

- (iii) To capture and query information relevant to health care quality;
- (iv) To exchange electronic health information with, and integrate such information from other sources;
- (v) To protect the confidentiality, integrity, and availability of health information stored and exchanged; and
- (3) Has been certified to the certification criteria adopted by the Secretary:
 - (i) For at least one of the four criteria adopted at §170.314(a)(1), (a)(18), (a)(19), or (a)(20);
 - (ii) At §170.314(a)(3);
 - (iii) At §170.314(a)(5) through §170.314(a)(8);
 - (iv) Both §170.314(b)(1) and (2); or, both §170.314(b)(8) and §170.314(h)(1); or §170.314(b)(1) and (2) combined with either §170.314(b)(8) or §170.314(h)(1), or both §170.314(b)(8) and §170.314(h)(1);
 - (v) At §170.314(b)(7);
 - (vi) At §170.314(c)(1) through §170.314(c)(3);
 - (vii) At §170.314(d)(1) through §170.314(d)(8);
- (4) Has been certified to the certification criteria at §170.314(c)(1) and (2):
 - (i) For no fewer than 9 clinical quality measures covering at least 3 domains from the set selected by CMS for eligible professionals, including at least 6 clinical quality measures from the recommended core set identified by CMS; or
 - (ii) For no fewer than 16 clinical quality measures covering at least 3 domains from the set selected by CMS for eligible hospitals and critical access hospitals.

* * * * *

EFFECTIVE DATE NOTES: 2. At 79 FR 54478, Sept. 11, 2014, §170.102 was amended by removing the definitions of “2011 Edition EHR certification criteria” and “Complete EHR, 2011 Edition”, effective Mar. 1, 2015.

Subpart B—Standards and Implementation Specifications for Health Information Technology

SOURCE: 75 FR 44649, July 28, 2010, unless otherwise noted.

§ 170.200 Applicability.

The standards and implementation specifications adopted in this part apply with respect to Complete EHRs and EHR Modules.

§ 170.202 Transport standards.

The Secretary adopts the following transport standards:

(a) *Standard.* ONC Applicability Statement for Secure Health Transport (incorporated by reference in §170.299).

(b) *Standard.* ONC XDR and XDM for Direct Messaging Specification (incorporated by reference in §170.299).

(c) *Standard.* ONC Transport and Security Specification (incorporated by reference in §170.299).

[77 FR 54284, Sept. 4, 2012]

EFFECTIVE DATE NOTE: At 79 FR 54478, Sept. 11, 2014, §170.202 was amended by adding paragraph (d), effective Oct. 14, 2014. For the convenience of the user, the added text is set forth as follows:

§ 170.202 Transport standards.

* * * * *

(d) *Standard.* ONC Implementation Guide for Direct Edge Protocols (incorporated by reference in §170.299).

§ 170.204 Functional standards.

The Secretary adopts the following functional standards:

(a) *Accessibility. Standard.* Web Content Accessibility Guidelines (WCAG) 2.0, Level A Conformance (incorporated by reference in §170.299).

(b) *Reference source. Standard.* HL7 Version 3 Standard: Context-Aware Retrieval Application (Infobutton) (incorporated by reference in §170.299). (1) *Implementation specifications.* HL7 Version 3 Implementation Guide: URL-Based Implementations of the Context-Aware Information Retrieval (Infobutton) Domain, (incorporated by reference in §170.299).

(2) *Implementation specifications.* HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton) Service-Oriented Architecture Implementation Guide, (incorporated by reference in §170.299).

(c) *Clinical quality measure-by-measure data.* Data Element Catalog, (incorporated by reference in §170.299).

[77 FR 54284, Sept. 4, 2012]

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

The Secretary adopts the following content exchange standards and associated implementation specifications:

§ 170.205

(a) *Patient summary record*—(1) *Standard*. Health Level Seven Clinical Document Architecture (CDA) Release 2, Continuity of Care Document (CCD) (incorporated by reference in §170.299). *Implementation specifications*. The Healthcare Information Technology Standards Panel (HITSP) Summary Documents Using HL7 CCD Component HITSP/C32 (incorporated by reference in §170.299).

(2) *Standard*. ASTM E2369 Standard Specification for Continuity of Care Record and Adjunct to ASTM E2369 (incorporated by reference in §170.299).

(3) *Standard*. HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, (incorporated by reference in §170.299). The use of the “unstructured document” document-level template is prohibited.

(b) *Electronic prescribing*—(1) *Standard*. The National Council for the Prescription Drug Programs (NCPDP) Prescriber/Pharmacist Interface SCRIPT standard, Implementation Guide, Version 8, Release 1 (Version 8.1) October 2005 (incorporated by reference in §170.299)

(2) *Standard*. NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 (incorporated by reference in §170.299).

(c) *Electronic submission of lab results to public health agencies*. *Standard*. HL7 2.5.1 (incorporated by reference in §170.299). *Implementation specifications*. HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (incorporated by reference in §170.299).

(d) *Electronic submission to public health agencies for surveillance or reporting*—(1) *Standard*. HL7 2.3.1 (incorporated by reference in §170.299).

(2) *Standard*. HL7 2.5.1 (incorporated by reference in §170.299).

(3) *Standard*. HL7 2.5.1 (incorporated by reference in §170.299). *Implementation specifications*. PHIN Messaging Guide for Syndromic Surveillance (incorporated by reference in §170.299) and Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, Addendum to PHIN Messaging Guide for Syndromic Surveillance (incorporated by reference in §170.299).

45 CFR Subtitle A (10–1–14 Edition)

(e) *Electronic submission to immunization registries*—(1) *Standard*. HL7 2.3.1 (incorporated by reference in §170.299). *Implementation specifications*. Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol Implementation Guide Version 2.2 (incorporated by reference in §170.299).

(2) *Standard*. HL7 2.5.1 (incorporated by reference in §170.299). *Implementation specifications*. HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0 (incorporated by reference in §170.299).

(3) *Standard*. HL7 2.5.1 (incorporated by reference in §170.299). *Implementation specifications*. HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4, (incorporated by reference in §170.299).

(f) *Quality reporting*. *Standard*. The CMS Physician Quality Reporting Initiative (PQRI) 2009 Registry XML Specification (incorporated by reference in §170.299). *Implementation specifications*. Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry (incorporated by reference in §170.299).

(g) *Electronic transmission of lab results to public health agencies*. *Standard*. HL7 2.5.1 (incorporated by reference in §170.299). *Implementation specifications*. HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (incorporated by reference in §170.299) with Errata and Clarifications, (incorporated by reference in §170.299) and ELR 2.5.1 Clarification Document for EHR Technology Certification, (incorporated by reference in §170.299).

(h) *Clinical quality measure data import, export, and electronic submission*. *Standard*. HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture, (incorporated by reference in §170.299).

(i) *Cancer information*. *Standard*. HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition (incorporated by reference in §170.299). *Implementation specifications*. Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer

Registries, HL7 Clinical Document Architecture (CDA), (incorporated by reference in §170.299).

(j) *Electronic incorporation and transmission of lab results. Standard.* HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, (incorporated by reference in §170.299).

(k) *Clinical quality measure aggregate electronic submission. Standard.* Quality Reporting Document Architecture Category III, Implementation Guide for CDA Release 2 (incorporated by reference in §170.299).

[75 FR 44649, July 28, 2010, as amended at 75 FR 62690, Oct. 13, 2010; 77 FR 54284, Sept. 4, 2012]

EFFECTIVE DATE NOTE: At 79 FR 54478, Sept. 11, 2014, §170.205 was amended by removing and reserving paragraphs (b)(1), (c), (d)(1), (e)(1) and (2), and (f), effective Mar. 1, 2015.

§ 170.207 Vocabulary standards for representing electronic health information.

The Secretary adopts the following code sets, terminology, and nomenclature as the vocabulary standards for the purpose of representing electronic health information:

(a) *Problems*—(1) *Standard.* The code set specified at 45 CFR 162.1002(a)(1) for the indicated conditions.

(2) *Standard.* International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) July 2009 version (incorporated by reference in §170.299).

(3) *Standard.* IHTSDO SNOMED CT® International Release July 2012 (incorporated by reference in §170.299) and US Extension to SNOMED CT® March 2012 Release (incorporated by reference in §170.299).

(b) *Procedures*—(1) *Standard.* The code set specified at 45 CFR 162.1002(a)(2).

(2) *Standard.* The code set specified at 45 CFR 162.1002(a)(5).

(3) *Standard.* The code set specified at 45 CFR 162.1002(a)(4).

(4) *Standard.* The code set specified at 45 CFR 162.1002(c)(3) for the indicated procedures or other actions taken.

(c) *Laboratory tests*—(1) *Standard.* Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, when

such codes were received within an electronic transaction from a laboratory (incorporated by reference in §170.299).

(2) *Standard.* Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc. (incorporated by reference in §170.299).

(d) *Medications*—(1) *Standard.* Any source vocabulary that is included in RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine.

(2) *Standard.* RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release (incorporated by reference in §170.299).

(e) *Immunizations*—(1) *Standard.* HL7 Standard Code Set CVX—Vaccines Administered, July 30, 2009 version (incorporated by reference in §170.299).

(2) *Standard.* HL7 Standard Code Set CVX—Vaccines Administered, updates through July 11, 2012 (incorporated by reference in §170.299).

(f) *Race and Ethnicity. Standard.* The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997 (see “Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity,” available at http://www.whitehouse.gov/omb/fedreg_1997standards).

(g) *Preferred language. Standard.* As specified by the Library of Congress, ISO 639-2 alpha-3 codes limited to those that also have a corresponding alpha-2 code in ISO 639-1. (incorporated by reference in §170.299).

(h) *Smoking status. Standard.* Smoking status must be coded in one of the following SNOMED CT® codes:

(1) *Current every day smoker.* 449868002

(2) *Current some day smoker.* 428041000124106

(3) *Former smoker.* 8517006

(4) *Never smoker.* 266919005

(5) *Smoker, current status unknown.* 77176002

(6) *Unknown if ever smoked.* 266927001