§ 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:


(d) Electronic submission to public health agencies for surveillance or reporting. (1) Standard. HL7 2.3.1 (incorporated by reference in § 170.299).


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.


(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
§ 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 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.

(b) 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.


(5) [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/.


(2) ASTM E2369–05 (Adjunct to E2369): Standard Specification Continuity of Care Record,—Final Version 1.0 (V1.0), November 7, 2005, IBR approved for § 170.205.

(d) 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.


(3) [Reserved]

(e) Regenstrief Institute, Inc., LOINCR c/o Medical Informatics The Regenstrief Institute, Inc 410 West 10th Street, Suite 2000 Indianapolis, IN 46202–3012; Telephone (317) 423–5558 or http://loinc.org/.

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

(2) [Reserved]

(f) U.S. National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894; Telephone (301) 594–5983 or http://www.nlm.nih.gov/.


(2) [Reserved]

(g) Centers for Disease Control and Prevention, National Centers for Immunization and Respiratory Diseases Immunization Information System Support Branch—Informatics 1600 Clifton Road Mailstop: E–62 Atlanta, GA 30333


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


(5) [Reserved]

(h) 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.
(i) 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.
(2) [Reserved]

4. Revise subpart C to read as follows:
Subpart C—Certification Criteria for Health Information Technology
Sec. 170.300 Applicability.
170.302 General certification criteria for Complete EHRs or EHR Modules.
170.304 Specific certification criteria for Complete EHRs or EHR Modules designed for an ambulatory setting.
170.306 Specific certification criteria for Complete EHRs or EHR Modules designed for an inpatient setting.
§ 170.300 Applicability.
(a) The certification criteria adopted in this subpart apply to the testing and certification of Complete EHRs and EHR 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) Complete EHRs and EHR Modules are not required to be compliant with certification criteria that are designated as optional.

§ 170.302 General certification criteria for Complete EHRs or EHR Modules.
The Secretary adopts the following general certification criteria for Complete EHRs or EHR Modules.
Complete EHRs or EHR Modules must include the capability to perform the following functions electronically, unless designated as optional, and in accordance with all applicable standards and implementation specifications adopted in this part:
(a) Drug-drug, drug-allergy interaction checks—(1) Notifications. Automatically and electronically generate and indicate in real-time, notifications at the point of care for drug-drug and drug-allergy contraindications based on medication list, medication allergy list, and computerized provider order entry (CPOE).
(b) Drug-formulary checks. Enable a user to electronically check if drugs are in a formulary or preferred drug list.
(2) Adjustments. Provide certain users with the ability to adjust notifications provided for drug-drug and drug-allergy interaction checks.
(c) Maintain up-to-date problem list. Enable a user to electronically record, modify, and retrieve a patient’s problem list for longitudinal care in accordance with:
(1) The standard specified in § 170.207(a)(1); or
(2) At a minimum, the version of the standard specified in § 170.207(a)(2).
(d) Maintain active medication list. Enable a user to electronically record, modify, and retrieve a patient’s active medication list as well as medication history for longitudinal care.
(e) Maintain active medication allergy list. Enable a user to electronically record, modify, and retrieve a patient’s active medication allergy list as well as medication allergy history for longitudinal care.
(f) Record and chart vital signs—(1) Vital signs. Enable a user to electronically record, modify, and retrieve a patient’s vital signs including, at a minimum, height, weight, and blood pressure.
(2) Calculate body mass index. Automatically calculate and display body mass index (BMI) based on a patient’s height and weight.
(3) Plot and display growth charts. Plot and electronically display, upon request, growth charts for patients 2–20 years old.
(g) Smoking status. Enable a user to electronically record, modify, and retrieve the smoking status of a patient. Smoking status types must include: current every day smoker; current some day smoker; former smoker; never smoker; smoker, current status unknown; and unknown if ever smoked.
(h) Incorporate laboratory test results—(1) Receive results. Electronically receive clinical laboratory test results in a structured format and display such results in human readable format.
(2) Display test report information. Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).
(i) Incorporate results. Electronically attribute, associate, or link a laboratory test result to a laboratory order or patient record.
(j) Generate patient lists. Enable a user to electronically select, sort, retrieve, and generate lists of patients according to, at a minimum, the data elements included in:
(1) Problem list;
(2) Medication list;
(3) Demographics; and
(4) Laboratory test results.
(k) Medication reconciliation. Enable a user to electronically compare two or more medication lists.
(l) Submission to immunization registries. Electronically record, modify, retrieve, and submit immunization information in accordance with:
(1) The standard (and applicable implementation specifications) specified in § 170.205(e)(1) or § 170.205(e)(2); and
(2) At a minimum, the version of the standard specified in § 170.207(e).
(m) Patient-specific education resources. Enable a user to electronically identify and provide patient-specific education resources according to, at a minimum, the data elements included in the patient’s problem list; medication list; and laboratory test results; as well as provide such resources to the patient.
(n) Automated measure calculation. For each meaningful use objective with a percentage-based measure, electronically record the numerator and denominator and generate a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.
(o) Access control. Assign a unique name and/or number for identifying and tracking user identity and establish controls that permit only authorized users to access electronic health information.
(p) Emergency access. Permit authorized users (who are authorized for emergency situations) to access electronic health information during an emergency.
(q) Automatic log-off. Terminate an electronic session after a predetermined time of inactivity.
(r) Audit log. (1)—Record actions.
Record actions related to electronic health information in accordance with the standard specified in § 170.210(b).

(2) Generate audit log. Enable a user to generate an audit log for a specific time period and to sort entries in the audit log according to any of the elements specified in the standard at § 170.210(b).

(s) Integrity. (1) Create a message digest in accordance with the standard specified in § 170.210(c).

(2) Verify in accordance with the standard specified in § 170.210(c) upon receipt of electronically exchanged health information that such information has not been altered.

(3) Detection. Detect the alteration of audit logs.

(t) Authentication. Verify that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information.

(u) General encryption. Encrypt and decrypt electronic health information in accordance with the standard specified in § 170.210(a)(1), unless the Secretary determines that the use of such algorithm would pose a significant security risk for Certified EHR Technology.

(v) Encryption when exchanging electronic health information. Encrypt and decrypt electronic health information when exchanged in accordance with the standard specified in § 170.210(a)(2).

(w) Optional. Accounting of disclosures. Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(d).

§ 170.304 Specific certification criteria for Complete EHRs or EHR Modules designed for an ambulatory setting.

The Secretary adopts the following certification criteria for Complete EHRs or EHR Modules designed to be used in an ambulatory setting. Complete EHRs or EHR Modules must include the capability to perform the following functions electronically and in accordance with all applicable standards and implementation specifications adopted in this part:

(a) Computerized provider order entry. Enable a user to electronically record, store, retrieve, and modify, at a minimum, the following order types:

(1) Medications;

(2) Laboratory; and

(3) Radiology/imaging.

(b) Electronic prescribing. Enable a user to electronically generate and transmit prescriptions and prescription-related information in accordance with:

(1) The standard specified in § 170.205(b)(1) or § 170.205(b)(2); and

(2) The standard specified in § 170.207(d).

(c) Record demographics. Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, gender, race, ethnicity, and date of birth. Enable race and ethnicity to be recorded in accordance with the standard specified at § 170.207(f).

(d) Patient reminders. Enable a user to electronically generate a patient reminder list for preventive or follow-up care according to patient preferences based on, at a minimum, the data elements included in:

(1) Problem list;

(2) Medication list;

(3) Medication allergy list;

(4) Demographics; and

(5) Laboratory test results.

(e) Clinical decision support—

(1) Implement rules. Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in: problem list; medication list; demographics; and laboratory test results.

(2) Notifications. Automatically and electronically generate and indicate in real-time, notifications and care suggestions based upon clinical decision support rules.

(f) Electronic copy of health information. Enable a user to create an electronic copy of a patient’s clinical information, including, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list in:

(1) Human readable format; and

(2) On electronic media or through some other electronic means in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2); and

(ii) For the following data elements the applicable standard must be used:

(A) Problems. The standard specified in § 170.207(a)(1) or, at a minimum, the version of the standard specified in § 170.207(a)(2);

(B) Laboratory test results. At a minimum, the version of the standard specified in § 170.207(c); and

(C) Medications. The standard specified in § 170.207(d).

(g) Timely access. Enable a user to provide patients with online access to their clinical information, including, at a minimum, lab test results, problem list, medication list, and medication allergy list.

(h) Clinical summaries. Enable a user to provide clinical summaries to patients for each office visit that include, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list. If the clinical summary is provided electronically it must be:

(1) Provided in human readable format; and

(2) Provided on electronic media or through some other electronic means in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2); and

(ii) For the following data elements the applicable standard must be used:

(A) Problems. The standard specified in § 170.207(a)(1) or, at a minimum, the version of the standard specified in § 170.207(a)(2);

(B) Laboratory test results. At a minimum, the version of the standard specified in § 170.207(c); and

(C) Medications. The standard specified in § 170.207(d).

(j) Calculate and submit clinical quality measures—

(1) Calculate (i) Electronically calculate all of the core clinical measures specified by CMS for
eligible professionals. (ii) Electronically calculate, at a minimum, three clinical quality measures specified by CMS for eligible professionals, in addition to those clinical quality measures specified in paragraph (1)(i).

(2) Submission. Enable a user to electronically submit calculated clinical quality measures in accordance with the standard and implementation specifications specified in §170.205(f).

§170.306 Specific certification criteria for Complete EHRs or EHR Modules designed for an inpatient setting.

The Secretary adopts the following certification criteria for Complete EHRs or EHR Modules designed to be used in an inpatient setting. Complete EHRs or EHR Modules must include the capability to perform the following functions electronically and in accordance with all applicable standards and implementation specifications adopted in this part:

(a) Computerized provider order entry. Enable a user to electronically record, store, retrieve, and modify, at a minimum, the following order types:

(1) Medications;

(2) Laboratory and

(3) Radiology/imaging.

(b) Record demographics. Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, gender, race, ethnicity, date of birth, and date and preliminary cause of death in the event of mortality. Enable race and ethnicity to be recorded in accordance with the standard specified at §170.207(f).

(c) Clinical decision support—(1) Implement rules. Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in: problem list; medication list; demographics; and laboratory test results.

(2) Notifications. Automatically and electronically generate and indicate in real-time, notifications and care suggestions based upon clinical decision support rules.

(d) Electronic copy of health information. (1) Enable a user to create an electronic copy of a patient’s clinical information, including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, and procedures:

(i) In human readable format; and

(ii) On electronic media or through some other electronic means in accordance with:

(A) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and

(B) For the following data elements the applicable standard must be used:

(1) Problems. The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2);

(2) Procedures. The standard specified in §170.207(b)(1) or §170.207(b)(2);

(3) Laboratory test results. At a minimum, the version of the standard specified in §170.207(c); and

(4) Medications. The standard specified in §170.207(d).

(2) Enable a user to create an electronic copy of a patient’s discharge summary in human readable format and on electronic media or through some other electronic means.

(e) Electronic copy of discharge instructions. Enable a user to create an electronic copy of the discharge instructions for a patient, in human readable format, at the time of discharge on electronic media or through some other electronic means.

(f) Exchange clinical information and patient summary record—(1) Electronically receive and display. Electronically receive and display a patient’s summary record from other providers and organizations including, at a minimum, the following elements:

(i) Problem list, medication list, medication allergy list, and procedures in accordance with the standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2). Upon receipt of a patient summary record formatted according to the alternative standard, display it in human readable format;

(2) Electronically transmit. Enable a user to electronically transmit a patient’s summary record to other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, and procedures in accordance with:

(i) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and

(ii) For the following data elements the applicable standard must be used:

(A) Problems. The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2);

(B) Procedures. The standard specified in §170.207(b)(1) or §170.207(b)(2);

(C) Laboratory test results. At a minimum, the version of the standard specified in §170.207(c); and

(D) Medications. The standard specified in §170.207(d).

(g) Reportable lab results. Electronically record, modify, retrieve, and submit reportable clinical lab results in accordance with the standard (and applicable implementation specifications) specified in §170.205(c) and, at a minimum, the version of the standard specified in §170.207(c).

(h) Advance directives. Enable a user to electronically record whether a patient has an advance directive.

(i) Calculate and submit clinical quality measures—(1) Calculate. Electronically calculate all of the clinical quality measures specified by CMS for eligible hospitals and critical access hospitals.

(2) Submission. Enable a user to electronically submit calculated clinical quality measures in accordance with the standard and implementation specifications specified in §170.205(f).

Dated: July 9, 2010.

Kathleen Sebelius,
Secretary.

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