

Final Rule MU Standards Quick List with CFR Citation Cross walked to the Standard

Extracted from 45 CFR Part 170 RIN 0991-AB58 Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology – Pages 205 – 210 – PUBLIC INSPECTION DOCUMENT. Those exact pages are provided at the back of this document for reference.

7/25/2010

Disclaimer - This document is not an official federal document and has been created for public use and convenience by Robin Raiford, RN-BC, CPHIMS, FHIMSS as continuation of work that was done for the HITSP Education, Communication and Outreach Committee for ease of finding the official CFR citation of the Standards in Meaningful Use. It is intended as an informal guide only, designed to assist you in the evaluation of the final rules. You should not rely on any of the information in making any business decisions. None of the information constitutes legal advice or a legal opinion on how any of the referenced rules or laws apply to you or your organization or any other matters.

Please refer to the official ONC website for complete documentation and official federal documents at www.healthit.hhs.gov at this link – [Standards and Certification Criteria for Electronic Health Records](#)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary

45 CFR Part 170 RIN 0991-AB58
Health Information Technology: Initial Set of Standards, Implementation
Specifications, and Certification Criteria for Electronic Health Record Technology –
FINAL RULE 7/13/10 (Inspection Document)
Subpart B—Standards and Implementation Specifications for Health Information
Technology – *Below is a Summary list of the standards*

§170.205	Content Exchange Standards and Implementation Specifications For Exchanging Electronic Health Information
§170.205 (a)	(a) Patient summary record
§170.205 (a)(1)	CDA R2, CCD
§170.205 (a)(1)	CCD/HITSP32
§170.205 (a)(2)	CCR
§170.205 (b)	(b) Electronic prescribing.
§170.205 (b)(1)	NCPDP 8.1
§170.205 (b)(2)	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6
§170.205 (c)	(c) Electronic submission of lab results to public health agencies.
§170.205 (c)	HL7 2.5.1
§170.205 (c)	Implementation specifications. HL7 Health, Release 1 (US Realm)
§170.205 (d)	(d) Electronic submission to public health agencies for surveillance or reporting.
§170.205 (d)(1)	HL7 2.3.1
§170.205 (d)(2)	HL7 2.5.1
§170.205 (d)(2)	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
§170.205 (e)	(e) Electronic submission to immunization registries.
§170.205 (e)(1)	HL7 2.3.1 and Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol Implementation Guide Version 2.2
§170.205 (e)(2)	HL7 2.5.1 and HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0

Disclaimer - This document is not an official federal document and has been created for public use and convenience for ease of finding the official CFR citation of the Standards in Meaningful Use. Refer to www.healthit.hhs.gov for the official documents related to the EHR Incentive Program Standards and Certification

§170.205 (f)	(f) Quality reporting.
§170.205 (f)	PQRI 2009 Registry XML Specification
§170.207	Vocabulary standards for representing electronic health information.
§170.207 (a)	(a) Problems.
§170.207 (a)(1)	ICD–9–CM
§170.207 (a)(2)	SNOMED CT
§170.207 (b)	(b) Procedures.
§170.207 (b)(1)	ICD–9–CM
§170.207 (b)(2)	CPT–4 and HCPCS
§170.207 (c)	LOINC® version 2.27
§170.207 (d)	Any source vocabulary that is included in RxNorm [ADDED INFO - RxNorm includes First Databank, Micromedex, MediSpan, Gold Standard Alchemy, and Multum]
§170.207 (e)	HL7 Standard Code Set CVX - Vaccines Administered, July 30, 2009 version
§170.207 (f)	OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, October 30, 1997
§170.210	Standards for health information technology to protect electronic health information created, maintained, and exchanged.
§170.210 (a)	(a) Encryption and decryption of electronic health information
§170.210 (a)(1)	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
§170.210 (a)(2)	Any encrypted and integrity protected link.
§170.210 (b)	(b) Record actions related to electronic health information.
§170.210 (b)	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.
§170.210 (c)	(c) Verification that electronic health information has not been altered in transit.
§170.210 (c)	SHA-1 as specified in FIPS PUB 180-3 (October, 2008)
§170.210 (d)	(d) Record treatment, payment, and health care operations disclosures.
§170.210 (d)	Definition of the Term "Treatment"
§170.210 (d)	Definition of the Term "Payment"
§170.210 (d)	Definition of the Term "Health care operations"

Disclaimer - This document is not an official federal document and has been created for public use and convenience for ease of finding the official CFR citation of the Standards in Meaningful Use. Refer to www.healthit.hhs.gov for the official documents related to the EHR Incentive Program Standards and Certification

CFR Citation	Language from the ONC Standards and Certification FINAL RULE	Standard Brief Description
§170.205	Content Exchange Standards and Implementation Specifications for Exchanging Electronic Health Information	
§170.205 (a)	(a) Patient summary record	(a) Patient summary record
§170.205 (a)(1)	(1) Standard. Health Level Seven Clinical Document Architecture (CDA) Release 2, Continuity of Care Document (CCD) (incorporated by reference in §170.299).	CDA R2, CCD
§170.205 (a)(1)	Implementation specifications. The Healthcare Information Technology Standards Panel (HITSP) Summary Documents Using HL7 CCD Component HITSP/C32 (incorporated by reference in §170.299).	CCD/HITSP32
§170.205 (a)(2)	(2) Standard. ASTM E2369 Standard Specification for Continuity of Care Record and Adjunct to ASTM E2369 (incorporated by reference in §170.299).	CCR
§170.205 (b)	(b) Electronic prescribing.	(b) Electronic prescribing.
§170.205 (b)(1)	(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)	NCPDP 8.1
§170.205 (b)(2)	(2) Standard. NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 (incorporated by reference in §170.299).	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6
§170.205 (c)	(c) <u>Electronic submission of lab results to public health agencies.</u>	(c) <u>Electronic submission of lab results to public health agencies.</u>
§170.205 (c)	Standard. HL7 2.5.1 (incorporated by reference in §170.299).	HL7 2.5.1
§170.205 (c)	<u>Implementation specifications.</u> HL7 Health, Release 1 (US Realm) (incorporated by reference in §170.299).	Implementation specifications. HL7 Health, Release 1 (US Realm)
§170.205 (d)	(d) Electronic submission to public health agencies for surveillance or reporting.	(d) Electronic submission to public health agencies for surveillance or reporting.
§170.205 (d)(1)	(1) Standard. HL7 2.3.1(incorporated by reference in §170.299).	HL7 2.3.1
§170.205 (d)(2)	(2) <u>Standard.</u> HL7 2.5.1(incorporated by reference in §170.299).	HL7 2.5.1

Disclaimer - This document is not an official federal document and has been created for public use and convenience for ease of finding the official CFR citation of the Standards in Meaningful Use. Refer to www.healthit.hhs.gov for the official documents related to the EHR Incentive Program Standards and Certification

§170.205 (d)(2)	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).	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
§170.205 (e)	(e) Electronic submission to immunization registries.	(e) Electronic submission to immunization registries.
§170.205 (e)(1)	(1) Standard. HL7 2.3.1 (incorporated by reference in §170.299). <u>Implementation specifications.</u> 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).	HL7 2.3.1 and Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol Implementation Guide Version 2.2
§170.205 (e)(2)	(2) Standard. HL7 2.5.1 (incorporated by reference in §170.299). <u>Implementation specifications.</u> HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0 (incorporated by reference in §170.299).	HL7 2.5.1 and HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0
§170.205 (f)	(f) Quality reporting.	(f) Quality reporting.
§170.205 (f)	Standard. The CMS Physician Quality Reporting Initiative (PQRI) 2009 Registry XML Specification (incorporated by reference in §170.299). <u>Implementation specifications.</u> Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry (incorporated by reference in §170.299).	PQRI 2009 Registry XML Specification
§170.207	Vocabulary standards for representing electronic health information.	
§170.207 (a)	(a) Problems.	(a) Problems.
§170.207 (a)(1)	(1) <u>Standard.</u> The code set specified at 45 CFR 162.1002(a)(1) for the indicated conditions. [ADDED INFO from http://law.justia.com/us/cfr/title45/45-1.0.1.3.68.8.33.2.html 45 CFR 162.1002(a) For the period from October 16, 2002 through October 15, 2003: (1) International Classification of Diseases, 9th Edition, Clinical Modification, (ICD–9–CM), Volumes 1 and 2 (including The Official ICD–9–CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following conditions: (i) Diseases. (ii) Injuries. (iii) Impairments. (iv) Other health problems and their manifestations. (v) Causes of injury, disease, impairment, or other health problems.	ICD–9–CM

§170.207 (a)(2)	(2) <u>Standard</u> . International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) July 2009 version (incorporated by reference in §170.299).	SNOMED CT
§170.207 (b)	(b) Procedures.	(b) Procedures.
§170.207 (b)(1)	(1) <u>Standard</u> . The code set specified at 45 CFR 162.1002(a)(2). [ADDED INFO from http://law.justia.com/us/cfr/title45/45-1.0.1.3.68.8.33.2.html - this references CFR 162.1002(a)(2) International Classification of Diseases, 9th Edition, Clinical Modification, Volume 3 Procedures (including The Official ICD–9–CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals: (i) Prevention. (ii) Diagnosis. (iii) Treatment. (iv) Management.	ICD–9–CM
§170.207 (b)(2)	(2) <u>Standard</u> . The code set specified at 45 CFR 162.1002(a)(5). [ADDED INFO from http://law.justia.com/us/cfr/title45/45-1.0.1.3.68.8.33.2.html - this references 45 CFR 162.1002(a)(5) The combination of Health Care Financing Administration Common Procedure Coding System (HCPCS), as maintained and distributed by HHS, and Current Procedural Terminology, Fourth Edition (CPT–4), as maintained and distributed by the American Medical Association, for physician services and other health care services. These services include, but are not limited to, the following: (i) Physician services. (ii) Physical and occupational therapy services. (iii) Radiologic procedures. (iv) Clinical laboratory tests. (v) Other medical diagnostic procedures. (vi) Hearing and vision services. (vii) Transportation services including ambulance.	CPT–4 and HCPCS
§170.207 (c)	(c) <u>Laboratory test results</u> . <u>Standard</u> . 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).	LOINC® version 2.27
§170.207 (d)	(d) <u>Medications</u> . <u>Standard</u> . Any source vocabulary that is included in RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine.	Any source vocabulary that is included in RxNorm [ADDED INFO - RxNorm includes First Databank, Micromedex, MediSpan, Gold Standard Alchemy, and Multum]

Disclaimer - This document is not an official federal document and has been created for public use and convenience for ease of finding the official CFR citation of the Standards in Meaningful Use. Refer to www.healthit.hhs.gov for the official documents related to the EHR Incentive Program Standards and Certification

§170.207 (e)	(e) <u>Immunizations. Standard.</u> HL7 Standard Code Set CVX - Vaccines Administered, July 30, 2009 version (incorporated by reference in §170.299).	HL7 Standard Code Set CVX - Vaccines Administered, July 30, 2009 version
§170.207 (f)	(f) <u>Race and Ethnicity. Standard.</u> 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).	OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, October 30, 1997
§170.210	Standards for health information technology to protect electronic health information created, maintained, and exchanged.	
§170.210 (a)	(a) Encryption and decryption of electronic health information	(a) Encryption and decryption of electronic health information
§170.210 (a)(1)	(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).	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
§170.210 (a)(2)	(2) Exchange. Any encrypted and integrity protected link.	Any encrypted and integrity protected link.
§170.210 (b)	(b) Record actions related to electronic health information.	(b) Record actions related to electronic health information.
§170.210 (b)	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.	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.
§170.210 (c)	(c) Verification that electronic health information has not been altered in transit.	(c) Verification that electronic health information has not been altered in transit.
§170.210 (c)	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.	SHA-1 as specified in FIPS PUB 180-3 (October, 2008)
§170.210 (d)	(d) Record treatment, payment, and health care operations disclosures.	(d) Record treatment, payment, and health care operations disclosures.

<p>§170.210 (d)</p>	<p>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. [ADDED INFORMATION FROM http://www.access.gpo.gov/nara/cfr/waisidx_04/45cfr164_04.html 45 CFR 164.501 Terms defined - treatment, payment, and health care operations</p> <p>page 774 - Treatment means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another. [65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003]</p>	<p>Definition of the Term "Treatment"</p>
---------------------	--	---

For Informational Use Only

<p>§170.210 (d)</p>	<p>Page 743 - Payment means: (1) The activities undertaken by: (i) A health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan; or (ii) A health care provider or health plan to obtain or provide reimbursement for the provision of health care; and (2) The activities in paragraph (1) of this definition relate to the individual to whom health care is provided and include, but are not limited to: (i) Determinations of eligibility or coverage (including coordination of benefits or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims; (ii) Risk adjusting amounts due based on enrollee health status and demographic characteristics; (iii) Billing, claims management, collection activities, obtaining payment under a contract for reinsurance (including stop-loss insurance and excess of loss insurance), and related health care data processing; (iv) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges; (v) Utilization review activities, including precertification and preauthorization of services, concurrent and retrospective review of services; and (vi) Disclosure to consumer reporting agencies of any of the following protected health information relating to collection of premiums or reimbursement: (A) Name and address; (B) Date of birth; (C) Social security number; (D) Payment history; (E) Account number; and (F) Name and address of the health care provider and/or health plan.</p>	<p>Definition of the Term "Payment"</p>
---------------------	---	---

For Informational Use Only

<p>§170.210 (d)</p>	<p>Page 741-742 Health care operations means any of the following activities of the covered entity to the extent that the activities are related to covered functions:</p> <p>(1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;</p> <p>(2) Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities;</p> <p>(3) Underwriting, premium rating, and other activities relating to the creation, renewal or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance), provided that the requirements of § 164.514(g) are met, if applicable;</p> <p>(4) Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;</p>	<p>Definition of the Term "Health care operations"</p>
---------------------	---	--

For Informational Use Only

<p>§170.210 (d)</p>	<p>(5) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies; and</p> <p>(6) Business management and general administrative activities of the entity, including, but not limited to:</p> <ul style="list-style-type: none"> (i) Management activities relating to implementation of and compliance with the requirements of this subchapter; (ii) Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer. (iii) Resolution of internal grievances; (iv) The sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity; and (v) Consistent with the applicable requirements of § 164.514, creating deidentified health information or a limited data set, and fundraising for the benefit of the covered entity. 	<p>Definition of the Term "Health care operations" continued</p>
---------------------	---	--

For Informational Use Only

The Office of Management and Budget reviewed this final rule.

List of Subjects

45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Health care, Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

- For the reasons set forth in the preamble, 45 CFR subtitle A, subchapter D, part 170, is amended as follows:

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 CT®) 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