

§ 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,

a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine.

(e) *Immunizations. Standard.* HL7 Standard Code Set CVX—Vaccines Administered, July 30, 2009 version (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, October 30, 1997 (available at <http://www.whitehouse.gov/omb/rewrite/fedreg/ombdir15.html>).

EFFECTIVE DATE NOTE: At 77 FR 54284, Sept. 4, 2012, § 170.207 was amended by adding paragraphs (a)(3), (b)(3), (b)(4), revising paragraphs (c), (d), (e), and (f) and adding paragraphs (g) through (j), effective Oct. 4, 2012. For the convenience of the user, the added and revised text is set forth as follows:

**§ 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) \* \* \*

(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) \* \* \*

(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](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

(7) *Heavy tobacco smoker.* 428071000124103

(8) *Light tobacco smoker.* 428061000124105

(i) *Encounter diagnoses. Standard.* The code set specified at 45 CFR 162.1002(c)(2) for the indicated conditions.

(j) *Family health history.* HL7 Version 3 Standard: Clinical Genomics; Pedigree. (incorporated by reference in § 170.299).

**§ 170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.**

The Secretary adopts the following standards to protect electronic health information created, maintained, and exchanged:

(a) *Encryption and decryption of electronic health information—*(1) *General.* Any encryption 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 (incorporated by reference in § 170.299).

(2) *Exchange.* Any encrypted and integrity protected link.

(b) *Record actions related to electronic health information.* The date, time, patient identification, and user identification must be recorded when electronic health information is created, modified, accessed, or deleted; and an