

Dept. of Health and Human Services

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specified in paragraph (c)(3) of this section and attributed with LOINC® codes 68515-6 and 68516-4. The answers must be coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(1).

(6) *Alcohol use.* Alcohol use must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(3) of this section and attributed with LOINC® codes 72109-2, 68518-0 (with LOINC® answer list ID LL2179-1), 68519-8 (with LOINC® answer list ID LL2180-9), 68520-6 (with LOINC® answer list ID LL2181-7), and 75626-2.

(7) *Social connection and isolation.* Social connection and isolation must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(3) of this section and attributed with the LOINC® codes 76506-5, 63503-7 (with LOINC answer list ID LL1068-7), 76508-1 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)), 76509-9 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)), 76510-7 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)), 76511-5 (with LOINC answer list ID LL963-0), and 76512-3 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)).

(8) *Exposure to violence (intimate partner violence).* Exposure to violence: Intimate partner violence must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(3) of this section and attributed with the LOINC® code 76499-3, 76500-8 (with LOINC® answer list ID LL963-0), 76501-6 (with LOINC® answer list ID LL963-0), 76502-4 (with LOINC® answer list ID LL963-0), 76503-2 (with LOINC® answer list ID LL963-0), and 76504-0 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)).

(q) *Patient matching—(1) Phone number standard.* ITU-T E.123, Series E: Overall Network Operation, Telephone Service, Service Operation and Human Factors, International operation—General provisions concerning users: Notation for national and international telephone numbers, email addresses

and web addresses (incorporated by reference in § 170.299); and ITU-T E.164, Series E: Overall Network Operation, Telephone Service, Service Operation and Human Factors, International operation—Numbering plan of the international telephone service: The international public telecommunication numbering plan (incorporated by reference in § 170.299).

(2) [Reserved]

(r) *Provider type—(1) Standard.* Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy, April 2, 2015 (incorporated by reference in § 170.299).

(2) [Reserved]

(s) *Patient insurance—(1) Standard.* Public Health Data Standards Consortium Source of Payment Typology Code Set Version 5.0 (October 2011) (incorporated by reference in § 170.299).

(2) [Reserved]

[75 FR 44649, July 28, 2010, as amended at 77 FR 54284, Sept. 4, 2012; 79 FR 54478, Sept. 11, 2014; 80 FR 62744, Oct. 16, 2015; 80 FR 76871, Dec. 11, 2015; 85 FR 25940, May 1, 2020]

§ 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) [Reserved]

(2) *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, October 8, 2014 (incorporated by reference in § 170.299).

(b) [Reserved]

(c) *Hashing of electronic health information.* (1) [Reserved]

(2) *Standard.* A hashing algorithm with a security strength equal to or greater than SHA-2 as specified by NIST in FIPS Publication 180-4 (August 2015) (incorporated by reference in § 170.299).

(d) *Record treatment, payment, and health care operations disclosures.* The date, time, patient identification, user identification, and a description of the

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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 7.1.1 and 7.1.2 and 7.1.6 through 7.1.9 of the standard specified in § 170.210(h) and changes to user privileges when health IT 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 7.1.1 and 7.1.7 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).

(3) The audit log must record the information specified in sections 7.1.1 and 7.1.7 of the standard specified at § 170.210(h) when the encryption status of electronic health information locally stored by health IT on end-user devices is changed. 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 5905) Network Time Protocol Version 4, (incorporated by reference in § 170.299).

(h) *Audit log content.* ASTM E2147-18, (incorporated by reference in § 170.299).

[75 FR 44649, July 28, 2010, as amended at 77 FR 54285, Sept. 4, 2012; 79 FR 54478, Sept. 11, 2014; 80 FR 62745, Oct. 16, 2015; 85 FR 25940, May 1, 2020; 85 FR 70082, Nov. 4, 2020]

§ 170.213 United States Core Data for Interoperability.

Standard. United States Core Data for Interoperability (USCDI), July 2020

45 CFR Subtitle A (10–1–23 Edition)

Errata, Version 1 (v1) (incorporated by reference in § 170.299).

[85 FR 70082, Nov. 4, 2020]

§ 170.215 Application Programming Interface Standards.

The Secretary adopts the following application programming interface (API) standards and associated implementation specifications:

(a)(1) *Standard.* HL7® Fast Healthcare Interoperability Resources (FHIR®) Release 4.0.1 (incorporated by reference in § 170.299).

(2) *Implementation specification.* HL7 FHIR® US Core Implementation Guide STU 3.1.1 (incorporated by reference in § 170.299).

(3) *Implementation specification.* HL7 SMART Application Launch Framework Implementation Guide Release 1.0.0, including mandatory support for the “SMART Core Capabilities” (incorporated by reference in § 170.299).

(4) *Implementation specification.* FHIR Bulk Data Access (Flat FHIR) (v1.0.0: STU 1), including mandatory support for the “group-export” “OperationDefinition” (incorporated by reference in § 170.299).

(b) *Standard.* OpenID Connect Core 1.0, incorporating errata set 1 (incorporated by reference in § 170.299).

[85 FR 25941, May 1, 2020, as amended at 85 FR 70082, Nov. 4, 2020]

§ 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 a document in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, 330 C Street SW., Washington, DC 20201, call ahead to arrange for inspection at 202-690-7151, and is available from the sources listed below. It is also available for inspection at the National Archives and Records Administration (NARA). For