Final Rule MU Standards Quick List with CFR Citation Cross walked to the Standard


7/25/2010

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Please refer to the official ONC website for complete documentation and official federal documents at www.healthit.hhs.gov at this link − [Standards and Certification Criteria for Electronic Health Records](https://www.healthit.hhs.gov/)
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| §170.210 (d) | 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.  
[ADDED INFORMATION FROM http://www.access.gpo.gov/nara/cfr/waisidx_04/45cfr164_04.html]  
45 CFR 164.501 Terms defined - treatment, payment, and health care operations  

**Definition of the Term "Treatment"**  

**page 774 - Treatment** means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another. [65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003] |
Payment means:

(1) The activities undertaken by:
   (i) A health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan; or
   (ii) A health care provider or health plan to obtain or provide reimbursement for the provision of health care; and

(2) The activities in paragraph (1) of this definition relate to the individual to whom health care is provided and include, but are not limited to:
   (i) Determinations of eligibility or coverage (including coordination of benefits or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;
   (ii) Risk adjusting amounts due based on enrollee health status and demographic characteristics;
   (iii) Billing, claims management, collection activities, obtaining payment under a contract for reinsurance (including stop-loss insurance and excess of loss insurance), and related health care data processing;
   (iv) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;
   (v) Utilization review activities, including precertification and preauthorization of services, concurrent and retrospective review of services; and
   (vi) Disclosure to consumer reporting agencies of any of the following protected health information relating to collection of premiums or reimbursement:
      (A) Name and address;
      (B) Date of birth;
      (C) Social security number;
      (D) Payment history;
      (E) Account number; and
      (F) Name and address of the health care provider and/or health plan.
| **Page 741-742** Health care operations means any of the following activities of the covered entity to the extent that the activities are related to covered functions: |
| (1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment; |
| (2) Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities; |
| (3) Underwriting, premium rating, and other activities relating to the creation, renewal or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance), provided that the requirements of § 164.514(g) are met, if applicable; |
| (4) Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs; |

**Definition of the Term "Health care operations"**
§170.210 (d)  

(5) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies; and

(6) Business management and general administrative activities of the entity, including, but not limited to:

(i) Management activities relating to implementation of and compliance with the requirements of this subchapter;

(ii) Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer.

(iii) Resolution of internal grievances;

(iv) The sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity; and

(v) Consistent with the applicable requirements of § 164.514, creating deidentified health information or a limited data set, and fundraising for the benefit of the covered entity.

Definition of the Term "Health care operations" continued
The Office of Management and Budget reviewed this final rule.

List of Subjects

45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Health care, Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

For the reasons set forth in the preamble, 45 CFR subtitle A, subchapter D, part 170, is amended as follows:

PART 170 – HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

1. The authority citation for part 170 continues to read as follows:


2. Amend §170.102 by revising the definitions of “Complete EHR,” “Certified EHR Technology,” and “Disclosure” and adding the definition of “Human readable format” to read as follows:

§170.102 Definitions.

* * * * *

Certified EHR Technology means:

(1) A Complete EHR that meets the requirements included in the definition of a Qualified EHR and has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary; or
(2) A combination of EHR Modules in which each constituent EHR Module of the combination has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary, and the resultant combination also meets the requirements included in the definition of a Qualified EHR.

**Complete EHR** means EHR technology that has been developed to meet, at a minimum, all applicable certification criteria adopted by the Secretary.

**Disclosure** is defined as it is in 45 CFR 160.103.

* * * * *

**Human readable format** means a format that enables a human to read and easily comprehend the information presented to him or her regardless of the method of presentation.

* * * * *

- 3. Revise subpart B to read as follows:

**Subpart B—Standards and Implementation Specifications for Health Information Technology**

Sec.
170.200 Applicability.
170.202 [Reserved]
170.205 Content exchange standards and implementation specifications for exchanging electronic health information.
170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.
170.299 Incorporation by reference.

§170.200 Applicability.
The standards and implementation specifications adopted in this part apply with respect to Complete EHRs and EHR Modules.

§170.202 [Reserved]

§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 Adjunct to ASTM E2369 (incorporated by reference in §170.299).


(c) **Electronic submission of lab results to public health agencies.** **Standard.** HL7 2.5.1 (incorporated by reference in §170.299). Implementation specifications. HL7

(d) **Electronic submission to public health agencies for surveillance or reporting.** (1) **Standard.** HL7 2.3.1 (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).


§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).


§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 180-3 (October, 2008)) 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.

§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