

§ 170.100

45 CFR Subtitle A (10–1–11 Edition)

Subpart A—General Provisions

§ 170.100 Statutory basis and purpose.

The provisions of this subchapter implement sections 3001(c)(5) and 3004 of the Public Health Service Act.

[75 FR 36203, June 24, 2010]

§ 170.101 Applicability.

The standards, implementation specifications, and certification criteria adopted in this part apply to Complete EHRs and EHR Modules and the testing and certification of such Complete EHRs and EHR Modules.

§ 170.102 Definitions.

For the purposes of this part:

Certification criteria means criteria:

(1) To establish that health information technology meets applicable standards and implementation specifications adopted by the Secretary; or

(2) That are used to test and certify that health information technology includes required capabilities.

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.

EHR Module means any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary.

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.

Implementation specification means specific requirements or instructions for implementing a standard.

Qualified EHR means an electronic record of health-related information on an individual that:

(1) Includes patient demographic and clinical health information, such as medical history and problem lists; and

(2) Has the capacity:

(i) To provide clinical decision support;

(ii) To support physician order entry;

(iii) To capture and query information relevant to health care quality; and

(iv) To exchange electronic health information with, and integrate such information from other sources.

Standard means a technical, functional, or performance-based rule, condition, requirement, or specification that stipulates instructions, fields, codes, data, materials, characteristics, or actions.

[75 FR 2042, Jan. 13, 2010, as amended at 75 FR 36203, June 24, 2010; 75 FR 44649, July 28, 2010]

Subpart B—Standards and Implementation Specifications for Health Information Technology

SOURCE: 75 FR 44649, July 28, 2010, unless otherwise noted.

§ 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: