

Test Procedure for §170.306 (d)(1) Electronic Copy of Health Information

This document describes the test procedure for evaluating conformance of complete EHRs or EHR modules¹ to the certification criteria defined in 45 CFR Part 170 Subpart C of the Final Rule for Health Information Technology: Initial Set of standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology as published in the Federal Register on July 28, 2010. The document² is organized by test procedure and derived test requirements with traceability to the normative certification criteria as described in the Overview document located at http://healthcare.nist.gov/docs/TestProcedureOverview_v1.pdf. The test procedures may be updated to reflect on-going feedback received during the certification activities.

The HHS/Office of the National Coordinator for Health Information Technology (ONC) has defined the standards, implementation guides and certification criteria used in this test procedure. Applicability and interpretation of the standards, implementation guides and certification criteria to EHR technology is determined by ONC. Test procedures to evaluate conformance of EHR technology to ONC's requirements are defined by NIST. Testing of EHR technology is carried out by ONC-Authorized Testing and Certification Bodies (ATCBs), not NIST, as set forth in the final rule establishing the Temporary Certification Program (*Establishment of the Temporary Certification Program for Health Information Technology, 45 CFR Part 170; June 24, 2010.*)

Questions about the applicability of the standards, implementation guides or criteria should be directed to ONC at ONC.Certification@hhs.gov. Questions about the test procedures should be directed to NIST at hit-tst-fdbk@nist.gov. Note that NIST will automatically forward to ONC any questions regarding the applicability of the standards, implementation guides or criteria. Questions about functions and activities of the ATCBs should be directed to ONC at ONC.Certification@hhs.gov.

CERTIFICATION CRITERIA

This Certification Criterion is from the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology Final Rule issued by the Department of Health and Human Services (HHS) on July 28, 2010.

§170.306 (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:

¹ Department of Health and Human Services, 45 CFR Part 170 Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule, July 28, 2010.

² Disclaimer: Certain commercial products are identified in this document. Such identification does not imply recommendation or endorsement by the National Institute of Standards and Technology.

- (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).

Per Section III.D of the preamble of the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule where the electronic copy of health information certification criterion is discussed:

- “We do not specify that electronic media such as thumb drives or CDs must be used. An eligible hospital will be able to determine, consistent with its security posture, if certain electronic media is permissible and if so, what types. It will also be able to determine the means and location through which an electronic copy may be provided, e.g., at the records management department or office. As the commenter suggested, a patient portal would be an acceptable mechanism to provide an electronic copy.”
- “At a minimum, Certified EHR Technology must be capable of generating an electronic copy of health information that includes the elements specified by the certification criterion in an electronic copy. We do not specify the time period for which the electronic copy must cover as a condition of certification.”
- “To provide guidance and clarification to the industry, we will recognize any source vocabulary that is identified by NLM’s RxNorm Documentation as a source vocabulary included in RxNorm. We are therefore revising the standard to state: “Any source vocabulary that is included in RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine.” We note that in section 3.1, of the most recent release of the “RxNorm Documentation (06/07/10, Version 2010-3),” NLM has identified the following source vocabularies as being included in RxNorm.
 - GS - Gold Standard Alchemy
 - MDDDB - Medi-Span Master Drug Data Base
 - MMSL - Multum MediSource Lexicon
 - MMX - Micromedex DRUGDEX
 - MSH - Medical Subject Headings (MeSH)
 - MTHFDA - FDA National Drug Code Directory
 - MTHSPL - FDA Structured Product Labels
 - NDDF - First DataBank NDDF Plus Source Vocabulary
 - NDFRT - Veterans Health Administration National Drug File - Reference Terminology
 - SNOMED CT - SNOMED Clinical Terms (drug information)
 - VANDF - Veterans Health Administration National Drug File

INFORMATIVE TEST DESCRIPTION

This section provides an informative description of how the test procedure is organized and conducted. It is not intended to provide normative statements of the certification requirements.

This test evaluates the capability for a Complete EHR or EHR Module 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, in the formats and vocabularies specified by the referenced standards. Per the FR criteria, the test procedure does not evaluate the capability to create an electronic copy that includes other types of patient information.

The Vendor provides part of the test data and NIST provides part of the test data for this test procedure.

The test procedure consists of one section:

- **Create** - evaluates the capability to create a copy of a patient's clinical information either on electronic media or some other electronic means and in HL7 CCD format or ASTM CCR format using the specified vocabularies. The patient's clinical information includes diagnostic test results, problems, medications, medication allergies, and procedures in human-readable form
 - The Tester uses the Vendor-identified function(s) and Vendor-entered data to create a copy of patient clinical information, including diagnostic test results, problems, medications, medication allergies, and procedures on electronic media or via another electronic means formatted in HL7 CCD or ASTM CCR
 - The Tester validates that the data rendered on the electronic media or via other electronic means are complete and in conformance

REFERENCED STANDARDS

§170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

Regulatory Referenced Standard

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).

§170.207 Vocabulary standards for representing electronic health information.

Regulatory Referenced Standard

§170.207 Vocabulary standards for representing electronic health information.

Regulatory Referenced Standard

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.

45 CFR 162.1002(a)(1).
(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.

(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).

45 CFR 162.1002(a)(2).
(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.

§170.207 Vocabulary standards for representing electronic health information.	Regulatory Referenced Standard
<p>(2) <u>Standard</u>. The code set specified at 45 CFR 162.1002(a)(5).</p>	<p>45 CFR 162.1002(a)(5). (5) The combination of <i>Health Care Financing Administration Common Procedure Coding System (HCPCS)</i>, as maintained and distributed by HHS, and <i>Current Procedural Terminology, Fourth Edition (CPT-4)</i>, 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.</p>
<p>(c) <u>Laboratory test results. 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).</p>	
<p>(d) <u>Medications. 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.</p>	<p>Federal Register January 13, 2010 page 2031 footnote #17: GS - 10/01/2009 (Gold Standard Alchemy); MDDB - 10/07/2009 (Master Drug Data Base. Medi-Span, a division of Wolters Kluwer Health); MMSL - 10/01/2009 (Multum MediSource Lexicon); MMX - 09/28/2009 (Micromedex DRUGDEX); MSH - 08/17/2009 (Medical Subject Headings (MeSH)); MTHFDA - 8/28/2009 (FDA National Drug Code Directory); MTHSPL - 10/28/2009 (FDA StructuredProduct Labels); NDDF - 10/02/2009 (First DataBank NDDF Plus Source Vocabulary); SNOMED CT - 07/31/2009 (SNOMED Clinical Terms (drug information) SNOMED International); VANDF - 10/07/2009 (Veterans Health Administration National Drug File).</p>

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.306.d.1 – 1: Create an electronic copy of a patient’s clinical information

DTR170.306.d.1 – 1: Create an electronic copy of a patient’s clinical information

Required Vendor Information

VE170.306.d.1 – 1.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test

VE170.306.d.1 – 1.02: Vendor shall identify the EHR function(s) that are available to 1) select the patient, 2) create a copy of a patient's clinical information on electronic media or other electronic means in HL7 CCD format or ASTM CCR format including diagnostic test results, problem list, medication list, medication allergy list, list and procedure list

Required Test Procedure

TE170.306.d.1 – 1.01: Tester shall select one test data set from TD170.306.d.1

TE170.306.d.1 – 1.02: Vendor shall enter Vendor-supplied test data and/or NIST-supplied test data/examples into the patient record based on the data set selected by the Tester from TD170.306.d.1, including

- Diagnostic test results
- Problem list
- Medication list,
- Medication allergy list
- Procedure list

TE170.306.d.1 – 1.03: Using the Vendor-supplied test data and/or NIST-supplied test data/examples and the EHR function(s) identified by the Vendor, the Tester shall create a copy of the patient's clinical information on electronic media or other electronic means in the Vendor-selected HL7 CCD format or ASTM CCR format, including

- Diagnostic test results
- Problem list
- Medication list
- Medication allergy list
- Procedure list

TE170.306.d.1 – 1.04: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the copy of the patient's clinical information has been created correctly and without omission

Inspection Test Guide

IN170.306.d.1 – 1.01: Using the Vendor-supplied test data and/or the NIST-supplied test data/examples in the TD170.306.d.1. data set selected by the Tester, Tester shall verify that all of the patient clinical information data are stored in the patient's record, including

- Diagnostic test results
- Problems
- Medications
- Medication allergies
- Procedures

IN170.306.d.1 – 1.02: Using the NIST-supplied conformance testing tool identified in the Conformance Test Tools section of this test procedure, Tester shall verify that the copy of the patient's clinical information has been created in HL7 CCD format or ASTM CCR format, using the specified vocabularies, and in human readable form correctly and without omission, including

- Diagnostic test results

- Problems
- Medications
- Medication allergies
- Procedures

TEST DATA

This Test Procedure requires the vendor to supply part of the test data. The Tester shall address the following:

- Vendor-supplied test data shall ensure that the functional and interoperable requirements identified in the criterion can be adequately evaluated for conformance
- Vendor-supplied test data shall strictly focus on meeting the basic capabilities required of an EHR relative to the certification criterion rather than exercising the full breadth/depth of capability that an installed EHR might be expected to support
- Tester shall record as part of the test documentation the specific Vendor-supplied test data that was utilized for testing

Part of the test data is provided by NIST for this Test Procedure to ensure that the functional and interoperable requirements identified in the criteria can be adequately evaluated for conformance, as well as to provide consistency in the testing process across multiple ONC-Authorized Testing and Certification Bodies (ATCBs). The NIST-supplied test data focus on evaluating the basic capabilities required of EHR technology, rather than exercising the full breadth/depth of capability that an installed EHR might be expected to support. The test data is formatted for readability of use within the testing process. The format is not prescribing a particular end-user view or rendering. No additional requirements should be drawn from the format.

The Tester shall use and apply the NIST-supplied test data during the test, without exception, unless one of the following conditions exists:

- The Tester determines that the Vendor product is sufficiently specialized that the NIST-supplied test data needs to be modified in order to conduct an adequate test. Having made the determination that some modification to the NIST-supplied test data is necessary, the Tester shall record the modifications made as part of the test documentation.
- The Tester determines that changes to the test data will improve the efficiency of the testing process; primarily through using consistent demographic data throughout the testing workflow. The Tester shall ensure that the functional and interoperable requirements identified in the criterion can be adequately evaluated for conformance and that the test data provides a comparable level of robustness.

Any departure from the NIST-supplied test data shall strictly focus on meeting the basic capabilities required of EHR technology relative to the certification criterion rather than full breadth/depth of capability that installed EHR technology might be expected to support.

The Test Procedures require that the Tester enter the test data into the EHR being evaluated for conformance. The intent is that the Tester fully controls the process of entering the test data in order to ensure that the data are correctly entered as specified in the test procedure. If a situation arises where it is impractical for a Tester to directly enter the test data, the Tester, at their discretion, may instruct the Vendor to enter the test data, so long as the Tester remains in full control of the testing process, directly observes the test data being entered by the Vendor, and validates that the test data are entered correctly as specified in the test procedure.

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TD170.306.d.1: Electronic copy of patient’s health information

<Information Source> is the author for the entire document and is required in HITSP/C32. Individual entries (e.g., Medications, Allergies) may also have authors, but are not required to have them. If an individual entry does not have a specific author, the author of the entire document is assumed to be the author.

E-copy of Health Information - Data Set #1

<Information Source> for all data for this patient: Vendor-supplied (e.g., Josephine McTavish, MD)

Patient

Name	Date of Birth	Gender	Identification Number	Identification Number Type	Address/Phone
Vendor-supplied (e.g., Mary Talbot)	Vendor-supplied (e.g., 06/17/1950)	Vendor-supplied (e.g., Female)	Vendor-supplied (e.g., 989375998)	Vendor-supplied (e.g., Medical Record Number)	Vendor-supplied (e.g., 345 Vine Street Flint, Michigan 48503 810-673-9753)

Problem List

ICD-9 Code	Patient Problem	Status	Date Diagnosed
428.0	Congestive Heart Failure	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 02/22/2010)
410.90	Acute Myocardial Infarction	Vendor-supplied (e.g., Resolved)	Vendor-supplied (e.g., 09/16/2007)

SNOMED Code	Patient Problem	Status	Date Diagnosed
42343007	Congestive Heart Failure	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 02/22/2010)
57054005	Acute Myocardial Infarction	Vendor-supplied (e.g., Resolved)	Vendor-supplied (e.g., 09/16/2007)

Medication List (Use RxNorm code or the Vendor-supplied code that is mapped to the RxNorm code listed in the test data; generic and brand names for medications are provided to allow for specific configuration of the individual EHRs)

RxNorm Code	Product	Generic Name	Brand Name	Strength	Dose	Route	Frequency	Date Started	Status
201372	Medication	captopril	Capoten	25 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., TID)	Vendor-supplied (e.g., 02/25/2010)	Vendor-supplied (e.g., Active)
200820	Medication	spironolactone	Aldactone	25 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., QID)	Vendor-supplied (e.g., 02/25/2010)	Vendor-supplied (e.g., Active)
309888	Medication	digoxin	Lanoxin	125 mcg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., QD)	Vendor-supplied (e.g., 02/25/2010)	Vendor-supplied (e.g., Active)
628958	Medication	potassium chloride	Klor-Con	10 mEq	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., BID)	Vendor-supplied (e.g., 02/25/2010)	Vendor-supplied (e.g., Active)
198039	Medication	nitroglycerin	Nitroglycerin	400 mcg	Vendor-supplied (e.g., 1 Tablet)	SL	Vendor-supplied (e.g., PRN chest pain)	Vendor-supplied (e.g., 09/20/2007)	Vendor-supplied (e.g., Active)

Medication Allergy List (The SNOMED Allergy Type Code is required by HITSP/C83, which is a component of the HITSP/C32 implementation guide specified by ONC in the Final Rule)

SNOMED Allergy Type Code	Medication/Agent Allergy	Reaction	Adverse Event Date
416098002 -- Drug Allergy (disorder)	Vendor-supplied (including medication/agent allergy and associated RxNorm code)	Vendor-supplied (e.g., Wheezing)	Vendor-supplied (e.g., 03/02/2007)

Diagnostic Test Results (Vendor may provide test results as test panel)

LOINC Code	Test	Result	Abnormal Flag	Date Performed
2951-2	Sodium	138 mEq/L	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 02/24/2010)
2823-3	Potassium	4.3 mEq/L	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 02/24/2010)
2075-0	Chloride	98 mEq/L	Vendor-supplied	Vendor-supplied

LOINC Code	Test	Result	Abnormal Flag	Date Performed
			(e.g., normal)	(e.g., 02/24/2010)
2951-2	Sodium	126 mEq/L	Vendor-supplied (e.g., below normal)	Vendor-supplied (e.g., 02/22/2010)
2823-3	Potassium	3.0 mEq/L	Vendor-supplied (e.g., below normal)	Vendor-supplied (e.g., 02/22/2010)
2075-0	Chloride	94 mEq/L	Vendor-supplied (e.g., below normal)	Vendor-supplied (e.g., 02/22/2010)

Procedure List

ICD-9 Code	Procedure	Status	Date Performed
00.66	Percutaneous transluminal coronary angioplasty	Vendor-supplied (e.g., Completed)	Vendor-supplied (e.g., 09/17/2007)
37.21	Cardiac catheterization	Vendor-supplied (e.g., Completed)	Vendor-supplied (e.g., 10/01/2006)

CPT Code	Procedure	Status	Date Performed
92982	Percutaneous transluminal coronary angioplasty	Vendor-supplied (e.g., Completed)	Vendor-supplied (e.g., 09/17/2007)
93501	Cardiac catheterization	Vendor-supplied (e.g., Completed)	Vendor-supplied (e.g., 10/01/2006)

E-copy of Health Information - Data Set #2

<Information Source> for all data for this patient: Vendor-supplied (e.g., James Sharpe, MD)

Patient

Name	Date of Birth	Gender	Identification Number	Identification Number Type	Address/Phone
Vendor-supplied (e.g., Victoria Wade)	Vendor-supplied (e.g., 03/23/1954)	Vendor-supplied (e.g., Female)	Vendor-supplied (e.g., 9896469798)	Vendor-supplied (e.g., Medical Record Number)	Vendor-supplied (e.g., 266 York Street Morton, Illinois 61550 309-354-8275)

Problem List

ICD-9 Code	Patient Problem	Status	Date Diagnosed
780.2	Syncope and collapse, vasovagal attack	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 02/15/2010)
434.91	Cerebrovascular Accident (Stroke)	Vendor-supplied (e.g., Resolved)	Vendor-supplied (e.g., 07/09/2009)
599.0	Urinary tract infection	Vendor-supplied (e.g., Recurrent)	Vendor-supplied (e.g., 09/22/2008)
496.0	Chronic Obstructive Pulmonary Disease	Vendor-supplied (e.g., Chronic)	Vendor-supplied (e.g., 08/12/2007)
401.9	Hypertension, essential	Vendor-supplied (e.g., Chronic)	Vendor-supplied (e.g., 05/16/2006)

SNOMED Code	Patient Problem	Status	Date Diagnosed
398665005	Vasovagal syncope	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 02/15/2010)
230690007	Cerebrovascular Accident (Stroke)	Vendor-supplied (e.g., Resolved)	Vendor-supplied (e.g., 07/09/2009)
197927001	Recurrent urinary tract infection	Vendor-supplied (e.g., Recurrent)	Vendor-supplied (e.g., 09/22/2008)
13645005	Chronic Obstructive Lung Disease	Vendor-supplied (e.g., Chronic)	Vendor-supplied (e.g., 08/12/2007)
59621000	Essential Hypertension	Vendor-supplied (e.g., Chronic)	Vendor-supplied (e.g., 05/16/2006)

Medication List (Use RxNorm code or the Vendor-supplied code that is mapped to the RxNorm code listed in the test data; generic and brand names for medications are provided to allow for specific configuration of the individual EHRs)

RxNorm Code	Product	Generic Name	Brand Name	Strength	Dose	Route	Frequency	Date Started	Status
213482	Medication	lisinopril	Zestril	30 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., Q Day)	Vendor-supplied (e.g., 07/15/2009)	Vendor-supplied (e.g., Active)
213169	Medication	clopidogrel	Plavix	75 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., Q Day)	Vendor-supplied (e.g., 07/15/2009)	Vendor-supplied (e.g., Active)

RxNorm Code	Product	Generic Name	Brand Name	Strength	Dose	Route	Frequency	Date Started	Status
212549	Medication	amlodipine	Norvasc	5 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., Q Day)	Vendor-supplied (e.g., 07/15/2009)	Vendor-supplied (e.g., Active)
539712	Medication	nitrofurantoin	Macrobid	100 mg	Vendor-supplied (e.g., 1 Capsule)	PO	Vendor-supplied (e.g., Q Day)	Vendor-supplied (e.g., 09/22/2008)	Vendor-supplied (e.g., No Longer Active)
836370	Medication	ipratropium bromide monhydrate	Atrovent inhaler	18 mcg/puff	Vendor-supplied (e.g., 2 puffs)	By oral inhalation	Vendor-supplied (e.g., QID)	Vendor-supplied (e.g., 08/14/2007)	Vendor-supplied (e.g., Active)
884175	Medication	clonidine hydrochloride	Catapres	0.1 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., BID)	Vendor-supplied (e.g., 05/16/2006)	Vendor-supplied (e.g., Active)

Medication Allergy List (The SNOMED Allergy Type Code is required by HITSP/C83, which is a component of the HITSP/C32 implementation guide specified by ONC in the Final Rule)

SNOMED Allergy Type Code	Medication/Agent Allergy	Reaction	Adverse Event Date
416098002 -- Drug Allergy (disorder)	Vendor-supplied (including medication/agent allergy and associated RxNorm code)	Vendor-supplied (e.g., Nausea, vomiting, rash, dizziness, headache)	Vendor-supplied (e.g., 03/25/2003)

Diagnostic Test Results (Vendor may provide test results as test panel)

LOINC Code	Test	Result	Abnormal Flag	Date Performed
718-7	Hemoglobin	13 g/dl	Vendor-supplied (e.g., normal)	02/17/2010
4544-3	Hematocrit	38%	Vendor-supplied (e.g., normal)	02/17/2010
2951-2	Sodium	136 mEq/L	Vendor-supplied (e.g., normal)	02/17/2010
2823-3	Potassium	3.9 mEq/L	Vendor-supplied (e.g., normal)	02/17/2010

LOINC Code	Test	Result	Abnormal Flag	Date Performed
630-4	Urine culture, routine	Negative: No growth	Vendor-supplied (e.g., normal)	10/02/2008

Procedure List

ICD-9 Code	Procedure	Status	Date Performed
66.39	Bilateral tubal ligation	Vendor-supplied (e.g., Completed)	Vendor-supplied (e.g., 06/14/1990)

CPT Code	Procedure	Status	Date Performed
58600	Bilateral tubal ligation	Vendor-supplied (e.g., Completed)	Vendor-supplied (e.g., 06/14/1990)

E-copy of Health Information - Data Set #3

<Information Source> for all data for this patient: Vendor-supplied (e.g., Laura Reed, MD)

Patient

Name	Date of Birth	Gender	Identification Number	Identification Number Type	Address/Phone
Vendor-supplied (e.g., Jane Gibbons)	Vendor-supplied (e.g., 08/18/1957)	Vendor-supplied (e.g., Female)	Vendor-supplied (e.g., 967383398)	Vendor-supplied (e.g., Medical Record Number)	Vendor-supplied (e.g., 2010 Lamont Street Morton, Illinois 61550 309-374-1743)

Problem List

ICD-9 Code	Patient Problem	Status	Date Diagnosed
715.35	Right hip osteoarthritis	Vendor-supplied (e.g., Resolved)	Vendor-supplied (e.g., 02/12/2010)
414.01	Coronary Artery Disease (CAD)	Vendor-supplied (e.g., Chronic)	Vendor-supplied (e.g., 05/05/2002)

SNOMED Code	Patient Problem	Status	Date Diagnosed
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SNOMED Code	Patient Problem	Status	Date Diagnosed
239872002	Right hip osteoarthritis	Vendor-supplied (e.g., Resolved)	Vendor-supplied (e.g., 02/12/2010)
53741008	Coronary Arteriosclerosis	Vendor-supplied (e.g., Chronic)	Vendor-supplied (e.g., 05/05/2002)

Medication List (Use RxNorm code or the Vendor-supplied code that is mapped to the RxNorm code listed in the test data; generic and brand names for medications are provided to allow for specific configuration of the individual EHRs)

RxNorm Code	Product	Generic Name	Brand Name	Strength	Dose	Route	Frequency	Date Started	Status
855320	Medication	warfarin	Coumadin	3 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., Q Day)	Vendor-supplied (e.g., 02/15/2010)	Vendor-supplied (e.g., Active)
213169	Medication	clopidogrel	Plavix	75 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., Q Day)	Vendor-supplied (e.g., 05/15/2002)	Vendor-supplied (e.g., Active)
212549	Medication	amlodipine	Norvasc	5 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., Q Day)	Vendor-supplied (e.g., 07/15/2009)	Vendor-supplied (e.g., Active)

Medication Allergy List (The SNOMED Allergy Type Code is required by HITSP/C83, which is a component of the HITSP/C32 implementation guide specified by ONC in the Final Rule)

SNOMED Allergy Type Code	Medication/Agent Allergy	Reaction	Adverse Event Date
416098002 -- Drug Allergy (disorder)	Vendor-supplied (including medication/agent allergy and associated RxNorm code)	Vendor-supplied (e.g., Hives, photosensitivity)	Vendor-supplied (e.g., 06/06/1998)

Diagnostic Test Results (Vendor may provide test results as test panel)

LOINC Code	Test	Result	Abnormal Flag	Date Performed
718-7	Hemoglobin	11.2 g/dl	Vendor-supplied (e.g., below normal)	Vendor-supplied (e.g., 06/05/2009)
4544-3	Hematocrit	34%	Vendor-supplied (e.g., below normal)	Vendor-supplied (e.g., 06/05/2009)

LOINC Code	Test	Result	Abnormal Flag	Date Performed
34714-6	Prothrombin Time/ International Normalized Ratio (PT/INR)	3.1	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 06/05/2009)

Procedure List

ICD-9 Code	Procedure	Status	Date Performed
81.51	Total Hip Replacement, Right	Vendor-supplied (e.g., Completed)	Vendor-supplied (e.g., 02/14/2010)
37.21	Cardiac catheterization	Vendor-supplied (e.g., Completed)	Vendor-supplied (e.g., 05/05/2002)

CPT Code	Procedure	Status	Date Performed
27130	Total Hip Replacement, Right	Vendor-supplied (e.g., Completed)	Vendor-supplied (e.g., 02/14/2010)
93501	Cardiac catheterization	Vendor-supplied (e.g., Completed)	Vendor-supplied (e.g., 05/05/2002)

E-copy of Health Information - Data Set #4

<Information Source> for all data for this patient: Vendor-supplied (e.g., Morton Shaefer, MD)

Patient

Name	Date of Birth	Gender	Identification Number	Identification Number Type	Address/Phone
Vendor-supplied (e.g., Phillip Jones)	Vendor-supplied (e.g., 03/08/1962)	Vendor-supplied (e.g., Male)	Vendor-supplied (e.g., 998777349)	Vendor-supplied (e.g., Medical Record Number)	Vendor-supplied (e.g., 540 Granite Street, Blanchard, Oklahoma 73010 405-228-7744)

Problem List

ICD-9 Code	Patient Problem	Status	Date Diagnosed
410.90	Acute Myocardial Infarction	Vendor-supplied (e.g., Resolved)	Vendor-supplied (e.g., 07/12/2010)
414.01	Coronary Artery Disease (CAD)	Vendor-supplied	Vendor-supplied

ICD-9 Code	Patient Problem	Status	Date Diagnosed
		(e.g., Chronic)	(e.g., 07/05/2000)

SNOMED Code	Patient Problem	Status	Date Diagnosed
57054005	Acute Myocardial Infarction	Vendor-supplied (e.g., Resolved)	Vendor-supplied (e.g., 07/12/2010)
53741008	Coronary Arteriosclerosis	Vendor-supplied (e.g., Chronic)	Vendor-supplied (e.g., 07/05/2000)

Medication List (Use RxNorm code or the Vendor-supplied code that is mapped to the RxNorm code listed in the test data; generic and brand names for medications are provided to allow for specific configuration of the individual EHRs)

RxNorm Code	Product	Generic Name	Brand Name	Strength	Dose	Route	Frequency	Date Started	Status
198039	Medication	nitroglycerin	Nitroglycerin	400 mcg	Vendor-supplied (e.g., 1 Tablet)	SL	Vendor-supplied (e.g., PRN chest pain)	Vendor-supplied (e.g., 07/15/2010)	Vendor-supplied (e.g., Active)
213169	Medication	clopidogrel	Plavix	75 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., Q Day)	Vendor-supplied (e.g., 07/05/2000)	Vendor-supplied (e.g., Active)
212549	Medication	amlodipine	Norvasc	5 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., Q Day)	Vendor-supplied (e.g., 07/05/2000)	Vendor-supplied (e.g., Active)

Medication Allergy List (The SNOMED Allergy Type Code is required by HITSP/C83, which is a component of the HITSP/C32 implementation guide specified by ONC in the Final Rule)

SNOMED Allergy Type Code	Medication/Agent Allergy	Reaction	Adverse Event Date
416098002 -- Drug Allergy (disorder)	Vendor-supplied (including medication/agent allergy and associated RxNorm code)	Vendor-supplied (e.g., Rash and anaphylaxis)	Vendor-supplied (e.g., 07/12/2010)

Diagnostic Test Results (Vendor may provide test results as test panel)

LOINC Code	Test	Result	Abnormal Flag	Date Performed
14647-2	Total cholesterol	220 mg/dl	Vendor-supplied	Vendor-supplied

LOINC Code	Test	Result	Abnormal Flag	Date Performed
			(e.g., above high normal)	(e.g., 07/15/2010)
14927-8	Triglycerides	165 mg/dl	Vendor-supplied (e.g., above high normal)	Vendor-supplied (e.g., 07/15/2010)
718-7	Hemoglobin	12.8 g/dl	Vendor-supplied (e.g., below normal)	Vendor-supplied (e.g., 2/18/2010)
4544-3	Hematocrit	44%	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 2/18/2010)

Procedure List

ICD-9 Code	Procedure	Status	Date Performed
00.66	Percutaneous transluminal coronary angioplasty	Vendor-supplied (e.g., Completed)	Vendor-supplied (e.g., 07/15/2010)

CPT Code*	Procedure	Status	Date Performed
92982	Percutaneous transluminal coronary angioplasty	Vendor-supplied (e.g., Completed)	Vendor-supplied (e.g., 07/15/2010)

E-copy of Health Information - Data Set #5

<Information Source> for all data for this patient: Vendor-supplied (e.g., Janice Shulke, MD)

Patient

Name	Date of Birth	Gender	Identification Number	Identification Number Type	Address/Phone
Vendor-supplied (e.g., Christopher Morris)	Vendor-supplied (e.g., 07/25/1965)	Vendor-supplied (e.g., Male)	Vendor-supplied (e.g., 9784578034)	Vendor-supplied (e.g., Medical Record Number)	Vendor-supplied (e.g., 775 Hallow Street Marshalltown Iowa 50158 641-544-7744)

Problem List

ICD-9 Code	Patient Problem	Status	Date Diagnosed
540.0	Acute Appendicitis	Vendor-supplied (e.g., Resolved)	Vendor-supplied (e.g., 01/09/2010)

ICD-9 Code	Patient Problem	Status	Date Diagnosed
434.91	Cerebrovascular Accident (Stroke)	Vendor-supplied (e.g., Resolved)	Vendor-supplied (e.g., 07/09/2009)
250.02	Diabetes Mellitus, Type 2	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 03/30/2009)
401.9	Hypertension, Essential	Vendor-supplied (e.g., Chronic)	Vendor-supplied (e.g., 02/25/2008)

SNOMED Code	Patient Problem	Status	Date Diagnosed
74400008	Appendicitis	Vendor-supplied (e.g., Resolved)	Vendor-supplied (e.g., 01/09/2010)
230690007	Cerebrovascular Accident (Stroke)	Vendor-supplied (e.g., Resolved)	Vendor-supplied (e.g., 07/09/2009)
44054006	Diabetes Mellitus, Type 2	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 03/30/2009)
59621000	Essential Hypertension	Vendor-supplied (e.g., Chronic)	Vendor-supplied (e.g., 02/25/2008)

Medication List (Use RxNorm code or the Vendor-supplied code that is mapped to the RxNorm code listed in the test data; generic and brand names for medications are provided to allow for specific configuration of the individual EHRs)

RxNorm Code	Product	Generic Name	Brand Name	Strength	Dose	Route	Frequency	Date Started	Status
213169	Medication	clopidogrel	Plavix	75 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., Q Day)	Vendor-supplied (e.g., 07/15/2009)	Vendor-supplied (e.g., Active)
205875	Medication	glyburide	Diabeta	2.5 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., Q AM)	Vendor-supplied (e.g., 03/30/2009)	Vendor-supplied (e.g., Active)
200801	Medication	furosemide	Lasix	20 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., BID)	Vendor-supplied (e.g., 02/25/2008)	Vendor-supplied (e.g., Active)
628958	Medication	potassium chloride	Klor-Con	10 mEq	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., BID)	Vendor-supplied (e.g., 02/25/2008)	Vendor-supplied (e.g., Active)

RxNorm Code	Product	Generic Name	Brand Name	Strength	Dose	Route	Frequency	Date Started	Status
884175	Medication	clonidine hydrochloride	Catapres	0.1 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., BID)	Vendor-supplied (e.g., 02/25/2008)	Vendor-supplied (e.g., Active)

Medication Allergy List (The SNOMED Allergy Type Code is required by HITSP/C83, which is a component of the HITSP/C32 implementation guide specified by ONC in the Final Rule)

SNOMED Allergy Type Code	Medication/Agent Allergy	Reaction	Adverse Event Date
416098002 -- Drug Allergy (disorder)	Vendor-supplied (including medication/agent allergy and associated RxNorm code)	Vendor-supplied (e.g., Rash, dizziness, headache)	Vendor-supplied (e.g., 06/05/2008)

Diagnostic Test Results (Vendor may provide test results as test panel)

LOINC Code	Test	Result	Abnormal Flag	Date Performed
14771-0	Fasting Blood Glucose	126 mg/dl	Vendor-supplied (e.g., above high normal)	Vendor-supplied (e.g., 07/15/2010)
2823-3	Potassium	4.3 mEq/L	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 07/15/2010)
14927-8	Triglycerides	178 mg/dl	Vendor-supplied (e.g., above high normal)	Vendor-supplied (e.g., 07/15/2010)

Procedure List

ICD-9 Code	Procedure	Status	Date Performed
47.09	Emergency Appendectomy	Vendor-supplied (e.g., Completed)	Vendor-supplied (e.g., 01/09/2010)

CPT Code	Procedure	Status	Date Performed
44950	Emergency Appendectomy	Vendor-supplied (e.g., Completed)	Vendor-supplied (e.g., 01/09/2010)

CONFORMANCE TEST TOOLS

The following testing tools are available to evaluate conformance to the standards referenced in this test procedure:

- HL7 CCD/HITSP C32 – NIST provides an HL7 CCD/HITSP C32 validation tool designed specifically to support this test procedure. The tool is available in two forms:
 - a downloadable package for local installation available at <http://xreg2.nist.gov/cda-validation/mu.html>
 - a web-accessible validator which is hosted by NIST available at <http://xreg2.nist.gov/cda-validation/mu.html>

Support for these tools is available by contacting

[Andrew McCaffrey](mailto:andrew.mccaffrey@nist.gov) (andrew.mccaffrey@nist.gov)

Computer Scientist

National Institute of Standards and Technology (NIST)

Information Technology Laboratory

- ASTM CCR – Open Health Data provides an ASTM CCR validation tool designed specifically to support this test procedure. The tool is available through the following:
 - Files can be retrieved from the SourceForge site:
<http://sourceforge.net/projects/ccrvalidator>
 - Direct link to the file:
<http://sourceforge.net/projects/ccrvalidator/files/ValidationService/1.0/ValidationService-1.0.war/download>
 - Source code location:
<http://ccrvalidator.svn.sourceforge.net/viewvc/ccrvalidator/branches/>
- HL7 CCD style sheet – HL7 provides a style sheet to render HL7 CCD structured documents as part of the CCD specifications package. Contact HL7 directly for the specification package.

The following information is provided to assist the Tester in interpreting the conformance reports generated by the NIST conformance testing tools.

The HL7 CCD/HITSP C32 and ASTM CCR validation tools evaluate individual conformance statements which have been derived from the standards and implementation guides identified in the Final Rule and the test data provided in this test procedure. The validation tools evaluate the submitted CCD/CCR instance for each conformance statement, and then produce a conformance report. The Tester should consider that a report containing only Affirmative and Warning messages indicates general conformance to the standard and test data expectations. If reported, Errors should be considered as significant departures from the standard or test data requirements which need to be corrected in order to claim conformance. ATCBs will need to further analyze each error to determine if, in the context of meeting the criterion and overall meaningful use objective, the error results in a failure of the Test Procedure by the EHR technology. The tester may need to inspect test data values derived from required vocabularies and code sets.

Document History

Version Number	Description of Change	Date Published
0.5	Original draft version	April 9, 2010
1.0	Updated to reflect Final Rule	July 21, 2010
1.0	Updated to remove "Pending" from header	August 13, 2010
1.1	<ul style="list-style-type: none"> • Removed "draft" from introductory paragraph • In the Certification Criteria section, Section III.D of the preamble – RxNorm verbiage was added <p>In the Informative Test Description section</p> <ul style="list-style-type: none"> • Changed verbiage "using vocabulary coded values" to "using the specified vocabularies" <p>In the Normative Test Procedure section</p> <ul style="list-style-type: none"> • Added verbiage instructing Tester to select only one data set from the Test Data <p>In the Test Data section</p> <ul style="list-style-type: none"> • Updated the Test Data introduction verbiage • Defined <Information Source> • Moved <Information Source> data to beginning of each data set and made it Vendor-supplied data • Deleted "Time" of Birth in heading and test data • Removed Type column from Problem List, Medication Allergy List, Diagnostic Test Results, and Procedure List • For the Medication List in each data set <ul style="list-style-type: none"> ○ Added (Use RxNorm code or the Vendor-supplied code that is mapped to the RxNorm code listed in the test data; generic and brand names for medications are provided to allow for specific configuration of the individual EHRs) ○ Deleted any medications for which an RxNorm code could no longer be found ○ Replaced any RxNorm codes that did not apply to both the brand and generic medication names ○ Corrected any instances where brand name was in the generic name column and generic name was in the brand name column • For the Medication Allergy List in each data set <ul style="list-style-type: none"> ○ Added (The SNOMED Allergy Type Code is required by HITSP/C83, which is a component of the HITSP/C32 implementation guide specified by ONC in the Final Rule) ○ Changed heading from "SNOMED Allergy Code" to "SNOMED Allergy Type Code" ○ Replaced all previous SNOMED allergy code data with SNOMED allergy <u>type</u> code data "416098002 – Drug Allergy (disorder)" ○ Changed the Medication/Agent Allergy data to "Vendor-supplied (including medication/agent allergy and associated RxNorm code)" ○ Changed heading from "Date Recorded" to "Adverse Event Date" ○ Deleted all but one row of Medication Allergy List data in each data set 	September 24, 2010