/ptp13-700hhs_white.pdf

III. Issues Specific to Voluntary Certification for 2015

The AMA has attached detailed comments in response to the issues raised in the proposed rule in the format requested by the ONC. There are, however, four key issues that we believe warrant highlighting: 1) Transparency; 2) Usability; 3) Quality; and 4) Program Integrity.

1. Transparency

Rather than trying to define a "complete EHR," the AMA encourages transparency that will allow physicians to have a clear understanding of what they are purchasing. We believe that terminology is not enough to solve this problem. More transparency is needed in communicating to physicians and health care organizations what they are receiving when purchasing products. Information must be provided in a uniform manner—similar to a nutrition label—that clearly articulates what is, and is not contained within CEHRT. The AMA also does not believe that the ONC should create separate certification packages; we believe packages will cause more confusion than it will solve. In particular, one individual's definition of "care coordination" may not be the same as another, which could lead to confusion.

We support the use of a singular ONC Certification Mark to identify products that have met CEHRT status. However, we are more concerned with the transparency of CEHRT functionality and any associated requirements that help educate the consumer with their purchasing decisions. Physicians and other purchasers must be well informed as to what functions, features, and capabilities are supported by CEHRT. In addition, it is vital that this information is standardized so that consumers have the opportunity to make apples-to-apples comparisons when deciding on their EHRs.

2. Usability

Data Lock-in and Portability

The AMA supports efforts that improve data liquidity and reduce data "lock-in." Waiting until Version 2017 to develop use cases and certification criterion, however, is missing the immediate need of CEHRT users and their patients. We believe part of what is contributing to data lock-in is a lack of well-defined standards set by ONC for porting the data from one location to the next. We encourage more guidance on how to improve data lock-in, but also caution that overly complex certification criteria can cause vendors to focus too much time on meeting these requirements. A simplistic certification approach should focus on basic changes that will improve usability, including migrating data. We also believe more focus should be placed on the incorporation of metadata in EHRs and leveraging the concept of web APIs (e.g., Fast Healthcare Interoperability Resources) to facilitate interoperability and EHR modularity.

Safety-Enhanced Design

The AMA supports the use of formative and summative usability testing in the design of EHRs. **We believe the approach that has been outlined by one of your SHARPC grantees that is an expert in EHR usability, the MedStar Institute for Innovation/MedStar Health Research Institute, is an appropriate and reasonable course to pursue.** They have proposed that for safety enhanced design (SED) vendors should have two options to demonstrate their User Centered Design (UCD) process. These options are outlined in more detail in our attached comments.

Computerized Physician Order Entry (CPOE)

Physicians participating in the MU program are vocalizing workforce concerns associated with who is and is not permitted to enter orders into an EHR. Many of the complaints stem from the MU program requirement that only licensed medical professionals and credentialed medical assistants are permitted to enter orders, a requirement that is creating confusion and serious workflow challenges for many physicians. For example, medical scribes, who are not licensed but often aid physicians in entering information into an EHR while the physician speaks with the patient, can be precluded from entering physician orders under this policy.

The AMA understands the intention behind the restrictions associated with order entry. In this instance, however, we believe the better approach is to allow the individual physician or their institution to decide how to facilitate CPOE and ensure timely patient access to medically necessary drugs or therapies through the utilization of its specific care team. **To best address the significant usability issues stemming from the current CPOE policy, we believe that physicians, medically licensed professionals, credentialed medical assistants, and other trained individuals as deemed appropriate by the individual provider should be able to enter orders for patients.**

Data Exchange

We support the requirement that CEHRT must be able to receive no less than 95 percent of all possible *Consolidated Clinical Document Architecture* (CCDA) variations. However, we request further information as to how the ONC intends to test such a requirement and how it will define "success." We also continue to encourage efforts to improve patient matching. We support the development of an open-source algorithm that could be used by vendors to assist in patient matching and encourage better testing tools in the data management space to verify the capabilities of algorithms.

3. <u>Quality</u>

The AMA supports ONC's and CMS' efforts to promote the use and adoption of standards that facilitate improved quality of care. We believe that the use of HIT and health information exchange is critical to facilitate quality improvement and outcomes based care. However, the number of Medicare quality reporting programs and stringent requirements make it very hard for physicians to successfully report. **We strongly urge HHS not to expand the quality reporting requirements until the HIT infrastructure challenges identified below are resolved, more flexibility is instituted with meeting the requirements, and quality measures are updated on a yearly basis. Furthermore, CMS quality reporting programs need to be better aligned so that physicians should only have to meet one set of quality requirements.** Challenges include:

- Complex and poorly understood reporting requirements;
- Lack of alignment among reporting programs;
- Lack of standardized clinical data terminologies to allow information in the EHRs/registries to be exchanged and captured seamlessly;
- Lack of developed standards to appropriately capture electronic quality measures within the EHR. Quality measures rely on demographic data, which is housed in the practice management system, plus additional demographic information that is often not needed for clinical diagnosis;

- Obstacles for physicians meeting Clinical Decision Support since it is tied to MU quality requirements;
- Lack of transparency in the development of quality measures (eCQMs are only updated every three years, not annually like the Physician Quality Reporting System [PQRS]);
- Module certification for registries to report for PQRS.

4. Program Integrity Concerns

The AMA believes that there is significant misunderstanding among some stakeholders about the utility of audit logs for program integrity investigations or audits. Audit logs contain voluminous data that require specialized expertise and training to understand. This is chiefly because audit logs have been designed for troubleshooting technological issues and, therefore, focuses on software and hardware processes rather than documentation of clinical integrity or intent. We strongly caution against the notion that audit logs present a panacea for program integrity detection and enforcement. We also have serious concerns about the negative impact that a requirement of continuous audit log functionality will have on patient care and EHR adoption. Running of audit logs may harm system performance during peak load times. Also, requiring audit logging without defining how long information must be retained will effectively require physicians and vendors to keep log data in perpetuity—greatly expanding the storage space and cost of EHR software. **For these reasons, we do not support certification requirements that require a vendor or provider to keep the EHR's audit log on at all times and prohibit disabling this feature when necessary.**

We appreciate the opportunity to provide ONC with these comments and look forward to a continued dialogue on creating and implementing an improved EHR certification process. If we can be of any further assistance, please contact Mari Savickis, Assistant Director, Federal Affairs, at (202) 789-7414 or mari.savickis@ama-assn.org.

Sincerely,

James L. Madara, MD

Attachment

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: The AMA supports the proposal in the 2015 Edition proposed rule "to split the 'computerized provider order entry' certification criterion into three separate certification criteria with each criterion focused on one of the three order types." Allowing for separate certification criteria could expand consumer choice and innovation. However, a method must be in place to clearly communicate to consumers what CPOE features are supported within their certified electronic health record technology (CEHRT). We suggest creating a standardized "feature list"—similar to a nutrition label—that clearly identifies what features are and are not included in the purchase of CEHRT. Furthermore, this list should be available on both the vendor's website and within the ONC's Certified Health IT Product List (CHPL). The AMA understands the intention behind the restrictions associated with order entry. In this instance, however, we believe the better approach is to allow the individual physician or their institution to decide how to facilitate CPOE and ensure timely patient access to medically necessary drugs or therapies through the utilization of its specific care team. To best address the significant usability issues stemming from the current CPOE policy, we believe that physicians, medically licensed professionals, credentialed medical assistants, and other trained individuals as deemed appropriate by the individual provider should be able to enter orders for patients.	

§ 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*

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

Public Comment Field: See response to § 170.315(a)(1)

§ 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: See response to § 170.315(a)(1)

§ 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: The AMA agrees that including allergy interaction checks can be an important tool for physicians and patients. We urge ONC to use alerts in the most effective manner possible and not create alerts that interfere with physician workflow. Data collected from EHRs should be utilized to improve the validity and usefulness of these alerts. We strongly believe that information regarding compliance with drug-allergy checks should be limited primarily to the provider or health care organization and should only be used to facilitate improvements in care quality.

§ 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: The AMA supports expanding the ability for CEHRT to record demographic data. We do not, however, believe that physicians should be required to record all of this information, especially if not relevant to their practice. Furthermore, the AMA strongly urges that CEHRT users not be required to enter null values in fields that are not appropriate to their patients or where patients are not willing to provide this information. ONC may also wish to expand the demographic data to include other information that may be especially relevant to specialties and sub-specialties or for population health purposes.

§ 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: The AMA supports the concept of recording vital signs in a standardized format. However, as noted by some stakeholders, clinicians should continue to have the flexibility to record patient information as they best see fit. Therefore, we propose that standardized vocabularies should be required in CEHRT as an option that administrators and physicians could enable. Entities will then have the option, by policy, to record vitals using vocabularies that are in line with their standards of practice. Providing this option will allow physicians to choose a standardized approach to syntactically and semantically interoperate. The AMA also supports the addition of metadata and other contextual information to be used in conjunction with vitals. However, we strongly urge that ONC and CMS not require clinicians to record this additional information to successfully meet the MU program requirements.

§ 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: No comment.

§ 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: No comment.

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

MU Objective

Maintain active medication allergy list.

2015 Edition EHR Certification Criterion

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

(i) Ambulatory setting**.** Over multiple encounters; or

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

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

Public Comment Field: No comment.

§ 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:

The AMA appreciates ONC's attention to data elements that highlight potential disparities in care and possible social determinants that can be used to improve patient outcomes. We recommend a thorough environmental scan to assess use of these data elements as well as a thorough review of the standards landscape prior to requiring an EHR to filter on these data elements.

We believe that quality measurement and clinical decision support (CDS) are important tools for high quality patient care. We also believe that quality measurement and CDS must be employed together to improve patient outcomes. We recommend that the efforts currently underway to align the standards associated with clinical quality measures and CDS continue until full alignment and consensus is reached and the standards are fully tested.

§ 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: The AMA strongly supports that CEHRT allow users to search within an electronic note and across separate electronic notes. We also believe metadata should be included as part of an electronic note. Additionally, we urge that CEHRT filter search requests and results by contextual information (e.g., user, date, diagnosis) to facilitate finding relevant data. Because search functions are particularly helpful for EHR users, we urge ONC to include this certification criterion for v.2015 rather than waiting for v.2017.

§ 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:

As noted by the Health Information Technology Standards Committee (HITSC), the National Council for Prescription Drug Programs (NCPDP) Formulary and Benefit Standard currently has several limitations that reduce its usefulness for physicians. In particular, the inability of the Formulary and Benefit Standard to provide real-time, patient- and drug-specific data to physicians at the point of prescribing limits the current utility and reliability of the standard. We believe requiring physicians to perform formulary checks via a standard with these problems and potential inaccuracies would waste valuable physician time and resources. The AMA therefore strongly recommends that the formulary check certification criteria be left as-is (in its flexible form) until a standard that can provide accurate, real-time formulary data is identified.

Currently, we believe it is premature to recommend a particular standard for the 2015 Edition, however, we urge the industry to swiftly move forward in identifying and implementing a standard that would provide reliable, drug-specific benefit information at the point of prescribing. Numerous efficiencies would be gained through such a standard, such as the ability for physicians to determine prescription prior authorization requirements in a proactive manner compared to the current reactive system where such benefit restrictions are not made apparent until the patient presents a prescription at the pharmacy.

§ 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: The AMA supports the use of the HL7 Pedigree standard and implementation guidance for documentation of family health history. The Pedigree model is approved by the American National Standards Institute (ANSI), is the Healthcare Information Technology Standards Panel (HITSP) accepted standard, and is in the process of becoming an international standard through the International Standards Organization (ISO). We believe this standard:

- Provides a standard method for transmitting and receiving family history information in sufficient detail to allow CDS;
- Promotes prevention and early detection of hereditary disease;
- Enables CDS applications to run effectively; and
- Establishes a domain of family health history in a convergence point of EHR, patient health record and genomics to promote patient care.

§ 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: See response to § 170.315(a)(10).

§ 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: The AMA recommends option #3: requesting standard developers to create patient friendly version(s) of their datasets/standards that are used for various purposes (for example CPT for reporting and reimbursement) that can be used to electronically identify patient-specific education resources. We believe the inclusion of non-certified methods provides patients and their physicians the freedom to choose from a wider array of medical education resources. As newer resources come online and are available via mobile technology, we believe certification should not limit how patients identify which resources are best suited for their education.

§ 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: No comment.

§ 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: The AMA supports the ability for CEHRT to record unique device identifiers (UDIs). We also believe the clinical document architecture (CDA) is an appropriate place to accommodate the UDI for instances cited in 170.315(b)(1)—Transitions of care, 170.315(b)(6)—Data portability, 170.315(e)(1)—View, download, and transmit to third party, and 170.315(e)(2)—Clinical summary. Automatic identification and data capture (AIDC) should be used to record the UDI, as manually entering this information may be subject to human error and can prove to be time consuming.

§ 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: The AMA supports moving certification in a direction that emphasizes the testing of individual CEHRT. We feel that too little attention is placed on testing after ONC certification. We urge ONC to bolster testing requirements and include acceptation handling for both content and transport capabilities in EHRs. We also support the requirement that CHERT be able to receive no less than 95 percent of all possible consolidated clinical document architecture (CCDA) variations. However, we request further information on how ONC intends to test such a requirement and what the definition of "success" is. We also support increased attention on methods to improve patient matching. We support the development of an open-source algorithm that could be used by vendors to assist in patient matching and encourage better testing tools in the data management space to verify the capabilities of algorithms. In addition, we urge that more attention be placed on emerging technologies (e.g., Fast Healthcare Interoperability Resources (FHIR)) that can facilitate interoperability and support modularity in EHR technology.

§ 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: 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: No comment.

§ 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: The AMA supports aligning the display of laboratory tests and value/results with Clinical Laboratory Improvement Amendments (CLIA) requirements. **Where possible, ONC should try to coordinate certification requirements with existing legal and regulatory requirements to avoid confusion.**	

§ 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: The AMA believes certification requirements should prioritize efforts that improve data liquidity and reduce data "lock-in." The lack of data portability is among the chief complaints physicians cite with respect to their existing EHRs, and it greatly reduces the benefits of CEHRT. Waiting until v.2017 to develop use cases and certification criterion is missing the immediate need of CEHRT users and their patients. More focus should be placed on the incorporation of metadata in EHRs and leveraging the concept of APIs (e.g., FHIR) to facilitate interoperability and EHR modularity.	

Clinical Quality Measures – Electronically Processing eMeasures	
Preamble FR Citation: 79 FR 10902	**Specific questions in preamble?** *Yes*
Public Comment Field: See response to Clinical Quality Measures – Functions and Standards for CQM Certification	

Clinical Quality Measures – Functions and Standards for CQM Certification	
Preamble FR Citation: 79 FR 10903	**Specific questions in preamble?** *Yes*

Public Comment Field:

The AMA supports ONC's and CMS' efforts to promote the use and adoption of clinical quality measures (CQMs). We believe, however, that standards must be rigorously assessed for readiness using well defined criteria before promoting their use. Factors to consider regarding readiness include:

• technical infrastructure and architecture;

• necessary alignment and harmonization with other standards, including the Physician Quality Reporting System (PQRS); and

• alignment with program goals and objectives.

We also support a phased, step-by-step approach to promoting or recommending standards, so that organizations can meet competing technology and reporting demands.

As quality measure developers, we support the continued use of the Health Quality Measures Format (HQMF) as the standard for representing a quality measure specification. However, we believe that additional testing and implementation of the HQMF is necessary to evaluate EHR and provider readiness. Information learned from testing and implementation could then inform the appropriate point in time in which EHR technology could demonstrate certification against the HQMF.

§ 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: See response to Clinical Quality Measures – Functions and Standards for CQM Certification

§ 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: See response to Clinical Quality Measures – Functions and Standards for CQM Certification

§ 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: See response to Clinical Quality Measures – Functions and Standards for CQM Certification

§ 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: See response to § 170.315(a)(10) (Clinical decision support)

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

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

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

Public Comment Field: The AMA supports the concept of increasing security for eRx of controlled substances but that the current two-factor authentication process has limited the utility of eRx, forcing physicians to default to paper for a portion of their prescriptions. This has impacted the overall adoption and use of eRx. As two-factor authentication requires "something you know and something you have," we suggest ONC consider the work originating from the National Strategy for Trusted Identities in Cyberspace (NSTIC) and the Identity Ecosystem Steering Group (IDESG). We encourage ONC to explore the notion that an individual's trusted identity be used as the second factor (i.e. something you have) in authentication.

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

§ 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: While the AMA understands the potential benefits of tracking auditable events, the AMA does not support limiting the ability of a provider to disable an EHR's audit log. First, audit logs are generally designed for troubleshooting technological issues and, therefore, focus on software and hardware processes rather than elaborating on user intent or the appropriateness of their actions. Second, continuous audit logging may harm system performance, especially during peak load times. Rather than turning off this function to facilitate fraud, many providers need this authority so that they can simply ensure EHRs remain functional for patients. Requiring audit logging without defining information retention will effectively require providers and vendors to keep log data in perpetuity – greatly expanding the storage space and cost of EHR software. Ultimately, prohibiting this function is likely to have unintended consequences for patients and physicians.

§ 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.

§ 170.315(d)(4) (Amendments)

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.

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

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*

Public Comment Field: Given the concerns expressed by EHR vendors over the complexity of implementing an accounting of disclosures solution, the AMA believes that this criterion should not be a mandatory requirement for certification. Furthermore, as evidenced by the feedback provided at a recent ONC hearing, the cost, time, and effort it would take for vendors and providers to meet this requirement would be prohibitive and unmanageable. Testifiers also indicated, and we agree, that requiring such a mandate fails to achieve the desired outcome. Patients are not seeking reams of unreadable data; they often want more general and basic information about their health care data. We believe ONC should focus on ways to provide this information in a more appropriate, user friendly format.

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

MU Objective

EPs

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

EHs and CAHs

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

2015 Edition EHR Certification Criterion

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

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

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

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

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

(B) Download.

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) The user who took the action; and

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

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

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

(e)(1)(ii)(A) is accessible by the patient.

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

Public Comment Field: The AMA supports increasing patient access to their health information and providing individuals the opportunity to view, download, or transmit their information to third parties. With respect to decoupling transport and content, we ask that ONC see our previous comments regarding Transition of Care. We support patients having access to their diagnostic images and believe they should have the ability to view, download, or transmit their images as they see fit. However, the EHR is not the appropriate application to manage diagnostic images. At most, the EHR should direct individuals to the originating picture archiving and communication system (PACS), which houses these images. If the images are not stored digitally, the EHR should provide information as to how to request analog copies. Duplicating diagnostic image storage in the EHR will significantly increase storage needs, costs, and could limit the image's utility as Digital Imaging and Communications in Medicine (DICOM) viewers are not routinely imbedded in patient portals. Additionally, the OpenNotes project has shown some potential and benefit in its limited deployment. However, at this time, we do not believe it is a mature enough function to be included as a certification criterion, especially since it has only been deployed at a limited number of facilities.

§ 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: The AMA continues to have serious concerns with the MU summary of care requirement. We believe summary of care documents are helpful; however, the manner in which they are currently rendered in EHRs for physicians and patients restricts their utility. To improve their usefulness, we support efforts to allow providers to limit what is contained in clinical summaries to ensure patients receive and understand information that is most relevant to their care needs. Until summary of care documents are constructed in such a manner that makes them actionable and useable for most patients, we fear this requirement of MU will not improve care quality. Physicians also tell us that patients routinely discard clinical summaries shortly after they receive them, often while they are still in the doctor's office. The AMA therefore believes patients should have a choice to not receive these summaries.

§ 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: See response to 170.315(f)(2) (Transmission to immunization registries)

§ 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: The AMA is supportive of bi-directional data exchange between EHRs, including cancer and immunization registries. Yet, the certification requirement fails to address the need for bi-directional exchange for national clinical registries or clinical data standardization for any other purpose. As proposed in the HIT Policy Committee's Stage 3 Meaningful Use recommendations, certification requirements should require bi-directional exchange between EHRs and other registries. Cancer and immunization registries, while helpful, are primarily used for surveillance, epidemiology, and point of care information transfer. In comparison, national clinical registries can be used for quality improvement support (e.g., reporting and benchmarking) or other related activities.

In addition, cancer and immunization registries started with a standardized data model that each state/region had to implement, requiring the data to be very specific. EHR vendors should provide clinical data in a standard format that is backed by standardized data definitions instead of providers incurring the cost of middleware vendors to map and transmit the data when providers have already purchased the EHR. This is an added cost without any added value.

The ability to transmit clinical data to national clinical registries using standardized data definitions will assist physicians and health care systems. Many of these registries are also utilized for payment programs, including PQRS and certain CMS coverage decisions. ONC could utilize existing national standards that are already housed within an EHR to begin this data transmission process. The AMA requests that if ONC moves forward with this ask that they engage with the physician community and the AMA so that the clinical content of this work is accurate and widely adopted.

§ 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: See response to 170.315(f)(2) (Transmission to immunization registries).

§ 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: See response to 170.315(f)(2) (Transmission to immunization registries).

§ 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: See response to 170.315(f)(2) (Transmission to immunization registries).

§ 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: See response to 170.315(f)(2) (Transmission to immunization registries).

§ 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: The AMA believes automated recording should fully support the physician practice when audits are directed at Meaningful Use measures. Furthermore, this criterion should be thoroughly tested to achieve certification, and once certified, physicians should not be held accountable for the automated results.

§ 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:

The AMA supports the use of formative and summative usability testing in the design of EHRs. We believe the approach outlined by one of the SHARPC grantees, the MedStar Institute for Innovation/MedStar Health Research Institute, is an appropriate and reasonable course to pursue. They have proposed, that for safety enhanced design (SED), vendors should have two options to demonstrate their UCD process:

1. For those vendors who do not already have a rigorous summative testing process they should be allowed to attest to their UCD process and provide the summative testing results. However, ONC should set minimum guidelines such as guidelines on sample size and type of participant. Doing so could help avoid challenges with vendors providing varying levels of detail and would bring more consistency to the process.

2. For vendors with a rigorous UCD process in place, they should be able to use the byproducts of their process to meet the SED requirements, and can opt to demonstrate the process as opposed to providing summative test results. This would include evidence of formative testing, amongst other things.

MedStar identifies several criteria for defining a "rigorous" process ,which could include:

1. Several cycles of formative testing are performed with at least 5-8 participants per cycle;

2. Participants must be experts that are outside of the vendor organization;

3. Vendor must be able to demonstrate that the formative testing results were documented and changes were effectively made to the product based on the formative testing results; and

4. Iterative mockups and prototype should be submitted as evidence of UCD (these would not be made public, but would be reviewed by the accrediting bodies).

§ 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: The AMA supports reporting of non-percentage-based measures. In addition, the reports created by this suggested criterion should be sufficient to fully document that a physician or other provider has satisfied the criteria for Meaningful Use, limiting any additional documentation or attestation requirements.

§ 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: The AMA is not for or against the concept of a "complete EHR;" rather, we are more concerned that physicians and other providers have a clear understanding of what they are purchasing. We believe that terminology is not enough to solve this problem. More transparency is needed in communicating to physicians and providers what they are receiving when purchasing products. Information must be provided in a uniform manner—similar to a nutrition label—that clearly articulates what features are and are not contained within CEHRT. This is especially important where products may not be certified to particular CQMs on which a provider intends to report, limiting the provider's ability to successfully meet the MU requirements. Information outlining the product's criteria should be readily apparent when purchasing an EHR and also available on the ONC's website.	

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: The AMA supports the use of a singular ONC Certification Mark as a method for identifying products that have met CEHRT status. However, as previously stated, we are more concerned with the transparency of CEHRT functionality and seek tools to help educate the consumer with their purchasing decisions. Providers must be well informed as to what functions, features, and capabilities are supported by CEHRT. In addition, it is vital that this information is standardized so that consumers have the opportunity to compare "apples-to-apples" when deciding on their purchases.	

Certification Packages for EHR Modules	
Preamble FR Citation: 79 FR 10921	**Specific questions in preamble?** *Yes*
Public Comment Field: The AMA does not believe ONC should create separate certification packages; in fact, we think this will cause more confusion than it will solve. For example, one individual's definition of "care coordination" may not be the same as another, which could lead to misunderstandings about what is or is not included in the product. Again, we emphasis that specific functionalities need to be listed, in a standardized format, so that providers understand the capabilities and limitations of their EHRs.	

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: The AMA believes the collection and use of additional patient data elements may be beneficial in some instances; however, we believe the collection of such data should not be mandated. For instance, the inclusion of sexual orientation and gender identity (SO/GI) data fields should be included in CEHRT but physicians would not be required to report this information.	

Medication Allergy Coding	
Preamble FR Citation: 79 FR 10925	**Specific questions in preamble?** *Yes*
Public Comment Field: No comment.	

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: The AMA suggests adopting option #2 that would maintain the 2014 Edition approach. We believe this approach has allowed flexibility, reducing the burden of the certification process. However, as stated previously, ONC should refocus their EHR certification process to include a far more robust post and pre-EHR certification testing process. This expanded testing regime could include additional privacy and security (P&S) tests constructed in a way that reflects "real world" events that EHRs face in production environments.	

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: No comment.	

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

Blue Button +	
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: The AMA supports the requirement that CEHRT must provide the end user with the ability to merge and unmerge electronic patient records. We believe this functionality is vital to improving data transfer and interoperability and will be a key component to improving care coordination.	

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: The AMA believes that, while certification of other types of HIT and for other health care settings is well-intended, given the number of challenges we are experiencing with EHRs, expanding certification may not be appropriate at this time. It is not feasible to identify what HIT innovations will develop over the next few years, which may lead ONC to pursue certification of products that are not necessary or not appropriate for the future of health care. We believe a better approach would be to focus on ensuring that certification of EHRs is improved before ONC attempts to certify other products for a broader range of providers. We are concerned that the existing certification problems could be further magnified elsewhere in the industry. Instead, we believe ONC should focus on pre and post-certification testing of CEHRT to ensure usability, safety, and performance when HIT is deployed in the field.	