

# 1

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## 1 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

§ 170.314(b)(3)

Electronic prescribing. Enable a user to electronically create prescriptions and prescription-related information for electronic transmission in accordance with:

- (i) The standard specified in § 170.205(b)(2); and
- (ii) At a minimum, the version of the standard specified in § 170.207(h).

## 1 - Proposed STANDARDS

§ 170.205(b)(2)

NCPDP SCRIPT version 10.6

§ 170.207(h)

RxNorm February 6, 2012 Release

### 1 - HITSC Comments

Allow HL7 V2.x as a standard solely for discharge medications fulfilled within the hospital facility. Alternatively, give consideration to excluding these prescriptions from the numerator and denominator.

### Context and Additional Information

- (1) Discharge prescriptions filled by a pharmacy within the walls of a hospital facility frequently use HL7 v.2.x prescribing messages, however, even though the pharmacy inside the hospital facility may be in a different legal entity from the source of the discharge medication order it should be able to use the hospital's HL7 messaging within the same facility. Any valid HL7 v.2.x prescribing message should be included in certification and should be allowed for hospital discharge prescriptions when used inside a single hospital facility. Valid HL7 v.2.x prescribing messages are easily testable in certification according to the previous analysis reported to the work group by NIST staff.
- (2) Recommend NCPDP version 10.6 for external transmission.

## 2

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### 2- Proposed STANDARDS

§ 170.207(f)

OMB standards for race and ethnicity

§ 170.207(j)

Preferred language - ISO 639-1:2002

§ 170.207(k)

Cause of death - ICD-10-CM

### 2- Proposed 2014 Edition EHR CERTIFICATION CRITERIA

§ 170.314(a)(3)

Demographics.

- (i) Enable a user to electronically record, change, and access patient demographic data including preferred language, gender, race, ethnicity, and date of birth.
  - (A) Enable race and ethnicity to be recorded in accordance with the standard specified in § 170.207(f) and whether a patient declines to specify race and/or ethnicity.
  - (B) Enable preferred language to be recorded in accordance with the standard specified in § 170.207(j) and whether a patient declines to specify a preferred language.

Inpatient setting only. Enable a user to electronically record, change, and access preliminary cause of death in the event of a mortality in accordance with the standard specified in § 170.207(k).

#### 2- HITSC Comments

- (1) Change referenced vocabulary standard for preliminary cause of death to just refer to ICD-10.
- (2) Preferred language should be expressed by constraining 639-2 to those that are in ISO 639-1.
- (3) For race and ethnicity, the OMB standard should be used for 2014 edition certification while expressing that a higher degree of specificity could be used and that consideration be given to requiring more specific codes in the future.

# 3

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## 3 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

§ 170.314(a)(4)

Vital signs, body mass index, and growth charts.

- (i) Vital signs. Enable a user to electronically record and change, and access recordings of a patient's vital signs including, at a minimum, height/length, weight, and blood pressure.
- (ii) Calculate body mass index. Automatically calculate and electronically display body mass index based on a patient's height and weight.
- (iii) Optional – plot and display growth charts. Plot and electronically display, upon request, growth charts for patients.

## 3 - Proposed STANDARDS

None.

### 3 - HITSC Comments

Consistent with the previously issued HITSC recommendations on the assignment of code sets to clinical concepts for use in quality measures (transmitted 9/9/2011), the HITSC suggests that EHR technology be certified to use LOINC to identify laboratory test names and results, non-laboratory studies, and assessment instruments; SNOMED-CT for findings appropriate results, and responses to physical examination; and UCUM for units of measure.

# 4

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## 4 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

§ 170.314(a)(5)

Problem list. Enable a user to electronically record, change, and access a patient's problem list for longitudinal care in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3).

## 4 - Proposed STANDARDS

§ 170.207(a)(3)

SNOMED-CT<sup>®</sup> International Release January 2012

### 4 - HITSC Comments

Clarify the intent of “longitudinal” and “in accordance with”. With respect to the latter, explicitly consider the case where the provider uses a clinical interface terminology that is mapped to SNOMED-CT on the back end.

### 4 - Context and Additional Information

1. Suggest clarifying the phrase “in accordance with, at a minimum, the version of the standard...”
2. Suggest defining the term longitudinal, as this term can be interpreted in different ways, e.g. longitudinal over all care in a life span, longitudinal over care from a single provider, etc.
3. Regarding SNOMED CT – Need clarification regarding whether this means all data must be recorded in SNOMED CT (suggest this is too prescriptive), stored as SNOMED CT or represented as SNOMED CT.
4. Also need to clarify whether the end user must see the SNOMED CT representation of data collected, as this is invisible to the user in many cases.
5. The proposed rule as it stands is ambiguous regarding what exactly is required. One possible interpretation (which I think would be highly problematic) is that the EHR must display official SNOMED-CT descriptions (e.g. when presenting the user with search results during the process of adding a problem, or when displaying a problem list). This would preclude the use of clinical interface terminologies (CITs), which provide lexical variants for concepts from standardized terminologies like SNOMED-CT. CITs can improve user adoption of structured data entry processes (by increasing the recall when searching for a term) and allow for problem lists to more accurately reflect the clinician's thinking (by representing concepts in the specific lexical form they prefer), while still allowing for the benefits of data coded in standardized terminologies. A rephrasing of this portion of the regulation that I think would address this issue

would be as follows: *Enable a user to electronically record, change, and access a patient’s problem list for longitudinal care in using terms from, at a minimum, the version of the standard specified in § 170.207(a)(3), or terms mapped to, at a minimum, the standard specified in § 170.207(a)(3).*

6. The SNOMED-CT<sup>®</sup> standard should include the US Extension to SNOMED-CT<sup>®</sup> (citation to National Library of Medicine). The US extension will be required (e.g. for adopting pre-coordinated terms in SNOMED CT to match those found in US ICD-10-CM). This comment would apply to all certification criteria where the standard is implicated.
7. Need for the longitudinal aspect of the criteria to be well defined based on the definition from the HITPC with testing criteria well aligned to address the definition. A clear definition for longitudinal care. Patient-centric definition should reflect longitudinal care across the continuum of care in both ambulatory (multiple encounters) and inpatient (multiple hospitalizations). See proposed rule preamble for discussion (Note: change in definition will affect medication list and medication allergy list certification criteria – potentially making them “revised” certification criteria instead of “unchanged”).

# 5

## 5 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

### § 170.314(a)(8)

Clinical decision support.

- (i) Evidence-based decision support interventions. Enable a user to select (or activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in each one or any combination of the following:
  - (A) Problem list;
  - (B) Medication list;
  - (C) Medication allergy list;
  - (D) Demographics;
  - (E) Laboratory tests and values/results; and
  - (F) Vital signs.
- (ii) Linked referential clinical decision support.
  - (A) Enable a user to retrieve diagnostic or therapeutic reference information in accordance with the standard specified at § 170.204(b)(1).
  - (B) Enable a user to access the reference information specified in paragraph (ii)(A) relevant to patient context based on the data elements included in each one or any combination of the following:
    - ( 1) Problem list
    - ( 2) Medication list;
    - ( 3) Medication allergy list;
    - ( 4) Demographics;
    - ( 5) Laboratory tests and values/results; and
    - ( 6) Vital signs.
- (iii) Configure clinical decision support.
  - (A) Enable interventions and reference resources specified in paragraphs (a)(8)(i) and (ii) to be configured by an identified set of users (e.g., system administrator) based on each one of the following:
    - ( 1) A user's role;
    - ( 2) Clinical setting; and

- ( 3) Identified points in the clinical workflow.
- (B) Enable interventions to be triggered, based on the data elements specified in paragraph (a)(8)(i), when a summary care record is incorporated pursuant to § 170.314(b)(1).
- (iv) Automatically and electronically interact. Interventions selected and configured in accordance with paragraphs (a)(8)(i)-(iii) must automatically and electronically occur when a user is interacting with EHR technology.
- (v) Source attributes. Enable a user to review the attributes for each intervention or reference source for all clinical decision support resources including:
  - (A) Bibliographic citation (clinical research/guideline) including publication;
  - (B) Developer of the intervention (translation from clinical research/guideline);
  - (C) Funding source of the intervention development technical implementation; and
  - (D) Release and, if applicable, revision date of the intervention.

## 5 - Proposed STANDARDS

§ 170.204(b)(1)

HL7 Context-Aware Knowledge Retrieval (“Infobutton”) Standard, International Normative Edition 2010

### HITSC Comments

1. The certification criterion for CDS should express functional requirements that highlight patient specificity but not require certification to the HL7 “infobutton” standard.
2. Clarification should be provided with respect to the temporal aspect of incorporated summary care record. It should be based on context and be post-reconciliation (“trigger point for firing CDS”).

### Context and Additional Information

1. HL7 Infobutton is a useful standard for information retrieval and should be required in certification for the purpose of information retrieval, however, simple HTML web links should be added to certification and also should be able to be used for information retrieval. Information retrieval and linked references are important, but should not be classified as clinical decision support alongside interventions such as an alert or a reminder. The key distinction is for EHR technology to have the ability to enable a user to act (e.g. to retrieve information), versus having the ability to require a user to act (e.g. to click through an alert or reminder).
2. Clarify “in each one or any combination of the following.” Because vaccinations are not typically included in the medication list, and because they are not called out, one could interpret this to mean that CDS for vaccinations is excluded. Suggest “one or any combination of...” and suggest calling out vaccinations as a separate item. If the intent is for inclusion of one or more, suggest

limiting the list to things of highest value. For example, demographics and vital signs may be used as filtering criteria, but are likely not a starting point for referential CDS.

3. Is this a broad list of things that can be included in CDS, or that must? In other words, is there a minimum “bar”?
4. The Infobutton Implementation Guide should be included in the standard reference – not just the normative standard: URL-based Implementations of the Context-Aware Information Retrieval (Infobutton) Domain; Infobutton Request, Release 3 (Jan 2010)
5. A standard code system is required to implement the expected requirement, “that EHR technology enable interventions to be triggered when the specified data elements are incorporated into a summary care record pursuant to the capability specified at § 170.314(b)(1) (transitions of care – incorporate summary care record).” Value sets of information derived from or analogous to those in CQMs will be needed to implement this requirement. Thus, a standard code system to represent the data will be needed. The code systems should be specified for types of data as they are for CQMs. These should be aligned with the 090911 HITSC\_CQMVG\_VTF Transmittal Letter recommendations.
6. (iii) Configure CDS
  - iiiA3 – Suggest defining clinical work flow, or broadening to “care process.” There are many actors who all have a part to play in clinical workflow.
  - iiiB – Suggest clarifying “data elements”
  - Use of the word “electronic” in iv seems superfluous
7. The notification of an alert (related to a CDS) should be real time and face up or have the option that the end user gets a display that can require an action later (i.e. RN gets physician alert when ordering medication).
8. The data elements required for measurement need to be made clear but general (flexible) enough to allow for how systems log CDS alert related activity (audit logs).
9. The display of the CDS rule source information should be concretely stated as to valid options for that display – whether a display of textual information, links to internal or external sources or other means.



# 6

## 6 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

### § 170.314(a)(17)

Inpatient setting only – electronic medication administration record.

- (i) In combination with an assistive technology that provides automated information on the “rights” specified in paragraphs (i)(A) through (i)(D), enable a user to electronically verify the following before administering medication(s):
  - (A) Right patient. The patient to whom the medication is to be administered matches the medication to be administered.
  - (B) Right medication. The medication to be administered matches the medication ordered for the patient.
  - (C) Right dose. The dose of the medication to be administered matches the dose of the medication ordered for the patient.
  - (D) Right route. The route of medication delivery matches the route specified in the medication order.
- (ii) Right time. Electronically record the time and date in accordance with the standard specified at § 170.210(g), and user identification when a medication is administered.

## 6 - Proposed STANDARD

### § 170.210(g)

Synchronized clocks - RFC 1305 NTP or RFC 5905 NTPv4

### 6 - HITSC Comments

Assistive technology is not clearly defined. Make clear what the meaning of “automated” is for purpose of the test procedure when the objective states that manual transcription should not be required – does that mean that all “five rights” activities are based on some automated method or is some manual interaction allowed such as patient selection, signing the administration event, performing witnessing if required for patient identification as completed and other steps that still may depend on user interaction to make an entry into the system?

# 7

## 7 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

### § 170.314(e)(2)

Ambulatory setting only – clinical summaries. Enable a user to provide clinical summaries to patients for each office visit that include, at a minimum, the following data elements: provider’s name and office contact information; date and location of visit; reason for visit; patient’s name; gender; race; ethnicity; date of birth; preferred language; smoking status; vital signs and any updates; problem list and any updates; medication list and any updates; medication allergy list and any updates; immunizations and/or medications administered during the visit; procedures performed during the visit; laboratory tests and values/results, including any tests and values/results pending; clinical instructions; care plan, including goals and instructions; recommended patient decision aids (if applicable to the visit); future scheduled tests; future appointments; and referrals to other providers. If the clinical summary is provided electronically, it must be:

- (i) Provided in human readable format; and
- (ii) Provided in a summary care record formatted according to the standard adopted at § 170.205(a)(3) with the following data elements expressed, where applicable, according to the specified standard(s):
  - (A) Race and ethnicity. The standard specified in § 170.207(f);
  - (B) Preferred language. The standard specified in § 170.207(j);
  - (C) Smoking status. The standard specified in § 170.207(l);
  - (D) Problems. At a minimum, the version of the standard specified in § 170.207(a)(3);
  - (E) Encounter diagnoses. The standard specified in § 170.207(m);
  - (F) Procedures. The standard specified in § 170.207(b)(2) or § 170.207(b)(3);
  - (G) Laboratory test(s). At a minimum, the version of the standard specified in § 170.207(g);
  - (H) Laboratory value(s)/result(s). The value(s)/results of the laboratory test(s) performed; and
  - (I) Medications. At a minimum, the version of the standard specified in § 170.207(h).

## 7 - Proposed STANDARDS

§ 170.205(a)(3) Consolidated CDA	§ 170.207(a)(3) SNOMED-CT <sup>®</sup> International Release January 2012
§ 170.207(f) OMB standards for race and ethnicity	§ 170.207(m) ICD-10-CM
§ 170.207(j) Preferred language - ISO 639-1:2002 (change per prior recommendation)	§ 170.207(b)(2) or § 170.207(b)(3) HCPCS and CPT-4 or ICD-10-PCS
§ 170.207(l) Smoking status types	§ 170.207(g) LOINC version 2.38
	§ 170.207(h) RxNorm February 6, 2012 Release

### 7 - HITSC Comments

1. Endorse use of Consolidated CDA as a single content standard
2. Recommend the use of RxNorm for Medication Allergy terminology, inclusive of generic and brand drugs, drug classes, active and inactive ingredients.
3. Encounter diagnosis should adopt SNOMED CT instead of ICD-10. The preamble indicates the intent is to capture and represent the data primarily for clinical purposes and clinical accuracy where SNOMED CT is most appropriate, not for billing classification and other administrative purposes where ICD would be most appropriate. This comment applies to all certification criteria where encounter diagnoses are mentioned.
4. ICD-10-PCS should be replaced with SNOMED-CT. This comment applies to all certification criteria where ICD-10-PCS is mentioned as the standard for procedures.

### 7 - Context and Additional Information

1. The clinical operations workgroup recommends RxNORM has matured substantially and should be used to the extent possible for medication-related terminology including generic drugs, drug classes, active and inactive ingredients including contaminants or unintended ingredients (e.g., egg or yeast in vaccines). Allergy vocabulary should use RxNORM RxCUI identifiers for ingredient allergies and drug class instead of UNII and NDF-RT.
2. It should be clarified that an adverse effect would be expected to be included in “problem list” coded according to SNOMED-CT.

# 8

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## 8 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

§ 170.314(a)(14)

Patient lists. Enable an **EP or EH user** to electronically select, sort, access, and create lists of patients according to, at a minimum, the data elements included in:

- (i) Problem list;
- (ii) Medication list;
- (iii) Demographics; and
- (iv) Laboratory tests and values/results.

## 8 - Proposed STANDARDS

None.

### 8 - HITSC Comments

Make recommended edits to certification criteria.

### 8 - Context and Additional Information

Please see related comment on row 13 for immunization registries, requesting guidance on using standards to transmit lists of patients.

# 9

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## 9 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

§ 170.314(a)(16)

Patient-specific education resources. Enable a user to electronically identify and provide patient-specific education resources according to:

- (i) (i) At a minimum, each one of the data elements included in the patient's: problem list; medication list; and laboratory tests and values/results; and
- (ii) The standard specified at § 170.204(b)(1).

## 9 - Proposed STANDARDS

§ 170.204(b)(1)

HL7 Context-Aware Knowledge Retrieval (“Infobutton”) Standard, International Normative Edition 2010

### 9 - HITSC Comments

Make the HL7 “infobutton” standard optional for certification as this would also permit the use/implementation of other methods to provide patients with education resources, such as html web links.

# 10

## 10 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

§ 170.314(b)(1) and § 170.314(b)(2)

Transitions of care – incorporate summary care record. Upon receipt of a summary care record formatted according to the standard adopted at § 170.205(a)(3), electronically incorporate, at a minimum, the following data elements: Patient name; gender; race; ethnicity; preferred language; date of birth; smoking status; vital signs; medications; medication allergies; problems; procedures; laboratory tests and values/results; the referring or transitioning provider's name and contact information; hospital admission and discharge dates and locations; discharge instructions; reason(s) for hospitalization; care plan, including goals and instructions; names of providers of care during hospitalization; and names and contact information of any additional known care team members beyond the referring or transitioning provider and the receiving provider.

Transitions of care – create and transmit summary care record.

(i) Enable a user to electronically create a summary care record formatted according to the standard adopted at § 170.205(a)(3) and that includes, at a minimum, the following data elements expressed, where applicable, according to the specified standard(s):

(A) Patient name; gender; date of birth; medication allergies; vital signs; laboratory tests and values/results; the referring or transitioning provider's name and contact information; names and contact information of any additional care team members beyond the referring or transitioning provider and the receiving provider; care plan, including goals and instructions;

(B) Race and ethnicity. The standard specified in § 170.207(f);

(C) Preferred language. The standard specified in § 170.207(j);

(D) Smoking status. The standard specified in § 170.207(1);

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

(F) Encounter diagnoses. The standard specified in § 170.207(m);

(G) Procedures. The standard specified in § 170.207(b)(2) or § 170.207(b)(3);

(H) Laboratory test(s). At a minimum, the version of the standard specified in § 170.207(g);

(I) Laboratory value(s)/result(s). The value(s)/results of the laboratory test(s) performed;

(J) Medications. At a minimum, the version of the standard specified in § 170.207(h); and

(ii) Inpatient setting only. Hospital admission and discharge dates and location; names of providers of care during hospitalization; discharge instructions; reason(s) for hospitalization; and indication of whether an advance directive exists.

(iii) Transmit. Enable a user to electronically transmit the summary care record created in paragraph (i) in accordance with:

(A) The standards specified in § 170.202(a)(1) and (2).

(B) Optional. The standard specified in § 170.202(a)(3).

## 10 - Proposed STANDARDS

§ 170.205(a)(3) Consolidated CDA	§ 170.207(b)(2) or § 170.207(b)(3) HCPCS and CPT-4 or ICD-10-PCS
§ 170.207(f) OMB standards for race and ethnicity	§ 170.207(g) LOINC version 2.38
§ 170.207(j) Preferred language - ISO 639-1:2002	§ 170.207(h) RxNorm February 6, 2012 Release
§ 170.207(l) Smoking status types	§ 170.202(a)(1) Applicability Statement for Secure Health Transport
§ 170.207(a)(3) SNOMED-CT <sup>®</sup> International Release January 2012	§ 170.202(a)(2) XDR and XDM for Direct Messaging
§ 170.207(m) ICD-10-CM	(Optional) § 170.202(a)(3) SOAP-Based Secure Transport RTM version 1.0

### 10 - HITSC Comments

1. The certification criterion should require the first Direct specification at 170.202(a)(1) for certification “Applicability Statement for Secure Health Transport” and designate both of the two other referenced transport standards at 170.202(a)(2) and (a)(3) as optional.
2. Endorse use of Consolidated CDA as a single content standard
3. Standards citations should be fully specific. This applies to all certification criteria.
4. The collection of all organizations that will be communicating using NwHIN Direct, NwHIN Connect and other protocols in the US will ultimately be numbered in the hundreds of thousands, including not only organizations that use EHRs but those providing applications to support collaboration with patients or their designees as direct users. Such a diverse group will be unable to synchronize their upgrade to new standards even if they all have adopted the latest version of CEHRT. Some will inevitably be using the old version of a standard even as others are beginning to adopt a newer version. In order for a sender to begin using a new standard it would have to wait until all receivers were ready to receive it. It is impossible to know this much less for the most advanced organizations to wait until the least advanced have upgraded. There is a real danger of a deadlock that prevents the adoption of updated standards. Such deadlocks have presented or drastically slowed improvement in standards in the past. Fortunately there is a model for avoiding the deadlock available in the standards associated with the Internet, a much more complex network than even U.S. healthcare. In many standards such as electronic mail formats and transport level security the standards-writers anticipated the issue and designed the standards to support asynchronous cutover. Through these design techniques it is not only possible for the new organization to continue to receive information in the old

standard it is also possible for the less advanced organization to receive transactions using the upgraded standard and function as well as they would with transactions in the old standard.

Achieving asynchronous cutover in the general case requires consultation with HL7 and other SDOs that produce the standards. This is not feasible within the timeframe when the final rules for the 2014 Edition of standards must begin adoption, but ONC must establish leadership in working with the SDOs in time for the 2016 Edition. By that time the approach must be defined and certification criteria must be established to ensure that CEHRT can exchange transactions in the role of the more up-to-date system and the role of the less up-to-date system. At the same time ONC and CMS should establish a regulatory approach that allows meaningful use credit for continued support of the 2014 Edition for a period of time after the 2016 Edition becomes effective.

## 10 - Context and Additional Information

1. Different transmission protocols best fit different communities, different providers, different patients, or different transfer of care scenarios. Therefore eligible professionals and hospitals should be allowed to use any standard transmission protocol for purposes of the MU measure.
2. Require further definition of care plan (**CMS gives a brief definition of a care plan and requests comments in the MU rule**)
3. Note that "... additional known care team members..." being required in the testing should not be included unless further definition of what constitutes a known care team members is provided and a pertinent value set is referenced.
4. Need for clear and specific guidance relating MU measures to use of named standards (matching MU measures to Certification Criteria)
  - Affirm where transport standards are required for certification (i.e., the transport standards SMIME/SMTP and SOAP (proposed as optional for certification) are only required for certification to the "transition of care" certification criterion and that only the Direct transport standards are required for certification to the "view, download, and transmit to 3<sup>rd</sup> party" certification criterion).
  - Affirm for the MU transmit to 3<sup>rd</sup> party requirement that **any** transport standard can be used
  - Affirm that the standards for "incorporate lab results" certification (S&I Lab results interface) are not required for the MU incorporating laboratory results objective/measure
  - Clarify the relationship of all certified standards with MU objectives/measures
5. Consider adding additional elements to the summary of care record, such as surgical history.
6. Standard that defines two types of care teams: institutional care team and patient centered care team. Institutional care team may be hospital focused for acute event, and can accommodate the patient and designee(s) e.g. patient generated data. Patient centered care team assumes multiple institutions, providers, setting, designees and patient in design.



# 11

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## 11 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

§ 170.314(b)(4)

Clinical information reconciliation. Enable a user to electronically reconcile the data elements that represent a patient’s active medication, problem, and medication allergy list as follows. For each list type:

- (i) Electronically display the data elements from two or more sources in a manner that allows a user to view the data elements and their attributes, which must include, at a minimum, the source and last modification date.
- (ii) Enable a user to merge and remove individual data elements.
- (iii) Enable a user to review and validate the accuracy of a final set of data elements and, upon a user’s confirmation, automatically update the list.

## 11 - Proposed STANDARDS

None.

### 11 - HITSC Comments

Ability to perform actions should be based on role, as in “configure CDS” of the certification criterion.

### 11 - Context and Additional Information

1. Suggest including “other allergies” in addition to medication allergies.
2. Clinical information reconciliation needs to accommodate a specific data element that indicates that the information (lists or individual) has been reconciled with time stamp and clinician responsible. Adherence can also be included with the reconciliation and provided by the patient, (or designee) and also time date stamped with author. Metadata should carry with all data transactions.

# 12

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## 12 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

§ 170.314(b)(6)

Inpatient setting only – transmission of electronic laboratory tests and values/results to ambulatory providers. Enable a user to electronically create laboratory tests and values/results for electronic transmission in accordance with:

- (i) The standard (and applicable implementation specifications) specified in § 170.205(k); and
- (ii) At a minimum, the version of the standard specified in § 170.207(g).

## 12 - Proposed STANDARDS

§ 170.205(k)

HL7 2.5.1 and HL7 Version 2.5.1 Implementation Guide: Standards and Interoperability Framework Lab Results Interface, Release 1 (US Realm)

§ 170.207(g)

LOINC version 2.38

### 12 - HITSC Comments

1. Affirm use of the LRI specification and LOINC for new interfaces, but recommend grandfathering of existing interfaces that functionally meet the meaningful use criteria.
2. Note that full LOINC coding of all tests and analytes is not necessary to address the policy goals; rather, the subset that accounts for most frequent ambulatory use and alignment with quality measures and public health requirements should be the requirement.

# 13

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## 13 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

§ 170.314(f)(1) and § 170.314(f)(2)

Immunization information. Enable a user to electronically record, change, and access immunization information.

Transmission to immunization registries. Enable a user to electronically create immunization information for electronic transmission in accordance with:

- (i) The standard and applicable implementation specifications specified in § 170.205(e)(3); and
- (ii) At a minimum, the version of the standard specified in § 170.207(i).

## 13 - Proposed STANDARDS

§ 170.205(e)(3)

HL7 2.5.1 and Implementation Guide for Immunization Messaging Release 1.3

§ 170.207(i)

CVX code set: August 15, 2011 version

### 13 - HITSC Comments

Endorse selected standards

### 13 - Context and Additional Information

1. It would be useful to have a standard for updating registries with groups or lists of patients instead of only individual patient transactions. Standards organizations (i.e., HL7 for the v.2.5.1 message) should be consulted to recommend the most appropriate standard specification for these “batch” updates.
2. Strong support for ONC’s change in terminology from “retrieve and modify” to “access and change” and the clarification that this criterion does not include in scope retrieval of immunization data from an external source to the EHR. Support for the use of the selected standard.

# 14

## 14 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA\

### § 170.314(e)(1)

View, download, and transmit to 3<sup>rd</sup> party.

- (i) Enable a user to provide patients (and their authorized representatives) with online access to do all of the following:
  - (A) View. Electronically view in accordance with the standard adopted at § 170.204(a), at a minimum, the following data elements:
    - (1) Patient name; gender; date of birth; race; ethnicity; preferred language; smoking status; problem list; medication list; medication allergy list; procedures; vital signs; laboratory tests and values/results; provider's name and contact information; names and contact information of any additional care team members beyond the referring or transitioning provider and the receiving provider; and care plan, including goals and instructions.
    - (2) Inpatient setting only. Admission and discharge dates and locations; reason(s) for hospitalization; names of providers of care during hospitalization; laboratory tests and values/results (available at time of discharge); and discharge instructions for patient.
  - (B) Download. Electronically download:
    - (1) A file in human readable format that includes, at a minimum:
      - (i) Ambulatory setting only. All of the data elements specified in paragraph (e)(1)(i)(A)(1).
      - (ii) Inpatient setting only. All of the data elements specified in paragraphs (e)(1)(i)(A)(1) and (e)(1)(i)(A)(2).
    - (2) A summary care record formatted according to the standards adopted at § 170.205(a)(3) and that includes, at a minimum, the following data elements expressed, where applicable, according to the specified standard(s):
      - (i) Patient name; gender; date of birth; medication allergies; vital signs; the provider's name and contact information; names and contact information of any additional care team members beyond the referring or transitioning provider and the receiving provider; care plan, including goals and instructions;
      - (ii) Race and ethnicity. The standard specified in § 170.207(f);
      - (iii) Preferred language. The standard specified in § 170.207(j);
      - (iv) Smoking status. The standard specified in § 170.207(l);
      - (v) Problems. At a minimum, the version of the standard specified in § 170.207(a)(3);
      - (vi) Encounter diagnoses. The standard specified in § 170.207(m);
      - (vii) Procedures. The standard specified in § 170.207(b)(2) or § 170.207(b)(3);
      - (viii) Laboratory test(s). At a minimum, the version of the standard specified in § 170.207(g);
      - (ix) Laboratory value(s)/result(s). The value(s)/results of the laboratory test(s) performed;

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- (x) Medications. At a minimum, the version of the standard specified in § 170.207(h); and
  - (xi) Inpatient setting only. The data elements specified in paragraph (e)(1)(i)(A)(2).
- (3) Images formatted according to the standard adopted at § 170.205(j).
- (C) Transmit to third party. Electronically transmit the summary care record created in paragraph (e)(1)(i)(B)(2) or images available to download in paragraph (e)(1)(i)(B)(3) in accordance with:
- (1) The standard specified in § 170.202(a)(1); and
  - (2) The standard specified in § 170.202(a)(2).
- (ii) Patient accessible 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)-(C), the following information must be recorded and made accessible to the patient:
- (1) The electronic health information affected by the action(s);
  - (2) The date and time each action occurs in accordance with the standard specified at § 170.210(g);
  - (3) The action(s) that occurred; and
  - (4) User identification.
- (B) EHR technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) if it is also certified to the certification criterion adopted at § 170.314(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) is accessible by the patient.

## 14 - Proposed STANDARDS

§ 170.204(a) Web Content Accessibility Guidelines (WCAG) 2.0, Level AA Conformance	§ 170.207(m) ICD-10-CM
§ 170.205(j) DICOM PS 3—2011	§ 170.207(b)(2) or § 170.207(b)(3) HCPCS and CPT-4 or ICD-10-PCS
§ 170.205(a)(3) Consolidated CDA	§ 170.207(g) LOINC version 2.38
§ 170.207(f) OMB standards for race and ethnicity	§ 170.207(h) RxNorm February 6, 2012 Release
§ 170.207(j) Preferred language - ISO 639-1:2002	§ 170.202(a)(1) Applicability Statement for Secure Health Transport
§ 170.207(l) Smoking status types	§ 170.202(a)(2) XDR and XDM for Direct Messaging
§ 170.207(a)(3) SNOMED-CT® International Release January 201	§ 170.210(g) Synchronized clocks - RFC 1305 NTP or RFC 5905 NTPv4

### 14 - HITSC Comments

1. TLS should be added to the certification criterion and designated as optional for certification
2. Endorse use of Consolidated CDA
3. Apply vocabulary recommendations from 170.314(e)(2)
4. Apply transport recommendations from § 170.314(b)(1) and § 170.314(b)(2)
5. Recommend modularity of the View, Download and Transport requirements to enable models that unify patient experience across EHRs
6. *The intent of the Transport standards specified in § 170.202(a) is not clear.* Part of the confusion derives from the fact that the citations themselves are incomplete. We assume that (1) and (2) refer to the two core specifications from the Direct Project, and the only “SOAP-

Based Secure Transport RTM version 1.0” we could find is the modular specification developed through the Standards and Interoperability Framework effort to modularize the Nationwide Health Information Network (NwHIN, nee NHIN) specifications – correctly titled “NwHIN SOAP-Based Secure Transport RTM version 1.0.” We are confident that these references will be complete and accurate in the final regulation. Further confusion comes from the inconsistency between the two certification criteria that reference the Transport standards – one of which (Transitions of Care) requires § 170.202(a)(1) and (2), and cites (3) as “optional,” while the other (Transmit to 3<sup>rd</sup> Parties) requires only (1) and (2). We believe the criteria need to be consistent.

7. The intent of criteria § 170.314(e)(1)(i)(C) (Transmit to 3<sup>rd</sup> Party) and § 170.314(e)(1)(ii) (Patient accessible log) is unclear. Some of our Workgroup members interpreted § 170.314(e)(1)(i)(C) as a codification of the HITECH requirement to enable a patient to request that an electronic copy of their health information be sent to a 3<sup>rd</sup> party, others interpreted it more generally to include all transmissions to third party. This confusion led to differences in interpretations of the criterion requiring that the log of activities, including transmissions to third parties, be made accessible to the patient – some interpreting this criterion as requiring only that the log of “patient engagement” activities be made accessible, while others interpreting it as a requirement to provide patients access to a full accounting of all disclosures to 3<sup>rd</sup> parties. Based on the language on § 170.314(e)(ii)(A) above (when electronic health info is viewed, downloaded or transmitted using the capabilities in noted in this sub-section), it seems this log is specific to only actions/events that happened via the online capability. Some workgroup members’ reading of the language in the preamble suggests a much broader interpretation (page 13839 states that EHRs would certify to “this criterion would include the capability to track who has viewed, downloaded, or transmitted to a third party electronic health information and that patients would have access to this information”). Other members reading of the preamble suggest that these provisions of the certification criterion are intended to apply patient-requested transmissions to third parties, and logging of activities relating to patient interactions. To make the provisions of this certification criterion more explicit, we suggest clarifying that (e)(1)(i)(C) refers to transmissions requested by the patient, and that (e)(1)(ii) refers to the activities addressed in § 170.314(e).
8. EHR technology needs to be capable of securing all on-line interactions – whether these interactions be for accessing, exchanging, viewing, or downloading electronic content and services, or for messaging between two parties. Securing exchanges is addressed by the Transport standards specified in § 170.202, which are required for certification of the capability to exchange summary records needed for care transitions [§170.314(b)(2)(ii)], and the capability to transmit summary records to third parties [§170.314(e)(1)(i)(C)]. Securing messaging between providers and patients is addressed by §170.314(e)(3), which requires authentication, encryption, and integrity protection capabilities. However, no certification criteria or standards are specified for securing the viewing and downloading of information to patients specified in §170.314(e)(1)(i)(A) and §170.314(e)(1)(i)(B). We recommend adding a criterion requiring the capability to establish a secure channel for viewing and downloading content, structured similar to the criterion for secure messaging [§170.314(e)(3)]. That is: Ambulatory setting only – secure channel. Enable a user to establish a secure channel with a patient device that enables a patient to view and download content in a manner that ensures:
  - (i) Both the patient and EHR technology are authenticated; and

- (ii) All content exchanged using the channel is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

#### **14 - Context and Additional Information**

1. Patient download capability should be required to use Consolidated CDA. This format can meet the requirements for individual empowerment (i.e., to enable individuals to print, view, and store their information while at the same time its use advances interoperability by also enabling incorporation of discrete structured data into other systems in useful ways that simple free text (e.g. Blue Button) cannot).
2. Standards citation for XDM and XDR should refer to "IHE XDM" and "IHE XDR."



# 15

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## 15 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

§ 170.314(e)(3)

Ambulatory setting only – secure messaging. Enable a user to electronically send messages to, and receive messages from, a patient in a manner that ensures:

- (i) Both the patient and EHR technology are authenticated; and
- (ii) The message content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

## 15 - Proposed STANDARDS

§ 170.210(f)

Any encryption and hashing algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2.

### 15 - HITSC Comments

Please see comments under “view, download, and transmit to 3<sup>rd</sup> party” certification criterion.

# 16

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## 16 -Proposed 2014 Edition EHR CERTIFICATION CRITERIA

§ 170.314(d)(1)

Authentication, access control, and authorization.

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

## 16 -Proposed STANDARDS

None.

### 16 - HITSC Comments

No suggested revisions.

# 17

## 17 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

### § 170.314(d)(2)

#### Auditable events and tamper-resistance.

- (i) Enabled by default. The capability specified in paragraph (d)(2)(ii) must be enabled by default (i.e., turned on) and must only be permitted to be disabled (and re-enabled) by a limited set of identified users.
- (ii) Record actions. Record actions related to electronic health information, audit log status and, as applicable, encryption of end-user devices in accordance with the standard specified in § 170.210(e).
- (iii) Audit log protection. Actions recorded in accordance with paragraph (d)(2)(ii) must not be capable of being changed, overwritten, or deleted.
- (iv) Detection. Detect the alteration of audit logs.

## 17 - Proposed STANDARDS

### § 170.210(e)

Record actions related to electronic health information, audit log status, and encryption of end-user devices.

1. When EHR technology is used to record, create, change, access, or delete electronic health information, the following information must be recorded:
  - (i) The electronic health information affected by the action(s);
  - (ii) The date and time each action occurs in accordance with the standard specified at § 170.210(g);
  - (iii) The actions(s) that occurred;
  - (iv) Patient identification; and
  - (v) User identification.
2. When the audit log is enabled or disabled, the following must be recorded:
  - (i) The date and time each action occurs in accordance with the standard specified at § 170.210(g); and
  - (ii) User identification.
3. As applicable, when encryption of electronic health information managed by EHR technology on end-user devices is enabled or disabled, the following must be recorded:
  - (i) The date and time each actions occurs in accordance with the standard specified at § 170.210(g); and

- (ii) User identification.

### 17 - HITSC Comments

1. Suggest that it be clarified that if the audit log can be disabled that it only be able to be done so by a limited set of users. § 170.314(d)(2)(i) should state that “may only be disabled by a limited set of users” (if at all).
2. § 170.314(d)(2)(iii) disallows the purging of audit logs after the required legal retention period has expired. We recommend adding “except when disposing of log information after a legally defined retention period.” The concern is that if EHRs make it impossible to “delete” audit trails, then providers will be forced to retain the records forever -- which is not the legal requirement.
3. § 170.314(d)(2)(iii) requires that audit logs “not be capable of being changed, overwritten, or deleted.” § 170.314(d)(2)(iv) then requires a developer to implement the capability to “detect the alteration of audit logs.” If the system does not allow the audit logs to be altered, then there will never be anything to detect. So (iv) seems superfluous.

### 17 - Context and Additional Information

Recommend being more explicit in describing the level of how the “action taken” should be captured (what was done, level of specificity viz. data, e.g., status change from/to, record level details, etc.). This level of detail would be necessary for the audit log to be valuable from a medico-legal perspective. Test procedures should address scenarios such as sequential changes to a record (e.g., problem list, medication history) to establish that actions taken can be tracked appropriately.

# 18

## 18 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

### § 170.314(d)(3)

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

## 18 - Proposed STANDARDS

### § 170.210(e)

Record actions related to electronic health information, audit log status, and encryption of end-user devices.

1. When EHR technology is used to record, create, change, access, or delete electronic health information, the following information must be recorded:
  - (i) The electronic health information affected by the action(s);
  - (ii) The date and time each action occurs in accordance with the standard specified at § 170.210(g);
  - (iii) The actions(s) that occurred;
  - (iv) Patient identification; and
2. User identification.
3. When the audit log is enabled or disabled, the following must be recorded:
  - (i) The date and time each action occurs in accordance with the standard specified at § 170.210(g); and
  - (ii) User identification.
4. As applicable, when encryption of electronic health information managed by EHR technology on end-user devices is enabled or disabled, the following must be recorded:
  - (i) The date and time each actions occurs in accordance with the standard specified at § 170.210(g); and
  - (ii) User identification

## 18 - HITSC Comments

1. Suggest that it be clarified that if the audit log can be disabled that it only be able to be done so by a limited set of users.
2. As a general rule, we recommend that existing standards developed, maintained and governed by standards development organizations (SDOs), such as HL7, IHE, or IHTSDO, be preferred over writing standards language into regulations. The primary reasons for this position are: 1) an SDO standard has undergone much more extensive review and socialization than a list of requirements embedded in an NPRM; 2) an SDO standard is much more broadly adopted than a “standard” embedded in a regulation, and therefore more likely to take on uniform interpretation. For example, consider interpretation of the word

“change” in § 170.210(e)(4) above – the granularity of the “change” that triggers an audit record can have significant impacts on operations; and 3) an SDO standard is maintained by an external standards body, so when changes are needed, the standard can be changed without reenacting new regulation. In the case of the audit criterion, we are suggesting adopting the audit requirements of ASTM E2147 only (Section 5) as being preferred over enumerating a list of requirements embedded in the regulation.

# 19

## 19 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

### § 170.314(d)(4)

Amendments.

- i. Enable a user to electronically amend a patient's health record to:
  - (A) Replace existing information in a way that preserves the original information; and
  - (B) Append patient supplied information, in free text or scanned, directly to a patient's health record or by embedding an electronic link to the location of the content of the amendment.
- ii. Enable a user to electronically append a response to patient supplied information in a patient's health record.

## 19 - Proposed STANDARDS

None.

### 19 - HITSC Comments

Section 170.314(d)(4)(i)(B) is over-specified and introduces potential security and integrity risks. Patient-supplied information may take any form (including structured CCDA), not just "free text or scanned," and "embedding an electronic link" can be interpreted in many ways – including some that would create security and integrity risks. While this criterion incorporates language contained in the HIPAA Privacy Rule referencing both "appending" and "linking," the HIPAA language does not limit the form of information to "free text or scanned" nor does it mention "electronic links" (which would introduce security and integrity risks). The HIPAA Privacy Rule says "*Making the amending*. The covered entity must make the appropriate amendment to the protected health information or record that is the subject of the request for amendment by, at a minimum, identifying the records in the designated record set that are affected by the amendment and appending or otherwise providing a link to the location of the amendment." Note that no "electronic link" is mentioned.

To align with this regulatory language, while avoiding over-specifying this criterion and thereby constraining implementation options, we suggest changing (B) to read: "Append, or provide a link to, patient-supplied information." This recommendation also responds to ONC's request for comment on whether EHR technology should be required to be capable of appending patient-supplied information in both free-text and scanned format, or only one of these methods. Our response to this request for comment is that no format should be specified. Eliminating the reference to "in free text or scanned" allows different forms of patient-supplied information to be incorporated – including structured CCDA! This approach also is similar to (ii), which does not specify a form or method to append the response. Of course this wording change would not preclude the possibility of making the link a link to an external URL, but we would hope that the risk assessment would lead to a different solution.

## 20

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### 20 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

§ 170.314(d)(5)

Automatic log-off. Terminate an electronic session after a predetermined time of inactivity.

### 20 - Proposed STANDARDS

None.

#### 20 - HITSC Comments

No suggested revisions.

## 21

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### 21 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

§ 170.314(d)(6)

Emergency access. Permit an identified set of users to access electronic health information during an emergency.

### 21 - Proposed STANDARDS

None.

#### 21 - HITSC Comments

No suggested revisions.



# 22

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## 22 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

§ 170.314(d)(7)

Encryption of data at rest. Paragraph (d)(7)(i) or (d)(7)(ii) must be met to satisfy this certification criterion.

- i. If EHR technology manages electronic health information on an end-user device and the electronic health information remains stored on the device after use of the EHR technology on that device has stopped, the electronic health information must be encrypted in accordance with the standard specified in § 170.210(a)(1). This capability must be enabled by default (i.e., turned on) and must only be permitted to be disabled (and re-enabled) by a limited set of identified users.
- ii. Electronic health information managed by EHR technology never remains stored on end-user devices after use of the EHR technology on those devices has stopped.

## 22 - Proposed STANDARDS

None.

### 22 - HITSC Comments

We note that key management is not addressed in any certification criteria. Effective key management is critical to secure exchange. However, it is unclear how the general requirement to protect encryption keys can most effectively be incorporated into the certification criteria.

# 23

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## 23 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

§ 170.314(d)(8)

### Integrity.

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

## 23 - Proposed STANDARDS

None

### 23 - HITSC Comments

No suggested revisions.

# 24

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## 24 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

§ 170.314(d)(9)

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

## 24 - Proposed STANDARDS

§ 170.210(d)

Record treatment, payment, and health care operations disclosures. The date, time, patient identification, user identification, and a description of the disclosure must be recorded for disclosures for treatment, payment, and health care operations, as these terms are defined at 45 CFR 164.501.

### 24 - HITSC Comments

No suggested revisions.

# 25

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## 25 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

§ 170.314(a)(13)

Family health history. Enable a user to electronically record, change, and access a patient’s family health history.

## 25 - Proposed STANDARDS

None.

### 25 - HITSC Comments

1. There is concern that the HL7 Pedigree standard for familial relationships is not yet in wide adoption, and that most EHRs used some manner of non-structured or “provider built” code set values for family relationships – perhaps at most the HL7 Pedigree standard could be suggested as an optional criterion
2. The use of the HL7 Pedigree standard as the exclusive requirement for capture of familial relationships may require new development for many EHRs to build ability to either support reference mapping of current capture for family relationships or introduce issues of data comparability without implementing such reference mappings for stored activity data for purpose of normalizing references to family relationships that may have been in use for some time that are “non-standard” – pushing the industry to consider more widespread use of the HL7 Pedigree standard may be good to signal, but not require for Stage 2 certification so vendors can make appropriate plans to support its use.
3. The use of the HL7 Pedigree standard could impose some impact with not only clinical workflow but also on registration workflow where at least some familial relationships are captured that may share a common current code set with clinical use of familial relationships where next of kin and family relationships are defined through registration conversations for certain purposes and documented for family history clinically. Some time needs to be given to assess the impact of adapting to the use of the HL7 code set for one or both purposes.

# 26

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## 26 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

§ 170.314(f)(7) and § 170.314(f)(8)

Ambulatory setting only –cancer case information. Enable a user to electronically record, change, and access cancer case information.

Ambulatory setting only – transmission to cancer registries. Enable a user to electronically create cancer case information for electronic transmission in accordance with:

- i. The standard (and applicable implementation specifications) specified in § 170.205(i); and
- ii. At a minimum, the versions of the standards specified in § 170.207(a)(3) and § 170.207(g).

## 26 - Proposed STANDARDS

§ 170.205(i)

HL7 CDA, Release 2 and Implementation Guide for Healthcare Provider Reporting to Central Cancer Registries, Draft, February 2012)

§ 170.207(a)(3)

SNOMED CT<sup>®</sup> International Release January 2012

§ 170.207(g)

LOINC version 2.38

### 26 - HITSC Comments

We believe that this proposed standard is not currently in wide use. It is a distinct standard from the Consolidated CDA and would represent net new development requirement for most EHR vendors. However, we recognize that ambulatory EHR technology developers are not required to be certified to this certification criterion based on the proposed revised definition of Certified EHR Technology and that certification to this proposed certification criterion would be based on customer needs.

# 27

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## 27 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

§ 170.314(a)(18)

Inpatient setting only – advance directives. Enable a user to electronically record whether a patient has an advance directive.

## 27 - Proposed STANDARDS

None.

### 27 - HITSC Comments

No suggested revisions.

# 28

## 28 - Proposed 2014 Edition EHR CERTIFICATION CRITERIA

### § 170.314(c)(1)-(3)

#### (1) Clinical quality measures – capture and export.

- i. Capture. Electronically record all of the data elements that are represented in the standard specified in § 170.204(c).
- ii. Export. Electronically export a data file that includes all of the data elements that are represented in the standard specified in § 170.204(c).

#### (2) Clinical quality measures – incorporate and calculate.

- i. Incorporate. Electronically incorporate all of the data elements necessary to calculate each of the clinical quality measures included in the EHR technology.
- ii. Calculate. Electronically calculate each clinical quality measure that is included in the EHR technology.

#### (3) Clinical quality measures – reporting. Enable a user to electronically create for transmission clinical quality measurement results in a data file defined by CMS.

## 28 - Proposed STANDARDS

### § 170.204(c)

#### NQF Quality Data Model

### 28 - HITSC Comments

1. Standards: Recommend use of a constrained NQF QDM that only includes reference to data that should be included in EHRs. ONC should require that the EHR support capture and export of those QDM data elements that are used in whatever CQMs are required for MU.
2. The NPRM lists the QDM and its calculations as the issue to be considered and, perhaps, tested for certification. It is recommended that, instead, the essential requirements for certification listed in the final rule include all of the expected data requirements for the CQMs included in the Final Rule from CMS. And secondly, that those requirements are consistent with data requirements for certification for the interoperability and clinical decision support use case. Constraining the QDM is not the issue. It is recommended that testing of measures is needed and also that education of measure developers is needed to appropriately constrain eMeasures in concert with the parsimonious and more expanded certification requirements.

## 28 - Context and Additional Information

The Clinical Quality Workgroup had the additional following comments:

- ( 1) (c)(1)(ii) – Use existing PQRS XML format since QRDA format is not yet an available standard.
- ( 2) (c)(1)(ii) – Want to verify that data can be exported to another module outside the EHR for 3<sup>rd</sup> party analysis, & then submitted from that module to CMS.
- ( 3) ( c)(3) – Needs clarification. Does this mean report of patient level data, or aggregate data?
- ( 4) Question: What is the difference between (1)(ii) “export” and (3) “report?”



# Testing/Test Procedures

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## Privacy and Security Workgroup:

1. As a general comment, while we are not commenting on the CMS meaningful-use Stage 2 rule, ONC needs to make sure that the language in the metrics is clear as to how the standards are to be implemented/used to meet the corresponding MU metrics.
2. **Specific testing comments for “view, download, and transmit to 3<sup>rd</sup> party” certification criterion:** Need new TPs to test capabilities to:
  - View and Download: Adapt Timely Access TP for both view and download. Need to include all data element specified in criteria, and to apply to EHs as well as EPs. TP for download must include both creation of document (first 4 TPs) and download capability.
  - b) Transmit record to 3<sup>rd</sup> party [(i)(C)] – The first 6 TP links above are related to creation of a clinical document – transmission is not covered. So they should be adaptable for testing transmissions from a patient portal using Direct. Also need to generate a CCDA (rather than CCD or CCR). Need to establish trust-chain for the recipient beforehand. Use of appropriate S/MIME and signatures. Consider using the send-functions of the reference implementation for Direct as TP.
  - c) Patient Accessible Logs: Generation of audit trail for actions relating to patient login, viewing, downloading, transmitting to 3<sup>rd</sup> party, and viewing audit trail is not addressed in existing TPs. Need new TPs.
  - General comment: Test procedures should respond to the lowest level of “what” (security need should be addressed) without prescribing “how” to address it beyond what is specified in prescribed standards and certification criteria. Consider that the “how” could be addressed by prevailing industry practices such as those documented in NIST guidance, and that such practices might change more often than Meaningful Use Criteria. Also consider that there might be only one or two alternatives to satisfy the requirement. But this, in and of itself, does not mean that the requirement is too prescriptive.
3. **Specific testing comments for “secure messaging” certification criterion**
  - Patient and EHR Technology are authenticated: Since this criterion does not constrain implementation options, we see no way to objectively test conformance with this criterion. We suggest requiring the developer to document (attestation) how the EHR product meets this criterion. Service Organization Control (SOC) Type 2 reports and PCI third-party verification of controls are examples of approaches for addressing such “untestable” criteria, without thwarting market innovation or limiting architectural choices, such as cloud computing.
  - Message Content Encrypted and Integrity-protected: Here again, the criterion and the standard referenced are not specific enough to objectively test conformance. We suggest using a testing procedure based on attestation, similar to the current General Encryption TP

**4. Specific testing comments for “authentication, access control, and authorization” certification criterion**

- TP does not authenticate the identity asserted by the user. TP needs to 1) confirm that the asserted identity is a user recognized by the EHR (identification); 2) confirm that the actual identity is the one asserted (authentication); 3) confirm that the authenticated user has been authorized to perform the action being attempted (authorization). Current TP addresses only (1) and (3).
- There is very little difference between the Access Control and the Authentication TPs (neither addresses identification or authentication). Recommend re-drafting to create 3 separate TPs for 1) identification; 2) authentication; and 3) authorization.
- Consider the definition of Authentication contained in NIST 800-63-1 “Successful authentication requires that the Claimant prove through a secure authentication protocol that he or she possesses and control the token”.

**5. Specific testing comments for “auditable events and temper-resistance” certification criterion**

- Current TPs test only “(ii) Record actions.” Need TPs to test that EHR enables auditing by default (i); protects the audit log (iii); and detects alteration of audit logs (iv).
- For (i), suggest checking to assure that system is configured to audit required actions when the system is initialized.
- For (iii) and (iv) - audit protection and alteration detection - may need to be “tested” through attestation. Perhaps consider testing whether the access privileges (or roles) defined for the system prohibit write access by other than the audit system, or whether the system writes the audit log to write-once-read-many media.
- Requiring a developer to implement the capability to “detect the alteration of audit logs” in a system that is “not capable of being changed, overwritten, or deleted” seems superfluous. (We noted this in our comments re the NPRM.)

**6. Specific testing comments for “audit report(s)” certification criterion:** The current TP seems to be appropriate for the certification criterion. The four components of the TP cover the key elements required in the criteria (including create audit report, constrain report for a period of time, sort entries). However, the workgroup has recommended changing the standard in the NPRM to reference ASTM E2147-01.

**7. Specific testing comments for “amendments” certification criterion:** Need new TPs to test 1) capability to append content to a health record; 2) capability to record the fact that the content was provided by the patient; 3) capability to append a response to the patient-provided information; and 4) capability of EHR to enable a user to replace existing information while preserving original information.

**8. Specific testing comments for “encryption of data at rest” certification criterion**

- Current TP is for testing general capability to encrypt and decrypt. There is a need for new TPs to test capability to determine whether EHR technology manages any data on end-user devices; and if so, test EHR capability to encrypt data on end-user device managed by the EHR OR to remove all data stored on end-user device during EHR session, at end of that session.
- The WG expressed some concern about the overlap in time for the 2011 “General Encryption” criterion and the 2014 “Encryption of Data at Rest” criterion during any period of time when the two criterion might be applicable.

**9. Specific testing comments for “integrity” certification criterion**

- For those components of the EHR architecture that use the transport standards specified in §170.202(a), integrity testing will be part of the transport TP and would not need to be separately tested.
- For those components that do not use the transport standards specified in §170.202(a), such as secure messaging with consumers (§170.314(e)(3), we recommend using the TPs used for Stage 1 integrity testing.
- In both cases, we recommend including a TP to demonstrate protection of the integrity hash – not just the ability to create and pass the hash value.

10. **Specific testing comments for “accounting of disclosures” certification criterion:** Given that the final rule on accounting of disclosures has not been issued, no changes to the testing procedures are warranted.

11. **No suggested changes for testing to “automatic log-off” and “emergency access” certification criteria.**

## Implementation Workgroup:

### General Testing Comments on the NPRM

1. Explicitly test for the kinds of qualifying activities that are expected to be part of the measure (CPOE and general comment)
  - Consider ‘countable’ workflow scenarios in the test procedure
    - Including context of the user interaction (EH and EP)
  - Also address workflow situations that should not be counted for measure
  - Design clinical scenarios that test more than one measure
2. Where applicable, test procedures should verify that the EHR has the ability to affirm “none” to a MU objective (clinical and measurement)
  - i.e., No problem, no medication allergy, no advanced directive, no change in current meds...
  - Means of affirmation should reduce physician burden ... medication reconciliation specific to ‘meds prescribed by individual physician’ and dealing with all other meds in a streamlined fashion, i.e. “acknowledge” in lieu of verify medication as part of active medication list
3. The test procedure should include examples of valid clinical scenarios that constitute “notification”
  - Notification may not need to be interactive to the end user at the time the decision support rule “fires” and could include a variety of means of “notification”
4. Where appropriate, test procedures should define/differentiate users, roles and alert levels, and identify acceptable means of methods of notification

5. Where applicable, test procedures should identify and test the default functions within the EHR if necessary data is not recorded in the EHR
  - i.e., If a patient communication preference is not provided
6. Test procedures should verify that the EHR has the capability to produce reports in the format selected by the user
  - i.e., Generating a paper or electronic summary of care record
7. Test procedures should allow for clinical reconciliation
  - i.e., Enter new allergy/cancel an old one/maintain chain of custody - (clinical summary)
8. Where applicable, test procedures should verify that the EHR has the ability to mark information within the EHR as invalid
  - i.e., Advanced directives could be validated by the use of a date and timestamp
9. Where appropriate, test procedures should verify that outputs of an EHR activity are provided in human readable format
10. Test procedures should include clear definitions, where appropriate
11. The test procedure should support the capture of audit evidence of measurement events not the outcome such as
  - Tracking overrides
  - Identifying the number of alerts fired
  - The provider identity and role of the user who took action in response to the alert
- 12. Specific Comments on Testing Procedures for Transitions of care – incorporate summary care record / Transitions of care – create and transmit summary care record**
  - Add specificity to tester to confirm that no known Meds, Allergies or Med allergies is explicitly coded in the CCDA document.
  - Include verification of all minimum requirements as per the referenced specification.
  - Clarify: “electronically incorporate, at a minimum, the following data elements: Patient name; gender; race; ethnicity; preferred language; ...” Is the intention of this to include the discrete data integration into the receiving EHR?
  - Suggest requiring specific minimum vital signs: “vital signs including, at a minimum, height/length, weight, and blood pressure.”
  - Need specificity on the specific document types for CCDA to be tested.
  - Need to add test for required transport protocols. 170.202(a)(1); 170.202(a)(2); 170.202(a)(3)
- 13. Specific Comments on Testing Procedures for CDS**
  - The test procedure should include negative and positive qualification for the CDS rules
  - CDS test procedures should clarify if the factors listed in the objective and certification criteria should be tested individually or in combination ( i.e. all demographics, or specific combinations: age and gender and meds in use with either CDS or clinical summary (workflow and measurement comment))
- 14. Specific Testing Comments on eMAR**
  - Clinical scenarios needed eMAR – include clinical workflow scenarios to test the “five rights”

- Where appropriate, test procedures should differentiate between manual and automated processes of the EHR
- i.e. eMAR assisted technology - confirmatory action by end user ensuring clinical judgment

**15. Specific Comments on Testing Procedures for Public Health Reporting**

- Clinical scenarios are needed to ‘prove’ the functionality works
- Submission process
- Test data examples should take into account the common submission requirements of a representative sample of the State immunization registry
- Technical improvements are required for public health lab reporting result
- A conformance testing tool for syndromic surveillance should be developed for this test procedure so vendors can test the output file before going through certification
- Recommend alignment with The Centers for Disease Control and Prevention recommendation for syndrome reporting that will include more data elements than were tested in Stage 1

**16. Specific Comment on Testing for the e-prescribing Standards**

- Test procedures should include explicit and thorough examples of prescriptions (related to Sig, DAW, refills, instructions to pharmacist, etc.)
- Test procedures might also consider routing to retail and mail order pharmacies (see PVD segment Reference Number field and stipulate NCPDP IDs and pharmacy names for both).

**17. Specific Comment on Audit Reports**

- These criteria are very high level and vague, though they do explicitly establish information to be captured (date/time, user, patient, and “action taken”).
- We recommend being more explicit in describing the level of how the “action taken” should be captured (what was done, level of specificity viz. data, e.g., status change from/to, record level details, etc.). This level of detail would be necessary for the audit log to be valuable from a medico-legal perspective. Test procedures should address scenarios such as sequential changes to a record (e.g., problem list, medication history) to establish that actions taken can be tracked appropriately.

## Policy-oriented Comments

- Electronic Prescribing - Require electronic prescribing of controlled substances as a menu option for MU Stage 2 and core in MU Stage 3
- Problem List - In order for some Practices to meet MU, users would have to explicitly enter into the chart that there was no new diagnosis, which does not improve patient care and causes users extra steps for the sole purpose of counting.

- A simple solution would be to be sure it is possible to enter problems in the problem list.
- e.g., "Evidence-based Prevention", is not quite a problem, but may be a valid reason for a visit. And if an annual physical in a healthy 35-year-old involves neither a problem nor a legitimate reason for visit, so be it.
- One issue is the importance of recording that a physician has determined there is no problem as opposed to assuming that affirmation if a record exists in EMR with no problem stated. This is clearly more important in a multi-user EHR than a single user EHR and it is also important in order to be able to interoperably convey the state of the record.
- Requiring a Chart for a patient with no entered Diagnosis should be tested, but specifically recording no new problems for a visit/encounter for a patient with existing problems should not be required.
- CDS
  - Medication allergies are specified, but there are other allergies such as latex and peanut allergies that would change planned clinical treatment. Suggest including "medication and other allergies"
  - **Question:** Are things like smoking, suicide risk, and falls in the elderly included? Suggest being more specific about the types of things that are included.
- eMAR
  - "Automated tracking" should not specify a particular method of automation such as barcode scanning, RF devices or other similar technologies – all may be acceptable means of automation.
- Inpatient setting only – transmission of electronic laboratory tests and values/results to ambulatory providers.  
**(Not proposed by CMS)** MU Objective: Provide structured electronic laboratory results to eligible professionals. /MU Measure: Hospital labs send (directly or indirectly) structured electronic clinical lab results to the ordering provider for more than 40 percent of electronic lab orders received.

Denominator

The included results in the denominator are only those lab test results completed for outpatient services and excludes the results generated for inpatient services. Similarly, the denominator should include all those test results that are electronically entered into the hospital lab system, either through electronic submission from the outpatient provider or manually entered into the electronic lab system by the hospital employee. The denominator would exclude any lab services provided as third party or outsources services to other hospitals or similar entities.

Issue: Confusion about whether the term "test results that are electronically entered into the lab system" refers to literally to results or to the results that arise in fulfilling orders entered into the lab system. Assumption: the latter.

Issue: Confusion on the meaning of "all those test results that are electronically entered into the hospital lab system, either through electronic submission from the outpatient provider or manually entered into the electronic lab system by the hospital

employee." Since manual entry is included in the denominator we suggest the policy committee consider the revised language below.

Issue: How to count retransmissions due to the fulfillment of other results within a battery or amendments to a result.

Proposed Resolution: Coordinate with policy group to revise the statement of intent. Suggested revision (with the second option being favored by the HITSC IWG):

Workgroup Statement on Intent: The included results in the denominator are only those lab test results completed for outpatient services and excludes the results generated for inpatient services. Similarly, the denominator should include all those test results for which orders are electronically entered into the hospital lab system, either through electronic submission from the outpatient provider or manually entered into the electronic lab system by the hospital employee. The denominator would exclude any lab services provided as third party or outsources services to other hospitals or similar entities. The numerator and denominator would exclude any retransmission of results.

Or, an alternative based on orders:

Workgroup Statement on Intent: The denominator should include all orders entered all unique orders for outpatient services including those entered electronically and those entered manually by hospital personnel.

Numerator - The numerator should include all unique orders for which one or more of the results were transmitted electronically as structured data.

- Immunization Registries

At least several States have made communicating a patient's consent decision relative to the disclosure of immunization data by the provider (or consent to its re-disclosure by the external agency collecting it) a de facto requirement for production electronic submission of immunization data. In Stage 1, there was no particular requirement for collecting such a consent decision as a part of the test procedure for this criterion. Is it ONC's intent that this criterion test for the collection of a patient's consent decision in the PD1-12 Protection Indicator of the referenced implementation specification? Unless consent is tested as a part of the conformance test for the specification, we could have a case where EHRs in use in States that do have such consent requirements associated to production submission have what amounts to an incomplete certification as to the production "use" requirements that are important to CMS's "use" requirements for this objective in Stage 2.

- View, Download, and Transmit to 3<sup>rd</sup> Party
  - EP or EH should be able to use certificated base EHR, base EHR plus modules or self-certify software to meet this measure.
  - Requirement should not include the need to certify interoperability between modules.

## HITSC Comments on ONC Standards & Certification Criteria NPRM

- Patient preference should be allowed to choose for method of receiving their data and system should port in accordance with that method.
- Incorporate InfoButton standard for all patient facing systems.
- Patient should have access to raw and computable data on them.
- MU comment - Four and two business days are too long. The patient portal or other patient access should be capable of automatically populated with the patient information entered by the provider.
- **Advance Directives**
  - The Patient Engagement Workgroup believes that the certification criterion should be modified to accommodate scanned copies with reconciliation and version control.
- **CQMs**
  - (c)(1)(i) – Quality measures should have the ability to use patient-submitted data, which is not typically captured in EHRs.
- **Patient Communication Preference (not proposed by CMS as an MU objective/measure)**
  - The Implementation Workgroup and Patient Engagement Workgroup believe that patient communication preference should be recorded for use in all situations where it is relevant.