

Test Procedure for §170.304 (f) 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.

§170.304 (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:

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.

- (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).

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:

- Meaningful Use Stage 1 Measure: More than 50% of all patients of the EP or the inpatient or emergency departments of the eligible hospital or CAH (POS 21 or 23) who request an electronic copy of their health information are provided it within 3 business days
- “By human readable format, we mean a format that enables a human to read and easily comprehend the information presented to them regardless of the method of presentation (e.g., computer screen, handheld device, electronic document).”
- “We do not specify the method by which an individual must receive an electronic copy of the specified health information, only that Certified EHR Technology be capable of electronically generating an electronic copy in human readable format and in accordance with one of the adopted summary record standards. While Certified EHR Technology must be capable of creating an electronic copy of a patient’s health information as specified in this certification criterion, we encourage Complete EHR and EHR Module developers to also include the capability to generate an electronic copy in a manner that allows eligible professionals (and eligible hospitals as this capability relates to Complete EHRs and EHR Modules designed for an inpatient setting) to comply with applicable provisions of the HIPAA Privacy and Security Rules.”
- “...in order to meet this certification criterion, Certified EHR Technology must be able to generate an electronic copy that is in human readable format and as a CCD or CCR. If Certified EHR Technology is capable of generating one copy that could meet both of these requirements, we would consider that to be a compliant implementation of this capability.”
- “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
 - MDDB - 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, and medication allergy list 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, and medication allergies 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, and medication allergies 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.

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

Regulatory Referenced Standard

(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

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).

(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).

§170.207 Vocabulary standards for representing electronic health information.	Regulatory Referenced Standard
<p><u>(d) 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>As of 6/10/2010 the following source vocabularies are listed by NLM:</p> <ul style="list-style-type: none">GS Gold Standard AlchemyMddb Medi-Span Master Drug Data BaseMMSL Multum MediSource LexiconMMX Micromedex DRUGDEXMSH Medical Subject Headings (MeSH)MTHFDA FDA National Drug Code DirectoryMTHSPL FDA Structured Product LabelsNDDF First DataBank NDDF Plus Source VocabularyNDFRT Veterans Health Administration National Drug File - Reference TerminologySNOMED CT SNOMED Clinical Terms (drug information)VANDF Veterans Health Administration National Drug File

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.304.f - 1: Create an electronic copy of a patient's clinical information

DTR170.304.f - 1: Create an electronic copy of a patient's clinical information

Required Vendor Information

- VE170.304.f – 1.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test
- VE170.304.f – 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, and medication allergy list

Required Test Procedure

- TE170.304.f – 1.01: Tester shall select one test data set from TD170.304.f.
- TE170.304.f – 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 TD170.304.f, including
- Diagnostic test results
 - Problem list
 - Medication list,
 - Medication allergy list
- TE170.304.f – 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

TE170.304.f – 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

IN170.304.f – 1.01: Using the Vendor-supplied test data and/or the NIST-supplied test data/examples in the TD170.304.f. 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

IN170.304.f – 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

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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TD170.304.f: 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., George Gonzales, MD)

Patient

Name	Date of Birth	Gender	Identification Number	Identification Number Type	Address/Phone
Vendor-supplied (e.g., Jeffrey Surret)	Vendor-supplied (e.g., 09/24/1960)	Vendor-supplied (e.g., Male)	Vendor-supplied (e.g., 999869999)	Vendor-supplied (e.g., Medical Record Number)	Vendor-supplied (e.g., 347 Grove Street Williamsport, Pennsylvania 17701 570-837-9933)

Problem List

ICD-9 Code	Patient Problem	Status	Date Diagnosed
250.02	Diabetes Mellitus, Type 2	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 09/16/2009)
272.4	Hyperlipidemia	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 05/05/2002)
414.01	Coronary Artery Disease (CAD)	Vendor-supplied (e.g., Chronic)	Vendor-supplied (e.g., 05/05/2002)
401.9	Hypertension, Essential	Vendor-supplied (e.g., Active)	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
44054006	Diabetes Mellitus, Type 2	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 09/16/2009)
55822004	Hyperlipidemia	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 05/05/2002)
53741008	Coronary Arteriosclerosis	Vendor-supplied (e.g., Chronic)	Vendor-supplied (e.g., 05/05/2002)
59621000	Essential Hypertension	Vendor-supplied (e.g., Active)	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
205875	Medication	glyburide	Diabeta	2.5 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., Q AM)	Vendor-supplied (e.g., 09/16/2009)	Vendor-supplied (e.g., Active)
617314	Medication	atorvastatin calcium	Lipitor	10 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., Q Day)	Vendor-supplied (e.g., 05/05/2002)	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., 05/05/2002)	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., 05/05/2002)	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)	Vendor-supplied (e.g., 06/27/1996)

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

LOINC Code	Test	Result	Abnormal Flag	Date Performed
14771-0	Fasting Blood Glucose	178 mg/dl	Vendor-supplied (e.g., above high normal)	Vendor-supplied (e.g., 09/16/2009)
14682-9	Creatinine	1.0 mg/dl	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 09/16/2009)
14937-7	BUN	18 mg/dl	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 09/16/2009)
2951-2	Sodium	141 mEq/L	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 09/16/2009)
14647-2	Total cholesterol	162 mg/dl	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 09/16/2009)
14646-4	HDL cholesterol	43 mg/dl	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 09/16/2009)
2089-1	LDL cholesterol	84 mg/dl	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 09/16/2009)
14927-8	Triglycerides	177 mg/dl	Vendor-supplied (e.g., above high normal)	Vendor-supplied (e.g., 09/16/2009)

E-copy of Health Information - Data Set #2

Patient

Name	Date of Birth	Gender	Identification Number	Identification Number Type	Address/Phone
Vendor-supplied (e.g., Joseph Rollo)	Vendor-supplied (e.g., 12/28/1984)	Vendor-supplied (e.g., Male)	Vendor-supplied (e.g., 9813450798)	Vendor-supplied (e.g., Medical Record Number)	Vendor-supplied (e.g., 867 Juniper Street Morton, Illinois 61550 309-377-8488)

“Source” for all data for this patient: Vendor-supplied (e.g., Curtis James, MD)

Problem List

ICD-9 Code	Patient Problem	Status	Date Diagnosed
493.00	Asthma, unspecified	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 12/22/2009)
250.02	Diabetes Mellitus, Type 2	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 08/10/2008)

SNOMED Code	Patient Problem	Status	Date Diagnosed
195967001	Asthma	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 12/22/2009)
44054006	Diabetes Mellitus, Type 2	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 08/10/2008)

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
979334	Medication	metaproterenol sulfate	Alupent Inhalation Aerosol	15 mg/ml	Vendor-supplied (e.g., 2 Puffs)	Inhaled	Vendor-supplied (e.g., Q4h)	Vendor-supplied (e.g., 12/22/2009)	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., 08/10/2008)	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 and anaphylaxis)	Vendor-supplied (e.g., 08/10/2008)

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

LOINC Code	Test	Result	Abnormal Flag	Date Performed
14771-0	Fasting Blood Glucose	70 mg/dl	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 12/22/2009)

LOINC Code	Test	Result	Abnormal Flag	Date Performed
26449-9	Eosinophil Count	2%	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 12/22/2009)

E-copy of Health Information - Data Set #3

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

Patient

Name	Date of Birth	Gender	Identification Number	Identification Number Type	Address/Phone
Vendor-supplied (e.g., Joyce Tyler)	Vendor-supplied (e.g., 11/12/1955)	Vendor-supplied (e.g., Female)	Vendor-supplied (e.g., 9639263266)	Vendor-supplied (e.g., Medical Record Number)	Vendor-supplied (e.g., 563 3 rd Street Fargo, North Dakota 58102 701-366-4958)

Problem List

ICD-9 Code	Patient Problem	Status	Date Diagnosed
486.0	Pneumonia	Vendor-supplied (e.g., Resolved)	Vendor-supplied (e.g., 01/22/2010)
496.0	Chronic Obstructive Pulmonary Disease	Vendor-supplied (e.g., Chronic)	Vendor-supplied (e.g., 10/10/1999)

SNOMED Code	Patient Problem	Status	Date Diagnosed
233604007	Pneumonia	Vendor-supplied (e.g., Resolved)	Vendor-supplied (e.g., 01/22/2010)
13645005	Chronic Obstructive Lung Disease	Vendor-supplied (e.g., Chronic)	Vendor-supplied (e.g., 10/10/1999)

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
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RxNorm Code	Product	Generic Name	Brand Name	Strength	Dose	Route	Frequency	Date Started	Status
308460	Medication	azithromycin	Azithromycin	250 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., Q Day)	Vendor-supplied (e.g., 01/22/2010)	Vendor-supplied (e.g., No Longer Active)
836370	Medication	ipratropium bromide monhydrate	Atrovent Inhaler	18 mcg/puff	Vendor-supplied (e.g., 2 Puffs)	Inhaled	Vendor-supplied (e.g., QID)	Vendor-supplied (e.g., 10/10/1999)	Vendor-supplied (e.g., Active)
630208	Medication	albuterol sulfate	Albuterol Inhaler	2.5 mg/3ml	Vendor-supplied (e.g., 2 Puffs)	Inhaled	Vendor-supplied (e.g., Q4h PRN shortness of breath)	Vendor-supplied (e.g., 10/10/1999)	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., 06/10/2009)

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

LOINC Code	Test	Result	Abnormal Flag	Date Performed
718-7	Hemoglobin	16 g/dl	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 12/22/2009)
4544-3	Hematocrit	45%	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 12/22/2009)
34534-8	Electrocardiogram	Normal Sinus Rhythm	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 12/22/2009)

E-copy of Health Information - Data Set #4

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

Patient

Name	Date of Birth	Gender	Identification Number	Identification Number Type	Address/Phone
Vendor-supplied (e.g., Sarah Ebbert)	Vendor-supplied (e.g., 10/08/1962)	Vendor-supplied (e.g., Female)	Vendor-supplied (e.g., 998822799)	Vendor-supplied (e.g., Medical Record Number)	Vendor-supplied (e.g., 856 Salt Street, Shawville, Pennsylvania 16873 814-645-6489)

Problem List

ICD-9 Code	Patient Problem	Status	Date Diagnosed
272.4	Hyperlipidemia	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 07/05/2006)
401.9	Hypertension, Essential	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 07/05/2006)

SNOMED Code	Patient Problem	Status	Date Diagnosed
55822004	Hyperlipidemia	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 07/05/2006)
59621000	Essential Hypertension	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 07/05/2006)

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
617314	Medication	atorvastatin calcium	Lipitor	10 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., Q Day)	Vendor-supplied (e.g., 07/05/2006)	Vendor-supplied (e.g., Active)

RxNorm Code	Product	Generic Name	Brand Name	Strength	Dose	Route	Frequency	Date Started	Status
200801	Medication	furosemide	Lasix	20 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., BID)	Vendor-supplied (e.g., 07/05/2006)	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., 07/05/2006)	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., Rash and anaphylaxis)	Vendor-supplied (e.g., 05/22/1998)

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

LOINC Code	Test	Result	Abnormal Flag	Date Performed
2823-3	Potassium	4.5 mEq/L	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 07/15/2009)
14647-2	Total cholesterol	180 mg/dl	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 07/15/2009)
14646-4	HDL cholesterol (≥40 mg/dl)	41 mg/dl	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 07/15/2009)
2089-1	LDL cholesterol (<100 mg/dl)	120 mg/dl	Vendor-supplied (e.g., above high normal)	Vendor-supplied (e.g., 07/15/2009)
14927-8	Triglycerides (<150 mg/dl)	187 mg/dl	Vendor-supplied (e.g., above high normal)	Vendor-supplied (e.g., 07/15/2009)

E-copy of Health Information - Data Set #5

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

Patient

Name	Date of Birth	Gender	Identification Number	Identification Number Type	Address/Phone
Vendor-supplied (e.g., Michael Charles)	Vendor-supplied (e.g., 02/21/1965)	Vendor-supplied (e.g., Male)	Vendor-supplied (e.g., 987730987)	Vendor-supplied (e.g., Medical Record Number)	Vendor-supplied (e.g., 689 Dun Street Aurora, Colorado 80011 303-544-9988)

Problem List

ICD-9 Code	Patient Problem	Status	Date Diagnosed
250.02	Diabetes Mellitus, Type 2	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 07/17/2009)
401.9	Hypertension, Essential	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 06/05/2008)

SNOMED Code	Patient Problem	Status	Date Diagnosed
44054006	Diabetes Mellitus, Type 2	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 07/17/2009)
59621000	Essential Hypertension	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 06/05/2008>

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
205875	Medication	glyburide	Diabeta	2.5 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., Q AM)	Vendor-supplied (e.g., 07/17/2009)	Vendor-supplied (e.g., Active)

RxNorm Code	Product	Generic Name	Brand Name	Strength	Dose	Route	Frequency	Date Started	Status
200801	Medication	furosemide	Lasix	20 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., BID)	Vendor-supplied (e.g., 06/05/2008)	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., 06/05/2008)	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., Diarrhea, nausea, vomiting)	Vendor-supplied (e.g., 03/25/1997)

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

LOINC Code	Test	Result	Abnormal Flag	Date Performed
14771-0	Fasting Blood Glucose (70–100 mg/dl)	145 mg/dl	Vendor-supplied (e.g., above high normal)	07/17/2009
2823-3	Potassium (3.5–5.3 mEq/L)	4.5 mEq/L	Vendor-supplied (e.g., normal)	07/17/2009
14927-8	Triglycerides (<150 mg/dl)	187 mg/dl	Vendor-supplied (e.g., above high normal)	07/17/2009

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 the introductory paragraph • In the Certification Criteria section, Section III.D of the preamble – RxNorm verbiage was added In the Informative Test Description section <ul style="list-style-type: none"> • Changed verbiage "using vocabulary coded values" to "using the specified vocabularies" In the Normative Test Procedure section <ul style="list-style-type: none"> • Added verbiage instructing Tester to select only one data set from the Test Data In the Test Data section <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, and Diagnostic Test Results • 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