

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:
Authority: 42 U.S.C. 300jj–11; 42 U.S.C. 300jj–14; 5 U.S.C. 552.

■ 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.

170.207 Vocabulary standards for representing 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:

(a) *Patient summary record*—(1) *Standard.* Health Level Seven Clinical Document Architecture (CDA) Release 2, Continuity of Care Document (CCD) (incorporated by reference in § 170.299).
Implementation specifications. The Healthcare Information Technology Standards Panel (HITSP) Summary Documents Using HL7 CCD Component HITSP/C32 (incorporated by reference in § 170.299).

(2) *Standard.* ASTM E2369 Standard Specification for Continuity of Care Record and Adjunct to ASTM E2369 (incorporated by reference in § 170.299).

(b) *Electronic prescribing.* (1) *Standard.* The National Council for the Prescription Drug Programs (NCPDP) Prescriber/Pharmacist Interface SCRIPT standard, Implementation Guide, Version 8, Release 1 (Version 8.1) October 2005 (incorporated by reference in § 170.299)
(2) *Standard.* NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 (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 Version 2.5.1 Implementation Guide: Electronic

Laboratory Reporting to Public Health, Release 1 (US Realm) (incorporated by reference in § 170.299).

(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. Public Health Information Network HL7 Version 2.5 Message Structure Specification for National Condition Reporting Final Version 1.0 and Errata

and Clarifications National Notification Message Structural Specification (incorporated by reference in § 170.299).

(e) *Electronic submission to immunization registries.* (1) *Standard.* HL7 2.3.1 (incorporated by reference in § 170.299). *Implementation specifications.* Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol Implementation Guide Version 2.2 (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).

(f) *Quality reporting.* *Standard.* The CMS Physician Quality Reporting Initiative (PQRI) 2009 Registry XML Specification (incorporated by reference in § 170.299). *Implementation specifications.* Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry (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 CTR) 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).
(f) *Race and Ethnicity. Standard.* The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, October 30, 1997 (available at <http://www.whitehouse.gov/omb/rewrite/fedreg/ombdir15.html>).

§ 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:

(a) *Encryption and decryption of electronic health information—(1) General.* Any encryption algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140–2 (incorporated by reference in § 170.299).

(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.

(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) Health Level Seven Implementation Guide: Clinical Document Architecture (CDA) Release 2—Continuity of Care Document (CCD), April 01, 2007, IBR approved for § 170.205.

(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) [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 E2369–05: Standard Specification for Continuity of Care Record (CCR), year of adoption 2005, ASTM approved July 17, 2006, IBR approved for § 170.205.

(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.ncdp.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) [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/>.

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

(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

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

(2) 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.
(3) HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0, May 1, 2010, IBR approved for § 170.205.

(4) Public Health Information Network HL7 Version 2.5 Message Structure Specification for National Condition Reporting Final Version 1.0, including Errata and Clarifications, National Notification Message Structural Specification, 8/18/2007, August 18, 2007, 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.

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

(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) [Reserved]

(j) 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.

■ 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).

(2) *Adjustments.* Provide certain users with the ability to adjust notifications provided for drug-drug and drug-allergy interaction checks.

(b) *Drug-formulary checks.* Enable a user to electronically check if drugs are in a formulary or preferred drug list.

(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).

(3) *Incorporate results.* Electronically attribute, associate, or link a laboratory test result to a laboratory order or patient record.

(i) *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.**

(j) *Medication reconciliation.* Enable a user to electronically compare two or more medication lists.

(k) *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).

(l) *Public health surveillance.*

Electronically record, modify, retrieve, and submit syndrome-based public health surveillance information in accordance with the standard (and applicable implementation specifications) specified in § 170.205(d)(1) or § 170.205(d)(2).

(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).

(i) *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, diagnostic tests results, problem list, medication list, and medication allergy list 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 summary record to other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list 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, diagnostic test results, 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 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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