



May 29, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
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200 Independence Avenue, SW
Washington, DC 20201

Karen B. DeSalvo, MD, MPH
National Coordinator for Health IT
Acting Assistant Secretary for Health
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Suite 729-D
200 Independence Avenue, SW
Washington, DC 20201

Re: 2015 Edition Health Information Technology (Health IT) Certification Criteria, Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications [RIN 0991-AB93]

Dear Acting Administrator Slavitt and Dr. DeSalvo,

On behalf of the American College of Physicians (ACP), I am writing to share our comments on the Office of the National Coordinator for Health Information Technology's (ONC) 2015 Edition Health Information Technology (Health IT) Certification Criteria proposed rule. We appreciate the hard work by ONC staff that goes into this rulemaking process, and acknowledge their commitment to working with stakeholders from across the health IT spectrum that will be affected by what is finalized from this proposed rule.

The American College of Physicians is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 141,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

ACP welcomes this opportunity and hopes that you will consider our comments, which are listed below in the ONC provided public comment template, as you work to develop your final rule. Should you have any questions, please contact Thomson Kuhn, Sr. Systems Architect, at tkuhn@acponline.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'P Basch', with a long horizontal flourish extending to the right.

Peter Basch, MD, FACP
Chair, Medical Informatics Committee
American College of Physicians

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

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| § 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) <u>Computerized provider order entry – medications</u> . 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: | |
| CMS/ONC should study the role of the individuals entering data. Meaningful Use (MU) has now enabled Computerized Provider Order Entry (CPOE), and there has been little, if any, data looking at CPOE by role. Drug-drug and drug-allergy interaction alerts are the source of most alert fatigue. While additional structured documentation in the EHR should not be a requirement, the capability to capture a reason or comment with the recording of a check or action would be favorable. We have an opportunity to improve how drug-drug and drug-allergy interactions are presented, such as within the ordering screen, such that we reduce alert fatigue and decrease the chances of someone ignoring a critical alert. | |

| | |
|--|--|
| § 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 | |
| (2) <u>Computerized provider order entry – diagnostic imaging</u> . 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 |

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

Public Comment Field:

Is this stating that an EHR must make imaging reports available to patients as structured data? Following the existing paradigm of delivery of information to patients in electronic format, the delivery is not as documents or free text, but rather as specified data elements. Most radiology reports are not standardized and structured – and until they are, we cannot require EHRs to represent them in ways other than how they were created.

§ 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.

2015 Edition Health IT Certification Criterion

(3) 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:

Drug-drug and drug-allergy interaction alerts are the source of most alert fatigue. While additional structured documentation in the EHR should not be a requirement, the capability to capture a reason or comment with the recording of a check or action would be favorable. We have an opportunity to improve how drug-drug and drug-allergy interactions are presented, such as within the ordering screen, such that we reduce alert fatigue and decrease the chances of someone ignoring a critical alert.

§ 170.315(a)(5) Demographics

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

§ 170.315(a)(5) Demographics

2015 Edition Health IT Certification Criterion

(4) 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*

Public Comment Field:

In order to ensure accuracy during the “roll-up” of more granular race and ethnicity codes into less granular codes, there must be a single map that is used by all vendors.

Race and ethnicity as it exists today has been built to help track disparities in care based on categories that may not make medical sense for the current ethnic diversity in the United States.

Further, at some point, clinicians may wish to track categories other than self-declared race and ethnicity, including social determinants of health, such that knowledge of such backgrounds can help to increase awareness of conditions that are more prevalent in certain populations.

Preliminary Cause of Death and Date of Death: As Cerner and Epic continue to gain customers, the capabilities for inpatient systems will also exist for outpatient settings; and as such, the capability to record “date of death” should include an exact date and an approximation if the EP is informed after the fact that the patient died, but doesn’t have the exact date.

§ 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

(5) 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.
- (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 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:

How do ONC and CMS propose to capture serial and positional vital signs, such as, if there is an indication of which blood pressure the provider has designated as the “working blood pressure” where multiple blood pressures have been recorded during a visit; or even if a blood pressure is obtained during an occasion where that blood pressure should not be included for hypertension quality measurement (as is currently permitted under NQF 0018)? All of these details must be specified.

Further, it is becoming increasingly clear that under more accurate blood pressure entries for establishing blood pressure control may come from ambulatory monitors or even home blood pressure readings. How do ONC and CMS intend for these to be captured?

§ 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

- (6) 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:

The Clinical Decision Support (CDS) community should applaud the desire to record the response to a CDS intervention. However, the description listed in the proposed rule is suggestive only of a “pop-up” event/action rule that has been so frequently assessed as obtrusive and overly frequent. A more measured approach is to determine specific types of CDS and to clearly define (based on industry agreement) what provenance is to be saved based on CDS interventions. For example, since many order sets are developed as a means for providing the right options up front and avoid pop-up alerts, we need to specify what types of changes are most appropriate to save and indicate alteration of compliance (e.g., change to dose levels and/or frequency of a medication, completely removing essential medications – and how to identify essential, and similar factors for other essential elements of an order set). Similar criteria will help evaluate appropriate use/misuse of documentation templates that are developed for clinical decision support. The proposed rule refers to some type of capture of actions based on allergy alerts. However, the action may occur much later and not necessarily immediately after the alert. Similar to the comments on order sets and documentation templates, a more defined set of requirement is important before a rule creates an undefined requirement. A clear, nationwide effort in user centered design about how to best evaluate the effectiveness of clinical decision support would go a long way to determine what should be required. The current language is too vague to provide useful guidance and direction. Such an approach to collecting information about CDS overrides would only be useful if there was some indication that ONC was doing so for the purpose of improving the usefulness of such alerts. Providers might even willingly increase their clicks if they believed that doing so might make a difference to them and future users of EHR technology.

§ 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

- (7) 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 problem with requiring formulary and benefit information is the poor quality and low value of the current information. Formulary and benefit information are often inaccurate. Also, the lack of transparency in the data causes confusion and extra work for physicians and extra costs to patients. If the information were truly useful to physicians and their patients in making prescribing decisions, they would be calling for its availability. We urge ONC to investigate the problems with formulary and benefit data before requiring its use.

We already know the following to be problems:

1) SureScripts only has a quality assurance process for formulary format, but there is no quality assurance for formulary content.

2) SureScripts currently requires that “formulary alternatives” be displayed such that all alternatives are displayed, which is not necessarily what prescribers would expect. Thus, the required display includes an alphabetical list of all in-class drugs, which includes drugs that have an equal formulary status or even a less favorable formulary status. Prescribers would be far more likely to use a formulary where the option “formulary alternatives” would display only when a more favorable formulary alternative actually existed.

3) The lexicon for indicating formulary status is not intuitive or known to most prescribers (“P” status), nor is it clear to providers how “P” status applies to the level of copay.

ACP would be happy to work with ONC and others to define the attributes of actionable informational displays in the EHR in order to enable optimization of cost effective prescribing.

Requiring the incorporation and maintenance of what could be thousands of formulary and benefit files on each physician’s system does not make sense. Certified systems should be capable of querying for data from reliable sources when needed.

§ 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

- (8) 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*

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

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

Included in 2015 Edition Base EHR Definition?

No

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

- (9) 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](#)

Public Comment Field:

ONC and CMS should ensure that this standard does not require a provider to enter a family history as a pedigree, only that it makes it possible. Family history should be able to be captured as both structured and free text entries.

§ 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

- (10) 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*

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

Public Comment Field:

The new proposed requirement, that a Health IT module would be required to demonstrate that it could enable a user to record and access information directly and electronically shared by a patient, raises a number of concerns. In particular, the requirement that data could come from multiple sources, including patient information provided directly from a mobile device, is especially troubling. What functions will be required and what will not? Since no standard is specified, must the system be capable of accepting data via any method chosen by any 3rd party application vendor? Can the system specify a single proprietary method that will be used by only that vendor? Is the receiving system, and, in fact, the receiving practice able to require that sending applications meet specific security requirements? The way this is written, it appears unlikely that any particular practice will be capable of accepting data from even a subset of their patients. Without strict standards for data and security, this requirement can only lead to chaos. We are not aware of any mature standards that could serve this purpose.

This capability should allow for complete or partial documentation. Thus, a provider who implants a device should have the ability to document (hopefully via barcode technology) all of the fields below; a provider who is recording a device as historical information should be able to document what they know (e.g., pacemaker – 2013). It is thus clear that provenance for such documentation is also important.

This requirement displays a common misunderstanding that the best way for interoperability to work is for all entities having contact with a patient to have and maintain all of the information that exists about that patient. This approach results in any provider assuming that their information is accurate. In fact, as soon as a copy of information makes its way from the authoritative source to a receiver, that copy can no longer be trusted as accurate. While that same data sit in multiple record systems, the patient continues to interact elsewhere in the system, rendering all of those copies useless and dangerous. Instead, the focus should be on maintaining easy and efficient query access to authoritative sources rather than wasting innumerable resources maintaining obsolete copies of information everywhere.

§ 170.315(a)(20) Implantable device list

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

§ 170.315(a)(20) Implantable device list

2015 Edition Health IT Certification Criterion

- (11) 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

Public Comment Field:

This capability should allow for complete or partial documentation. Thus, a provider who implants a device should have the ability to document (hopefully via barcode technology) all of the fields below; a provider who is recording a device as historical information should be able to document what they know (e.g., pacemaker – 2013). It is thus clear that provenance for such documentation is also important.

This requirement displays a common misunderstanding that the best way for interoperability to work is for all entities having contact with a patient to have and maintain all of the information that exists about that patient. This approach results in any provider assuming that their information is accurate. In fact, as soon as a copy of information makes its way from the authoritative source to a receiver, that copy can no longer be trusted as accurate. While that same data sit in multiple record systems, the patient continues to interact elsewhere in the system, rendering all of those copies useless and dangerous. Instead, the focus should be on maintaining easy and efficient query access to authoritative sources rather than wasting innumerable resources maintaining obsolete copies of information everywhere.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

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

2015 Edition Health IT Certification Criterion

- (12) 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*

Public Comment Field:

While it would be beneficial for social, psychological, and behavioral data to be available to physicians and other clinicians treating patients, it is critical that these data be as accurate as possible. A large body of research makes it clear that how, when, where, and by whom these data are collected can have significant impact on their accuracy. If the assumed scenario underlying these requirements is that doctors and other non-behavioral healthcare providers will ask these questions in the course of a clinical visit, then the accuracy of all these data could be suspect at best, and their collection will prove to be an enormous waste of resources.

While it might be beneficial for work data to be available to physicians and other clinicians treating patients, it is critical that these data be as accurate as possible. Relying on patient recall is unlikely to be effective. Patients with complex work histories are likely to forget or fail to mention critical employment periods. There are government sources from which these data should be collected, such as the IRS.

While it might be beneficial for service data to be available to physicians and other clinicians treating patients, it is critical that these data be as accurate as possible. Relying on patient recall is unlikely to be effective. There are government sources from which these data should be collected, such as the Department of Defense.

§ 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

- (13) 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

Public Comment Field:

The projects that led to the development of Health eDecisions (HeD) and the underlying virtual medical record (VMR) have been abandoned, and the participants have moved on to new draft standards that appear to be better suited. ONC should not call for the implementation of obsolete standards. While the more appropriate standards are not yet ready, ONC would be better off waiting until they are ready, rather than feeling compelled to include something in this rule.

The now-obsolete HeD artifact now established by Clinical Quality Framework (CQF) and the HL7 Draft Standard for Trial Use (DSTU) is not implemented in any commercial product as a routine method for delivering decision support. It has not been proven to be effective. In limited work in some HHS contracts, the data could be compiled from the HeD artifact but the curly brackets issue inherent to Arden Syntax remained – i.e., mapping the value sets to data used locally like in the customer site but not necessarily across all vendor implementations. Moreover, there is no authoring engine for HeD artifacts that is available commercially or through HHS. Development of HeD artifacts is mostly challenged by the authoring and knowledge engineering efforts that fail to occur, and over-expectation of the ability to capture data. The enterprise is currently not sustainable with the tooling available in the industry.

The data model in development by HL7 (QUICK) is a hybrid of the classes defined by the HHS Quality Data Model (now used for development of clinical quality measures) and the VMR. QUICK is currently in development and is also being moved into Fast Health Care interoperability Resource (FHIR). Until the data model is stabilized, any use of HeD is highly premature. The logic expression model is also relatively new, only recently passed for DSTU by HL7. It has not been in use sufficiently to assure it is ready for a nationwide deployment. While the goal of a common format for clinical decision support is laudable and something that is sorely needed, HeD or any other formalism remains premature for inclusion in any rule.

Note – all clinical software should be able to support evaluation tools that calculate semi-complex logic. The simplest example might be a Braden Scale and a more complex example an Apache score. All software should be able to use evaluation tools to arrive at correct determinations based on such tools and a sample set for certification testing seems appropriate. Software should also be able to use the results of such evaluation tools directly in clinical decision support algorithms used within the software (without requiring HeD). Thus, a vendor might be asked to create a specific rule using the vendor’s own CDS mechanism that incorporates results of such evaluation tools, and evaluate if the software responses are correct. However, specific formalisms remain premature and basically, such formalisms are still in development.

§ 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

(14) 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:

This seems like a good idea, particularly for smaller vendors that either subscribe as a vendor, or allow customers to subscribe to CDS services.

§ 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.

§ 170.315(b)(1) Transitions of care

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 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)
 - (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

§ 170.315(b)(1) Transitions of care

Preamble FR Citation: 80 FR 16831

Specific questions in preamble? Yes

Public Comment Field:

C-CDA Data Provenance Request for Comment: Vendors develop EHRs to capture and display information, mostly related to financial incentives. Provenance information about data elements originating elsewhere is best obtained from their original source. Hence, data analytics for clinical decision support and quality measurement may be best managed by evaluating data from each of the original sources. A number of analytic vendors, like Optum, have started to do just that.

§ 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).

2015 Edition Health IT Certification Criterion

- (2) 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.

§ 170.315(b)(3) Electronic prescribing

Preamble FR Citation: 80 FR 16835

Specific questions in preamble? Yes

Public Comment Field:

This requirement is reasonable *if* the units of creams, ointments, inhalers, etc. are made available and obvious to the prescriber. Thus, current practice for inhalers might be to prescribe “Disp 1” where the pharmacist might know to change the prescription to “17gm.” Such a limitation without ready access to that information would limit prescribers’ ability to prescribe medications that are not pills or capsules.

A similar effort would need to occur with required syntax for 90 day prescriptions. Thus, while the current approach might be to prescribe “Disp-3” it would have to be abundantly clear if what was accepted was this, or “17g x 3” or “Disp 51g.”

Perhaps even more important than standardizing to metric would be clarity surrounding solutions or suspensions that are topical, ear drops, or eye drops. ePrescribing med lists do not include this information, and prescribers often ensure that what they think is an eye drop is prescribed by use of free text in the instructions field or comment field.

Along with the traditional prescription information, there needs to be a structured approach to indicate the authorizing prescriber. Otherwise, when a prescriber authorizes a medication renewal for a colleague’s patient – renewal requests always flow to the covering prescriber. Further, occasionally as a courtesy, physicians authorize a renewal for a provider in a different specialty. Without an indication of the authorizing prescriber, this act of courtesy now links that medication (for purposes of cost attribution) to this provider, instead of the prescription originator. The alternative is to adopt a patient unfriendly approach, which is to tell patients that only the originating prescriber can renew their own medications.

This structured “sig” must permit complex dosing instructions, tapering dosages, etc.

§ 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

- (3) 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:

We support the proposed changes to this function. We understand that moving structured data from one data format to another is difficult and may be incomplete. There are a number of steps that vendors can take to make the process as accurate, complete, and efficient as possible. We agree that this capability would need to be user-focused and user driven. We also agree that a typical user would not want to move everything available, but would want to select data by patient, by type of data, and by period of time. We agree with the requirements to support specific structural and vocabulary standards as specified in the rule.

§ 170.315(b)(7) Data segmentation for privacy – send

Included in 2015 Edition Base EHR Definition?

No

§ 170.315(b)(7) Data segmentation for privacy – send

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

- (4) 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:

The proposed standard is too immature for selection. Given that its function is to hide accurate clinical information from providers of care, we believe that this standard must undergo far more rigorous testing and pilot use than other standards. The risks of harm are too high.

A number of federal and state health information privacy laws and regulations are more privacy-protective than the HIPAA Privacy Rule. Typically, these rules require a patient’s permission (often referred to as “consent” in these rules) in writing in order for the individually identifiable health information regulated by those laws to be shared.

This rule will allow patients and/or legislation to hide information from providers according to complicated rules that if carried to the permitted extreme, at will. The initial adoption would lock the whole document except for designated receivers without further consent from the patient. The initial goal is to allow some data to be sent from drug abuse and alcohol treatment centers, but the standard allows any patient to specify any individual item of data and who can see it when and for what purpose. This is a very slippery slope. This will be the beginning of Swiss cheese medical records, and will add an unacceptable burden to providers chasing down consents. We believe that health IT systems must clearly alert physicians and other clinicians to the fact that the patient has chosen to sequester data so that the physician or other clinician can discuss the matter with the patient prior to delivering care.

§ 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

- (5) 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:

This should be reworded such that an EHR module should be able to default to inherited document level tagging so that providers do not have to take additional steps to re-tag a document to prevent unauthorized disclosures.

§ 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

- (6) 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

Public Comment Field:

We agree that a care plan without health status and outcomes and without interventions is not sufficient. These elements are especially valuable since the planned interventions are expected to drive the care given at the receiving site and the health status and outcomes are considered when performing the interventions. Moreover, these are the sections that clinical quality measures address when seeking to assure there is a care plan and that the interventions include specific items.

However, the Care Plan standard was the result of long and intense discussions among representatives of many stakeholder groups. In the end, the diverse group of participants and balloters came to a consensus that the Health Status and Interventions sections should not be required. ONC should accept the outcome of that process and not impose further requirements beyond what are already in the standard. Past decisions by ONC to add certification criteria that went beyond the requirements in the standards resulted in confusion and implementation errors. In all cases, ONC should stick to the language of its chosen standards, and push for desired changes through the Standards Development Organization process.

§ 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

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

Public Comment Field:

This statement is laudable but it is the execution that will judge its value. A user should be able to export the data for analysis whenever the user chooses. However, exporting the QRDA is an expectation for sending data to CMS as part of a complete data set. Exporting more often, i.e., whenever the user decides, is a different use case and QRDA may not represent the right solution. Exporting may include sending all data to another analysis engine to determine the extent to which a provider complies as of the current date –i.e., an aggregate analysis based on existing data. Requiring each analysis engine to import QRDA may be excessive.

Moreover, the standards are developed by an international standards organization, HL7 – some are US domain only (QRDA) and others international (HQMF). The proposed rule conflates the two and it should be clear that the requirement should be using a true standard – and one that has been tested and in place in real world settings to assure it is acceptable and usable. QRDA has been shown to have flaws that are only now being addressed. And QRDA has a new balloted version that will be published before the Final Rule is published. The most recent QRDA should be adopted (i.e., the ballot update from January 2015 HL7 ballot cycle), not earlier imperfect ones. Otherwise, ONC is perpetuating errors.

§ 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

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

Public Comment Field:

HQMF is an evolving standard and the newest version is just being balloted now (incorporating the Clinical Quality Language and maintaining QDM), as indicated above. Assuming the current HL7 ballot succeeds, the resolved and published version should be the subject of the Final Rule. However, expecting clinical software to import and calculate a measure is excessive. EHRs are developed to capture information – analytic engines are developed to analyze. An analytic engine might be expected to import a CQM if that CQM is based on feasible and valid and reliable data that might normally be found within clinical settings based on normal workflow. Clearly, many CQMs expect excessive and non-feasible data. Also, since HQMF is still evolving, it is premature to expect that EHRs or any analytic engine can automatically import an HQMF *measure*. More testing and work is required. Even Mitre had difficulty importing the latest version of HQMF into Bonnie. Stabilization is needed.

This statement (on user ability to import CQM data) is confusing. Very likely it refers to the ability to include data documented elsewhere in the EHR so it can be used to calculate a quality measure. If that is the case, any structured information coming from a C-CDA should be “in play” here and not just information needed to calculate a quality measure. If the information is captured elsewhere and not generally available in eCQMs, the data element for the measure should have proven non-feasible as part of measure testing. If such testing has not been performed, the measure itself is faulty, not the EHR or clinical software. Often, the measures require structured data in excess of structured data requirements for interoperability and that is a design flaw of the process, not a failure of the EHR vendor. Vendors should not be expected to support any amount of data concepts and classifications that measure developers determine important to evaluate quality. The measure developers and endorsers should be equally responsible to consider truly common feasible data in developing and evaluating the value of their measures.

While some providers may need the ability to process large numbers of records, this capability does not need to reside in a health IT module certified for import and calculate. Not all functionality must be included within particular certified modules. Processing large numbers of records is a function that could easily be provided by a third-party service called from a certified module, for those who need it.

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*

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

Public Comment Field:

The public has an opportunity to provide input and vote on HL7 standards. When such standards, such as QRDA Category 1 and 3 successfully update based on balloting and comments, it is based on public user input that provides an opportunity to fix issues inherent in earlier versions of the standard. By requiring the CMS version of these standards, the Meaningful Use program is at risk for falling behind the DSTU standard updates in HL7 because CMS systems are not ready to accommodate updates that might benefit providers and vendors. While there is also risk that the HL7 process is slow and CMS guidance can circumvent less responsive HL7 processes, the risk for delay incurred by CMS systems that are slow to update is greater. The updates should be based on the most recent HL7 balloted standards and vendors and CMS should equally need to accommodate for the more recent standards. ONC regulations should select the most appropriate version of each standard to meet the need, and the industry should not be held back due to technical capabilities of CMS or another agency expecting to receive the data. Third parties are available to serve the need.

§ 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 in § 170.202(a).
- (ii) Activity history log.
- (A) When electronic health information is viewed, downloaded, or transmitted to a third-party using the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section or when an application requests electronic health information using the capability specified at paragraph (e)(1)(iii) of this section, the following information must be recorded and made accessible to the patient:
- (1) The action(s) (i.e., view, download, transmission, API response) that occurred;
 - (2) The date and time each action occurred in accordance with the standard specified at § 170.210(g);
 - (3) The user who took the action; and
 - (4) Where applicable, the addressee to whom an ambulatory summary or inpatient summary was transmitted.
- (B) Technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of this section if it is also certified to the certification criterion adopted at §170.315(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) is accessible by the patient.

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

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

- (iii) 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:

Activity History Log: This is reasonable as long as it is "intended" destination, and not a requirement to capture receipt, or retransmission after transmission to the intended recipient.

§ 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

Public Comment Field:

We support bidirectional exchange for this and all other public health reporting functions.

§ 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.

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 proposed flexibility comes at an unacceptable cost. By not specifying a standard, ONC places all practices and other providers, as well as vendors, at the mercy of whatever requirements a local agency chooses to impose. A typical practice may be required to report in three different states using entirely different technologies, standards, and processes. The cost and burden are unacceptable. The burden must be placed upon the public health community to develop a single reporting hub where all reports for all purposes are submitted using the same technologies, standards and processes.

In addition, all public health reporting must be bidirectional. Providers should not be seen as unpaid servants of government agencies, physicians and their patients should directly benefit from the data exchanged.

§ 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.

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

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

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)(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

- (4) 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

Public Comment Field:

A typical practice may be required to report in three different states using entirely different technologies, standards, and processes. These costs and burdens are unacceptable. The burden must be placed upon the public health community to develop a single reporting hub where all reports for all purposes are submitted using the same technologies, standards and processes.

In addition, all public health reporting must be bidirectional. Providers should not be seen as unpaid servants of government agencies, physicians and their patients should directly benefit from the data exchanged.

The SDC standards proposed are far too immature for selection at this time. ONC must develop and comply with a fixed definition of maturity that includes actual use, beyond pilot testing, of a published standard or information governance (IG).

The second rule requires a capability called structured data capture in the EMR. This is a mechanism for third parties to pop an input form up in front of the clinician and ask for data. The initial application is for public health, and providers would have to fill out what ever case report form that public health agency delivered to them regardless of how this will put providers at the mercy of any ill-conceived , or excessive data request and add to their inbox work and interruptions. This additional burden is unacceptable. The capability should be built into the systems and not limited to use by public health. It should be adopted by hospital administrations or any regulatory agency for any data gathering purposes they conceive.

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

Included in 2015 Edition Base EHR Definition?

No

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

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 – 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 HL7 standard proposed is far too immature for selection at this time. ONC must develop and comply with a fixed definition of maturity that includes actual use, beyond pilot testing, of a published standard or IG. This particular standard requires the collection of many data elements that are not part of C-CDA 1 or 2. Collection of all of these idiosyncratic structured and coded elements will place a tremendous burden on the reporting physicians. EHR systems will have to be modified to collect these data – increasing the costs to all users. Finally, the specifications some of the required elements actually conflict with the specifications for the elements in C-CDA. How will a reporting practice deal with the fact that all data for all patients are not comparable?

§ 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

2015 Edition Health IT Certification Criterion

- (1) 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:

We support summative testing, and we urge that options be field tested as soon as possible to allay the concerns of those who oppose this activity.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

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 to 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 esMD initiative has not yet published a standard. There have been no pilot tests, and the in-ballot document could not pass any test of maturity. The cost to implement this new requirement in an existing certified EHR will be expensive by any estimate. This standard is not ready for recognition at this time.

Further, based on prior history of prior authorization approaches that were not created by a multi-stakeholder process which included providers, we do not believe that this process would reduce administrative burden. The entire process of prior authorization as conceived by payers typically is retrospective and nontransparent. As the ACP has commented before, the best prior authorization process is avoidance – made possible via the provision of transparent, accurate, understandable and actionable information, which includes the prior authorization rules and if there is/are suitable alternatives that do not require prior authorization.

Pharmacogenomics Data – Request for Comment

Preamble FR Citation: 80 FR 16869

Specific questions in preamble? Yes

Public Comment Field:

For reasons that go beyond size pharmacogenomics and other genomic data are not a good candidate for inclusion within individual patient records in EHR systems. A much better model of data management is imaging data managed by a PACS. Genomic data will be more valuable and useful if they are stored in carefully curated systems and available for all uses.

Furthermore, Drug-Drug and Drug-Allergy interaction alerts are the largest source of alert fatigue for the smallest potential value. Adding another source of alerts without inclusion of a rigorous process to filter only the most relevant interactions is likely to worsen this problem, and not necessarily add any value.

ACP does not believe that there is sufficient technologic maturity to support privacy for genetic data, segmented to the genetic data atom.

Base EHR Definitions

Preamble FR Citation: 80 FR 16870

Specific questions in preamble? No

Public Comment Field:

While smoking is a significant health concern, clinical software should capture tobacco use and not be limited to smoking. Given the rise of “smokeless electronic cigarettes” the term might be better expressed as “nicotine use status.” The AMA-PCPI measure addressing tobacco cessation is specific about all tobacco use and for very good clinical reasons based on evidence. Moving the industry to a more limited approach perpetuates inadequate surveillance and management.

If there is a capability to effect a change in how tobacco use is captured at this time, some of the existing MU required definitions should be dropped, as they lack clinical significance and have been a source of confusion for providers. For example, the categorization of current smokers as “current every day” or “current some day” is without clinical significance, and has led many providers to stop capturing what is significant to capture cancer risk and documentation requirements for determination of use of CT scanning for lung cancer screening (approximate packs per day) – which can result in a pack year determination.

Common Clinical Data Set Definition

Preamble FR Citation: 80 FR 16871

Specific questions in preamble? No

Public Comment Field:

In response to a query from ONC, the ACP Medical Informatics Committee performed an analysis of the proposal to create a common clinical Data Set Definition. The specific recommendations can be found here:

http://www.acponline.org/acp_policy/letters/acp_cedalvo_letter_ccds_2015.pdf

Unique Device Identifier(s): The industry should applaud the need to capture Unique Device Identification (UDIs) in electronic software. However, the description is not sufficient. All reference to such a device, when included in interoperable communication, should include the UDI as provenance (and preferably information about the circumstances of the device's original use). The current reference requires only the original recording software to indicate the UDI and related information.

Assessment and Plan of Treatment, Goals, and Health Concerns: Whatever inclusions are made, nothing should be allowed to conflict with the way that the sections and data elements are specified in C-CDA v.2.0. If the standard is rendered invalid by the rule, the result will be confusion and chaos. ONC has tried this in the past and we have all paid for it.

Alignment with Clinical Practice: The safest approach would be to limit the use of highly prescriptive inclusion / exclusion criteria – further assuming that not all technology and behavior has to be specified in order to be useful. That would permit innovation and clinical appropriateness to exist within guardrails, and not assume that innovation and clinical appropriateness can be predicted and thus accommodated within rulemaking.

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:

Object Identifiers (OIDs) for Certain Code Systems: The table lists RxNorm for medications but lists no code system for immunizations. Further in the document, the proposed rule refers to submitting CVX (HL7 Standard Code Set) and NDC (National Drug Code) codes for immunizations. If electronic health IT is to use a standard for immunizations, the table should consistently include immunizations with other types of information. Providers share immunization data with each other and not just with immunization registries. All users of health IT information should be required to move forward equally, using the same terminologies. Thus, if immunization allergy and diagnosis checking is to occur based on RxNorm then immunizations should be rightfully included as medication substances and ONC should bring all users of the information up to the 21st century. Limitations that require alternate mechanisms for sharing data because of public health's failure to move forward should not penalize developers of innovative current and future software systems and interoperability. This confusing situation finds its way into clinical decision support and clinical quality measure definitions, thus creating an irrational way of sharing and using information artificially codified due to misalignment of change in the clinical care and public health communities.

“In-the-Field” Surveillance and Maintenance of Certification

Preamble FR Citation: 80 FR 16876

Specific questions in preamble? *Yes*

Public Comment Field:

We support summative testing, and we urge that options be field tested as soon as possible to allay the concerns of those who oppose this activity.

Transparency and Disclosure Requirements

Preamble FR Citation: 80 FR 16880

Specific questions in preamble? *No*

Public Comment Field:

Researchers should be able to name any product, as well as to describe functions and show screenshots in appropriate publications. We support the added transparency and disclosure proposed.

That said, it would also be useful for health IT developers to explain nuance in added costs, where appropriate, based on end-user training and implementation decisions, as well as added costs based on data receiver requirements. For example, a provider may modify an EHR to include non-numeric results in a numeric field, which require a process of validation, data scrubbing, and revalidation. Or, a data recipient may place unique requirements on the EHR vendor, which add costs due to local requirements. Thus, a disclosure of costs for the provision of a particular service may reasonably indicate what may result in added costs, and the source of those added costs.

“Decertification” of Health IT – Request for Comment

Preamble FR Citation: 80 FR 16886

Specific questions in preamble? *Yes*

Public Comment Field:

Researchers should be able to name any product, as well as to describe functions and show screenshots in appropriate publications.

We support the added transparency and disclosure proposed.

That said, it would also be useful for health IT developers to explain nuance in added costs, where appropriate, based on end-user training and implementation decisions, as well as added costs based on data receiver requirements. For example, a provider may modify an EHR to include non-numeric results in a numeric field, which require a process of validation, data scrubbing, and revalidation. Or, a data recipient may place unique requirements on the EHR vendor, which add costs due to local requirements.

Thus, a disclosure of costs for the provision of a particular service may reasonably indicate what may result in added costs, and the source of those added costs.