THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

OSUPhysicians

May 29, 2015

To: National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology

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

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

§ 170.315(a)(1) Computerized provider order entry – medications
Included in 2015 Edition Base EHR Definition? Yes, as an alternative to § 170.315(a)(2) or (3)
Stage 3 MU Objective Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.
2015 Edition Health IT Certification Criterion (1) Computerized provider order entry – medications. Technology must enable a user to record, change, and access medication orders.
Preamble FR Citation: 80 FR 16814 **Specific questions in preamble?** *Yes*
Public Comment Field: We do not see a need for additional certification on CPOE of medications and diagnostic imaging and support the proposal to preserve the ONC 2014 Edition criterion unchanged in the ONC 2015 Edition. You request comment on whether a Health IT module "should be able to include any or all of the following data elements: secondary diagnosis codes; reason for order; and comment fields entered by the ordering provider, if they are provided to the ordering provider in their order entry screen" (16814). We currently do not require a diagnosis code for inpatient orders. We do not require a reason for order for labs (inpatient or ambulatory). Comments should not be required.

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

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

2015 Edition Health IT Certification Criterion

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

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

Public Comment Field:

We believe that the proposed criterion for labs (a) (2) goes beyond the point of order entry to address the electronic transmission of laboratory orders, which is not functionality required to meet the proposed measurement. We agree with other users of our EHR (Epic) who have concerns that implementing the standards proposed by ONC would require us to significantly redo our existing lab order interfaces to minimal benefit.

We recommend that you remove this criterion from the 2015 Base EHR definition and instead preserve the 2014 Edition criterion for lab CPOE unchanged

You request comment on whether a Health IT module "should be able to include any or all of the following data elements: secondary diagnosis codes; reason for order; and comment fields entered by the ordering provider, if they are provided to the ordering provider in their order entry screen" (16814). We currently do not require a diagnosis code for inpatient orders. We do not require a reason for order for labs (inpatient or ambulatory). Comments should not be required.

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

Included in 2015 Edition Base EHR Definition?

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

Stage 3 MU Objective

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

2015 Edition Health IT Certification Criterion

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

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

Public Comment Field:

We do not see a need for additional certification on CPOE of medications and diagnostic imaging and support the proposal to preserve the ONC 2014 Edition criterion unchanged in the ONC 2015 Edition.

You request comment on whether a Health IT module "should be able to include any or all of the following data elements: secondary diagnosis codes; reason for order; and comment fields entered by the ordering provider, if they are provided to the ordering provider in their order entry screen" (16814). We currently do not require a diagnosis code for inpatient orders. We do not require a reason for order for labs (inpatient or ambulatory). Comments should not be required.

§ 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
2015 Edition Health IT Certification Criterion
(4) Vital signs, body mass index, and growth charts. (i) Vital signs. Enable a user to record, change, and access, at a minimum, a patient's height, weight, diastolic blood pressure, systolic blood pressure, heart rate, respiratory rate, temperature, oxygen saturation in arterial blood by pulse oximetry, body mass index [ratio], and mean blood pressure in accordance with the following (The patient's height/length, weight, diastolic blood pressure, systolic blood pressure, heart rate, respiratory rate, temperature, oxygen saturation in arterial blood by pulse oximetry, body mass index [ratio], and mean blood pressure must be recorded in numerical values only.): (A) The standard specified in § 170.207(k)(1) and with the associated applicable unit of measure for the vital sign in the standard specified in § 170.207(m)(1); (B) Metadata. For each vital sign in paragraph (a)(6)(i) of this section, the technology must also record the following: (1) Date and time of vital sign measurement or end time of vital sign measurement; (2) The measuring- or authoring-type source of the vital sign measurement; and (3) Optional. Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g); and (C) Metadata for oxygen saturation in arterial blood by pulse oximetry. For the oxygen saturation in arterial blood by pulse oximetry, the technology must enable a user to record, change, and access the patient's inhaled oxygen concentration identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with LOINC® code 8478-0.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Public Comment Field:

Vitals:

If the entry, display and reporting of the DPB and SBP is finalized as proposed, we agree with entering separately, but disagree with displaying and storing them separately as it would drastically have negative impacts on system views, reports/graphs and workflows.

Heart Rate:

Other than Cardiology specialists, majority of clinicians do not treat pulse and heart rate as separate measurements. Therefore, we would like to request that the certified EHR technology have the ability to capture one or both.

Storage and Exchange of Units:

We agree with our certified vendor's (Epic) statement: *"The phrase "data a user enters into a health IT system is semantically and syntactically identical to the information coming out of the system and being exchanged" (50) is ambiguous. It is not clear whether this goal restricts transformations such as unit conversions. EHR users tell us that prohibiting unit conversion (for example, making it unacceptable to present 5'5" as 1.7 meters) has little or no value in increasing data validity and enormous detriment to clinician workflow. For example, it would make it almost impossible to present and compare a sequence of vitals (such as heights) that were taken using a variety of units (such as feet/inches and meters). It would increase cognitive burden if providers are not able to see vitals in a consistent display."*

Editing Calculated Values:

We agree with our certified vendor's (Epic) statement: *"The proposal states that users must be able to "electronically record, change, and access" the required vital signs. However, the following vital signs are typically calculated values rather than entered or editable values:*

- *Body mass index (BMI)*
- *Mean blood pressure*
- *Pediatric vital signs: BMI per age and sex*

The final rule should be clarified because clinicians generally do not "record" or "change" these calculated vital signs and it is unnecessary to require the ability to change these values."

UCUM Version 1.9

We agree with our certified vendor's (Epic) statement: *"You propose to adopt UCUM Version 1.9 for units. The Unified Code of Units of Measure, Revision 1.9, October 23, 2013 ("UCUM Version 1.9") does not support multiple mixed units of measure. For example, with this standard, users could no longer enter or transmit a patient's height in the format 6'1" because this value contains two units of measure. Users have told us they find using feet/inches and pounds/ounces (for baby weights) useful and would not want to have to switch all usages.*

We ask for additional clarification around what UCUM Version 1.9 units of measure are applicable to each vital. The proposal is unclear whether every unit must be supported, whether there is a subset the ONC is considering, or whether it is at the discretion of the healthcare organization and their EHR. We propose that the final rule clearly states that these decision be left to the healthcare organization and their EHR. UCUM includes some units that are not applicable to healthcare settings. For example, there is no interest in entering a patient's weight in slugs or blood pressure in millibars."

§ 170.315(a)(12) Smoking status

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

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

Public Comment Field:

Standards for Smoking Status Codes:
We agree with our certified vendor's (Epic) statement: "*ONC proposes to adopt a more flexible approach to how smoking status is recorded, changed, and accessed in any of the available codes for smoking status in the September 2014 Release of the U.S. Edition of SNOMED CT. ONC indicates that they do not "expect the user interface to include a drop-down menu" of all of the available SNOMED CT codes as this "could have negative workflow effects" and that instead they "expect health IT developers and health care providers would work together to establish the appropriate implementation give the care setting." (68) We agree that generally a flexible approach to smoking status capture is appropriate.*"

End-User Display:
We agree with our certified vendor's (Epic) statement: *"Comments for ONC on Vitals, Smoking Status, and Family History - Draft - 5 - In the past, ONC has attempted to clarify that codes for identifying smoking status do not dictate display to end users and that other methods for capturing smoking status can be used as long as the system can map to the appropriate code for reporting and interoperability. It would be helpful to explicitly clarify again that this criterion is not intended to dictate display or methods for capture to avoid overly prescriptive certification."*

§ 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

(6) 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:

We agree with our certified EHR vendor's (Epic) statement in that *"there is limited value in the proposed requirement to support the ability to request educational resources based on the patient's preferred language because, as you acknowledge, educational resources are often not available in other languages. With the exception of three or four of the most commonly spoken languages, most other languages do not have educational resources that are accessible using the Infobutton standard. As materials in more languages become available and as demand grows, the industry will adopt this feature due to market forces, and it is unnecessary to include it in this criterion."*

§ 170.315(a)(20) Implantable device list

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(7) 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:

We feel that the ability to scan in any implant that has been updated with an available UDI barcode to our EHR system would be of great value. We do see that some lab areas and ambulatory areas often have implant cards available and use more of a free text generic implant data entry methodology. These should continue to be available workflow for ambulatory sites with the addition of entering free text implant card details without the need for a scanner.

§ 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

(8) 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:

We understand why ONC would want to establish a standard for capturing this information. Overall much of this information is captured in a wide variety of places in the patient chart and in combinations with additional items that we deem necessary (where groupings make sense to our organization and which may have more or less detail than what is being prescribed). Our EHR currently gives us the flexibility to capture the data we need in the workflows we feel are most appropriate to our organization. We are concerned that certification of this data may limit the flexibility we currently have and cause us to do major rework of the tools and workflows we currently have to document this data. We feel we will need to do a lot of work reconciling content (flowsheets, smart links, questionnaires, reports, best practice alerts etc.) if these standards cause our EHR vendor to have to limit the flexibility we currently have (become over prescriptive).

The proposal indicates that patients should have the opportunity to decline to specify an assessment response, but the proposed assessments do not include standard values for patient declines. We concur with examples given by our EHR vendor: “for example, education has a “Refused” option, but financial resource strain does not. Including such values for each assessment will support the exchange of information with other systems and help with consistency in data capture and user experience. For assessments consisting of several questions, such as AUDIT-C, it is unclear whether patients would decline the entire assessment or would individually decline particular questions” We agree that declining an entire set of questions would be more practical.

Practices for capturing gender identity information are not well defined yet, transgender initiatives are in process. Given the sensitive nature of the gender identity topic we need to have the flexibility to iteratively refine our approach in collaboration with healthcare delivery organizations, rather than locking into defined regulation. Flexibility is key.

§ 170.315(b)(1) Transitions of care

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

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

2015 Edition Health IT Certification Criterion

(1) Transitions of care.

(i) Send and receive via edge protocol. Technology must be able to:

(A) Send transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(d); and

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

(C) XDM processing. Receive and make available the contents of a XDM package formatted in accordance with the standard adopted in § 170.205(p)(1) if the technology is also being certified using an SMTP-based edge protocol.

(ii) Validate and display.

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

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

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

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

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

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

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

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

§ 170.315(b)(1) Transitions of care

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

(iii) Create.

(A) Enable a user to create a transition of care/referral summary:

(1) Formatted according to the standards adopted in § 170.205(a)(3);

(2) Formatted according to the standards adopted in § 170.205(a)(4); and

(3) Includes, at a minimum, the Common Clinical Data Set and the following data expressed, where applicable, according to the specified standard(s):

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

(ii) Cognitive status;

(iii) Functional status;

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

(v) Inpatient setting only. Discharge instructions.

(B) Patient matching data quality. Technology must be capable of creating a transition of care/referral summary that includes the following data and, where applicable, represent such data according to the additional constraints specified below:

(1) Data. first name, last name, maiden name, middle name (including middle initial), suffix, date of birth, place of birth, current address, historical address, phone number, and sex.

(2) Constraint. Represent last/family name according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0.

(3) Constraint. Represent suffix according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0 (JR, SR, I, II, III, IV, V, RN, MD, PHD, and ESQ). If no suffix exists, the field should be entered as null.

(4) Constraint. Represent the year, month and date of birth are required fields while hour, minute and second should be optional fields. If hour, minute and second are provided then either time zone offset should be included unless place of birth (city, region, country) is provided; in latter local time is assumed. If date of birth is unknown, the field should be marked as null.

(5) Constraint. Represent phone number (home, business, cell) in the ITU format specified in ITU-T E.123 and ITU-T E.164. If multiple phone numbers are present, all should be included.

(6) Constraint. Represent sex in accordance with the standard adopted at § 170.207(n)(1).

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

§ 170.315(b)(1) Transitions of care

Public Comment Field:

Receiving and Incorporating Summary of Care Documents:
We support the standardization of using USPS address format for patient mailing address matching.

Sending Two Documents:
The proposal that Health IT modules send two documents for transitions of care, one document for C-CDA R1.1 and one document for C-CDA R2.0, is problematic for the following reasons. The documents cannot be programmatically identified as identical because they show different information as required by the respective standard. R2.0 documents contain additional document sections, such as Goals and Health Concerns. Clinicians are likely to be confused by receiving two similar documents and might spend unnecessary time evaluating the documents for differences. Also, healthcare organizations would need twice the storage space for these documents, which means purchasing and maintaining additional servers to store the documents.

The HL7 Dual Capable C-CDA Task Force is looking to create a document that is compliant with both C-CDA R1.1 and C-CDA R2.0. However, this is a large undertaking with potentially negative ramifications, such as rolling back useful changes in R2.0 so that the document can conform to R1.1, like the consistency between LOINC and SNOMED codes for codifying observations.

Rather than requiring both documents to be sent, we recommend the following:

- An ONC 2015 Edition certified Health IT module must be able send documents conformant to C-CDA R2.0.
- An ONC 2015 Edition certified Health IT module must be able to process either a document conformant to C-CDA 1.1 or 2.0.
- An ONC 2014 Edition certified Health IT module must be able to process a document conformant to C-CDA R1.1 but is only expected to show, and not process, a document conformant to C-CDA R2.0.

These requirements encourage healthcare organizations to use the latest functionality and support more robust interoperability.

Templates:
We agree with the C-CDA R2.0 proposal for three new document templates: Care Plan, Referral Note, and Transfer Summary. We believe this to be helpful and more “meaningful” to healthcare providers.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(2) 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*

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

Public Comment Field:

Patient Choice of Data to be Shared:

According to our certified vendor's (Epic) summary "DS4P encourages the patient to be an active participant in the segmentation/filtering process by selecting which data should be marked at each level. Therefore, the patient is choosing which data will be shared, in what circumstances, and with which clinicians.", we feel it is not appropriate for our patients to make this decision as it could have negative impacts on the care they receive. This also may set expectations for patient that they have a choice on how their medical record is segmented and who can see what in their medical record. From a HIPAA and privacy perspective, this would probably be good for the patients. However, it could create problems. That is, if the patient creates an intricate release within this system—release my HIV results to Dr. X, Y, and Z but not Dr. S—or—only tell Dr. Y I am on antidepressants—this is not something we would necessarily honor through a release of information processes. For example, if Dr. S or Dr. Y called us and said that they needed information on the patient due to an emergency, we may release the information to these providers without the patient's authorization for treatment purposes.

Obligation and Refrain Policies: (such as "no collect," "no integrate," "no relink," "no reuse")

We disagree with the proposal for one provider to send another provider information they may rely on to give care, but not allow the receiving provider to integrate the information into their own medical record. This may violate the requirements of the definition of a "designated record set" under HIPAA (http://www.bricker.com/services/resource-details.aspx?resourceid=318) such that if a provider is relying on the information to provide care, even if it is an outside record, then it is to become part of the patient's designated record set that must be released to the patient upon the patient's request.

Effects on Patient Care:

We agree with our certified vendor's (Epic) following statements regarding the effects that data segmentation could have on patient care.

*"**Hiding information.** Obligation and Refrain Policies may require Health IT systems and healthcare organizations to hide documents or certain information, such as medications, from providers. This information should not be hidden because it can adversely impact patient care. Consider a scenario where a patient who is taking lithium for bipolar disorder is later prescribed a diuretic for hypertension by a cardiologist who is not able to view the patient's lithium prescription. Lithium can interact with a diuretic, resulting in a neurological disorder or death.*

***Pseudonyms.** Obligation policy may require a document to be pseudonymized prior to receiving the document. As a result, it may be difficult to match the document to the correct patient record, which increases the number of duplicate patient records and the risk of filing a document to the wrong chart.*

***Patient control.** Because many patients haven't had clinical training, they may not have the expertise to know what information is safe to hide or may not realize that they are hiding information from providers who need it to make well-informed medical decisions. The data segmentation policies are complex, so they may have a false sense of security that their information is protected without truly understanding how it's being used or reused. For example, a patient may choose to disclose her history of a malignant tumor removal to only her PCP. When her PCP notices a small lung nodule, he orders an x-ray. Because the radiologist who views the x-ray is unaware of the history of a malignant tumor, he does not have an elevated level of suspicion for metastatic lesions and does not complete timely follow-up.*

***Not integrating discrete data into a patient's chart.** If a document is tagged as "No Integrate," the discrete data in the document can't be reconciled. Discrete data needs to be reconciled so that it is available for clinical decision support and prompts providers to consider a patient's allergies or medication interactions when ordering additional medications.*

***Care coordination.** Documents need to be visible to the entire treatment team and not only the staff physician. If segmentation prevents some members of the care team (for examples, nurses, nurse practitioners, and pharmacists) from seeing documents while allowing others to see it (for example, physicians, physician assistants), then team-based approaches will be less effective because not everyone on the team is aware of a patient's complete chart. In addition, healthcare organizations could inadvertently be held liable for "leaking" sensitive information and violating DS4P requirements if a PCP enters information in a note that has been disclosed only to him, regardless of its criticality.*

***Identifying segmented data.** Healthcare software users will have to de-identify large blocks of user-entered text, such as progress notes or discharge summaries that include manually typed or transcribed protected health information, which can be time-consuming and expensive.*

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

Public Comment Field Continued:

Effects on Patient Care: (continued)

Population health management. *Providers who use population health tools to manage patients with certain conditions might miss patients with restricted health information, resulting in larger risks and higher costs later in their treatment.*

Removal of documents used to make clinical decisions. *Documents that are "deleted after use" may not be included in legal medical records. This can negatively impact clinicians' ability to make medical decisions, knowing that certain patient information may no longer be available in the future. Also, healthcare organizations will no longer have a complete chart to defend medical decisions during a lawsuit or justify claims to insurance providers."*

§ 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

(3) 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:

Refer to comments for criterion 170.315(b)(7).

§ 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

(4) 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 with the proposal to have a separate Care Plan document as we feel it could be beneficial for different roles that do not need the entire Continuity of Care (CCD) document. However, we would like ONC to reduce or refrain from including duplicative information in the Care Plan that is already available in the CCD to minimize length and only include information highly relevant for longitudinal care.

§ 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:

Messaging in HL7 2.5.1 We support the proposal to adopt HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5 because it resolves known issues in the previous release and offers improved support for standardized data transmission. However we would recommend allowing data to be sent per the state's standard if they are not able to support a newer version so that we can continue to use this measure to meet the requirement.

Replace CVX with NDC codes: It would be beneficial to keep historical data with CVX and move forward with NDC. EHRs should be able to send both CVX and NDC codes when both are available and able to send just one code if just one is available or able to be received. This would allow healthcare organizations and immunization registries to benefit from using NDC codes when possible, while still giving registries the flexibility to accept CVX codes during a transitional period.

Bidirectional interface: Technology for this type of data exchange (bidirectional) remains immature and if the registry is unable to participate in bidirectional exchange healthcare organizations should not be penalized. Organizations should be able to meet the measure even if the registry cannot support querying. It should be noted that if bidirectional exchange is available a "reconciliation" function (not auto reconciliation) is needed so that the provider has the ultimate control over what data from the registry is included in the patient record (since we have found that state registry databases are not always a reliable source of data).

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

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

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

2015 Edition Health IT Certification Criterion

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

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

Public Comment Field:

In regard to the optional certification criterion for certified EHR technology used in the ambulatory settings, we support our EHR vendor's suggestion that you remove the optional criterion and instead standardize criteria for syndromic data submission by providers, for example by requiring eligible professionals as well as eligible hospitals to use Release 2.0 of the PHIN Messaging Guide for Syndromic Surveillance.

§ 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

(3) 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:

Are any public health agencies able to receive live case reports currently? What we have found is that when a standard is not mature it creates significant hurdles for implementation, especially in the realm of public health reporting. We are concerned that public health agencies do not have the bandwidth to tackle case reporting by the 2017 and 2018 and that this measure may be one that should be deferred to later timeframes.

§ 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 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*

Public Comment Field:

We agree with the proposal for making this certification criterion optional.

Required Certificates

We disagree with the proposed criterion that requires each provider and all their delegated signers to register for eMDRs and obtain certificates. We support our certified vendor's (Epic) statement: *"Obtaining and maintaining certificates, especially for a large number of providers, can be expensive and resource intensive. Instead, the standard should permit use of a single organizational level certificate, as supported for e-prescribing of controlled substances."*

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.

"Removal" of Meaningful Use Measurement Certification Requirements	
Preamble FR Citation: 80 FR 16873	**Specific questions in preamble?** *No*
Public Comment Field:	
We agree with the removal of the Meaningful Use Measurement certification requirements that correspond to the "Topped Out", redundant and duplicative objectives for both eligible professional and eligible hospitals that CMS is proposing to remove from the Meaningful Use Stage 3 rule "in order to reduce the reporting burden on providers for measures already achieving widespread adoption."	

Referencing the ONC Health IT Certification Program	
Preamble FR Citation: 80 FR 16874	**Specific questions in preamble?** *No*
Public Comment Field:	
We like it when the certification criteria directly relates to an MU objective threshold or attestation requirement. However, we dislike the inclusion of multiple certification criteria that do not pertain specifically to the Meaningful Use program, such as 170.315(i)(1) Electronic submission of medical documentation. We would like to request that ONC provide clear direction on if/what would be needed for potential future audits to support the implementation of certification only criteria. We agree with the proposal to make the 2015 Edition certification requirements, including the electronic reporting of quality measures, optional in 2017 and required in 2018 as this will allow time for developers and participating providers to make the necessary technical and operational changes while still providing "early adopters" the opportunity to report one year prior. If the 2015 Edition is required in 2017 there is a high probability that CMS and/or ONC would have to again modify the 2017 reporting requirements to assist providers struggling to meet the requirements (similar to the 2015-2017 "mod" rule proposed currently).	