

§ 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).

EFFECTIVE DATE NOTE: At 77 FR 54284, Sept. 4, 2012, §170.202 was added, effective Oct. 4, 2012.

§ 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).

EFFECTIVE DATE NOTE: At 77 FR 54284, Sept. 4, 2012, §170.204 was added, effective Oct. 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:

(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).

(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).

(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).

§ 170.207

(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).

(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).

[75 FR 44649, July 28, 2010, as amended at 75 FR 62690, Oct. 13, 2010]

EFFECTIVE DATE NOTE: At 77 FR 54284, Sept. 4, 2012, §170.205 was amended by adding paragraphs (a)(3), (d)(3), (e)(3), and (g) through (k), effective Oct. 4, 2012. For the convenience of the user, the added text is set forth as follows:

§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:

(a) * * *
(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.

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(d) * * *
(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).

(e) * * *
(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).

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(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

45 CFR Subtitle A (10–1–12 Edition)

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).

§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).

(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).

(c) *Laboratory test results. 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).

(d) *Medications. Standard.* Any source vocabulary that is included in RxNorm,