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

RE: NPRM: Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology

The Notices of Proposed Rulemaking for the 2014 Edition of the Standards, Implementation Specifications and Certification Criteria for Electronic Health Record Technology and the Revisions to the Permanent Certification Program for Health Information Technology mark a major, positive step forward in the nation's efforts to improve health and health care by putting modern information technology (IT) tools at the fingertips of medical professionals and consumers alike. Health Level Seven members strongly support the development and widespread implementation of interoperable healthcare IT and congratulate the Office of National Coordinator on producing this thoughtful document.

Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organization (SDO) dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7's 2,300+ members represent approximately 500 organizations that represent more than 90% of the information systems vendors serving healthcare in the US.

HL7's comments are provided below in the preferred template and represent hours of review and reflection by the members of its Working Groups.

Proposed 2014 Edition EHR Certification Criteria

New Certification Criteria

Ambulatory and Inpatient Setting

§ 170.314(a)(9) - Electronic notes

MU Objective

Record electronic notes in patient records. *(Not proposed by CMS)*

2014 Edition EHR Certification Criterion

Electronic notes. Enable a user to electronically record, access, and search electronic notes.

Preamble FR Citation: 77 FR 13838

Specific questions in preamble? *No*

Public Comment Field:

While we understand the need for an ability to search free text considering available data sources, we suggest that ONC should encourage capture and exchange of all clinical documentation using structured data and agreed to standard vocabulary to enable clinical decision support within and across EHRT. Use of standard exchange mechanisms such as Consolidated CDA document types or V2 messages would then further improve the ability to use the data in a meaningful way.

§ 170.314(a)(12) - Imaging

MU Objective

Imaging results and information are accessible through Certified EHR Technology.

2014 Edition EHR Certification Criterion

Imaging. Electronically indicate to a user the availability of a patient's images and/or narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable immediate electronic access to such images and narrative interpretations.

Preamble FR Citation: 77 FR 13838

Specific questions in preamble? *Yes*

Public Comment Field:

Although it is possibly too premature to adopt the Consolidated CDA Diagnostic Imaging Report in Stage 2, we suggest that ONC communicates a direction towards this standard to complement the DICOM image standard for use in exchanging images and their interpretations. The Consolidated CDA Diagnostic Imaging Report standard was developed jointly between HL7 and DICOM and is starting to get traction in the industry.

§ 170.314(a)(13) - Family health history

MU Objective

Record patient family health history as structured data.

2014 Edition EHR Certification Criterion

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

Preamble FR Citation: 77 FR 13838

Specific questions in preamble? *Yes*

Public Comment Field:

HL7 supports the inclusion of Family History in Meaningful Use Stage 2. The HL7 Pedigree (Family History) model standard is based on several successful long-term implementations within clinical settings, and has been accepted by ANSI. In addition, the HL7 Clinical Genomics workgroup is actively maintaining Family History/Pedigree models and developing a supplementary, US Realm specific, implementation guide (again based on clinical implementations), to facilitate broad adoption.

The Surgeon General's My Family Health Portrait is widely used, is based on the HL7 model, and is interoperable with Microsoft HealthVault. In order to make the products of the My Family Health Portrait tool interoperable in an EHR environment, developers used existing standards including the HL7 Family History Model, LOINC, SNOMED-CT and HL7 Vocabulary. The tool includes an applicable subset of information from the minimum core dataset for family health history, pursuant to recommendations by the American Health Information Community (AHIC). Another HL7 Pedigree-based tool used at multiple hospitals is Hughes riskApps. The software performs a cancer risk assessment that helps to identify and manage women at high risk for hereditary breast and ovarian cancer. It also features a cardiology study module, a lymphedema study module, and a prenatal module. Other tools, like Intermountain Healthcare's Our Family Health, are currently developing HL7 messaging.

In 2008 the HITSP Family History Decision Support for Genetic Risk Analysis Component Interoperability Specification was created. It is used to communicate genetic and family history information from healthcare IT applications to a clinical decision support system that provides an assessment of genetic risk of disease for a patient. It uses the Fully LOINC-Qualified Genetic Variation Model, Release 1, and Pedigree, Release 1 models to support the communication of genetic and family history information to the clinical decision support system, and to support the communication of risk information from that system back to the originator.

We would also point out that while not as rich as the cited Pedigree standard, the Consolidated CDA Family History templates do meet the stated minimum goal of capturing "the health history of a patient's first-degree relatives".

To ensure the successful implementation of the Stage 2 requirement, HL7 Clinical Genomics workgroup pledges to (1) promote its current and future standards, along with education, adoption and implementation of the standard, (2) interface with the larger community for Release 2 input and piloting/testing opportunities, (3) publish an implementation guide (HL7 Pedigree Family History Release 2, US Realm), (4) promote the AHIC minimum data set as a data capture standard, and (5) work with CMS and ONC towards a strategy for future data transmission requirements, interoperability, and use of family health history data in clinical decision support.

Personalized health plans should be created on an individual level with one's doctor and be based on many factors, including one's family health history. Understanding family genetics and history can help take personalized preventative measures specific to a patient's risks.

§ 170.314(e)(1) - View, download, and transmit to 3rd party

MU Objective

EPs

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

EHS and CAHs

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

2014 Edition EHR Certification Criterion

View, download, and transmit to 3rd party.

Enable a user to provide patients (and their authorized representatives) with online access to do all of the following:

View. Electronically view in accordance with the standard adopted at § 170.204(a), at a minimum, the following data elements:

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.

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.

Download. Electronically download:

A file in human readable format that includes, at a minimum:

Ambulatory setting only. All of the data elements specified in paragraph (e)(1)(i)(A)(1).

Inpatient setting only. All of the data elements specified in paragraphs (e)(1)(i)(A)(1) and (e)(1)(i)(A)(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):

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;

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

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

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

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

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

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

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

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

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

Inpatient setting only. The data elements specified in paragraph (e)(1)(i)(A)(2).

Images formatted according to the standard adopted at § 170.205(j).

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:

The standard specified in § 170.202(a)(1); and

The standard specified in § 170.202(a)(2).

Patient accessible log.

§ 170.314(e)(1) - View, download, and transmit to 3rd party

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:

The electronic health information affected by the action(s);

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

The action(s) that occurred; and

User identification.

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.

Standard(s) and Implementation Specifications

§ 170.204(a) (Web Content Accessibility Guidelines (WCAG) 2.0, Level AA Conformance); § 170.205(a)(3) (Consolidated CDA); § 170.205(j) (DICOM PS 3—2011); § 170.207(f) (OMB standards for the classification of federal data on race and ethnicity); § 170.207(j) (ISO 639-1:2002 (preferred language)); § 170.207(l) (smoking status types); § 170.207(a)(3) (SNOMED-CT[®] International Release January 2012); § 170.207(m) (ICD-10-CM); § 170.207(b)(2) (HCPCS and CPT-4) or § 170.207(b)(3) (ICD-10-PCS); § 170.207(g) (LOINC version 2.38); § 170.207(h) (RxNorm February 6, 2012 Release); § 170.202(a)(1) (Applicability Statement for Secure Health Transport) and § 170.202(a)(2) (XDR and XDM for Direct Messaging); and § 170.210(g) (synchronized clocks).

Preamble FR Citation: 77 FR 13838-41

Specific questions in preamble? *Yes*

Public Comment Field:

We suggest to create consistent definitions and terminology across criteria as it relates to Clinical Summary, Summary of Care Record, etc. There is consensus in the HL7 Structured Documents workgroup that “Documentation of Care” is the most appropriate name for this document.

We suggest that SNOMED is used as the standard vocabulary for Encounter Diagnosis rather than ICD-10-CM.

In these and other criteria there is inconsistent use of vocabulary relative to audit reports, patient accessible logs etc. where this criterion and other criteria can benefit from consistency. We suggest that ONC initiates discussions, e.g., through the S&I Framework, with the appropriate SDOs to arrive at a common set of vocabulary, possibly format, for use in the different security related reporting requirements that enable consistent capture and transmission with standard, computable, interoperable, and human-readable vocabulary and formats.

We noticed that NPRM references an outdated version of the Consolidated CDA guide. The latest published version is December 2011. We also note that references to Consolidated CDA are ambiguous and may be interpreted as pointing to CCD. We suggest this be corrected to point to the Consolidated CDA guide.

The CDA Consolidation guide is a compilation of 9 document types (CCD, Consultation Note, Diagnostic Imaging Report, Discharge Summary, History and Physical Note, Operative Note, Procedure Note, Progress Note, Unstructured Document), and in general, when referencing Consolidated CDA, it is not clear if the reference is strictly to Consolidated CDA's CCD and/or to other document types. In some cases, such as where a criterion requires inclusion of an encounter diagnosis, it might be inferred that the NPRM is referencing some other document type, since CCD doesn't contain an encounter diagnosis template. (Note – we are putting Consolidated CDA back through ballot, in order to ensure that, at a minimum, CCD does have CDA templates for those data elements felt to be essential within the MU2 NPRM, including the encounter diagnosis. We thank the S&I group for formulating this list).

While the standards referenced are essential, we are concerned that the ability to implement in particular the

§ 170.314(e)(1) - View, download, and transmit to 3rd party

transmission requirements requires more guidance and infrastructure to be successful. Direct standards are referenced, but HIE using various IHE profiles support the objectives as well. The larger challenge though is with the ability to transmit to third parties considering the current state of directories and the need to properly authenticate the intended recipient to protect PHI. We suggest in the absence of guidance and directory maturity to push the transmission requirements to a future edition.

Ambulatory Setting

§ 170.314(f)(7) - Cancer case information; and (f)(8) - Transmission to cancer registries

MU Objective

Capability to identify and report cancer cases to a State cancer registry, except where prohibited, and in accordance with applicable law and practice.

2014 Edition EHR Certification Criteria

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

(f)(8) Ambulatory setting only – transmission to cancer registries. Enable a user to electronically create cancer case information for electronic transmission in accordance with:

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

Standards and Implementation Specifications

§ 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[®] International Release January 2012); and § 170.207(g) (LOINC version 2.38).

Preamble FR Citation: 77 FR 13844

Specific questions in preamble? *No*

Public Comment Field:

Currently, the proposed implementation guide is not harmonized with the Consolidated CDA guide. We suggest that for improved consistency the proposed guide be harmonized first and then incorporated by reference in the next edition.

Inpatient Setting

§ 170.314(b)(3) - Electronic prescribing

MU Objective

Generate and transmit permissible discharge prescriptions electronically (eRx).

§ 170.314(b)(3) - Electronic prescribing

2014 Edition EHR Certification Criterion

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

The standard specified in § 170.205(b)(2); and

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

Standards

§ 170.205(b)(2) (NCPDP SCRIPT version 10.6) and § 170.207(h) (RxNorm February 6, 2012 Release).

Preamble FR Citation: 77 FR 13844-45

Specific questions in preamble? *No*

Public Comment Field:

We suggest that when an EH/CAH transmits prescriptions upon discharge to a hospital based pharmacy per patient preference, even if that pharmacy is a different legal entity, that HL7 V2 prescribing messages are permissible, thus avoiding replacement of standards based interfaces unnecessarily and enabling providers to include these transactions in their overall objective measure threshold.

§ 170.314(b)(6) - Transmission of electronic laboratory tests and values/results to ambulatory providers

MU Objective

Provide structured electronic laboratory results to eligible professionals.

2014 Edition EHR Certification Criteria

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:

The standard (and applicable implementation specifications) specified in § 170.205(k); and

At a minimum, the version of the standard specified in § 170.207(g).

Standards and Implementation Specifications

§ 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); and § 170.207(g) (LOINC version 2.38).

Preamble FR Citation: 77 FR 13845

Specific questions in preamble? *No*

Public Comment Field:

We are concerned with the expanding the scope of an EHR to incorporate LIS capabilities. We also note that the scope of the proposed implementation guide focused on LIS to EHR communication for ambulatory laboratory test results. Since not every hospital's EHR is involved in the communication of a hospital based LIS to ambulatory providers, we suggest that this criterion is optional to allow EHR software developers to determine whether their capabilities are involved in the communication of lab results from a hospital based LIS to ambulatory providers, and if they are whether this guide is already suitable to fit that flow.

Revised Certification Criteria

Ambulatory and Inpatient Setting

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§ 170.314(a)(3) - Demographics

MU Objective

Record the following demographics: preferred language; gender; race; ethnicity; date of birth; and for the inpatient setting only, date and preliminary cause of death in the event of mortality in the EH or CAH.

2014 Edition EHR Certification Criterion

Demographics.

Enable a user to electronically record, change, and access patient demographic data including preferred language, gender, race, ethnicity, and date of birth.

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.

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).

Standards

§ 170.207(f)(OMB standards); § 170.207(j) (ISO 639-1:2002); and § 170.207(k) (ICD-10-CM).

Preamble FR Citation: 77 FR 13846

Specific questions in preamble? *No*

Public Comment Field:

We support the recording, storing, and reporting of demographic data as structured data. For race/ethnicity we suggest the use of CDC vocabulary as it is consistent with OMB's vocabulary while it allows for finer grained data capture.

§ 170.314(a)(8) - Clinical decision support

MU Objective

Use clinical decision support to improve performance on high-priority health conditions.

2014 Edition EHR Certification Criterion

Clinical decision support.

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:

Problem list;

Medication list;

Medication allergy list;

Demographics;

Laboratory tests and values/results; and

Vital signs.

Linked referential clinical decision support.

Enable a user to retrieve diagnostic or therapeutic reference information in accordance with the standard

§ 170.314(a)(8) - Clinical decision support

specified at § 170.204(b)(1).

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.

Configure clinical decision support.

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.

Enable interventions to be triggered, based on the data elements specified in paragraph (a)(8)(i), when a summary record is incorporated pursuant to § 170.314(b)(1).

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.

Source attributes. Enable a user to review the attributes for each intervention or reference source for all clinical decision support resources including:

- Bibliographic citation (clinical research/guideline) including publication;
- Developer of the intervention (translation from clinical research/guideline);
- Funding source of the intervention development technical implementation; and
- Release and, if applicable, revision date of the intervention.

Standards

§ 170.204(b)(1) (HL7 Context-Aware Knowledge Retrieval (“Infobutton”) Standard, International Normative Edition 2010).

Preamble FR Citation: 77 FR 13847

Specific questions in preamble? *Yes*

Public Comment Field:

We should note that the Context-Aware Knowledge Retrieval Standard Normative Edition by itself is not implementable. It can be implemented in conjunction with one of the two available implementation guides: the URL-based Implementation Guide and/or the SOA-based Implementation Guide. We suggest that the URL-based Implementation Guide is more widely used at this stage.

We request clarification on the meaning of “hard-wire”. Does it mean having static links to Web-based resources or having content stored within the EHR?

§ 170.314(a)(8) - Clinical decision support

We suggest clarification on the section on linked referential clinical decision support (8)(ii), especially the meaning of “any combination of the following”. Although the standard allows a main search criteria to be composed of multiple concepts, to our knowledge there is no experience combining concepts from different domains (e.g., problems and medications) in the same Infobutton request. We request clarification on how to count interventions as there is no standard definition for intervention.

§ 170.314(a)(16) - Patient-specific education resources

MU Objective

Use clinically relevant information from Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient.

2014 Edition EHR Certification Criterion

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

- (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).

Standard

§ 170.204(b)(1) (HL7 Context-Aware Knowledge Retrieval (Infobutton) Standard, International Normative Edition 2010).

Preamble FR Citation: 77 FR 13847-48

Specific questions in preamble? *No*

Public Comment Field:

We seek clarification whether the intent is to require EHRT that currently have patient education content imported in their products to also provide Web-based patient education access using the Infobutton Standard in order to meet standards certification criteria and/or the EHR incentive, or replace the internal capabilities? We suggest that replacement would not be reasonable.

§ 170.314(b)(1) - Transitions of care - incorporate summary care record; and (b)(2) - Transitions of care - create and transmit summary care record

MU Objective

The EP, EH, or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.

2014 Edition EHR Certification Criteria

(1) 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.

(2) Transitions of care – create and transmit summary care record.

§ 170.314(b)(1) - Transitions of care - incorporate summary care record; and (b)(2) - Transitions of care - create and transmit summary care record

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):

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;

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

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

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

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

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

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

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

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

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

Inpatient setting only. Hospital admission and discharge dates and location; names of providers of care during hospitalizations; discharge instructions; and reason(s) for hospitalization.

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

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

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

Standards

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

Preamble FR Citation: 77 FR 13848-49

Specific questions in preamble? *Yes*

Public Comment Field:

We note the need identified earlier for synchronizing various definitions. The same comments apply to this criterion as we have stated earlier as it relates to the standards related to the Consolidated CDA and relevant vocabulary.

The CDA Consolidation guide is a compilation of 9 document types (CCD, Consultation Note, Diagnostic Imaging Report, Discharge Summary, History and Physical Note, Operative Note, Procedure Note, Progress Note, Unstructured Document), and in general, when referencing Consolidated CDA, it is not clear if the reference is strictly to Consolidated CDA's CCD and/or to other document types. In some cases, such as where a criterion requires inclusion of an encounter diagnosis, it might be inferred that the NPRM is referencing some other document type, since CCD doesn't contain an encounter diagnosis template. (Note – we are putting Consolidated CDA back through ballot, in order to ensure that, at a minimum, CCD does have CDA templates for those data elements felt to be essential within the MU2 NPRM, including the encounter diagnosis. We thank the S&I group for formulating this list).

We request clarification on the notion of “incorporation” provided in the rule. Incorporation for laboratory results

§ 170.314(b)(1) - Transitions of care - incorporate summary care record; and (b)(2) - Transitions of care - create and transmit summary care record

received through messages, specifically those using the Laboratory Results Interface, is distinctly different than for those laboratory results received as part of a document. Including data from structured documentation IS NOT THE SAME as what you would do for laboratory results. There is an implication that incorporation requires reconciliation of data that goes over and above what is done for laboratory results.

We suggest that reconciliation must be done for certain data elements, while for others, when properly structured/identified (e.g., supporting lab results), one could more automatically incorporate if necessary. We should note though that incorporation of individual data within a document may not be appropriate, whether through reconciliation or automatic. E.g., provenance meta data is important to aid in the reconciliation, e.g., source/author. Other reasons that incorporation cannot be automated are that [1] many EHRs require that a term be in their Problem List Master File in order to get onto the Problem List; [2] many EHRs have local Problem terms that are mapped to SNOMED, and as a result, we can't assume that two CCDs, each having a Problem mapped to the same SNOMED code, are both referring to exactly the same thing. Consequently we believe this requirement should be optional, based on the discretion and need for the clinician to consolidate certain data within their EHRT. We request clarification of the term "incorporate" more specifically for the respective criteria as the general definition provided is too ambiguous. In this instance, the term "reference" may be more appropriate so it is clear that documents do not have to be decomposed into separate fields and stored as individual fields, although it does not preclude EHRT to support decomposing a document into its structured content and selectively copy this into the EHRT with or without manual intervention.

We suggest that by MU Stage 3 ONC proposes adoption of the privacy and security standards for XDR and XDM transport metadata as specified in the ONC Data Segmentation for Privacy Initiative such as HL7 Confidentiality Codes, and other Privacy and Security vocabulary we have recommended in our comments.

§ 170.314(b)(5) - Incorporate laboratory tests and values/results

MU Objective

Incorporate clinical laboratory test results into Certified EHR Technology as structured data.

2014 Edition EHR Certification Criteria

Incorporate laboratory tests and values/results.

(i) Receive results.

(A) Ambulatory setting only.

(1) Electronically receive clinical laboratory tests and values/results formatted in accordance with the standard (and implementation specifications) specified at § 170.205(k) and, at a minimum, the version of the standard specified in § 170.207(g).

(2) Electronically display the tests and values/results received in human readable format.

(B) Inpatient setting only. Electronically receive clinical laboratory tests and values/results in a structured format and electronically display such tests and values/results in human readable format.

(ii) Display test report information. Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).

(iii) Incorporate tests and values/results. Electronically incorporate a laboratory test and value/result with a laboratory order or patient record.

Standards and Implementation Specifications

§ 170.205(k) (HL7 2.5.1 and HL7 Version 2.5.1 Implementation Guide: Standards and Interoperability Framework)

§ 170.314(b)(5) - Incorporate laboratory tests and values/results

Lab Results Interface, Release 1 (US Realm); and § 170.207(g) (LOINC version 2.38).

Preamble FR Citation: 77 FR 13849-50

Specific questions in preamble? *Yes*

Public Comment Field:

We appreciate the selection of this implementation guide and the support for LOINC in general, but are concerned with referencing version 2.38 of LOINC as the vocabulary. One concern is that LOINC is subject to frequent updates. Additionally we are concerned that LOINC is called out separately, while the implementation guide includes references to other vocabulary s as well. Lastly we are concerned that referencing both the implementation guide and the underlying standard will result in ambiguity as the implementation guide includes capabilities primarily from V2.5.1, but also V2.7.1. In fact V2.7.1 was explicitly pursued to address certain capabilities necessary to support the implementation guide’s objectives. Consequently one may be conflicted as to what V2.5.1 and LRI IG actually means.

We suggest to only reference the implementation guide, not the underlying standard, as the guide indicates where to use what version. Furthermore we suggest that the rules indicate that vocabulary shall be used in accordance with the implementation guide, or be very explicit what data should or should not be used. Lastly we request a more flexible process to adopt more current vocabulary, e.g., using references to government issued publications that provide adequate advance notice of pending changes to vocabulary. We suggest that this approach is adopted across all references in the proposed rule that involve implementation guides and vocabulary.

We suggest to further clarify that EHRT must retain standard vocabulary when to enable ongoing communication across EHRTs and other HIT within and outside the provider. We recognize that until related systems, e.g., laboratory information systems, have complementary certification requirements that the EHRT may not receive results using standard vocabulary. We encourage ONC to work with CMS and others to promote adoption of this implementation guide by laboratories.

§ 170.314(c) - Clinical quality measures: (c)(1) - Capture and export; (c)(2) - Incorporate and calculate; and (c)(3) - Reporting

MU Objective

N/A

2014 Edition EHR Certification Criteria

Clinical quality measures – capture and export.

Capture. Electronically record all of the data elements that are represented in the standard specified in § 170.204(c).

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

Clinical quality measures – incorporate and calculate.

Incorporate. Electronically incorporate all of the data elements necessary to calculate each of the clinical quality measures included in the EHR technology.

Calculate. Electronically calculate each clinical quality measure that is included in the EHR technology.

§ 170.314(c) - Clinical quality measures: (c)(1) - Capture and export; (c)(2) - Incorporate and calculate; and (c)(3) - Reporting

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

Standard

§ 170.204(c) (NQF Quality Data Model).

Preamble FR Citation: 77 FR 13850-53

Specific questions in preamble? *Yes*

Public Comment Field:

While promotion of the NQF QDM helps enhance consistency in the definition of clinical quality measures, we must point out that the QDM is not so much an interoperability specification as it is a Domain Analysis Model, and as such, may not be "testable" in the way ONC has envisioned, particularly in regards to export. The NPRM states that "we expect that exported quality data would be formatted according to the standard vocabularies in the QDM...". Interoperability specifications are required to enable appropriate formatting. QRDA would fit that need and is currently available as QRDA Category 1 while work is in progress to further enhance this specification. HL7 is currently balloting a revision to QRDA Category 1 and a QDM-based QRDA, which is, to our knowledge, the ONLY formal representation of the 2011 NQF QDM. HL7 would recommend the adoption of the QDM-based QRDA Category 1 for 170.314(c)(1) Clinical Quality Measures – capture and export: (ii) Export. If this is felt to be premature, then we suggest that until an export format is agreed to, that the criterion does not include a requirement to export the data for clinical quality measures. Inclusion of a criterion without a standard would only result in promotion of a wide variety of exchange methods that would lead to more effort to reconcile.

§ 170.314(d)(2) - Auditable events and tamper-resistance; and (d)(3) - Audit report(s)

MU Objective

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

2014 Edition EHR Certification Criteria

(d)(2) Auditable events and tamper-resistance.

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.

Record actions. Record actions related to electronic health information and audit log status in accordance with the standard specified in § 170.210(e).

Audit log protection. Actions recorded in accordance with paragraph (d)(3)(ii) must not be capable of being changed, overwritten, or deleted.

Detection. Detect the alteration of audit logs.

(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

§ 170.314(d)(2) - Auditable events and tamper-resistance; and (d)(3) - Audit report(s)

log according to each of the elements specified in the standard at § 170.210(e).

Standards

§ 170.210(e) Record actions related to electronic health information, audit log status, and encryption of end-user devices.

When EHR technology is used to record, create, change, access, or delete electronic health information, the following information must be recorded:

The electronic health information affected by the action(s);

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

The actions(s) that occurred;

Patient identification; and

User identification.

When the audit log is enabled or disabled, the following must be recorded:

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

(ii) User identification.

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:

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

User identification.

Preamble FR Citation: 77 FR 13853-54

Specific questions in preamble? *No*

Public Comment Field:

We suggest focusing on overall monitoring of access and alterations, while being cautious about pursuing attainment of immutable audit logs and detection of audit logs. The reality is that standards and technology can still be circumvented by select individuals with malicious intent. Therefore, we suggest that standard formats and vocabularies be required for the Authentication, Access Control, and Authorization criteria be used for managing and recording Auditable Events including: (1) Clinical terminologies and HL7 Information Category codes to denote information objects; (2) HL7 Data Operations Codes to denote “actions”; and (3) ASTM E1986 Structural Role value set (constrained to meet the criteria requirements); HL7 Participation Function Codes associated with Security Permissions such as conveyed by the HL7 RBAC Permissions Catalog Codes to supplement User Identification where a User may play more than one role; HL7 EHR Functional Model; and HL7 Data Types to encode User Identification. Where there are gaps, ONC should work with relevant SDOs such as ISO, HL7, ASTM, OASIS XSPA, and IHE to develop standards needed to fully implement Auditable eventing capabilities in EHRs.

We suggest clarification that logging requires at a minimum date, time, and user id to determine who accessed certain electronic health information to support audit log, accounting of disclosures, etc. We furthermore suggest that EHRT requires more information to sufficiently log access to certain electronic health information that it uses vocabulary that is aligned with those recommended for other security requirements such as § 170.314(d)(2) Auditable events and tamper-resistance certification criteria.

We request clarification of what is considered alteration, e.g., moving data from one storage device to another involves a physical delete of data on the originating device. Logically that is not a delete when it was moved to another device. We agree it is critical to prevent, detect unauthorized alterations, but we should remain practical.

§ 170.314(f)(1) - Immunization information; and (f)(2) - Transmission to immunization registries

MU Objective

Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

2014 Edition EHR Certification Criteria

(f)(1) Immunization information. Enable a user to electronically record, change, and access immunization information.

(f)(2) 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).

Standards and Implementation Specifications

§ 170.205(e)(3) (HL7 2.5.1 and Implementation Guide for Immunization Messaging Release 1.3); and § 170.207(i) (CVX code set: August 15, 2011 version).

Preamble FR Citation: 77 FR 13855

Specific questions in preamble? *No*

Public Comment Field:

We suggest clarification that ongoing submission means that all relevant data is transmitted in a timely fashion as required by the registry.

We suggest it should be permissible to continue to use V2.3.1 through Stage 2 by those registries that already accept electronic transactions in that format, while for new implementations the proposed implementation guide is required. We believe this will enable a smoother transition.

We suggest that standards and implementation guides referenced in the proposed rules must go through an SDO's consensus balloting process to ensure wide opportunity to provide input and consideration, thus increasing buy-in by the community.

§ 170.314(f)(3) - Public health surveillance; and (f)(4) - Transmission to public health agencies

MU Objective

Capability to submit electronic syndromic surveillance data to public health agencies except where prohibited, and in accordance with applicable law and practice.

2014 Edition EHR Certification Criteria

(f)(3) Public health surveillance. Enable a user to electronically record, change, and access syndrome-based public health surveillance information.

Transmission to public health agencies. Enable a user to electronically create syndrome-based public health surveillance information for electronic transmission in accordance with:

§ 170.314(f)(3) - Public health surveillance; and (f)(4) - Transmission to public health agencies

Ambulatory setting only.

The standard specified in § 170.205(d)(2).

Optional. The standard (and applicable implementation specifications) specified in § 170.205(d)(3).

Inpatient setting only. The standard (and applicable implementation specifications) specified in § 170.205(d)(3).

Standards and Implementation Specifications

§ 170.205(d)(2) (HL7 2.5.1) and § 170.205(d)(3) (HL7 2.5.1 and the PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data HL7 Version 2.5.1)

Preamble FR Citation: 77 FR 13855-56

Specific questions in preamble? *No*

Public Comment Field:

We suggest that standards and implementation guides referenced in the proposed rules must go through an SDO's consensus balloting process to ensure wide opportunity to provide input and consideration, thus increasing buy-in by the community.

We suggest to strike §170.314(f)(4)(i)(B) as it is not necessary.

Ambulatory Setting

§ 170.314(e)(2) - Clinical summaries

MU Objective

Provide clinical summaries for patients for each office visit.

2014 Edition EHR Certification Criterion

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:

Provided in human readable format; and

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):

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

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

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

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

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

§ 170.314(e)(2) - Clinical summaries

Procedures. The standard specified in § 170.207(b)(2) or § 170.207(b)(3);
Laboratory test(s). At a minimum, the version of the standard specified in § 170.207(g);
Laboratory value(s)/result(s). The value(s)/results of the laboratory test(s) performed; and
Medications. At a minimum, the version of the standard specified in § 170.207(h).

Standards

§ 170.205(a)(3) (Consolidated CDA); § 170.207(f) (OMB standards for the classification of federal data on race and ethnicity); § 170.207(j) (ISO 639-1:2002 (preferred language)); § 170.207(l) (smoking status types); § 170.207(a)(3) (SNOMED-CT[®] International Release January 2012); § 170.207(m) (ICD-10-CM); § 170.207(b)(2) (HCPCS and CPT-4) or § 170.207(b)(3) (ICD-10-PCS); § 170.207(g) (LOINC version 2.38); § 170.207(h) (RxNorm February 6, 2012 Release).

Preamble FR Citation: 77 FR 13856-57

Specific questions in preamble? *Yes*

Public Comment Field:

Please see our earlier comments related to the use of Consolidated CDA, the proposed use of SNOMED for encounter diagnosis, and the need to use consistent terminology across Clinical Summary and Summary of Care Record.

Inpatient Setting

§ 170.314(f)(5) - Reportable laboratory tests and values/results; and (f)(6) - Transmission of reportable laboratory tests and values/results

MU Objective

Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice.

2014 Edition EHR Certification Criteria

Inpatient setting only – reportable laboratory tests and values/results. Enable a user to electronically record, change, and access reportable clinical laboratory tests and values/results.

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

The standard (and applicable implementation specifications) specified in § 170.205(g); and

At a minimum, the versions of the standards specified in § 170.207(a)(3) and § 170.207(g).

Standards and Implementation Specifications

§ 170.205(g) (HL7 2.5.1 and HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with errata); § 170.207(a)(3) (SNOMED CT[®] International Release January 2012); and § 170.207(g) (LOINC version 2.38).

Preamble FR Citation: 77 FR 13857

Specific questions in preamble? *No*

Public Comment Field:

We suggest clarification that ongoing submission means that all relevant data is transmitted in a timely fashion as

required by the agency.

We suggest the use of the SNOMED coding system for the specimen and body site descriptions and lab results when appropriate.

Unchanged Certification Criteria

a. *Refinements to Unchanged Certification Criteria*

§ 170.314(a)(4) - Vital signs, body mass index, and growth charts

MU Objective

Record and chart changes in the following vital signs: height/length and weight (no age limit); blood pressure (ages 3 and over); calculate and display body mass index (BMI); and plot and display growth charts for patients 0-20 years, including BMI.

2014 Edition EHR Certification Criterion

Vital signs, body mass index, and growth charts.

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.

Calculate body mass index. Automatically calculate and electronically display body mass index based on a patient's height and weight.

Optional – plot and display growth charts. Plot and electronically display, upon request, growth charts for patients.

Preamble FR Citation: 77 FR 13858

Specific questions in preamble? *No*

Public Comment Field:

In general, we feel that a potential ambiguous situation arises where the NPRM promotes a functional requirement without a corresponding interoperability specification. Here, we would suggest the use of LOINC or SNOMED codes for height/weight, BMI, etc., and encourage transmission of this data as discrete, structured values (value + uom).

§ 170.314(a)(11) - Smoking status

MU Objective

Record smoking status for patients 13 years old or older.

2014 Edition EHR Certification Criterion

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

§ 170.314(a)(11) - Smoking status

Standard

§ 170.207(l) (smoking status types)

Preamble FR Citation: 77 FR 13858

Specific questions in preamble? *No*

Public Comment Field:

We suggest that ONC requests IHTSDO to extend SNOMED to address smoking status vocabulary, rather than perpetuating communication of text strings. Alternatively, in response to S&I recommendations, HL7 is rebalancing the Consolidated CDA IG, with the addition of a Smoking Status template, including a SNOMED CT value set that we feel most closely aligns with the intent of the NPRM.

§ 170.314(d)(1) - Authentication, access control, and authorization

MU Objective

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

2014 Edition EHR Certification Criterion

Authentication, access control, and authorization.

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

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.

Preamble FR Citation: 77 FR 13858-59

Specific questions in preamble? *No*

Public Comment Field:

We request clarification on whether the criteria (1) applies to internal system and/or human users; or (2) applies to external system and/or human users that are recipients of “push” type health information exchanges such as those required for in the Incentive NPRM; or (3) excludes all external system and/or human users.

We note the lack of interoperable vocabulary standards by which to: (1) consistently specify electronic health information as distinguishable security objects; (2) specify whether the access is at a coarse or fine grain level as would likely be required for data segmentation for privacy; (3) encode the "actions" in a consistent and meaningful manner using standard data operations vocabulary; and (4) specify an interoperable value set of standard structural and functional roles. These gaps impact the computability and human readable utility of the related audit reports and the accounting of disclosure certification criteria.

We suggest to: (1) clarify the users to which the certification criteria apply; and (2) require adoption of the privacy and security standard vocabularies such as: HL7 Confidentiality Codes; HL7 Data Operations Codes; HL7 US Privacy Law, Information Sensitivity, Purpose of Use, Obligation, and Refrain Policy Act Codes; HL7 Information Category codes to denote information categories; clinical terminologies to denote information objects; ASTM E1986 Structural Role value set (constrained to meet the criteria requirements) to denote security roles; HL7 Participation Function codes associated with permissions, such as those encoded by the HL7 RBAC Permission Catalog to augment Unique User Identifiers, which may be associated with many roles; and HL7 Data Types to encode User Identification.

§ 170.314(d)(1) - Authentication, access control, and authorization

Where there are gaps, ONC should work with relevant SDOs such as ISO, HL7, ASTM, OASIS XSPA, and IHE to develop standards needed to fully implement Authentication, Access Control, and Authorization capabilities in EHRs.

170.314(d)(5) - Automatic log-off

MU Objective

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

2014 Edition EHR Certification Criterion

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

Preamble FR Citation: 77 FR 13859

Specific questions in preamble? *No*

Public Comment Field:

While we support this criterion, we suggest clarification that automatic log-off of an application does not lead to automatically terminate network connections of other applications active on, e.g., the desktop or server.

§ 170.314(d)(6) - Emergency access

MU Objective

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

2014 Edition EHR Certification Criterion

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

Preamble FR Citation: 77 FR 13859

Specific questions in preamble? *No*

Public Comment Field:

We suggest consistent use of vocabulary across security reporting and access requirements as enumerated in responses to other security related criterion.

b. Unchanged Certification Criteria Without Refinements

§ 170.314(a)(7) - Medication allergy list

MU Objective

Maintain active medication allergy list.

2014 Edition EHR Certification Criterion

Medication allergy list. Enable a user to electronically record, change, and access a patient's active medication allergy list as well as medication allergy history for longitudinal care.

§ 170.314(a)(7) - Medication allergy list

Preamble FR Citation: 77 FR 13859

Specific questions in preamble? *No*

Public Comment Field:

We note vocabulary discrepancies between MU2 NPRM referenced artifacts – Consolidated CDA references RxNorm along with UNII and NDF-RT for substance-based allergies, whereas the NQF QDM references RxNorm along with SNOMED CT for substance-based allergies. These conflicts are understandable, given that value sets are often nested within MU cited artifacts. HL7 would recommend that ONC either (work with HL7 to) proactively identify and resolve discrepancies and/or designate a "source of truth" that can be pointed to in the case of discrepancies. Because HL7 believes that standards are a prerequisite for functionality, we suggest that where possible, an interoperability specification should be that source of truth – an interoperability specification typically provides formal and testable criteria, and can serve as the focal point for harmonization across functional criteria, quality criteria, and interoperability. Here for instance, ONC might consider Consolidated CDA as the source of truth.

§ 170.314(d)(9) - Accounting of disclosures

MU Objective

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

2014 Edition EHR Certification Criterion

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

Preamble FR Citation: 77 FR 13859, 13871-72

Specific questions in preamble? *Yes*

Public Comment Field:

Accounting of Disclosures is already required under HIPAA. However, there is no standard electronic format currently available by which to encode Accounting of Disclosures that is computable, interoperable, and human readable. We are looking forward to work with ONC to initiate an effort to develop an Accounting of Disclosure standard format and vocabulary, including those we recommend for other Security Criteria. We believe that creation of this guidance can be achieved in time for the next MU edition.

§ 170.314(a)(18) - Advance directives

MU Objective

Record whether a patient 65 years old or older has an advance directive.

2014 Edition EHR Certification Criterion

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

Preamble FR Citation: 77 FR 13860

Specific questions in preamble? *No*

Public Comment Field:

We request clarification that structured data implies a Boolean indicator. If not, we request clearly defined vocabulary. We recognize that variations exist across states. We are looking forward to work with ONC and the

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§ 170.314(a)(18) - Advance directives

states to develop such vocabulary for subsequent editions.

Furthermore, we suggest ONC initiates development of an interoperable electronic document format to capture advance directives for subsequent editions. We suggest that knowledgeable Advance Directive experts work in collaboration with relevant SDOs such as HL7 and S&I Framework Consolidated CDA project to develop implementation guidance.

In addition to the comment provided in the template, we offer the following feedback:

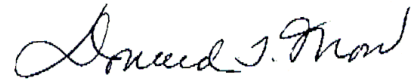
- We suggest that in the absence of implementation guidance for specialty registry to not include this objective/criterion into Stage 2. We are looking forward to work with ONC and the registries to establish appropriate implementation guidance.
- In support of patient communication preferences objective being considered in the EHR Incentive Program, we suggest the use of HL7 V2 Table 0202.
- In support of the recording of care plan goals and patient instructions objective being considered in the EHR Incentive Program, we suggest the use of the Consolidated CDA section for care plans as an initial step to support communication across providers. We note that as the need extends to dynamically maintain care plans across providers, that appropriate messaging/service formats are explored through the S&I Framework Longitudinal Care Coordination initiative.
- In support of recording the healthcare team members objective being considered in the EHR Incentive Program, we suggest the adoption of consistent vocabulary with those necessary to support security access and reporting requirements.
- In response to the request for public comments on Data Portability we would like to offer the following considerations. While for a patient moving from provider to provider Consolidated CDA is relevant, when moving data from EHRT-A to EHRT-B to support a provider's switching to another EHRT, much more data must be moved than what the Consolidated CDA is focusing on. For example, both static and dynamic patient data, as well as other operational data necessary to recreate the provider's information needs must be migrated. Not only clinical, but administrative and financial data must be migrated while maintaining key relationships. CDA was not developed for that purpose.
- In response to the request for public comments on Disability Status we would like to indicate that Consolidated CDA, in collaboration with S&I Long Term Care group, has made various revisions to accommodate the CCD Functional Status section. This does not address all aspects relevant to Disability Status, but provides a sound stepping stone to move this criterion forward.

HL7 appreciates the opportunity to comment on these NPRMs and stands ready to participate in these initiatives by providing a platform, where appropriate, to establish projects, balloting processes and to meet other requirements as needed.

Sincerely,



Charles Jaffe, MD, PhD, FACP, FACMI
Chief Executive officer



Donald T. Mon, PhD
Chairman of the Board