AMA
AMERICAN MEDICAL ASSOCIATION

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Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Karen B. DeSalvo, MD, MPH
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

Dear Acting Administrator Slavitt and Dr. DeSalvo:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to submit our comments on the Office of the National Coordinator for Health Information Technology's (ONC) 2015 Edition Health Information Technology (health IT) Certification Criteria.

The AMA is strongly committed to working with public and private stakeholders to ensure all aspects of health IT, including Electronic Health Records (EHRs), are safe, secure, usable, and interoperable. We believe the health IT industry has made positive advancements over the past five years in terms of digitizing medical records, expanding the electronic prescription of medications, increasing the electronic exchange of patient records, and leveraging the Internet for care coordination and patient engagement. These functions embody the greater utility of many EHRs on the market today. While the functions mentioned above will continue to be refined as technology and product design improves, there are many areas—especially usability and interoperability—that continue to warrant further attention and immediate prioritization. It is in this vein that we make the following recommendations to ONC both below and in the attached comment template.

- **Finalize a number of ONC's proposals with AMA's suggested comments, including:**
    - **Consolidated Clinical Document Architecture (C-CDA) Release 2.0 (R2) validation and testing;**
    - **More stringent safety enhanced design requirements;**
    - **Application Programing Interfaces (APIs);**
    - **"In the field" health IT surveillance; and**
    - **Transparency and disclosure requirements.**
- **Refrain from naming draft standards as part of the health IT certification program;**
- **Seek greater alignment between meaningful use (MU) Stage 3 and the 2015 certification process;**

- **Refrain from expanding health IT certification beyond the MU program;**
- **Further address registry reporting;**
- **Strongly consider vendors' ability to meet the growing complexity of quality measures; and**
- **Focus on high-value use cases & "cornerstone" issues.**

There are a number of issues that hinder the successful use of health IT to improve care; yet, we believe alignment and consolidation are solutions to many of the concerns listed above. We feel that if the Administration takes a multi-pronged approach and addresses our concerns in this letters, considers our comments on MU Stage 3, and incorporates our recommendations and feedback on ONC's Interoperability Roadmap, health care as a whole will improve, and we will move much closer to achieving the benefits identified in a Learning Health System.

Proposals that the AMA believes will improve health IT certification

C-CDA Release 2.0 Validation and Testing

In January 2015, the AMA, along with 36 other medical societies and organizations, made a number of recommendations that could be implemented in the near-term to improve the functionality of certified EHRs. One key recommendation was for ONC to develop C-CDA guidance and testing to further support data exchange. As identified in our letter, the C-CDA is a draft standard and its use as a mandatory requirement in the MU program has led to deficiencies in interoperability. However, since the C-CDA is currently the main method for data exchange across health IT products, we support ONC's proposal to identify C-CDA R2 as the new document standard. We also support the added attention to C-CDA conformance and system performance. This is a vital step in moving from data exchange to functional interoperability or the ability of a system to exchange, incorporate, and display data in a contextual and meaningful manner.

We do, however, seek clarity regarding how ONC will ensure two different systems will be able to exchange C-CDA documents if there is a version discrepancy. We are aware of vendor concerns with the backward-compatibility of R2 with R1.1. Additionally, we are aware of a recent Health Level Seven (HL7) Structured Documents Working Group (SDWG) effort to develop new Draft Standard for Trial Use (DSTU) updates to address specific issues in the current R2 DSTU. **While we do not agree with the use of draft standards, accommodations should be made to these changing standards and sufficient time should be provided to Standards Development Organizations so that Implementation Guidance can be further refined.** We also question the availability of stable testing tools to enable Accredited Testing Laboratories and health IT vendors to fully test applications standards conformance and that these products are made available to the market well in advance of the start of Stage 3.

Safety Enhanced Design

In our January 2015, letter we also cited concerns with ONC's certification process for validating whether EHR vendors used proper User Centered Design (UCD) techniques. Experts in human-factors design have noted on many occasions that health IT vendors should meet a minimum level of UCD principles. We suggested that ONC increase the robustness of its UCD certification requirements and to make testing reports easily accessible and understandable to the physician consumer.

We support the proposal to expand the number of certification criteria to which the UCD process must be applied and are encouraged by the submission requirements and compliance guidance provided. While ONC recommends 15 as the minimum number of testing participants used in the UCD process, there are no requirements on who must participate—only that the report must include the number and the participant's demographic characteristics. We understand that, due to the variation in intended users, ONC is reluctant to specify who must participate in the testing. **However, we believe ONC could specify a minimum number of participants actively practicing in a specific profession. We also suggest that ONC consider a conditional requirement—similar to its proposed privacy and security changes—that matches the testing participants to the intended use of the health IT module.**

In addition, because the wide variability among the Authorized Certification Bodies (ACBs) when it comes to reviewing vendor adherence to the safety enhance design requirements, some products may pass certification with less strict processes. Certification requirements hold very little value if the ACBs are not universally applying and upholding ONC requirements. **We therefore strongly suggest that ONC immediately release clear and specific guidance for ACBs on safety enhanced design adherence and routinely validate, through whatever means necessary, that ACBs are certifying at the same level.**

Application Programming Interfaces (APIs)

A key aspect to functional interoperability is a system's capacity to expose data securely. This is important for external reporting, product migration, and data visualization. Furthermore, solutions need to have low costs for development both in terms of time and resources. The AMA is encouraged that APIs can provide these solutions. Indeed, shortly after ONC posted a report in April 2014 by JASON, an independent group of scientists that advises the federal government on matters of science and technology, on the future of health IT infrastructure that highlighted APIs, the AMA released a new framework for improving EHR usability.[1] This framework, developed with the support of an external advisory committee of noted experts in the field of health IT, outlined eight usability priorities, including the need for EHR modularity and data liquidity. In each instance, APIs were identified as an important contributor to facilitating these goals.

ONC's proposed rule identifies APIs as one method for providing greater access to patient data held within EHRs. We support ONC's intent to guide the heath IT market in this direction. Although APIs are nothing new to software development, their use to support the needs of end users in health IT has been slow to gain traction. With the advancements in standards, such as Fast Healthcare Interoperability Resources (FHIR), and platforms, such as Substitutable Medical Applications & Reusable Technology (SMART), we believe there is significant potential to improve EHR usability and interoperability in the near future.

As applications or "apps" become more widespread, physicians and patients must have the tools and resources needed to be informed users and consumers of medical data. Many who currently access patient data do so directly from an EHR, either through the physician's interface or a patient portal. In

[1] Jason, A Robust Health Data Infrastructure. Available at http://healthit.gov/sites/default/files/ptp13-700hhs_white.pdf

both instances the EHR is required to provide the technical security to protect health information and, in most cases, the physician is responsible for the patient's privacy under the Health Insurance Portability and Accountability Act (HIPAA). Third-party apps, downloaded from an online store or used within a computer's Internet browser, are not subject to HIPAA requirements. The AMA is concerned that patients may use apps without realizing that their data can be accessed, viewed, or sold without their express permission. **We encourage ONC to develop materials well in advance of Stage 3 to educate patients and physicians to the benefits and possible concerns APIs and third-party apps may pose to protected health information.** We are also very cognizant that adding APIs does not necessarily equate to low-cost development or reasonable fees for physicians. We will be closely following this shift in the market. The AMA is also currently engaging with key stakeholders and will be taking steps in the near future to play a larger role in the evolution of health IT application development and associated software platforms.

Health IT Surveillance

Health IT products are complex and must be thoroughly tested and evaluated during development, deployment, and implementation. Many variables affect the performance of EHRs once they are installed and used by physicians, including customization, aging hardware, external dependencies, and an end user's level of training. While many of these are concerns unique to individual medical offices or hospitals, a product's inherent design and intended function should not deviate from the vendor's marketing material or contract requirements. The AMA is aware of many instances where products have not performed as sold to the physician or require additional features/enhancements to perform data exchange or reporting. In our January 2015 letter, we identified widespread concerns in the medical community regarding the safety, usability, and interoperability of EHRs and asked ONC to realign their certification program to focus on these issues.

We support ONC's proposed health IT surveillance and maintenance changes, especially adding randomized in-the-field surveillance to the existing reactive requirement. We are also supportive of ONC's intent to prioritize implementation surveillance to health IT capabilities related to interoperability, patient safety, and privacy and security. **As further noted in our comment template, we are concerned that ONC does not provide greater detail as to how burdensome this process will be for physicians and their office staff. We seek further clarification on what is expected by physicians during an in the field EHR audit.**

Transparency and disclosure requirements

In addition to the complexity of health IT products, the initial and long-term costs of EHRs limit their ability to improve care. Once a product is installed, an EHR vendor typically requires a monthly maintenance fee based on the initial cost of the product. These fees can range from a few thousand to tens of thousands of dollars a month. Additionally, each custom software change or interface needed to meet MU requirements contributes to unexpected costs, which burden physicians and divert resources from patient care. In 2013 and 2015, AMA sponsored two RAND studies which found that the lack of resources, both financial and human, needed to manage the increasing level of administrative challenges

are a significant issue facing physicians.[2,3] As a result, the AMA has advocated for greater transparency of vendor costs and product capabilities.

We are very supportive of the proposed transparency and disclosure requirements in ONC's certification rule. We also appreciate that ONC has cited the AMA in their proposal regarding the lack of transparency in EHR vendor contracts. **Yet, we believe ONC should expand their interest in transparency to encompass other cost layers, which may be introduced by entities outside the certification process.** We recognize that this would not be a required part of EHR certification. We would, however, like to see further data collection and reporting of instances that cause financial burden on a physician's use of health IT. At the very least, more should be done to eradicate health IT vendor "gag clauses," which preclude physicians from openly discussing patient safety issues outside of tightly-controlled vendor environments. We appreciate ONC's recent report on data blocking and encourage frequent reports of this type that highlight specific areas where the health IT industry can improve, self-regulate, or become more transparent.

Areas of concern based on ONC's proposals

The Inclusion of Draft Standards in Health IT Certification

The ability for two systems to communicate is heavily reliant on the use of standards and their coordinated implementation. Standards, not just technical standards, are fundamental building blocks to communication, transportation, finance, and measurement. While many standards originate out of pure need, technical standards have a tendency to be duplicative as each stakeholder may have unique interests in their development. Competing standards are nothing new and are well represented by the battle between VHS and Betamax in the late 1970s. While many can debate which standard was better, VHS won in large part due to its market acceptance and low cost. For health IT standards there are also competing interests; yet, standard development organizations provide a centralized place for stakeholder input to facilitate their natural development over time. Recent entries such as FHIR are gaining momentum through coordinated efforts like the Argonaut Project, its low cost to deploy, and open license. Yet, we recognize that FHIR is still evolving and its impact on the industry is not yet clear. The AMA is therefore supportive of ONC's acknowledgement of FHIR and its restraint at this time from officially naming it in their version 2015 proposed rule.

The AMA is concerned, however, that ONC has elected to name other draft standards in this proposed rule. We have previously cited many concerns with the C-CDA draft standard and other draft standards that are not mature, lack wide market acceptance, and are not well tested. We understand ONC's intent is to coordinate the market's attention on possible standards to address issues such as provider directories, privacy concerns, and nonrepudiation. We do believe these are key areas and have called for further prioritization on these cornerstones issues in other letters and public forums. **Based on internal and external conversations with health IT stakeholders, the AMA believes it is premature to name**

[2] Mark William Friedburg, et. al, "Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy," RAND, October 2013.
[3] Mark William Friedburg, et. al, "Effects of Health Care Payment Models on Physician Practice in the United States" RAND, March 2015.

Electronic Submission of Medical Documentation (esMD), Data Separation for Privacy (DS4P), Healthcare Provider Directory (HPD), and Laboratory Orders (LOI) in this version of health IT certification. We believe that many of these issues can be addressed by providing a wider range of maturing standards from which the market can choose, and therefore improve upon, or requiring that health IT seeking certification can show a functional output such as what ONC is proposing for APIs.

The Lack of Harmonization between Health IT Certification and MU Timelines

The development of health IT products is a time and resource intensive process requiring a well thought-out roadmap along with attainable goals. Many in the industry, including those who develop EHRs, strive to produce products that meet the needs of their consumers while also innovating to meet future requirements. The AMA has been a vocal advocate for more functional and usable EHRs and has identified that the majority of an EHR vendor's time is devoted to designing a product to meet MU objectives. We have commented, on various occasions, that it is our belief health IT development is too closely tied to the demands of federal programs and not the needs of patients and physicians. In our January 2015 sign-on letter, we called on ONC to reduce the burden on vendors and to retool the certification program to primarily focus on the testing and validation of system interoperability, usability, and safety. We do acknowledge that ONC has made some attempt to address our concerns; however, we feel the certification program is still too heavily focused on the MU program.

Specifically, the AMA is concerned with the volume and complexity of the certification requirements vendors will need to meet to deliver Version 2015 products. While the Stage 3 timeline is established by the Centers for Medicare & Medicare Services (CMS), we believe it is vital that both CMS and ONC concurrently identify the short timeline both agencies have established through their respective proposed rules. For instance, although the number of criteria a vendor must certify against has not increased, fully 55 percent of the criteria has either changed or are new. We are already hearing concerns from the vendor community on the complexity of both agencies' programs. The AMA believes the timeframe and requirements, as proposed, will simply not allow for vendors to innovate, design, test, deliver, and implement safe, secure, and usable products for physicians and patients well in advance of Stage 3. **We therefore ask both CMS and ONC to establish a more reasonable set of technological requirements and program objectives to allow the health IT industry to innovate and prioritize the development of products to meet the needs of actual end users.**

Expanding Health IT Certification Beyond the MU Program

The Health Information Technology for Economic and Clinical Health Act (HITECH) established core actions an eligible provider (EP) must take to become a meaningful user. These included quality reporting, electronically prescribing medications, and interoperability. The HITECH Act did not specify the exact design of the MU program. Instead, through various leadership priorities and policy objectives, both ONC and CMS have built the various stages of MU. Many in the industry, including the AMA, believe the original intent of HITECH was to incentivize the rapid adoption of health IT and to digitize the nation's medical record system. To that end, we believe the spirit of the Act has been accomplished. The AMA is very supportive of the continued use of safe and efficient technology in patient care. Unfortunately, we believe the MU program has evolved into a lever for the federal government to

prescribe the use of health IT without focusing on well-defined outcomes or actions that improve the quality of care.

The AMA is therefore very concerned with the Administration's growing desire to tie all forms of reimbursement (both public and private) to the use of certified technologies. While this may drive more data exchange, it does not address the root issue that the lack of interoperability is governed by factors outside the average practicing physicians' control. **We are also concerned with ONC's proposal to expand their certification program by providing an "a la carte" selection of criteria for other federal and non-federal payers.** This may perpetuate existing problems with EHRs, spreading them to other programs and technology.

Expanding the ONC certification program beyond MU could also negatively affect innovation and cause further dissatisfaction among participants. The AMA recognizes that physicians need tools that comply with the law. Nonetheless, we remain concerned with the utility of these products and the ability of vendors to deliver high-performing systems in sufficient time for physicians to incorporate their use safely and securely. **We recommend that ONC and CMS curtail their efforts to expand the MU and certification programs beyond the original intent of the HITECH Act. Until program goals, market forces, and payer models are aligned, the federal government should take a lighter touch to health IT regulation.**

Reporting to Clinical Registries and Public Health Agencies

CMS proposed in a recently released modified version of Stage 2, to consolidate all optional public health agency (PHA) and clinical data registry (CDR) objectives into one new mandatory objective. Essentially, this mandates an increased number of reporting requirements without addressing that physicians, who report through a CDR, should receive credit for MU quality measures and the Physician Quality Reporting System (PQRS). Physicians who are actively engaging in true quality improvement through a Qualified Clinical Data Registry (QCDR) will have to continue to report twice to satisfy MU quality requirements. The AMA is concerned that CMS' proposed measure forces more data to be exchanged without identifying the use or how it can facilitate a physician's quality reporting. **We believe submitting data to CDRs should not be just another MU objective; instead, the action of quality measurement reporting through CDRs should directly count toward a physician's quality measurement reporting objective in MU.**

Through various discussions with health IT stakeholders, we believe that due to the multitude of PHAs and CDRs each registry or state agency utilizes different interface, transport, or data packaging standards. Connecting a registry with certified health IT is cost prohibitive and many EHR vendors have not yet achieved interoperability with these systems given the conflicting priority of implementing other complex MU requirements. While there are efforts to mitigate these issues, widespread harmonization between registry, states, and health IT vendors will take time. In fact, we note that ONC's 2015 proposal does not address certification criteria for CDRs. We feel this is because ONC understands the registry community is varied with respect to capabilities and health IT maturity. **We therefore suggest ONC further review the capabilities of CDRs and work with other stakeholders to help develop a privately-led testing process that could be used to evaluate both CDR and PHA conformance to standards.** A program of

this type could benefit both health IT developers and registries by providing a live testing environment for standards refinement.

Quality Reporting

The AMA appreciates CMS' effort to attempt to align MU clinical quality requirements with PQRS by addressing future quality reporting requirements in the Medicare Physician Fee Schedule. However, we are concerned with vendors' ability to meet the growing complexity of quality measures, especially as the Merit-Based Incentive Payment System (MIPS) is implemented. As we move away from strictly process measures to outcomes, resource use, patient reported and appropriate use measures, a process is needed to ensure vendors update their systems to incorporate the new data elements, as well as assurances that clinical quality measures (CQMs) can be exchanged, captured, and transmitted within the EHR. **Given these challenges, we are concerned with CMS' proposal to move away from attestation to electronic reporting of CQMs by 2018. We urge CMS not to move forward with its MU Stage 3 proposal until the below health IT infrastructure challenges are resolved and continue to request more flexibility with meeting CQM requirements. Existing quality challenges include:**

- 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;
- Deficient CMS infrastructure to accept electronic transmission of measures (the only way for CMS to accept electronic CQMs (eCQM) is through electronic generation of files);
- Reliance on demographic data that are often not needed for clinical diagnosis and are often housed in the practice management system (PMS), which makes data collection difficult and costly;
- Obstacles for physicians meeting Clinical Decision Support since it is tied to MU quality requirements;
- Module certification for registries to report CQMs; and
- Require CQMs to be part of the MU program.

We are supportive of CMS' proposal to require vendors to certify to all eCQMs that are in the eligible provider selection list. Without an assurance that vendors will have to certify against the entire eCQM list, physicians will be on the hook to report on measures that are not the most clinically relevant or claim an exclusion and report separately to satisfy other CMS physician quality programs. For many specialty areas, there might not be a business case for vendors to update their systems with the relevant specialty specific measures due to the specialty being low volume and/or a small share of a vendor's market. Keep in mind, physicians who do not comply with quality requirements face a penalty or do not have the option to qualify for a bonus under MIPS. Therefore, physicians and patients should be assured they have the tools to assist with care, especially if CMS moves forward with its proposal to require electronic reporting by 2018.

Use Case & Cornerstone Prioritization

The AMA recognizes there must be a supportive business case to drive use and innovation as well as a solid infrastructure upon which to build meaningful information exchange. **The AMA believes the best way to advance interoperability is to prioritize cornerstone issues that are fundamental to information exchange and to focus on high value use cases.** We believe the four main interoperability cornerstones are: clinical data definitions and functional standards; provider directories; patient matching; and health IT security. We also believe that ONC should work with the industry to coalesce around a discrete and limited set of high value use cases, including closing the provider-to-provider referral loop. We have provided extensive detail in our Interoperability Roadmap feedback and urge ONC to consider those concepts as you review this letter. We fear that if the industry attempts to accomplish too much too fast—especially before resolving the aforementioned cornerstone issues—that interoperability efforts will be hindered rather than be advanced. **The AMA believes improving health IT and functional interoperability relies on these fundamental building blocks and should be prioritized by the Administration before adding new certification and other programmatic requirements.**

We strongly support ONC's intent in the proposed rule to drive the development of patient matching and provider directories. These are key resources that must be widely-available by health IT vendors, health care organizations, and health information service providers before robust and seamless interoperability can take place. The AMA is a co-founder of both Healtheway and Carequality and plays an active role in their work to advance patient and resource matching, provider directories, interoperability testing, and data sharing network governance and trust. We believe these efforts, along with efforts from CommonWell and the Argonaut Project, are making great strides independently of federal regulation. For this work to continue, and for others in the health IT community to contribute and participate in pilot projects, **the AMA believes the level of federal regulation, both in the form of reporting programs and certification requirements must be relaxed to allow natural market forces and supportive business cases to develop and evolve.**

Conclusion

The AMA appreciates the opportunity to offer our comments and recommendations and looks forward to working collaboratively to address the health IT certification concerns we outlined above. If we can be of any further assistance, please contact Matt Reid, Senior Health Information Technology Consultant, Federal Affairs, at 202-789-7419 or matt.reid@ama-assn.org.

Sincerely,

James L. Madara, MD

Enclosure

Office of the National Coordinator for Health IT
Proposed Rule Public Comment Template

2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications

Preface

This document is meant to provide the public with a simple and organized way to submit comments on the proposed certification criteria and modifications to the ONC Health IT Certification Program, and respond to specific questions posed in the preamble of the proposed rule, which is published in the *Federal Register* at 80 FR 16804. 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 modifications to the ONC Health IT Certification Program, 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 modifications to the ONC Health IT Certification Program. 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 various care and practice settings. It would also establish the capabilities and specify the related standards and implementation specifications that Certified Electronic Health Record Technology (CEHRT) would need to include, at a minimum, to support the achievement of meaningful use (MU) by providers under the CMS Medicare and Medicaid EHR Incentive Programs.

The following tables align with the presentation of the proposed certification criteria and modifications to the ONC Health IT Certification Program in the preamble of the proposed rule. The tables specify where the proposed 2015 Edition health IT certification criterion or criteria would be included in § 170.315. The tables also specify the proposed MU Stage 3 objective that the proposed 2015 Edition health IT certification criterion or criteria and associated standards and implementation specifications would 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. This field can be expanded as necessary for commenting.

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/#!documentDetail;D=HHS_FRDOC_0001-0572.

Proposed 2015 Edition Electronic Health Record (EHR) Certification Criteria, 2015 Edition Base EHR Definition, and ONC Health IT Certification Program Modifications

A. Provisions of the Proposed Rule affecting Standards, Implementation Specifications, Certification Criteria, and Definitions

§ 170.315(a)(1) Computerized provider order entry – medications
Included in 2015 Edition Base EHR Definition? Yes, as an alternative to § 170.315(a)(2) or (3)
Stage 3 MU Objective Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.
2015 Edition Health IT Certification Criterion (1) Computerized provider order entry – medications. Technology must enable a user to record, change, and access medication orders.
Preamble FR Citation: 80 FR 16814 **Specific questions in preamble?** *Yes*
Public Comment Field: The AMA agrees with the adoption of a criterion specific to medication ordering. Given the lack of standards for CPOE medication ordering, we concur that it is appropriate to maintain the 2014 criterion and refrain from referencing standards or implementation specifications.

§ 170.315(a)(2) Computerized provider order entry – laboratory
Included in 2015 Edition Base EHR Definition? Yes, as an alternative to § 170.315(a)(1) or (3)
Stage 3 MU Objective Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.

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

2015 Edition Health IT Certification Criterion

(2) Computerized provider order entry – laboratory.
- (i) Technology must enable a user to record, change, and access laboratory orders.
- (ii) Technology must be able to receive and incorporate a new or updated laboratory order compendium in accordance with the standard specified in § 170.205(l)(2) and, at a minimum, the version of the standard in § 170.207(c)(3).
- (iii) Ambulatory setting only. Technology must enable a user to create laboratory orders for electronic transmission in accordance with the standard specified in § 170.205(l)(1) and, at a minimum, the version of the standard in § 170.207(c)(3).

Preamble FR Citation: 80 FR 16814 **Specific questions in preamble?** *Yes*

Public Comment Field:

Click here to enter comments on § 170.315(a)(2) Computerized provider order entry – laboratory.

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

Included in 2015 Edition Base EHR Definition?

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

Stage 3 MU Objective

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

2015 Edition Health IT Certification Criterion

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

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

Public Comment Field:

Click here to enter comments on § 170.315(a)(3) Computerized provider order entry – diagnostic imaging

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

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

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

2015 Edition Health IT Certification Criterion

(4) Drug-drug, drug-allergy interaction checks for CPOE.
- (i) Interventions. Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list.
- (ii) Adjustments.
  - (A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.
  - (B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.
- (iii) Interaction check response documentation.
  - (A) Technology must be able to record at least one action taken and by whom in response to drug-drug or drug-allergy interaction checks.
  - (B) Technology must be able to generate either a human readable display or human readable report of actions taken and by whom in response to drug-drug or drug-allergy interaction checks.

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

Public Comment Field:

The AMA acknowledges the important role that DD/DAI CPOE interventions can play in protecting patient safety and agree with the continued inclusion of this criterion. We, however, urge caution in the proposed additional requirement for a health IT module to be able to record information regarding and generate reports indicating what actions were taken, and by whom, in response to DD/DAI checks. As indicated in the proposed rule, there is currently no consensus or standard for characterizing the severity of DD/DAI interactions. As such, there can be considerable variability in the clinical relevance and importance of the DD/DAI checks with which a physician is presented when ordering medications. CPOE systems with a large number of clinically insignificant DD/DAI notifications force physicians to respond to a barrage of alerts before being permitted to order medications. While the proposed rule suggests that DD/DAI action reports could assist with quality improvement and patient safety, physicians will undoubtedly be concerned that this information could be pulled in discovery for medical malpractice suits. With the knowledge that their response to every DD/DAI alert could later be questioned and analyzed, the efficiency of CPOE medication ordering will be reduced, as physicians may spend unnecessary time evaluating DD/DAI checks of low severity/limited clinical importance and providing a rationale for the action taken in response to the alerts to protect themselves against malpractice charges. Given the potential additional burdens that recording and reporting actions taken in response to DD/DAI could place upon physicians, we strongly recommend that this requirement not be adopted. If ONC does proceed with this requirement, we urge that user actions taken for DD/DAI alerts only be recorded for the small subset of DD/DAI interventions with the highest patient safety concerns. However, as previously indicated, the lack of consensus in characterizing DD/DAI severity will make it difficult to establish the subset of alerts to which this requirement would apply.

§ 170.315(a)(5) Demographics
Included in 2015 Edition Base EHR Definition? Yes
Stage 3 MU Objective N/A
2015 Edition Health IT Certification Criterion (5) Demographics. (i) Enable a user to record, change, and access patient demographic data including preferred language, sex, race, ethnicity, and date of birth. (A) Race and ethnicity. (1) Enable each one of a patient's races to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify race. (2) Enable each one of a patient's ethnicities to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify ethnicity. (3) Aggregate each one of the patient's races and ethnicities recorded in accordance with paragraphs (a)(5)(i)(A)(1) and (2) of this section to the categories in the standard specified in § 170.207(f)(1). (B) Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g)(2) and whether a patient declines to specify a preferred language. (C) Enable sex to be recorded in accordance with the standard specified in § 170.207(n)(1). (ii) Inpatient setting only. Enable a user to record, change, and access the preliminary cause of death and date of death in the event of a mortality.
Preamble FR Citation: 80 FR 16816 **Specific questions in preamble?** *No*

§ 170.315(a)(5) Demographics

Public Comment Field:

AMA commends the ONC for expanding the current requirements on race and ethnicity data. Health IT modules that are capable of recording multiple race and ethnicities in the "Race and Ethnicity – CDC" code system in the PHIN VADS—as well as aggregating each one of the patient's races and ethnicities to categories in the OMB standards for race and ethnicity—will support the standardization of collection for these key demographic areas. We support ONC's proposed rule that "Race and Ethnicity – CDC" code system in PHIN VADS (at minimum, Release 3.3.9) and the OMB standard become the race and ethnicity standards under the "Common Clinical Data Set" definition for certification to the 2015 edition. Additionally, we support ONC's proposed adoption of the Internet Engineering Task Force (IETF) Request for Comment 5646 standard for preferred language.

These proposals will enhance health care providers' ability to collect valid and reliable data on the demographic characteristics of patients receiving care, collect valid and reliable data on the quality of care delivered, and stratify the quality data by the relevant demographic subgroups, which can help reduce disparities in health care. We encourage health IT developers and providers to capture race and ethnicity in separate fields. We expect preferred language to be captured in a standard vocabulary code set such as PHIN-VADS.

However, it is not clear whether or not "Preliminary cause of death" will be tied to a standard (e.g., SNOMED CT, ICD9, and ICD10 Codes). If left in free text, this data element could be problematic when aggregation is performed.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

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

2015 Edition Health IT Certification Criterion

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Date and time of vital sign measurement or end time of vital sign measurement;
(2) The measuring or authoring-type source of the vital sign measurement;
(3) The patient's date of birth;
(4) The patient's sex in accordance with the standard specified in § 170.207(n)(1); and
(5) Optional. Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g).

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

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

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

(1) Date and time of vital sign measurement or end time of vital sign measurement;
(2) The measuring- or authoring-type source of the vital sign measurement;
(3) The patient's date of birth;
(4) The patient's sex in accordance with the standard specified in § 170.207(n)(1); and
(5) Optional. Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g).

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

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

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

(1) Date and time of vital sign measurement or end time of vital sign measurement;
(2) The measuring or authoring-type source of the vital sign measurement;
(3) The patient's date of birth;
(4) The patient's age in accordance with the standard specified in § 170.207(n)(1); and
(5) Optional. Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g).

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

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

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

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

Public Comment Field:

Click here to enter comments on § 170.315(a)(6) Vital signs, body mass index, and growth charts.

We support the use of LOINC terminology to standardize how vital signs are captured. The AMA, however, does not agree with the overly prescriptive approach to require specific LOINC codes to capture vital signs. Much like smoking status, we would encourage flexibility to allow for various clinical workflows. Similar to the history/pathway for smoking status, which needed to be scaled back, we envision the same problem will occur for vital signs.

With respect to blood pressure, the AMA agrees that mean blood pressure is valuable data to have recorded in the EHR, however, we encourage ONC to standardize the definition of this value. We also encourage that this data be captured as systolic and diastolic values and adhere to the same standards as blood pressure.

With regard to the metadata element "measuring-or authoring-type source of the vital sign measurement," we encourage the ONC to provide standard value sets for data entry.

For Source we recommend that the value set include:

- Office Blood Pressure Measurement;
- Self Measured Blood Pressure;
- 24 Hour Ambulatory Blood Pressure Measurement; and
- Out-of office Blood Pressure taken by a Healthcare Professional (pharmacist for example)

We also encourage the ONC to require the type of device, (if known), that took the blood pressure, including but not limited to:

- Automated Office Blood Pressure Device;
- Manual Office Blood Pressure Device;
- Home Blood Pressure device;
- Kiosk; and
- Wearable BP device

We encourage ONC to add criteria that attributes a finding, result, or decision (also known as treatment blood pressure) to a vital sign, specifically blood pressure. Multiple blood pressures can be taken during an office visit. Knowing the blood pressure that was used for treatment is valuable information for physicians to have in the treatment of hypertension. It should be noted that there is also a possible impact on clinical quality measurement (CQM). How CQM are calculated and reported should be further evaluated.

§ 170.315(a)(7) Problem list
Included in 2015 Edition Base EHR Definition? Yes
Stage 3 MU Objective N/A
2015 Edition Health IT Certification Criterion (7) Problem list. Enable a user to record, change, and access a patient's active problem list: (i) Ambulatory setting. Over multiple encounters in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4); or (ii) Inpatient setting. For the duration of an entire hospitalization in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4).
Preamble FR Citation: 80 FR 16819 **Specific questions in preamble?** *No*
Public Comment Field: Click here to enter comments on § 170.315(a)(7) Problem list.

§ 170.315(a)(8) Medication list
Included in 2015 Edition Base EHR Definition? Yes
Stage 3 MU Objective N/A
2015 Edition Health IT Certification Criterion (8) Medication list. Enable a user to record, change, and access a patient's active medication list as well as medication history: (i) Ambulatory setting. Over multiple encounters; or (ii) Inpatient setting. For the duration of an entire hospitalization.
Preamble FR Citation: 80 FR 16819 **Specific questions in preamble?** *No*
Public Comment Field: Click here to enter comments on § 170.315(a)(8) Medication list.

§ 170.315(a)(9) Medication allergy list
Included in 2015 Edition Base EHR Definition? Yes
Stage 3 MU Objective N/A

§ 170.315(a)(9) Medication allergy list

2015 Edition Health IT Certification Criterion

(9) Medication allergy list. Enable a user to record, change, and access a patient's active medication allergy list as well as medication allergy history:
(i) Ambulatory setting. Over multiple encounters; or
(ii) Inpatient setting. For the duration of an entire hospitalization.

Preamble FR Citation: 80 FR 16820 **Specific questions in preamble?** *No*

Public Comment Field:

We support the inclusion of pharmacogenomics variant causing the allergy if such information is known for the patient.

§ 170.315(a)(10) Clinical decision support

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

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

§ 170.315(a)(10) Clinical decision support

2015 Edition Health IT Certification Criterion

(10) Clinical decision support.

(i) Evidence-based decision support interventions. Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data:
- (A) Problem list;
- (B) Medication list;
- (C) Medication allergy list;
- (D) At least one demographic specified in paragraph (a)(5)(i) of this section;
- (E) Laboratory tests; and
- (F) Vital signs.

(ii) Linked referential clinical decision support.
- (A) Technology must be able to identify for a user diagnostic and therapeutic reference information in accordance with the standard and implementation specifications at § 170.204(b)(3) or (4).
- (B) For paragraph (a)(10)(ii)(A) of this section, technology must be able to identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (a)(10)(i)(A), (B), and (D) of this section.

(iii) Clinical decision support configuration.
- (A) Enable interventions and reference resources specified in paragraphs (a)(10)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role.
- (B) Technology must enable interventions to be:
  - (1) Based on the data referenced in paragraphs (a)(10)(i)(A) through (F) of this section.
  - (2) When a patient's medications, medication allergies, problems, and laboratory tests and values/results are incorporated from a transition of care/referral summary received and pursuant to paragraph (b)(2)(iii)(D) of this section.
  - (3) Ambulatory setting only. When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(4) of this section.

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

(v) Source attributes. Enable a user to review the attributes as indicated for all clinical decision support resources:
- (A) For evidence-based decision support interventions under paragraph (a)(10)(i) of this section:
  - (1) Bibliographic citation of the intervention (clinical research/guideline);
  - (2) Developer of the intervention (translation from clinical research/guideline);
  - (3) Funding source of the intervention development technical implementation; and
  - (4) Release and, if applicable, revision date(s) of the intervention or reference source.
- (B) For linked referential clinical decision support in paragraph (a)(10)(ii) of this section and drug-drug, drug-allergy interaction checks in paragraph (a)(4) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).

(vi) Intervention response documentation.
- (A) Technology must be able to record at least one action taken and by whom in response to clinical decision support interventions.
- (B) Technology must be able to generate either a human readable display or human readable report of actions taken and by whom in response to clinical decision support interventions.

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

§ 170.315(a)(10) Clinical decision support

Public Comment Field:

Regarding the proposal to require the Infobutton standard, the AMA is supportive of this certification requirement but recommends a modification. The AMA is aware of a large integrated delivery system in the Southwestern US that was unable to use the Infobutton functionality within their health IT system, even though it was present in their system. The EHR Vendor had a contractual relationship with one reference resource, and the health system had a contractual relationship with a different reference resource. Therefore, the health system could not use the Infobutton functionality and resorted to using other external resources.
The health system suggested that if the resources pinged by the Infobutton function could be contributed by the system or preferentially, this would facilitate use of the Infobutton standard within the EHR system. The AMA encourages ONC to consider a requirement that the Infobutton be connected to a reference resource of the end user's choice in the final rule.

§ 170.315(a)(11) Drug-formulary and preferred drug list checks

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

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

2015 Edition Health IT Certification Criterion

(11) Drug-formulary and preferred drug list checks. Technology must either meet paragraph (a)(11)(i) or (ii) of this section.
- (i) Drug formulary checks.
  - (A) Automatically check whether a drug formulary exists for a given patient and medication.
  - (B) Indicate for a user the last update of the drug formulary; and
  - (C) Receive and incorporate a formulary and benefit file in accordance with the standard specified in § 170.205(n)(1).
- (ii) Preferred drug list checks.
  - (A) Automatically check whether a preferred drug list exists for a given patient and medication.
  - (B) Indicate for a user the last update of the preferred drug list.

Preamble FR Citation: 80 FR 16821 **Specific questions in preamble?** *Yes*

§ 170.315(a)(11) Drug-formulary and preferred drug list checks

Public Comment Field:

The AMA strongly supports providing accurate, granular, and current information regarding patients' prescription drug coverage to physicians at the point of prescribing. Such data facilitate informed discussions between prescribers and patients regarding medication therapy choice and allow the prescriber to discover any concerns a patient may have regarding drug costs prior to sending a prescription to the pharmacy. Ensuring that a patient can afford the prescribed medication can significantly improve medication adherence and health outcomes.
We have overarching concerns regarding the quality and completeness of formulary data that are currently available to physicians in health IT modules. There is widespread industry acknowledgment that the formulary information presented to prescribers in their health IT modules is often incomplete at best, and dated and inaccurate in many cases. The NCPDP Formulary and Benefit Standard uses "flat files" to populate prescribers' health IT modules. As such, the information reported in this standard is static, at risk for being out of date, and unable to match the quality and accuracy of data that would be provided in a real-time pharmacy benefit check. Additionally, many pharmacy payers supply general formulary data (e.g., at a group level) instead of providing the granular, patient-specific data needed to make well-informed prescribing decisions at the point of care. Payers' formulary files also tend to be incomplete; for example, the prior authorization indicator is sparsely populated in health IT modules today, which renders physicians unable to determine coverage restrictions at the point of prescribing. Until physicians are confident of the completeness and accuracy of the formulary data available in their health IT modules, this certification criterion will continue to be a "checkbox" that offers little real utility or value to physicians.

Given the lack of a current standard for real-time pharmacy benefit inquiries, the utility of the NCPDP Formulary and Benefit standard should be maximized and enhanced. We recommend that health IT modules receive and incorporate formulary data using the NCPDP Formulary and Benefit Standard v3.0 and agree that the date the formulary information was last updated should be clearly displayed to the prescriber. Additionally, payers should be strongly encouraged to ensure the completeness and accuracy of the formulary files provided to health IT vendors. We acknowledge that the Formulary and Benefit Standard has been modified and improved since the release of v3.0 in December 2010, to include the addition of an expiration date in formulary files. However, given that Medicare Part D regulations require adoption of v3.0 effective March 1, 2015, we believe that it would be disruptive and burdensome to require a newer version of the standard for health IT module certification, as providers and vendors would be required to support both versions in order to comply with different federal regulations. We urge standard version harmonization across all federal programs.

As we previously indicated, the industry is in critical need of a real-time pharmacy benefit check transaction to support physicians in optimal medication selection at the point of prescribing. NCPDP's Real Time Pharmacy Benefits Inquiry Task Group is currently determining the business needs for this transaction and has identified patient pay, therapeutic alternatives, and coverage restrictions as the three major informational needs in a real-time pharmacy benefit check. Because the task group is in the early stages of its work, we believe that it is premature to recommend a particular standard to be used for real-time pharmacy benefit checks. However, we recommend that the industry strongly consider the ability of existing transactions, such as the

§ 170.315(a)(12) Smoking status

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

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

Public Comment Field:

While there are no guidelines to support inclusion in the eCQM, the AMA suggests proactively capturing e-cigarette usage in health IT systems to promote data capture.
The AMA agrees with the updates to smoking status and the recognition of the need to be more flexible in how health IT systems capture smoking status. Any certification criteria that overlaps the clinical concepts and/or value sets already in use within the current eCQMs need to be cross-referenced to ensure alignment. In addition, the certification rule is limited to smoking and does not include smokeless tobacco whereas the eMeasure is broader. We therefor encourage broadening the certification requirements to align with the eMeasure.

§ 170.315(a)(13) Image results

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

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

Public Comment Field:

Click here to enter comments on § 170.315(a)(13) Image results.

§ 170.315(a)(14) Family health history

Included in 2015 Edition Base EHR Definition?

No, but proposed for the EHR Incentive Programs CEHRT definition

§ 170.315(a)(14) Family health history

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(14) Family health history. Enable a user to record, change, and access a patient's family health history in accordance with the familial concepts or expressions included in, at a minimum, the version of the standard in § 170.207(a)(4).

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

Public Comment Field:

We support the recommendation for technology to enable a user to record, change, and access a patient's family health history electronically according to, at a minimum, the concepts or expressions for familial conditions.

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

Included in 2015 Edition Base EHR Definition?

No, but proposed for the EHR Incentive Programs CEHRT definition as an alternative to § 170.315(a)(14).

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(15) Family health history – pedigree. Technology must be able to create and incorporate a patient's family health history in accordance with the standard and implementation specification specified in § 170.205(m)(1).

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

Public Comment Field:

The AMA supports this proposal. Most physicians do not know how to draw a detailed pedigree. We believe that EHR systems could provide the tools to generate these for physicians and patients.

§ 170.315(a)(16) Patient list creation

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

§ 170.315(a)(16) Patient list creation

2015 Edition Health IT Certification Criterion

(16) Patient list creation. Enable a user to dynamically select, sort, access, and create patient lists by: date and time; and based on each one and at least one combination of the following data:
(i) Problems;
(ii) Medications;
(iii) Medication allergies;
(iv) At least one demographic specified in paragraph (a)(5)(i) of this section;
(v) Laboratory tests and values/results; and
(vi) Ambulatory setting only. Patient communication preferences.

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

Public Comment Field:

Click here to enter comments on §170.315(a)(16) Patient list creation

Because demographics are critical in creation and use of patient lists especially to reduce disparities in health care, the AMA recommends that the ONC require all demographic elements be included in this requirement.

Vital signs (e.g., weight, BMI and blood pressure) are also critical in the creation and usability of patient lists. For example, a physician might want to create a patient list of individuals that might be eligible to be referred to a recognized diabetes prevention program. In order to do this, a physician will need to use the following elements: problems (active and past), medications, age, race, lab results and BMI. We therefore encourage the ONC to include these values in the criteria.

We also encourage the ONC to consider adding Orders and Referrals. For example, a physician could create a patient list and refer patients to a recognized diabetes prevention program. That same physician could then want to follow-up with those patients. Also, a physician might want to refer additional patients who now qualify for the program but have not yet been referred.

Additionally, the responsible provider for overall long term care should be included to improve provider attribution, transitions of care, and care coordination.

Finally, we agree with having the functionality for patient list creation and support food and other types of allergies and adverse events in the creation of patient lists.

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

Included in 2015 Edition Base EHR Definition?

No

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

Stage 3 MU Objective

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

2015 Edition Health IT Certification Criterion

(17) Patient-specific education resources. Technology must be able to:
- (i) Identify patient-specific education resources based on data included in the patient's problem list and medication list in accordance with the standard (and implementation specifications) specified in § 170.204(b)(3) or (4); and
- (ii) Request that patient-specific education resources be identified in accordance with the standard in § 170.207(g)(2).

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

Public Comment Field:

Click here to enter comments on §170.315(a)(17) Patient-specific education resources

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(18) Electronic medication administration record.
- (i) In combination with an assistive technology that provides automated information on the "rights" specified in paragraphs (a)(18)(i)(A) through (E) of this section, enable a user to verify the following before administering medication(s):
  - (A) Right patient. The patient to whom the medication is to be administered matches the medication to be administered.
  - (B) Right medication. The medication to be administered matches the medication ordered for the patient.
  - (C) Right dose. The dose of the medication to be administered matches the dose of the medication ordered for the patient.
  - (D) Right route. The route of medication delivery matches the route specified in the medication order.
  - (E) Right time. The time that the medication was ordered to be administered compared to the current time.
- (ii) Right documentation. Record the time and date in accordance with the standard specified in § 170.210(g), and user identification when a medication is administered.

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

Public Comment Field:

Click here to enter comments on § 170.315(a)(18) Electronic medication administration record .

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

Included in 2015 Edition Base EHR Definition?

No, but proposed for the EHR Incentive Programs CEHRT definition

Stage 3 MU Objective

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

2015 Edition Health IT Certification Criterion

(19) Patient health information capture. Technology must be able to enable a user to:
- (i) Identify, record, and access patient health information documents;
- (ii) Reference and link to patient health information documents; and
- (iii) Record and access information directly shared by a patient.

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

Public Comment Field:

Click here to enter comments on § 170.315(a)(19) Patient health information capture.

§ 170.315(a)(20) Implantable device list

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(20) Implantable device list.
- (i) Enable a user to record, change, and access, a list of Unique Device Identifiers associated with a patient's Implantable Device(s).
- (ii) Parse the following data elements from a Unique Device Identifier:
  - (A) Device Identifier;
  - (B) Batch/lot number;
  - (C) Expiration date;
  - (D) Production date; and
  - (E) Serial number.
- (iii) Retrieve the "Device Description" attribute associated with a Unique Device Identifier in the Global Unique Device Identification Database.
- (iv) For each Unique Device Identifier in a patient's list of implantable devices, enable a user to access the following:
  - (A) The parsed data elements specified under paragraph (a)(20)(ii) of this section that are associated with the UDI; and
  - (B) The retrieved data element specified under paragraph (a)(20)(iii) of this section.

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

§ 170.315(a)(20) Implantable device list

Public Comment Field:

The AMA supports the additional capability of a health IT module to record, change, and access a list of unique device identifiers (UDIs) and make accessible to a user both the parsed and retrieved data. This will enable health IT to facilitate the widespread availability and use of UDIs to prevent device related adverse events, enhance clinical decision-making related to devices, improve the ability of clinicians to respond to device recalls and device-related safety information, and achieve other important benefits. Patient safety will only be enhanced if all health IT systems have this capability since, for example, an ambulatory practice may need device information about its patients even if the implant was placed elsewhere and is managed by other physicians. Also, as more procedures involving smaller devices are moving to office settings, the distinction of surgical or specific inpatient settings is artificial. Therefore, we do not support limiting this criterion to EHRs for surgical specialties or inpatient settings.
We agree that that incorporating UDIs in health IT is important and necessary to realize the significant promise of UDIs and FDA's UDI System to protect patient safety and improve health care quality and efficiency. Capturing UDIs in EHRs allows for linking the specific device information with related clinical information, which is critical for evaluating device performance. We believe that resources to capture UDIs should be focused on EHRs and clinical registries and not on other secondary data capture methods.

We agree with the proposed ability of a health IT module to parse the UDI into the various data elements. We also support the functionality of the EHR to pull in device description information from the Global Unique Device Identifier Database (GUDID).

We support the health IT module including the capability to change UDIs from a patient's implantable device list. This functionality would allow a user to delete erroneous or duplicative entries from a patient's implantable device list and update the list in the event that a device were removed from the patient, ensuring that patient information maintained and transferred is the most current.

We support the inclusion of UDI in the Common Clinical Data Set in order to facilitate the exchange of UDIs, which will increase the availability and reliability of patients' device information. We agree with the addition of new definitions for "Device Identifier," "Implantable Device," "Global Unique Device Identification Database (GUDID)," "Production Identifier," and "Unique Device Identifier."

We agree with the focus on the capabilities for the capture and exchange of UDI and not addressing "upstream" issues at this time.

§ 170.315(a)(21) Social, psychological, and behavioral data
Included in 2015 Edition Base EHR Definition? No
Stage 3 MU Objective N/A
2015 Edition Health IT Certification Criterion (21) Social, psychological, and behavioral data. Enable a user to record, change, and access, at a minimum, one of the following patient social, psychological, and behavioral data. (i) Sexual orientation. Enable sexual orientation to be recorded in accordance with the standard specified in § 170.207(o)(1) and whether a patient declines to specify sexual orientation. (ii) Gender identity. Enable gender identity to be recorded in accordance with the standard specified in § 170.207(o)(2) and whether a patient declines to specify gender identity. (iii) Financial resource strain. Enable financial resource strain to be recorded in accordance with the standard specified in § 170.207(o)(3) and whether a patient declines to specify financial resource strain. (iv) Education. Enable education to be recorded in accordance with the standard specified in § 170.207(o)(4) and whether a patient declines to specify education. (v) Stress. Enable stress to be recorded in accordance with the standard specified in § 170.207(o)(5) and whether a patient declines to specify stress. (vi) Depression. Enable depression to be recorded in accordance with the standard specified in § 170.207(o)(6) and whether a patient declines to specify stress. (vii) Physical activity. Enable physical activity to be recorded in accordance with the standard specified in § 170.207(o)(7) and whether a patient declines to specify physical activity. (viii) Alcohol use. Enable alcohol use to be recorded in accordance with the standard specified in § 170.207(o)(8) and whether a patient declines to specify alcohol use. (ix) Social connection and isolation. Enable social connection and isolation to be recorded in accordance the standard specified in § 170.207(o)(9) and whether a patient declines to specify social connection and isolation. (x) Exposure to violence (intimate partner violence). Enable exposure to violence (intimate partner violence) to be recorded in accordance with the standard specified in § 170.207(o)(10) and whether a patient declines to specify exposure to violence (intimate partner violence).
Preamble FR Citation: 80 FR 16826 **Specific questions in preamble?** *Yes, and also see requests for comment on work information (industry/occupation) data and U.S.uniformed/military service data*

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

Public Comment Field:

Workers' compensation claims submission has traditionally been an extremely manual, burdensome process for providers. Although some states do require support of eBilling for workers' compensation claims, the process is still heavily reliant on paper communications. Inclusion of a patient's industry and occupation data within a certified EHR could support the automation and streamlining of the workers' compensation claims process. Workers' compensation claims usually require extensive documentation of work-related information, including primary work activities and employment-related dates. Collection of these data within the EHR would facilitate electronic claims documentation and submission for workers' compensation and substantially reduce administrative burdens for physicians. We recommend a survey of workers' compensation documentation requirements across states to assist in the selection of industry and occupation data elements to be required in certified EHRs.

With respect to gender identity: "The preferred terminology for collecting sexual orientation and gender identity differs from the current SNOMED nomenclature" and suggests providers "always use the terminology that patients use to define themselves during verbal communication." (Cahill S et al. Plos One, 2014, 9(9), e107104) We believe that the term "transsexual" is outdated and should be changed to "transgender." If ONC cannot change "transsexual" we would like for ONC to add "transsexual" to the end of the choices. For example it should read "female-to-male transsexual gender". Ideally, it should read "transgender female-to-male."

§ 170.315(a)(22) Decision support – knowledge artifact

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(22) Decision support – knowledge artifact. Enable a user to send and receive clinical decision support knowledge artifacts in accordance with the standard specified in § 170.204(d)(1).

Preamble FR Citation: 80 FR 16830 **Specific questions in preamble?** *Yes*

§ 170.315(a)(22) Decision support – knowledge artifact

Public Comment Field:

The AMA supports the inclusion of Clinical Decision Support Knowledge Artifact as it will facilitate production and sharing of CDS and because it will align with the standards used to express clinical quality measures. However, the standards and infrastructure that support the CDS process are still being vetted within the HL7 community. As a result, the standards and infrastructure are not mature enough and need to evolve prior to requiring systems to certify against the standards.

§ 170.315(a)(23) Decision support – service

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(23) Decision support – service. Enable a user to send and receive electronic clinical guidance in accordance with the standard specified in § 170.204(e)(1).

Preamble FR Citation: 80 FR 16831 **Specific questions in preamble?** *Yes*

Public Comment Field:

Click here to enter comments on § 170.315(a)(23) Decision support – service.

§ 170.315(b)(1) Transitions of care

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

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

2015 Edition Health IT Certification Criterion

(1) Transitions of care.
- (i) Send and receive via edge protocol. Technology must be able to:
  - (A) Send transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(d); and
  - (B) Receive transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(d) from a service that has implemented the standard specified in §170.202(a).
  - (C) XDM processing. Receive and make available the contents of a XDM package formatted in accordance with the standard adopted in § 170.205(p)(1) if the technology is also being certified

§ 170.315(b)(1) Transitions of care

using an SMTP-based edge protocol.

(ii) Validate and display.

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

(1) Parse each of the document types formatted according to the following document templates: CCD; Consultation Note; History and Physical; Progress Note; Care Plan; Transfer Summary; Referral Note, and Discharge Summary.

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

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

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

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

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

(C) Section views. Allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary received and formatted in accordance with either of the standards adopted in § 170.205(a)(3) and (4).

§ 170.315(b)(1) Transitions of care

2015 Edition Health IT Certification Criterion (b)(1) Transitions of care, continued

(iii) Create.
- (A) Enable a user to create a transition of care/referral summary:
  - (1) Formatted according to the standards adopted in § 170.205(a)(3);
  - (2) Formatted according to the standards adopted in § 170.205(a)(4); and
  - (3) Includes, at a minimum, the Common Clinical Data Set and the following data expressed, where applicable, according to the specified standard(s):
    - (i) Encounter diagnoses. The standard specified in § 170.207(i) or, at a minimum, the version of the standard specified §170.207(a)(4);
    - (ii) Cognitive status;
    - (iii) Functional status;
    - (iv) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information; and
    - (v) Inpatient setting only. Discharge instructions.
- (B) Patient matching data quality. Technology must be capable of creating a transition of care/referral summary that includes the following data and, where applicable, represent such data according to the additional constraints specified below:
  - (1) Data. first name, last name, maiden name, middle name (including middle initial), suffix, date of birth, place of birth, current address, historical address, phone number, and sex.
  - (2) Constraint. Represent last/family name according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0.
  - (3) Constraint. Represent suffix according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0 (JR, SR, I, II, III, IV, V, RN, MD, PHD, ESQ). If no suffix exists, the field should be entered as null.
  - (4) Constraint. Represent the year, month and date of birth are required fields while hour, minute and second should be optional fields. If hour, minute and second are provided then either time zone offset should be included unless place of birth (city, region, country) is provided; in latter local time is assumed. If date of birth is unknown, the field should be marked as null.
  - (5) Constraint. Represent phone number (home, business, cell) in the ITU format specified in ITU-T E.123 and ITU-T E.164. If multiple phone numbers are present, all should be included.
  - (6) Constraint. Represent sex in accordance with the standard adopted at § 170.207(n)(1).

Preamble FR Citation: 80 FR 16831 **Specific questions in preamble?** *Yes*

Public Comment Field:

The AMA supports the idea that the data elements related to transitions of care should be more detailed, as well as standardized and interoperable. We also encourage the use of standards, when mature, in the transitions of care.

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

Included in 2015 Edition Base EHR Definition?

No

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

Stage 3 MU Objective

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

2015 Edition Health IT Certification Criterion

(2) Clinical information reconciliation and incorporation.

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

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

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

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

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

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

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

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

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

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

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

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

Public Comment Field:

Click here to enter text § 170.315(b)(2) Clinical information reconciliation and incorporation.

§ 170.315(b)(3) Electronic prescribing

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

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

§ 170.315(b)(3) Electronic prescribing

2015 Edition Health IT Certification Criterion

(3) Electronic prescribing.

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

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

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

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

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

§ 170.315(b)(3) Electronic prescribing

Public Comment Field:

e-Prescribing Transactions and Segments

The AMA supports improved functionalities of e-prescribing systems to facilitate increased electronic communications between prescribers and pharmacies. We agree that adoption of the NCPDP SCRIPT v10.6 RXCHG, CANRX, REFREQ, RXFILL, and RXHREQ could facilitate improvements in workflow efficiencies and patient outcomes. In particular, we believe that the RXFILL transaction could improve patient care and medication adherence by informing the prescriber of whether or not a patient has picked up a prescription.

However, as noted in the proposed rule, adoption of these transactions is currently inconsistent across the industry. While requiring health IT modules to demonstrate the ability to send and receive these new SCRIPT transactions would support provider adoption of the transactions, there is currently no comparable requirement for pharmacy implementation of these transactions. Because the value of the transactions lies in bidirectional communication between prescribers and pharmacies, we believe that it is premature to require support of these new transactions for health IT module certification. Without assurance or guarantee that pharmacies will significantly increase adoption of these transactions, there will be no benefit or advantage to physicians in requiring the health IT module support of these additional SCRIPT functionalities. We urge ONC to further explore the barriers towards widespread adoption of these transactions with a variety of industry stakeholders including prescribers, health IT module vendors, pharmacies, and pharmacy technology vendors, and facilitate collaboration and synchronized implementation across both prescriber and pharmacy systems.

Structured SIG

We recognize the potential of the structured and codified Sig to streamline and standardize prescriber-pharmacist communication, reduce confusion, and improve patient safety. However, we recommend delaying any certification criterion related to the structured and codified Sig until current constraints in the SCRIPT standard can be addressed. As noted in the proposed rule, limitations in the structured and codified Sig within NCPDP SCRIPT v10.6 prevent communication of complex and/or multi-step instructions. NCPDP SCRIPT v10.6 limits the Sig field to 140 characters; such field-size restrictions can lead prescribers to enter conflicting messages in the Sig and free text (Notes) field, which results in confusion at the pharmacy and the inevitable follow-up with prescribers. While later versions of the standard expand the field length, the utility of the structured and codified Sig will be limited until these newer versions of SCRIPT are adopted.

If ONC moves forward with implementing certification criterion related to the structured and codified SIG, we recommend adoption of the subset of codified SIG instructions included in the NCPDP SCRIPT Implementation Recommendations Version 1.29, rather than the full set of codified instructions. This smaller-scale implementation, which would be limited to common ambulatory prescription instructions, will increase the likelihood of successful adoption of the structured SIG. It will also allow any potential issues to be identified and addressed within a smaller and simpler subset of SIG instructions.

Medication Dosing

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(4) Incorporate laboratory tests and values/results.
- (i) Receive results.
  - (A) Ambulatory setting only.
    - (1) Receive and incorporate clinical laboratory tests and values/results in accordance with the standard specified in § 170.205(j)(2); and, at a minimum, the version of the standard specified in § 170.207(c)(3).
    - (2) Display the tests and values/results received in human readable format.
  - (B) Inpatient setting only. Receive clinical laboratory tests and values/results in a structured format and display such tests and values/results in human readable format.
- (ii) Display the test report information:
  - (A) Specified in 42 CFR 493.1291(a)(1) through (3) and (c)(1) through (7);
  - (B) Related to reference intervals or normal values as specified in 42 CFR 493.1291(d);
  - (C) For alerts and delays as specified in 42 CFR 493.1291(g) and (h); and
  - (D) For corrected reports as specified in 42 CFR 493.1291(k)(2).
- (iii) Attribute, associate, or link a laboratory test and value/result with a laboratory order or patient record.

Preamble FR Citation: 80 FR 16837 **Specific questions in preamble?** *Yes*

Public Comment Field:

The AMA supports this proposal and believes incorporated lab data should be searchable. Currently many lab reports are incorporated into EHR as pdf documents, so the data is not easily located. This change could improve the utility of lab and test results.

§ 170.315(b)(5) Transmission of laboratory test reports

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(5) Transmission of laboratory test reports. Technology must be able to electronically create laboratory test reports for electronic transmission in accordance with the standard specified in in § 170.205(j)(2) and, at a minimum, the version of the standard specified in § 170.207(c)(3).

Preamble FR Citation: 80 FR 16838 **Specific questions in preamble?** *No*

§ 170.315(b)(5) Transmission of laboratory test reports
Public Comment Field: As mentioned above, the AMA supports this proposal and believes lab data should be searchable.

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

§ 170.315(b)(6) Data portability

2015 Edition Health IT Certification Criterion

(6) Data portability.

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

(ii) Document creation configuration.

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

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

(2) Inpatient setting only. Discharge Summary.

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

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

(2) Cognitive status;

(3) Functional status;

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

(5) Inpatient setting only. Discharge instructions.

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

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

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

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

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

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

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

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

Public Comment Field:

The AMA supports the intent of this criterion. However, as proposed, the "data portability" requirement does not fully address the use case of extracting all patient information (including billing and A/R) out of an EHR with the intent to migrate between two vendor's products. We believe the criterion should be renamed "Bulk Export via C-CDA" as this more accurately reflects the function and provides a clearer description to the end user.

§ 170.315(b)(7) Data segmentation for privacy – send
Included in 2015 Edition Base EHR Definition? No
Stage 3 MU Objective N/A
2015 Edition Health IT Certification Criterion (7) Data segmentation for privacy – send. Technology must enable a user to create a summary record formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that is tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1).
Preamble FR Citation: 80 FR 16841 (also see 80 FR 16840) **Specific questions in preamble?** *No*
Public Comment Field: Click here to enter comments on § 170.315(b)(7) Data segmentation for privacy – send.

§ 170.315(b)(8) Data segmentation for privacy – receive
Included in 2015 Edition Base EHR Definition? No
Stage 3 MU Objective N/A
2015 Edition Health IT Certification Criterion (8) Data segmentation for privacy – receive. Technology must enable a user to: (i) Receive a summary record that is tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1); (ii) Apply document-level tagging and sequester the document from other documents received; and (iii) View the restricted document (or data), without incorporating the document (or data).
Preamble FR Citation: 80 FR 16842 (also see 80 FR 16840) **Specific questions in preamble?** *No*
Public Comment Field: Click here to enter comments on § 170.315(b(8))Data segmentation for privacy – receive.

§ 170.315(b)(9) Care plan
Included in 2015 Edition Base EHR Definition? No
Stage 3 MU Objective N/A
2015 Edition Health IT Certification Criterion (9) Care plan. Technology must enable a user to record, change, access, create, and receive care plan information in accordance with the Care Plan document template in the standard adopted in § 170.205(a)(4).
Preamble FR Citation: 80 FR 16842 **Specific questions in preamble?** *Yes*

§ 170.315(b)(9) Care plan

Public Comment Field:

The AMA fully supports the coordination of care across care sites, providers, and episodes of care.
With regard to the question: should we require the optional "Health Status Evaluations and Outcomes Section" and "Interventions Section (V2)" as part of certification—the AMA believes this level of standardization will increase the interoperability of EHRs.

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

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(1) Clinical quality measures – record and export.
- (i) Record. For each and every CQM for which the technology is presented for certification, the technology must be able to record all of the data that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of "patient reason," "system reason," or "medical reason."
- (ii) Export. A user must be able to export a data file formatted in accordance with the standard specified at § 170.205(h) for one or multiple patients that includes all of the data captured for each and every CQM to which technology was certified under paragraph (c)(1)(i) of this section. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.

Preamble FR Citation: 80 FR 16842 **Specific questions in preamble?** *Yes*

Public Comment Field:

The ability to export CQM data at any time would certainly be beneficial but vendors may face difficulties in because of the potential complexities of this type of functionality and any necessary add-ins. Cost for systems that enable this functionality may also be a barrier for the system user.

While the AMA supports the direction to align CQM and CDS standards, we are concerned a requirement to use these standards in a rule may be premature. We recommend ONC adopt a phased approach to requiring these new standards.

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

Included in 2015 Edition Base EHR Definition?

No, but proposed for the EHR Incentive Programs CEHRT definition

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(2) Clinical quality measures – import and calculate.

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

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

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

Public Comment Field:

User Ability to Import CQM Data: The ability to import CQM data at any time would certainly be beneficial, but vendors may face difficulties because of the potential complexities of this type of functionality.

Import of CQM Data: IT systems demonstrating ability to import data is a good start but this proposal should go further to say "import and understand" CQM data. Within the import of CQM data, there seems to be a strong preference towards eliminating the exemption for health IT modules who cannot demonstrate the data import capability. However, ONC also states that they agree there could be instances where a provider using one technology to record CQM data could not subsequently import the data into a different technology. The AMA believes ONC's proposal is ambiguous and we suggest adding explicit language in the final rule on whether the exemption is being proposed for removal.

Testing of Import and Calculate Functionalities: The ability to test a larger number of cases is likely to be a useful feature. The specific amount of test cases should not be a fixed number but derived based on the complexity of the CQM and the minimum number required to provide adequate "coverage" of the measure. ONC may wish to consider devising a formula by individual sites to determine the minimum number of test cases required for the calculation.

Additional clarification is needed to determine count of test cases and approach to CQM calculation.
The description on CQM import data needs clarification—data will be imported into what/where? Is it an import of the specification into the health IT system? Is it an import of quality measure results? The AMA recommends incorporating a definition of CQM data. Without this definition, we are unable to provide a clear recommendation.

Reserved for § 170.315(c)(3) Clinical quality measures – report

Included in 2015 Edition Base EHR Definition?

No, but proposed for the EHR Incentive Programs CEHRT definition

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(3) [Reserved]

Preamble FR Citation: 80 FR 16844 **Specific questions in preamble?** *No*

Public Comment Field:

Click here to enter comments on Reserved for § 170.315(c)(3) Clinical quality measures – report.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(4) Clinical quality measures – filter.
- (i) Technology must be able to record the data listed in paragraph (c)(4)(iii) of this section in accordance with the identified standards, where specified.
- (ii) Technology must be able to filter CQM results at the patient and aggregate levels by each one and any combination of the data listed in paragraph (c)(4)(iii) of this section.
- (iii) Data.
  - (A) TIN;
  - (B) NPI;
  - (C) Provider type;
  - (D) Patient insurance;
  - (E) Patient age;
  - (F) Patient sex in accordance with, at a minimum, the version of the standard specified in § 170.207(n)(1);
  - (G) Patient race and ethnicity in accordance with, at a minimum, the version of the standard specified in § 170.207(f)(2);
  - (H) Patient problem list data in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4); and
  - (I) Practice site address.

Preamble FR Citation: 80 FR 16844 **Specific questions in preamble?** *Yes*

Public Comment Field:

Click here to enter comments on § 170.315(c)(4) Clinical quality measures – filter.

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

Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

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

Public Comment Field:

Click here to enter comments on § 170.315(d)(1) Authentication, access control, and authorization.

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

Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

MU Objective

N/A

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

2015 Edition Health IT Certification Criterion

(2) Auditable events and tamper-resistance.

(i) Record actions. Technology must be able to:

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

(B) Record the audit log status (enabled or disabled) in accordance with the standard specified in § 170.210(e)(2) unless it cannot be disabled by any user; and

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

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

(iii) When disabling the audit log is permitted. For each capability specified in paragraphs (d)(2)(i)(A) through (C) of this section that technology permits to be disabled, the ability to do so must be restricted to a limited set of users.

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

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

Preamble FR Citation: 80 FR 16846 **Specific questions in preamble?** *Yes*

Public Comment Field:

Click here to enter comments on § 170.315(d)(2) Auditable events and tamper-resistance.

§ 170.315(d)(3) Audit report(s)

Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16847 **Specific questions in preamble?** *No*

Public Comment Field:

Click here to enter comments on § 170.315(d)(3) Audit report(s)

§ 170.315(d)(4) Amendments

Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

§ 170.315(d)(4) Amendments

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(4) Amendments. Enable a user to select the record affected by a patient's request for amendment and perform the capabilities specified in paragraph (d)(4)(i) or (ii) of this section.
- (i) Accepted amendment. For an accepted amendment, append the amendment to the affected record or include a link that indicates the amendment's location.
- (ii) Denied amendment. For a denied amendment, at a minimum, append the request and denial of the request to the affected record or include a link that indicates this information's location.

Preamble FR Citation: 80 FR 16847 **Specific questions in preamble?** *No*

Public Comment Field:

Click here to enter comments on § 170.315(d)(4) Amendments.

§ 170.315(d)(5) Automatic access time-out

Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(5) Automatic access time-out.
- (i) Automatically stop user access to health information after a predetermined period of inactivity.
- (ii) Require user authentication in order to resume or regain the access that was stopped.

Preamble FR Citation: 80 FR 16847 **Specific questions in preamble?** *Yes*

Public Comment Field:

Click here to enter comments on § 170.315(d)(5) Automatic access time-out.

§ 170.315(d)(6) Emergency access

Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16847 **Specific questions in preamble?** *No*

§ 170.315(d)(6) Emergency access

Public Comment Field:

Click here to enter comments on § 170.315(d)(6) Emergency access.

§ 170.315(d)(7) End-user device encryption

Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

- (i) Technology that is designed to locally store electronic health information on end-user devices must encrypt the electronic health information stored on such devices after use of the technology on those devices stops.
  - (A) Electronic health information that is stored must be encrypted in accordance with the standard specified in § 170.210(a)(3);
  - (B) Default setting. Technology must be set by default to perform this capability and, unless this configuration cannot be disabled by any user, the ability to change the configuration must be restricted to a limited set of identified users.
- (ii) Technology is designed to prevent electronic health information from being locally stored on end-user devices after use of the technology on those devices stops.

Preamble FR Citation: 80 FR 16847 **Specific questions in preamble?** *Yes*

Public Comment Field:

Click here to enter comments on § 170.315(d)(7) End-user device encryption.

§ 170.315(d)(8) Integrity

Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(8) Integrity.

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

Preamble FR Citation: 80 FR 16847 **Specific questions in preamble?** *Yes*

§ 170.315(d)(8) Integrity

Public Comment Field:

Click here to enter comments on § 170.315(d)(8) Integrity.

§ 170.315(d)(9) Accounting of disclosures

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16848 **Specific questions in preamble?** *No*

Public Comment Field:

Click here to enter comments on § 170.315(d)(9) Accounting of disclosures

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objectives

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

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

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

2015 Edition Health IT Certification Criterion

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

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

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

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

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

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

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

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

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

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

(5) Diagnostic image report(s).

(B) Download.

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

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

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

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

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

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

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

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

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

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

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

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

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

2015 Edition Health IT Certification Criterion, §170.315(e)(1) View, download, and transmit to 3rd party, continued

(i) Application access. Patients (and their authorized representatives) must be able to use an application that can interact with the following capabilities. Additionally, the following technical outcomes and conditions must be met through the demonstration of an application programming interface (API) that can respond to requests from other applications for data specified within the Common Clinical Data Set.

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

(B) Patient selection. The API must include a means for the application to query for an ID or other token of a patient's record in order to subsequently execute data requests for that record in accordance with (e)(1)(iii)(C) of this section.

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

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

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

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

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

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

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

Preamble FR Citation: 80 FR 16848 **Specific questions in preamble?** *Yes*

Public Comment Field:

Click here to enter comments on § 170.315(e)(1) View, download, and transmit to a third party

§ 170.315(e)(2) Secure messaging

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

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

§ 170.315(e)(2) Secure messaging

2015 Edition Health IT Certification Criterion

(2) Secure messaging. Enable a user to send messages to, and receive messages from, a patient in a manner that ensures:
- (i) Both the patient (or authorized representative) and technology user are authenticated; and
- (ii) The message content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

Preamble FR Citation: 80 FR 16850 **Specific questions in preamble?** *No*

Public Comment Field:

Click here to enter comments on § 170.315(e)(2) Secure messaging

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

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

2015 Edition Health IT Certification Criterion

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

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

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

Public Comment Field:

The AMA supports transitioning from CDX codes to NDCs for reporting administered vaccinations in future editions of the certification criteria due to the current use of NDCs in inventory management and provider workflow. We agree with allowing use of NDCs for administered vaccines in the 2015 edition but continuing to require CDX codes. This will allow both health IT developers and providers the opportunity to test NDCs for this purpose and gradually transition to the new reporting requirement, as well as ensure a smoother implementation process.

We do not support requiring CVX plus MVX for reporting administered vaccines. As indicated in the proposed rule, CVX plus MVX does not provide as much information as an NDC or facilitate inventory management. If vendors and providers are to invest the time and cost involved in changing the codes used in reporting administrated vaccines, they should be rewarded with a result that provides maximum utility and value. We concur that CDX codes should continue to be used for historical vaccination reporting.

We believe that it is premature to include immunization history information reconciliation in this certification criterion. Any immunization reconciliation process needs to consider the source of the immunization information and its reliability before being mixed with other data. For example, information regarding immunizations administered and recorded by providers is much more reliable than patient-reported immunization history. Before immunization data can be integrated and reconciled, there must be an assessment of its accuracy.

We agree with the elimination of the immunization information criterion, as it is redundant and unnecessary given the other immunization-related requirements.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

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

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

2015 Edition Health IT Certification Criterion

(2) Transmission to public health agencies—syndromic surveillance.
- (i) Ambulatory setting only.
  - (A) Technology must be able to create syndrome-based public health surveillance information for electronic transmission.
  - (B) Optional. Technology must be able to create syndrome-based public health surveillance information for electronic transmission that contains the following data:
    - (1) Patient demographics;
    - (2) Provider specialty;
    - (3) Provider address;
    - (4) Problem list;
    - (5) Vital signs;
    - (6) Laboratory test values/results;
    - (7) Procedures;
    - (8) Medication list; and
    - (9) Insurance.
- (ii) Inpatient setting only. Technology must be able to create syndrome-based public health surveillance information for electronic transmission in accordance with the standard (and applicable implementation specifications) specified in § 170.205(d)(4).

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

Public Comment Field:

The AMA agrees with continuing the current flexible approach for ambulatory syndromic surveillance certification due to the lack of mature standards for data exchange in this area. We also agree to maintain a distinction between the requirements of the inpatient setting vs. the ambulatory setting, as the ambulatory systems are still evolving. We agree to carry forward the 2014 Edition criteria into 2015.

§ 170.314(f)(3) Transmission to public health agencies – reportable laboratory tests and values/results

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

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

2015 Edition Health IT Certification Criterion

(3) Transmission to public health agencies – reportable laboratory tests and values/results. Technology must be able to create reportable laboratory tests and values/results for electronic transmission in accordance with
- (i) The standard (and applicable implementation specifications) specified in § 170.205(g)(2); and
- (ii) At a minimum, the versions of the standards specified in § 170.207(a)(4) and (c)(3).

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

§ 170.314(f)(3) Transmission to public health agencies – reportable laboratory tests and values/results

Public Comment Field:

Click here to enter comments on § 170.314(f)(3) Transmission to public health agencies – reportable laboratory tests and values/results

§ 170.315(f)(4) Transmission to cancer registries

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

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

2015 Edition Health IT Certification Criterion

(4) Transmission to cancer registries. Technology must be able to create cancer case information for electronic transmission in accordance with:
(i) The standard (and applicable implementation specifications) specified in § 170.205(i)(2); and
(ii) At a minimum, the versions of the standards specified in § 170.207(a)(4) and (c)(3).

Preamble FR Citation: 80 FR 16854 **Specific questions in preamble?** *Yes*

Public Comment Field:

The AMA supports this proposal as long as data can be appropriately de-identified to ensure privacy.

§ 170.315(f)(5) Transmission to public health agencies – case reporting

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

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

2015 Edition Health IT Certification Criterion

(5) Transmission to public health agencies – case reporting. Technology must be able to create case reporting information for electronic transmission in accordance with the standard specified in § 170.205(q)(1).

Preamble FR Citation: 80 FR 16855 **Specific questions in preamble?** *Yes*

§ 170.315(f)(5) Transmission to public health agencies – case reporting

Public Comment Field:

Click here to enter text comments on § 170.315(f)(5) Transmission to public health agencies – case reporting.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

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

2015 Edition Health IT Certification Criterion

(6) Transmission to public health agencies – antimicrobial use and resistance reporting. Technology must be able to create antimicrobial use and resistance reporting information for electronic transmission in accordance with the standard specified in § 170.205(r)(1).

Preamble FR Citation: 80 FR 16855 **Specific questions in preamble?** *No*

Public Comment Field:

The AMA supports antimicrobial stewardship but does not support mandating such a requirement as a condition of participation in any federal program. Adding such a mandate is likely to result in additional EHR costs for physician practices.

§ 170.315(f)(7) Transmission to public health agencies – health care surveys

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

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

2015 Edition Health IT Certification Criterion

(7) Transmission to public health agencies – health care surveys. Technology must be able to create health care survey information for electronic transmission in accordance with the standard specified in § 170.205(s)(1).

Preamble FR Citation: 80 FR 16856 **Specific questions in preamble?** *No*

Public Comment Field:

The AMA supports the proposal to automate health care surveys to increase sample size as long as participation is voluntary.

§ 170.315(g)(1) Automated numerator recording

Included in 2015 Edition Base EHR Definition?

No, but proposed for the EHR Incentive Programs CEHRT definition

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16856 **Specific questions in preamble?** *No*

Public Comment Field:

Click here to enter comments on § 170.315(g)(1) Automated numerator recording.

§ 170.315(g)(2) Automated measure calculation

Included in 2015 Edition Base EHR Definition?

No, but proposed for the EHR Incentive Programs CEHRT definition

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

Preamble FR Citation: 80 FR 16856 **Specific questions in preamble?** *No*

Public Comment Field:

Click here to enter comments on § 170.315(g)(2) Automated measure calculation.

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

Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

Stage 3 MU Objective

N/A

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

2015 Edition Health IT Certification Criterion

(3) Safety-enhanced design.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Public Comment Field:

The AMA believes the increased specificity for the reporting of summative test requirements is welcomed. However, greater detail is needed, specifically on how each of the measures is calculated. Detailed examples should be included and adherence to the process should be required. For example, a clear calculation for task success rates should be provided given that vendors did not follow the NIST documents.

We believe specific sample size requirements should be put in place and what constitutes an end-user demographic should also be more clearly specified so that vendors are aware of how many sub-populations are required for testing. In addition, the requirements should specify a minimum number of participants that should be actively practicing in their profession.

We believe that for meaningful comparisons to be made across vendor products a common set of use cases needs to be developed and required for summative testing.

An alternative to summative testing should be provided. This alternative should be evidence of the formative testing process for each of the 17 capabilities. Evidence may include: types of formative tests run, number and background of participants, results of those tests, list of lessons learned from the tests, and modifications made to the product as a result of the formative test.

§ 170.315(g)(4) Quality management system

Included in 2015 Edition Base EHR Definition?

No, but a mandatory certification requirement

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(4) Quality management system.

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

(A) Compliant with a QMS established by the Federal government or a standards developing organization; or

(B) Mapped to one or more QMS established by the Federal government or standards developing organization(s).

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

(iii) If different QMS were applied to specific capabilities, each QMS applied would need to be identified.

Preamble FR Citation: 80 FR 16858 **Specific questions in preamble?** *No*

§ 170.315(g)(4) Quality management system

Public Comment Field:

Click here to enter comments on § 170.315(g)(4) Quality management system

§ 170.315(g)(5) Accessibility technology compatibility

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

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

Public Comment Field:

Click here to enter comments on § 170.315(g)(5) Accessibility technology compatibility.

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

Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

Stage 3 MU Objective

N/A

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

2015 Edition Health IT Certification Criterion

(6) Consolidated CDA creation performance. The following technical and performance outcomes must be demonstrated related to Consolidated CDA creation. The capabilities required under paragraphs (g)(6)(i) through (iii) of this section can be demonstrated in tandem and do not need to be individually addressed in isolation or sequentially.

(i) Reference C-CDA match. Upon the entry of clinical data consistent with the Common Clinical Data Set, the technology must be able to create a data file formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that matches a gold-standard, reference data file.

(ii) Document-template conformance. Upon the entry of clinical data consistent with the Common Clinical Data Set, the technology must be able to create a data file formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that demonstrates a valid implementation of each of the following document templates (as applicable to the adopted standard):

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

(B) Inpatient setting only. Discharge Summary.

(iii) Vocabulary conformance. Upon the entry of clinical data consistent with the Common Clinical Data Set, the technology must be able to create a data file formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that demonstrates the required vocabulary standards (and value sets) are properly implemented.

Preamble FR Citation: 80 FR 16859 **Specific questions in preamble**? *Yes*

Public Comment Field:

Click here to enter comments on § 170.315(g)(6) Consolidated CDA creation performance.

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

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objectives

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

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

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

2015 Edition Health IT Certification Criterion

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

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

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

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

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

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

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

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

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

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

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

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

Public Comment Field:

Interoperability would allow patients and healthcare providers easier access to patient data. The AMA supports establishing API principles and standards to encourage interoperability.

The rule says it "broadly" specifies the technical outcomes required by certification criteria ONC wants to allow for a wider range of implementations. However, this goes against what was recommended in the transmittal letter cited in the proposed rule. It was said that by having more flexibility, it slows progress. Therefore, while we believe there should be flexibility, there also needs to be established parameters to help direct and expedite the development of these public APIs.

The standards are in the midst of significant evolutionary change (e.g., FHIR). With this in consideration, lead time must be given to vendors to allow for ample time for implementation into the next version.

The proposed rule mentions "fostering of an open ecosystem around APIs so that patients can share their information with the tools, applications, and platforms of their own choosing." The AMA is concerned with use of personal health information (PHI) and online applications (e.g., an app store). Many applications are developed by one-off developers who may have malicious intentions. Because there are no regulations or layer of security protecting patients, we are concerned with linking these applications to PHI.

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

Included in 2015 Edition Base EHR Definition?

No, but a mandatory certification requirement

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

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

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

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

§ 170.315(g)(8) Accessibility - centered design	
Preamble FR Citation: 80 FR 16861	**Specific questions in preamble?** *Yes*
Public Comment Field: Click here to enter text comments on § 170.315(g)(8) Accessibility - centered design.	

§ 170.315(h)(1) Direct Project
Included in 2015 Edition Base EHR Definition? Yes
Stage 3 MU Objective N/A
2015 Edition Health IT Certification Criterion (1) Direct Project. (i) Applicability Statement for Secure Health Transport. Technology must be able to send and receive health information in accordance with the standards specified in § 170.202(a). (ii) Optional – Applicability Statement for Secure Health Transport and Delivery Notification in Direct. Technology must be able to send and receive health information in accordance with the standard specified in § 170.202(e)(1).
Preamble FR Citation: 80 FR 16862 **Specific questions in preamble?** *No*
Public Comment Field: Click here to enter comments on § 170.315(h)(1) Direct Project

§ 170.315(h)(2) Direct Project, Edge Protocol, and XDR/XDM
Included in 2015 Edition Base EHR Definition? Yes, as an alternative to § 170.315(h)(1)
Stage 3 MU Objective N/A
2015 Edition Health IT Certification Criterion (2) Direct Project, Edge Protocol, and XDR/XDM. Technology must be able to send and receive health information in accordance with: (i) The standards specified in § 170.202(a); (ii) The standard specified in § 170.202(b); and (iii) Both edge protocol methods specified by the standard in § 170.202(d).
Preamble FR Citation: 80 FR 16863 (also see 80 FR 16862) **Specific questions in preamble?** *No*
Public Comment Field: Click here to enter comments on § 170.315(h)(2) Direct Project, Edge Protocol, and XDR/XDM.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

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

Public Comment Field:

Click here to enter comments on § 170.315(h)(3) SOAP Transport and Security Specification and XDR/XDM for Direct Messaging.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

(i) Query for an individual provider;
(ii) Query for an organizational provider;
(iii) Query for both individual and organizational providers in a single query; and
(iv) Query for relationships between individual and organizational providers.
(v) Optional - federation. In accordance with the standard specified in § 170.202(f)(1), technology must be able to process federated responses.

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

Public Comment Field:

Click here to enter comments on § 170.315(h)(4) Healthcare Provider Directory – query request.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

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

2015 Edition Health IT Certification Criterion

(5) Healthcare provider directory – query response. In accordance with the standard specified in § 170.202(f)(1), technology must be able to, at a minimum, respond to the following queries to a directory:
- (i) Query for an individual provider;
- (ii) Query for an organizational provider;
- (iii) Query for both individual and organizational providers in a single query; and
- (iv) Query for relationships between individual and organizational providers.
- (v) Optional - federation. In accordance with the standard specified in § 170.202(f)(1), technology must be able to federate queries to other directories.

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

Public Comment Field:

Click here to enter comments on § 170.315(h)(5) Healthcare Provider Directory – query response.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

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

2015 Edition Health IT Certification Criterion

(1) Electronic submission of medical documentation.

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

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

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

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

(ii) Digital signature.

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

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

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

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

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

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

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

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

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

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

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

Public Comment Field:

The ever-increasing documentation requirements of the Medicare program have been a long-standing concern for the provider community. The administrative burdens placed on physicians by prior authorization and other documentation programs reduce the amount of time and resources available for patient care. Moreover, these programs penalize and burden all physicians instead of targeting the small number of outliers who are submitting improper claims to Medicare.

Beyond our general frustration with the broad-stroked nature of the current Medicare documentation and prior authorization programs, the AMA has specific concerns regarding the certification criterion related to esMD. First, we believe that requiring support for the HL7 Implementation Guide for *CDA Release 2: Additional CDA R2 Templates – Clinical Documents for Payers – Set 1, Release 1 – US Realm* is premature. The HL7 Implementation Guide is currently in the balloting process and could still be significantly revised. It is unclear to us why ONC is proposing to require a standard that has yet to be finalized. Additionally, we cannot support use of a standard for which we are unable to review and evaluate the final version.

Beyond the incomplete nature of this standard, we also have more general concerns about the creation of separate standards for exchanging clinical documentation between providers and between providers and payers. Any pertinent clinical documentation regarding a patient's care will be included in templates for provider-to-provider information exchange, and a separate standard for payer purposes is unnecessary. Indeed, by creating a new documentation pathway for payer purposes, the CDP1 undermines the purpose and value of having a standard—i.e., having a single, standardized way to capture and exchange clinical information.

Conformance to the CDP1 IG would also create significant administrative burdens for physicians. Requiring physicians to provide a response to all templates (either with a specific answer or a particular null flavor) would be tremendously time-consuming and burdensome for physicians. With a physician being required to provide signatory authorization for all template responses, entering information and reviewing a template would require a large amount of a physician's time that would be better spent caring for patients. Although vendors may be able to automate some of these processes, few large EHR vendors have piloted such tasks sufficiently to ensure automation.

We are also concerned about the impact of required responses in the CDP IG on patient privacy. According to the HIPAA privacy and security standards, providers and other covered entities should only share the minimally necessary information to accomplish tasks related to patient care. The creation of a form that requires a response to all templates without regard to their necessity may increase the potential for the reporting of unnecessary information, especially were such information to be inserted by practice staff.

In sum, we urge reconsideration of the proposed requirements related to the esMD program due to the significant associated administrative burdens for providers. This proposal unfairly punishes all physicians in order to address a very small number of physicians who submit improper claims. Such an approach is overly inclusive, and we recommend that ONC work to

Gap Certification Eligibility Table for 2015 Edition Health IT Certification Criteria	
Preamble FR Citation: 80 FR 16867	**Specific questions in preamble?** *No*
Public Comment Field:	
Click here to enter comments on Gap Certification Eligibility Table for 2015 Edition Health IT Certification Criteria.	

Pharmacogenomics Data – Request for Comment	
Preamble FR Citation: 80 FR 16869	**Specific questions in preamble?** *Yes*
Public Comment Field:	
In general, the AMA supports the inclusion of pharmacogenomics data when good evidence exists linking variants to changes in drug metabolism or response, especially when clinical guidelines exist about dosing for variant carriers (such as those from the Clinical Pharmacogenomics Implementation Consortium).	

Base EHR Definitions	
Preamble FR Citation: 80 FR 16870	**Specific questions in preamble?** *No*
Public Comment Field:	
Click here to enter comments on Base EHR Definitions.	

Certified EHR Technology Definition	
Preamble FR Citation: 80 FR 16871	**Specific questions in preamble?** *No*
Public Comment Field:	
Click here to enter comments on Certified EHR Technology Definition.	

Common Clinical Data Set Definition	
Preamble FR Citation: 80 FR 16871	**Specific questions in preamble?** *No*

Common Clinical Data Set Definition
Public Comment Field:
The AMA supports the proposed revised definition of "common clinical data set" to replace "common MU data set" and the expansion beyond EHRs to include other health IT systems, in particular, clinical registries. The AMA applauds ONC's acknowledgment that the "Common Clinical Data Set" changes over time and should remain relevant to clinical practice. We encourage ONC to seek input from specialty societies and organizations such as the AMA and the PCPI to provide input on behalf of clinicians on ways to revise the Common Clinical Data Set to ensure it is directly tied to clinical actions and workflow.

Cross Referenced FDA Definitions	
Preamble FR Citation: 80 FR 16872	**Specific questions in preamble?** *No*
Public Comment Field:	
Click here to enter comments on Cross Referenced FDA Definitions.	

B. Provisions of the Proposed Rule Affecting the ONC Health IT Certification Program

The following comment tables are meant to capture proposals relevant to the ONC Health IT Certification Program.

Subpart E – ONC Health IT Certification Program	
Preamble FR Citation: 80 FR 16873	**Specific questions in preamble?** *No*
Public Comment Field:	
Click here to enter comments on Subpart E – ONC Health IT Certification Program.	

Health IT Modules	
Preamble FR Citation: 80 FR 16873	**Specific questions in preamble?** *No*
Public Comment Field:	
Click here to enter comments on Health IT Modules.	

"Removal" of Meaningful Use Measurement Certification Requirements	
Preamble FR Citation: 80 FR 16873	**Specific questions in preamble?** *No*

"Removal" of Meaningful Use Measurement Certification Requirements
Public Comment Field:
Click here to enter comments on "Removal" of Meaningful Use Measurement Certification Requirements.

Types of Care and Practice Settings	
Preamble FR Citation: 80 FR 16873	**Specific questions in preamble?** *Yes*
Public Comment Field:	
Click here to enter comments on Types of Care and Practice Settings.	

Referencing the ONC Health IT Certification Program	
Preamble FR Citation: 80 FR 16874	**Specific questions in preamble?** *No*
Public Comment Field:	
Click here to enter comments on Referencing the ONC Health IT Certification Program.	

Privacy and Security	
Preamble FR Citation: 80 FR 16875	**Specific questions in preamble?** *Yes*
Public Comment Field:	
Click here to enter comments on Privacy and Security.	

Design and Performance (§ 170.315(g))	
Preamble FR Citation: 80 FR 16876	**Specific questions in preamble?** *No*
Public Comment Field:	
Click here to enter comments on Design and Performance (§ 170.315(g)).	

"In-the-Field" Surveillance and Maintenance of Certification	
Preamble FR Citation: 80 FR 16876	**Specific questions in preamble?** *Yes*

"In-the-Field" Surveillance and Maintenance of Certification

Public Comment Field:

The AMA has asked for robust in-the-field surveillance in our comment letters and in public forums. We are supportive of ONC's expansion by adding randomized in-the-field surveillance to the existing reactive requirement. We are also supportive of ONC's intent to prioritize implementation surveillance to health IT capabilities related to interoperability, patient safety, and privacy and security.

We are concerned, however, that ONC does not go into greater detail as to how burdensome this process will be for physicians and their office staff. ONC is purposing to allow ACBs flexibility on how specifically the surveillance will be conducted, including the option for remote and on-site surveillance. We seek further clarity regarding what is expected of physicians during an onsite or remote visit by an ACB. We would also like to see further guidance that instructs the ACBs to work with physicians on scheduling these visits or if the visit can happen when physicians are not in clinic.

We are concerned that, if not expressly noted, a visit from an ACB may hinder a physician's ability to document their office visits in their EHR if changes must be made to accommodate the ACB visit—therefore precluding them from meeting MU requirements for that day. What if a physician cannot use his/her EHR during the in-the-field surveillance process? In this instance would there be any protection afforded to the physician participating in MU given that they must participate in a 365 day reporting period? If the ACB deems an EHR vendor is deficient, and for whatever reason the EHR product's certification is suspended, what protections will be in place to ensure physicians using suspended EHRs are not held accountable for MU participation? There needs to be more clarity as to what suspended means and how that affects physicians.

Transparency and Disclosure Requirements

Preamble FR Citation: 80 FR 16880 **Specific questions in preamble?** *No*

Transparency and Disclosure Requirements

Public Comment Field:

The AMA has asked for further certification and product transparency in our comment letters and in public forums. We also appreciate that ONC has cited the AMA regarding the costs associated with health IT and information exchange.

We are supportive of ONC's acknowledgment that, "health IT developers not disclosing known material limitations or additional types of costs associated with the implementation or use of certified health IT creates a substantial risk…" and therefore the proposal to expand which information health IT developers are required to disclose.

We strongly support the notion of a more specific cost structure to include all costs and fees physicians would be required to pay for any EHR function (MU related or not) outside the monthly service contract. This would include relevant factors including volume of transmissions, geography, interfaces, and exchange partner technology.

We do not, however, support ONCs suggestion that health IT vendors would not be required to disclose prices or price information. We understand that this could be seen as proprietary, however, we believe that in lieu of specific pricing information, vendors publish a range of prices for each service, interface, or extra function. A physician should have a relatively clear understanding of costs (in dollars) without the additional burden of calculating their own estimation of vendor fees and prices.

The AMA is aware of additional fees some HISPs and HIEs charge to exchange data in addition to what an EHR vendor may charge. It is not clear in ONC's regulation if these costs will be provided as well. We believe that in the spirt of transparency, ONC should collect HISP/HIE fees and/or pricing information and also list this information publically on its website.

Open Data Certified Health IT Product List (CHPL)

Preamble FR Citation: 80 FR 16883 **Specific questions in preamble?** *Yes*

Open Data Certified Health IT Product List (CHPL)

Public Comment Field:

The AMA is very supportive of ONC's open data initiative. We believe opening the CHPL to further public consumption will help the industry and health IT consumers compare and contrast products—leading to better design and enhanced competition.

We seek further clarity on the API functionality. Will the ACBs use this feature to upload data onto the CHPL or is it intended for download only?

We also propose adding an additional data element to the open data file. We are aware of instances where health IT vendors submit their products to multiple testing facilities to "shop" for the best results. This not only defeats the purpose of testing but also cheats other health IT vendors out of fair product comparison by physician consumers and purchasers. We suggest adding a data element that lists how many times the same version of health IT has been tested and at which facility the testing took place. We recognize it may be a challenge to collect this information into a single CHPL report, but we feel this is an important step in transparency and consumer choice.

Records Retention

Preamble FR Citation: 80 FR 16885 **Specific questions in preamble?** *No*

Public Comment Field:

Click here to enter comments on Records Retention.

Complaints Reporting

Preamble FR Citation: 80 FR 16885 **Specific questions in preamble?** *No*

Public Comment Field:

The AMA is supportive of ONC's complaints reporting proposal. We believe regular complaint reporting is necessary so that ONC can make better informed policy and changes to certification testing. We do believe, however, there should be some method of consistently posting this information online for public access.

Adaptations and Updates of Certified Health IT

Preamble FR Citation: 80 FR 16885 **Specific questions in preamble?** *Yes*

Adaptations and Updates of Certified Health IT

Public Comment Field:

The AMA is supportive of the new principle of proper conduct (PoPC). We believe this will help provide routinely updated information to ACBs on the status and progress of health IT as it improves. We also believe this will provide important information to alert ACBs to irregular events (e.g. multiple updates in a short period of time/few updates over a number of months) that may warrant in-the-field surveillance or further attention.

We are, however, concerned that there may be situations where health IT vendors make small, inconsequential changes to software code that could warrant, based on the proposed language, hundreds of individual line items in monthly vendor reports. Some cloud-based vendors may make software changes in their datacenters that do not effect end-users but improve performance. These may or may not need to be reported and could add undue burden on health IT vendors.

There are also instances where health IT products are deployed in the field and software changes are made for only one site or installation. In this instance would the health IT vendor be required to submit multiple reports—one for each site where different "flavors" of health IT products are in place?

"Decertification" of Health IT – Request for Comment

Preamble FR Citation: 80 FR 16886 **Specific questions in preamble?** *Yes*

"Decertification" of Health IT – Request for Comment

Public Comment Field:

The AMA discourages enforcing "compliance" of interoperability through the threat of decertification. Physicians have invested significant funds, not to mention time and resources, into purchasing and implementing certified EHRs, expecting that these systems will be interoperable. Decertification places the burden not on the non-compliant vendor but on the physician who must buy a new product, transfer patient data (which is a considerable expense), and devote staff time to training and implementing a new system. If an EHR becomes decertified, physicians have no recourse but will simply own a product that is deficient and can no longer be used to satisfy Meaningful Use.

We agree, however, that through ONC's proposed "in the field" surveillance if a health IT module or certified EHR does not continue to meet the level of functionality for witch it was certified against that there should some method of holding a certified product's vendor accountable. We support the notion that after a product is deemed noncompliant that an ACB would require a certified health IT module or certified complete EHR developer to take corrective action in instances where the technology fails to conform to the requirements of its certification. We believe this is a logical step to elevate the deficiencies identified by the ACB and would be the first step in remediation. We also support the proposal that a vendor would be required to submit a corrective action plan within 30 days of the date that the developer was notified by the ACB. Furthermore, we strongly support that an ACB would be required to report the corrective action plan and related data to the publicly accessible open data on ONC's Certified Health IT Product List (CHPL). We do suggest, however, that other methods of alerting purchasers and physicians using deficient health IT products should be considered, as those that have already purchased these products do not routinely check their products status on the CHPL. These methods could include requiring a certified health IT vendor to notify a physician consumer through email or other means that their product has been identified as noncompliant. This notification should include a web-link to the report posted in the CHPL and language that clearly states what a correction plan is occurring, how long the vendor has to become compliant, and how this could affect the physician's ability to comply with federal reporting requirements.

While we believe many health IT vendors will take immediate action to remedy an ACB-identified noncompliance, we support ONC's policy of permitting an ACB to initiate certification suspension procedures, and consequently certification termination, if certain requirements at not met by the vendor. If a certification termination action applied to a health IT vendor mitigating circumstances for physicians and other end-users who will be negatively impacted by this action must be in place. These should at the very least be: 1) a process to exempt physicians from the MU penalties, or any other reporting program that stipulates the use of certified health IT products, that apply if a physician fails to use certified technology as a result of using a product that was decertified; and 2) payment from vendors to offset the switching costs to another certified product.

Collections of Information – Paperwork Reduction Act	
Preamble FR Citation: 80 FR 16893	**Specific questions in preamble?** No
Public Comment Field:	
Click here to enter comments on Collections of Information – Paperwork Reduction Act.	

Regulatory Impact Statement	
Preamble FR Citation: 80 FR 16895	**Specific questions in preamble?** No
Public Comment Field:	
Click here to enter comments on Regulatory Impact Statement.	