§ 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:


(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. 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).

(3) 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 encryption status of electronic health information locally stored by EHR technology 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 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 (Adjacent to E2369): Standard Specification Continuity of Care Record,—Final Version 1.0 (V1.0), November 7, 2005, IBR approved for §170.205.

(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/.


(3) Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven