

## § 170.213

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