Department of Health and Human Services

§ 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:

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


(d) **Electronic submission to public health agencies for surveillance or reporting**—(1) **Standard.** HL7 2.5.1 (incorporated by reference in §170.299).

(2) **Standard.** HL7 2.5.1 (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).


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.


(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).


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

(2) Standard. RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine.


(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. 44966002
(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
§ 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:


(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 indication of which action(s) occurred and by whom must also be recorded.

(c) Verification that electronic health information has not been altered in transit. Standard. A hashing algorithm with a security strength equal to or greater than SHA–1 (Secure Hash Algorithm (SHA–1) as specified by the National Institute of Standards and Technology (NIST) in FIPS PUB 180–4 (March 2012)) must be used to verify that electronic health information has not been altered.

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

(e) Record actions related to electronic health information, audit log status, and encryption of end-user devices. (1)(i) The audit log must record the information specified in sections 7.2 through 7.4, 7.6, and 7.7 of the standard specified at §170.210(h) when EHR technology is in use.

(ii) The date and time must be recorded in accordance with the standard specified at §170.210(g).

(2)(i) The audit log must record the information specified in sections 7.2 and 7.4 of the standard specified at §170.210(h) when the audit log status is changed.

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

(f) Encryption and hashing of electronic health information. Any encryption and hashing algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the FIPS Publication 140–2 (incorporated by reference in §170.299).

(g) Synchronized clocks. The date and time recorded utilize a system clock that has been synchronized following (RFC 1305) Network Time Protocol, (incorporated by reference in §170.299) or (RFC 5905) Network Time Protocol Version 4, (incorporated by reference in §170.299).

(h) Audit log content. ASTM E2147–01(Reapproved 2009), (incorporated by reference in §170.299)
§ 170.299 Incorporation by reference.

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish notice of change in the Federal Register and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Also, it is available for inspection at U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave., SW., Washington, DC 20201, call ahead to arrange for inspection at 202–690–7151, and is available from the sources listed below.


(2) [Reserved]

(c) ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA, 19428–2959 USA; Telephone (610) 832–9585 or http://www.astm.org/.


(3) ASTM E2369–05 (Adjunct to E2369): Standard Specification Continuity of Care Record,—Final Version 1.0 (V1.0), November 7, 2005, IBR approved for §170.205.

(4) [Reserved]

(d) Centers for Disease Control and Prevention, 2500 Century Parkway, Mailstop E–78, Atlanta, GA 30333, USA (800–232–4636); http://www.cdc.gov/ehrmeaningfuluse/.


(4) HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0, May 1, 2010, IBR approved for §170.205.

(5) PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data, ADT Messages A01, A03, A04, and A08, HL7 Version 2.5.1 (Version 2.3.1 Compatible), Release 1.1, August 2012, IBR approved for §170.205.

(6) Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, ADT Messages A01, A03, A04, and A08, HL7 Version 2.5.1, Addendum to PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data (Release 1.1), August 2012, IBR approved for §170.205.

(7) HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4, August 1, 2012, IBR approved for §170.205.


(9) ELR 2.5.1 Clarification Document for EHR Technology Certification, July 16, 2012, IBR approved for §170.205.
(e) Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, Maryland 21244; Telephone (410) 786–3000

(1) CMS PQRI 2009 Registry XML Specifications, IBR approved for §170.205.


(6) Health Level Seven, 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104; Telephone (734) 677–7777 or http://www.hl7.org/

(1) Health Level Seven Standard Version 2.3.1 (HL7 2.3.1), An Application Protocol for Electronic Data Exchange in Healthcare Environments, April 14, 1999, IBR approved for §170.205.


(5) HL7 Version 3 Standard: Context-Aware Retrieval Application (Infobutton); Release 1, July 2010, IBR approved for §170.204.


(13) HL7 v2.5.1 IG: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 Errata and Clarifications, September, 29, 2011, IBR approved for §170.205.


(g) Internet Engineering Task Force (IETF), University of Delaware, Newark, DE 19716, Telephone (302) 831–8247, http://www.ietf.org/rfc.html.


(2) [Reserved]

(i) National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260–7518; Telephone (480) 477–1000; and Facsimile (480) 767–1042 or http://www.ncpdp.org.
¶ 170.299 Incorporation by reference.


(j) National Institute of Standards and Technology, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899–8930, http://csrc.nist.gov/groups/STM/cmvp/standards.html.


(1) Regenstrief Institute, Inc., LOINC® c/o Medical Informatics The Regenstrief Institute, Inc 410 West 10th Street, Suite 2000 Indianapolis, IN 46202–3012; Telephone (317) 423–5983 or http://loinc.org/.

(1) Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, June 15, 2009, IBR approved for § 170.207.

(2) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40, Released June 2012, IBR approved for § 170.207.

(m) U.S. National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894; Telephone (301) 594–5983 or http://www.nlm.nih.gov/.

(1) International Health Terminology Standards Development Organization Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), International Release, July 2009, IBR approved for § 170.207.


(3) US Extension to SNOMED CT® March 2012 Release, IBR approved for § 170.207.

(4) RxNorm, August 6, 2012 Full Release Update, IBR approved for § 170.207.

(5) Data Element Catalog, Version 1.1, October 2012, IBR approved for § 170.204.

(n) World Wide Web Consortium (W3C)/MIT, 32 Vassar Street, Room 32–G515, Cambridge, MA 02139 USA, http://www.w3.org/standards/

(1) Web Content Accessibility Guidelines (WCAG) 2.0, December 11, 2008, IBR approved for § 170.204.

(2) [Reserved]


EFFECTIVE DATE NOTE: At 79 FR 54478, Sept. 11, 2014, §170.299 was amended by adding paragraph (k)(4), effective Oct. 14, 2014. For the convenience of the user, the added text is set forth as follows:

§ 170.299 Incorporation by reference.

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