adopted in this part apply to health information technology and the testing and certification of Health IT Modules.

[85 FR 70082, Nov. 4, 2020]

§ 170.102 Definitions.

For the purposes of this part:

2015 Edition Base 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;

(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;

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

(3) Has been certified to the certification criteria adopted by the Secretary in—

(i) Section 170.315(a)(1), (2), or (3); (a)(5), (a)(9), (a)(14), (b)(1), (c)(1), (g)(7) and (9), and (h)(1) or (2);

(ii) Section 170.315(g)(8) or (10) for the period before December 31, 2022; and

(iii) Section 170.315(g)(10) on and after December 31, 2022.

2015 Edition health IT certification criteria means the certification criteria in § 170.315.

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.

Common Clinical Data Set means the following data expressed, where indicated, according to the specified standard(s):

(1) Patient name.

(2) *Sex:* The standard specified in § 170.207(n)(1).

(3) Date of birth.

(4) *Race:*

(i) The standard specified in § 170.207(f)(2); and

(ii) The standard specified in § 170.207(f)(1) for each race identified in accordance § 170.207(f)(2).

(5) *Ethnicity:*

(i) The standard specified in § 170.207(f)(2); and

(ii) The standard specified in § 170.207(f)(1) for each ethnicity identified in accordance § 170.207(f)(2).

(6) *Preferred language:* The standard specified in § 170.207(g)(2).

(7) Smoking status.

(8) *Problems:* At a minimum, the standard specified in § 170.207(a)(4).

(9) *Medications:* At a minimum, the standard specified in § 170.207(d)(3).

(10) *Medication allergies:* At a minimum, the standard specified in § 170.207(d)(3).

(11) *Laboratory test(s):* At a minimum, the standard specified in § 170.207(c)(3).

(12) Laboratory value(s)/result(s).

(13) *Vital signs:*

(i) The patient's diastolic blood pressure, systolic blood pressure, body height, body weight, heart rate, respiratory rate, body temperature, pulse oximetry, and inhaled oxygen concentration must be exchanged in numerical values only; and

(ii) In accordance with the standard specified in § 170.207(c)(3) and with the associated applicable unit of measure for the vital sign measurement in the standard specified in § 170.207(m)(1).

(iii) *Optional:* The patient's BMI percentile per age and sex for youth 2–20 years of age, weight for age per length and sex for children less than 3 years of age, and head occipital-frontal circumference for children less than 3 years of age must be recorded in numerical values only in accordance with the standard specified in § 170.207(c)(3) and with the associated applicable unit of measure for the vital sign measurement in the standard specified in § 170.207(m)(1). For BMI percentile per age and sex for youth 2–20 years of age and weight for age per length and sex for children less than 3 years of age, the reference range/scale or growth curve should be included as appropriate.

(14) *Procedures:*

(i) At a minimum, the version of the standard specified in § 170.207(a)(4) or § 170.207(b)(2); or

(ii) For technology primarily developed to record dental procedures, the standard specified in § 170.207(b)(3).

(iii) *Optional:* The standard specified in § 170.207(b)(4).

(15) Care team member(s).

(16) *Immunizations:* In accordance with, at a minimum, the standards specified in §170.207(e)(3) and (4).

(17) Unique device identifier(s) for a patient's implantable device(s): In accordance with the ''Product Instance'' in the ''Procedure Activity Procedure Section'' of the standard specified in §170.205(a)(4).

(18) *Assessment and plan of treatment:*

(i) In accordance with the ''Assessment and Plan Section (V2)'' of the standard specified in §170.205(a)(4); or

(ii) In accordance with the ''Assessment Section (V2)'' and ''Plan of Treatment Section (V2)'' of the standard specified in §170.205(a)(4).

(19) *Goals:* In accordance with the ''Goals Section'' of the standard specified in §170.205(a)(4).

(20) *Health concerns:* In accordance with the ''Health Concerns Section'' of the standard specified in §170.205(a)(4).

Day or Days means a calendar day or calendar days.

Device identifier is defined as it is in 21 CFR 801.3.

Disclosure is defined as it is in 45 CFR 160.103.

Electronic health information (EHI) is defined as it is in §171.102.

Fee is defined as it is in §171.102 of this subchapter.

Global Unique Device Identification Database (GUDID) is defined as it is in 21 CFR 801.3.

Health information technology means hardware, software, integrated technologies or related licenses, IP, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information.

Health IT 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.

Implantable device is defined as it is in 21 CFR 801.3.

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

Interoperability is, with respect to health information technology, such health information technology that—

(1) Enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;

(2) Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and

(3) Does not constitute information blocking as defined in §171.103 of this subchapter.

Interoperability element is defined as it is in §171.102 of this subchapter.

Production identifier is defined as it is in 21 CFR 801.3.

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.

Unique device identifier is defined as it is in 21 CFR 801.3.

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