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 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

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*.

(b) American National Standards Institute, Health Information Technology Standards Panel (HITSP) Secretariat, 25 West 43rd Street—Fourth Floor, New York, NY 10036, *http://www.hitsp.org*.

(1) HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component, HITSP/C32, July 8, 2009, Version 2.5, IBR approved for § 170.205.

(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/*.

(1) ASTM E2147–18 Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems, approved May 1, 2018, IBR approved for § 170.210(h).

(2)–(3) [Reserved]

(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/*.

(1) HL7 Standard Code Set CVX—Vaccines Administered, July 30, 2009, IBR approved for § 170.207.

(2) [Reserved]

(3) Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7)Standard Protocol Implementation Guide Version 2.2, June 2006, IBR approved for § 170.205.

(4) HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0, May 1, 2010, IBR approved for § 170.205.

(5) PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data, ADT Messages A01, A03, A04, and A08, HL7 Version 2.5.1 (Version 2.3.1 Compatible), Release 1.1, August 2012, IBR approved for § 170.205.

(6) Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, ADT MESSAGES A01, A03, A04, and A08, HL7 Version 2.5.1, Addendum to PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data (Release 1.1), August 2012, IBR approved for § 170.205.

(7)–(8) [Reserved]

(9) ELR 2.5.1 Clarification Document for EHR Technology Certification, July 16, 2012, IBR approved for § 170.205.

(10) PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0, April 21, 2015, IBR approved for § 170.205(d).

(11) Erratum to the CDC PHIN 2.0 Implementation Guide, August 2015; Erratum to the CDC PHIN 2.0 Messaging Guide, April 2015 Release for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, IBR approved for § 170.205(d).

(12) HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5, October 1, 2014, IBR approved for § 170.205(e).

(13) HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum, July 2015, IBR approved for § 170.205(e).

(14) HL7 Standard Code Set CVX—Vaccines Administered, updates through August 17, 2015, IBR approved for § 170.207(e).

(15) National Drug Code Directory (NDC)—Vaccine NDC Linker, updates through August 17, 2015, IBR approved for § 170.207(e).

(16) CDC Race and Ethnicity Code Set Version 1.0 (March 2000), IBR approved for § 170.207(f).

(e) Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, Maryland 21244; Telephone (410) 786–3000

(1) CMS PQRI 2009 Registry XML Specifications, IBR approved for § 170.205.

(2) 2009 Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry, Version 3.0, December 8, 2008 IBR approved for § 170.205.

(3) Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy, April 2, 2015, IBR approved for § 170.207(r).

(4) CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting Implementation Guide for 2020; published December 3, 2019, IBR approved for § 170.205(h).

(5) CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs Implementation Guide for 2020; published April 30, 2020, IBR approved for § 170.205(k).

(f) Health Level Seven, 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104; Telephone (734) 677–7777 or *http://www.hl7.org/*

(1) Health Level Seven Standard Version 2.3.1 (HL7 2.3.1), An Application Protocol for Electronic Data Exchange in Healthcare Environments, April 14, 1999, IBR approved for § 170.205.

(2) Health Level Seven Messaging Standard Version 2.5.1 (HL7 2.5.1), An Application Protocol for Electronic Data Exchange in Healthcare Environments, February 21, 2007, IBR approved for § 170.205.

(3) [Reserved]

(4) HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) HL7 Version 2.5.1: ORU^R01, HL7 Informative Document, February, 2010, IBR approved for § 170.205.

(5) HL7 Version 3 Standard: Context-Aware Retrieval Application (Infobutton); Release 1, July 2010, IBR approved for § 170.204.

(6)–(7) [Reserved]

(8) HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012, IBR approved for § 170.205.

(9) HL7 Clinical Document Architecture, Release 2.0, Normative Edition, May 2005, IBR approved for § 170.205.

(10)–(11) [Reserved]

(12) HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture, DTSU Release 2 (Universal Realm), Draft Standard for Trial Use, July 2012, IBR approved for § 170.205.

(13) HL7 v2.5.1 IG: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 Errata and Clarifications, September, 29, 2011, IBR approved for § 170.205.

(14) HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 1 (US Realm) Draft Standard for Trial Use, November 2012, IBR approved for § 170.205.

(15) HL7 Version 3 Standard: Context Aware Retrieval Application (''Infobutton''), Knowledge Request, Release 2, 2014 Release, IBR approved for § 170.204(b).

(16) HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1, August 9, 2013, IBR approved for § 170.204(b).

(17) HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4, June 13, 2014, IBR approved for § 170.204(b).

(18) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 1—Introductory Material, Release 2.1, August 2015, IBR approved for § 170.205(a).

(19) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 2—Templates and Supporting Material, Release 2.1, August 2015, IBR approved for § 170.205(a).

(20) HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture—Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 1—Introductory Material, June 2015, IBR approved for § 170.205(h).

(21) HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture—Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 2—Templates and Supporting Material, June 2015, IBR approved for § 170.205(h).

(22) HL7 CDA© Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1 (US Realm), Volume 1—Introductory Material, April 2015, IBR approved for § 170.205(i).

(23) HL7 CDA© Release 2 Implementation Guide: Reporting to Public Health

Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1 (US Realm), Volume 2—Templates and Supporting Material, April 2015, IBR approved for § 170.205(i).

(24) Errata to the HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 1 (US Realm), September 2014, IBR approved for § 170.205(k).

(25) HL7 Version 3 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1, Part 1: CDA R2 and Privacy Metadata Reusable Content Profile, May 16, 2014, IBR approved for § 170.205(o).

(26) HL7 Implementation Guide for CDA® Release 2—Level 3: Healthcare Associated Infection Reports, Release 1 (U.S. Realm), August 9, 2013, IBR approved for § 170.205(r).

(27) HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, HL7 Draft Standard for Trial Use, Volume 1—Introductory Material, December 2014, IBR approved for § 170.205(s).

(28) HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, HL7 Draft Standard for Trial Use, Volume 2—Templates and Supporting Material, December 2014, IBR approved for § 170.205(s).

(29) HL7 Version 3 (V3) Standard, Value Sets for AdministrativeGender and NullFlavor, published August 1, 2013, IBR approved for § 170.207(n) and (o).

(30) HL7® CDA® R2 Implementation Guide: C–CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2–US Realm, October 2019, IBR approved for § 170.205(a).

(31) HL7 FHIR® Bulk Data Access (Flat FHIR®) (v1.0.0: STU 1), August 22, 2019, IBR approved for § 170.215(a).

(32) HL7 FHIR SMART Application Launch Framework Implementation Guide Release 1.0.0, November 13, 2018, IBR approved for § 170.215(a).

(33) HL7 Fast Healthcare Interoperability Resources Specification (FHIR®) Release 4, Version 4.0.1: R4, October 30, 2019, including Technical Correction #1, November 1, 2019, IBR approved for § 170.215(a).

(34) HL7 FHIR® US Core Implementation Guide STU3 Release 3.1.1, August 28, 2020, IBR approved for § 170.215(a).

(g) Integrating the Healthcare Enterprise (IHE), 820 Jorie Boulevard, Oak Brook, IL, Telephone (630) 481–1004, *http://www.ihe.net/*.

(1) IHE IT Infrastructure Technical Framework Volume 2b (ITI TF–2b), Transactions Part B—Sections 3.29—2.43, Revision 7.0, August 10, 2010, IBR approved for § 170.205(p).

(2) [Reserved]

(h) Internet Engineering Task Force (IETF) Secretariat, c/o Association Management Solutions, LLC (AMS), 48377 Fremont Blvd., Suite 117, Fremont, CA, 94538, Telephone (510) 492–4080, *http://www.ietf.org/rfc.html*.

(1) [Reserved]

(2) Network Time Protocol Version 4: Protocol and Algorithms Specification, June 2010, IBR approved for § 170.210.

(3) Request for Comment (RFC) 5646, ''Tags for Identifying Languages, September 2009,'' copyright 2009, IBR approved for § 170.207(g).

(i) International Telecommunication Union (ITU), Place des Nations, 1211 Geneva 20 Switzerland, Telephone (41) 22 730 511, *http://www.itu.int/en/pages/default.aspx*.

(1) ITU–T E.123, Series E: Overall Network Operation, Telephone Service, Service Operation and Human Factors, International operation—General provisions concerning users: Notation for national and international telephone numbers, e-mail addresses and web addresses, February 2001, IBR approved for § 170.207(q).

(2) ITU–T E.164, Series E: Overall Network Operation, Telephone Service, Service Operation and Human Factors, International operation—Numbering plan of the international telephone service, The international public telecommunication numbering plan, November 2010, IBR approved for § 170.207(q).

(j) Library of Congress, Network Development and MARC Standards Office, Washington, DC 20540–4402, Tel: (202) 707–6237 or *http://www.loc.gov/standards/iso639-2/*.

(1)–(2) [Reserved]

(k) National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260–

7518; Telephone (480) 477–1000; and Facsimile (480) 767–1042 or *http://www.ncpdp.org*.

(1) National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005, IBR approved for §170.205.

(2) SCRIPT Standard, Implementation Guide, Version 10.6, October, 2008, (Approval date for ANSI: November 12, 2008), IBR approved for §170.205.

(3) SCRIPT Standard, Implementation Guide, Version 2017071 (Approval Date for ANSI: July 28, 2017), IBR approved for §170.205(b).

(l) National Institute of Standards and Technology, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899–8930, *http://csrc.nist.gov/groups/STM/cmvp/standards.html*.

(1) Annex A: Approved Security Functions for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, Draft, January 27, 2010, IBR approved for §170.210.

(2) Annex A: Approved Security Functions for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, Draft, May 30, 2012, IBR approved for §170.210.

(3) [Reserved]

(4) FIPS PUB 180–4, Secure Hash Standard (August 2015), IBR approved for §170.210(c).

(m) Office of the National Coordinator for Health Information Technology (ONC), 330 C Street SW., Washington, DC 20201, *http://healthit.hhs.gov*.

(1) Applicability Statement for Secure Health Transport, Version 1.1, July 10, 2012, IBR approved for §170.202; available at *http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__direct_project/3338*.

(2) XDR and XDM for Direct Messaging Specification, Version 1, March 9, 2011, IBR approved for §170.202; available at *http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__direct_project/3338*.

(3) Transport and Security Specification, Version 1.0, June 19, 2012, IBR approved for §170.202.

(4) ONC Implementation Guide for Direct Edge Protocols, Version 1.1, June 25, 2014, IBR approved for §170.202; available at *http://www.healthit.gov/sites/default/files/implementationguide fordirectedgeprotocolsv1_1.pdf*.

(5) United States Core Data for Interoperability (USCDI), Version 1, July 2020 Errata, IBR approved for §170.213; available at *https://www.healthit.gov/USCDI*.

(n) OpenID Foundation, 2400 Camino Ramon, Suite 375, San Ramon, CA 94583, Telephone +1 925–275–6639, *http://openid.net/*.

(1) OpenID Connect Core 1.0 Incorporating errata set 1, November 8, 2014, IBR approved for §170.215(b).

(2) [Reserved]

(o) Public Health Data Standards Consortium, 111 South Calvert Street, Suite 2700, Baltimore, MD 21202, *http://www.phdsc.org/*.

(1) Public Health Data Standards Consortium Source of Payment Typology Code Set Version 5.0 (October 2011), IBR approved for §170.207(s).

(2) [Reserved]

(p) Regenstrief Institute, Inc., LOINC® c/o Regenstrief Center for Biomedical Informatics, Inc., 410 West 10th Street, Suite 2000, Indianapolis, IN 46202–3012, *http://loinc.org/*.

(1) Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, June 15, 2009, IBR approved for §170.207.

(2) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40, Released June 2012, IBR approved for §170.207.

(3) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52, Released June 2015, IBR approved for §170.207(c).

(4) The Unified Code of Units for Measure, Revision 1.9, October 23, 2013, IBR approved for §170.207.

(q) The Direct Project, c/o the Office of the National Coordinator for Health Information Technology (ONC), 330 C Street SW., Washington, DC 20201, *http://healthit.hhs.gov*.

(1) Applicability Statement for Secure Health Transport, Version 1.2, August 2015, IBR approved for §170.202(a).

(2) Implementation Guide for Delivery Notification in Direct, Version 1.0, June 29, 2012, IBR approved for §170.202(e).

(r) U.S. National Library of Medicine, 8600 Rockville Pike, Bethesda, MD

20894; Telephone (301) 594–5983 or *http://www.nlm.nih.gov/*.

(1) International Health Terminology Standards Development Organization Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), International Release, July 2009, IBR approved for § 170.207.

(2) International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) International Release July 31, 2012, IBR approved for § 170.207.

(3) US Extension to SNOMED CT® March 2012 Release, IBR approved for § 170.207.

(4)–(5) [Reserved]

(6) International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, September 2015 Release, IBR approved for § 170.207(a).

(7) RxNorm, September 8, 2015 Full Release Update, IBR approved for § 170.207(d).

(s) World Wide Web Consortium (W3C)/MIT, 32 Vassar Street, Room 32–G515, Cambridge, MA 02139 USA, *http://www.w3.org/standards/*

(1) Web Content Accessibility Guidelines (WCAG) 2.0, December 11, 2008, IBR approved for § 170.204.

(2) [Reserved]

[75 FR 44649, July 28, 2010, as amended at 75 FR 62690, Oct. 13, 2010; 77 FR 54285, Sept. 4, 2012; 77 FR 72991, Dec. 7, 2012; 79 FR 54478, Sept. 11, 2014; 80 FR 62745, Oct. 16, 2015; 81 FR 72463, Oct. 19, 2016; 85 FR 25941, May 1, 2020; 85 FR 70082, Nov. 4, 2020]

Subpart C—Certification Criteria for Health Information Technology

SOURCE: 75 FR 44651, July 28, 2010, unless otherwise noted.

§ 170.300 Applicability.

(a) The certification criteria adopted in this subpart apply to the testing and certification of Health IT Modules.

(b) When a certification criterion refers to two or more standards as alternatives, use of at least one of the alternative standards will be considered compliant.

(c) Health Modules are not required to be compliant with certification criteria or capabilities specified within a certification criterion that are designated as optional.

(d) In § 170.315, all certification criteria and all capabilities specified within a certification criterion have general applicability (*i.e.*, apply to any health care setting) unless designated as ''inpatient setting only'' or ''ambulatory setting only.''

[75 FR 44649, July 28, 2010, as amended at 77 FR 54286, Sept. 4, 2012; 80 FR 62747, Oct. 16, 2015; 85 FR 25941, May 1, 2020; 85 FR 70083, Nov. 4, 2020]

§§ 170.302–170.306 [Reserved]

§ 170.314 [Reserved]

§ 170.315 2015 Edition health IT certification criteria.

The Secretary adopts the following certification criteria for health IT. Health IT must be able to electronically perform the following capabilities in accordance with all applicable standards and implementation specifications adopted in this part:

(a) *Clinical*—(1) *Computerized provider order entry—medications.* (i) Enable a user to record, change, and access medication orders.

(ii) *Optional.* Include a ''reason for order'' field.

(2) *Computerized provider order entry—laboratory.* (i) Enable a user to record, change, and access laboratory orders.

(ii) *Optional.* Include a ''reason for order'' field.

(3) *Computerized provider order entry—diagnostic imaging.* (i) Enable a user to record, change, and access diagnostic imaging orders.

(ii) *Optional.* Include a ''reason for order'' field.

(4) *Drug-drug, drug-allergy interaction checks for CPOE*—(i) *Interventions.* Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list.

(ii) *Adjustments.* (A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.