Test Procedure for §170.304 (h) Clinical Summaries

This document describes the test procedure for evaluating conformance of complete EHRs or EHR modules[1] 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 document[2] 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(h) Clinical summaries. Enable a user to provide clinical summaries to patients for each office visit that include, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list. If the clinical summary is provided electronically it must be:

(1) Provided in human readable format; and

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

[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 clinical summaries certification criterion is discussed:

- "Given the requests for additional clarity regarding the meaning of human readable format, we have decided to define the term in this final rule as follows: 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 (e.g., computer screen, handheld device, electronic document)."
- "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 a clinical summary to be provided to patients for each office visit 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. If the clinical summary is provided electronically, it must be provided in human readable format and on electronic media or through some other electronic means. Per the FR criteria, the test procedure does not evaluate the capability to create a clinical summary 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 is organized into two sections:

- Provide - evaluates the capability to provide clinical summaries to patients for each office visit that include diagnostic test results, problem list, medication list, and medication allergy list
    - Using Vendor-identified EHR function(s), the Tester enters the Vendor-supplied test data and/or NIST-supplied test data/examples for diagnostic test results, problems, medications, and medications allergies into a patient's EHR
    - Using Vendor-identified EHR function(s), the Tester creates a clinical summary
    - The Tester validates that the data rendered on the clinical summary are complete and accurate

- Provide electronically - evaluates the capability to provide the clinical summary either on electronic media or some other electronic means, in HL7 CDA CCD format or ASTM CCR format, using the specified vocabularies, and in human-readable form
    - Using Vendor-identified EHR function(s), the Tester generates an electronic version of the clinical summary on electronic media or via another electronic means formatted in HL7 CDA CCD or ASTM CCR
    - The Tester validates that the data rendered on the electronic media or via other electronic means are complete, in conformance and presented in human readable format

  For this portion of the test the medications test data will be evaluated for vocabulary conformance to the medications source vocabulary identified by the Vendor as implemented in the EHR. This may require a manual inspection of the test data in the patient summary record instance.

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
(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.	As of 6/10/2010 the following source vocabularies are listed by NLM: 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

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.304.h - 1: Provide clinical summaries to patients

DTR170.304.h - 2: Provide clinical summaries to patients electronically

DTR170.304.h – 1: Provide clinical summaries to patients

Required Vendor Information

VE170.304.h – 1.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test

VE170.304.h – 1.02: Vendor shall specify whether they wish to use HL7 CDA CCD or ASTM CCR

VE170.304.h – 1.03 Vendor shall identify the EHR function(s) that are available to 1) select the patient, 2) enter patient clinical information including diagnostic test results, problems, medications, and medication allergies 3) provide a clinical summary including diagnostic test results, problem list, medication list, and medication allergy list

Required Test Procedure

TE170.304.h – 1.01: Tester shall select one test data set from TD170.304.h.

TE170.304.h – 1.02: Tester shall select patient clinical information data from Vendor-supplied test data and/or NIST-supplied test data/examples for the selected data set in TD170.304.h

TE170.304.h – 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 select the patient's existing record and enter patient clinical information, including

- Diagnostic test results
- Problems
- Medications
- Medication Allergies

TE170.304.h – 1.04: 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 clinical summary for an office visit, including

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

TE170.304.h – 1.05: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the clinical summary has been created correctly and without omission

Inspection Test Guide

IN170.304.h – 1.01: Using the Vendor-supplied test data and/or the NIST-supplied test data/examples in the TD170.304.h data set selected by the Tester, Tester shall verify that all of the patient clinical data are entered correctly and without omission, including

- Diagnostic test results
- Problems
- Medications
- Medication allergies

IN170.304.h – 1.02: Using the Vendor-supplied test data and/or the NIST-supplied test data/examples in the TD170.304.h data set selected by the Tester, Tester shall verify that all of the patient clinical data are stored in the patient's record, including

- Diagnostic test results
- Problems
- Medications
- Medication allergies

IN170.304.h – 1.03: Tester shall verify that the clinical summary has been created in HL7 CCD format or ASTM CCR format, in human readable form and using vocabulary coded values correctly and without omission, including

- Diagnostic test results
- Problems
- Medications
- Medication allergies

DTR170.304.h – 2: Provide clinical summaries to patients electronically

Required Vendor Information

- Information as defined in DTR170.304.h - 1, and the following additional information is required

VE170.304.h – 2.01: Vendor shall identify the EHR function(s) that are available to provide a clinical summary on electronic media or other electronic means in HL7 CDA CCD format or ASTM CCR format including diagnostic test results, problem list, medication list, and medication allergy list

Required Test Procedure

TE170.304.h – 2.01: Using the EHR function(s) identified by the Vendor, the existing patient record, and patient clinical information entered in the DTR170.304.h – 1: Provide Clinical Summaries to Patients test, the Tester shall create the clinical summary on electronic media or other electronic means in HL7 CDA CCD or ASTM CCR format, including

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

TE170.304.h – 2.02: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the electronic version of the clinical summary has been created correctly and without omission

Inspection Test Guide

IN170.304.h – 2.01: Using the Vendor-supplied test data and/or the NIST-supplied test data/examples entered in the DTR170.304.h – 1: Provide Clinical Summaries to Patients test, Tester shall verify that the clinical summary has been created in HL7 CDA CCD or ASTM CCR format, using the specified vocabularies, and in human readable form correctly and without omission, including

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

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.

TD170.304.h.: Clinical summaries

<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.

Clinical Summaries - Data Set #1

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

Patient

Name	Date of Birth	Gender	Identification Number	Identification Number Type	Address/Phone
Vendor-supplied (e.g., Jonas Barnaby)	Vendor-supplied (e.g., 07/14/1961)	Vendor-supplied (e.g., Male)	Vendor-supplied (e.g., 969988999)	Vendor-supplied (e.g., Medical Record Number)	Vendor-supplied (e.g., 478 Charles Street, Williamsport, Pennsylvania 17701 570-857-8593)

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., 07/20/2010)
272.4	Hyperlipidemia	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 02/20/2010)

SNOMED Code	Patient Problem	Status	Date Diagnosed
44054006	Diabetes Mellitus, Type 2	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 07/20/2010)
55822004	Hyperlipidemia	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 02/20/2010)

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., 07/20/2010)	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., 02/20/2010)	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., 07/20/2010)
14647-2	Total cholesterol	262 mg/dl	Vendor-supplied (e.g., Above high normal)	Vendor-supplied (e.g., 02/20/2010)
14646-4	HDL cholesterol	78 mg/dl	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 02/20/2010)
2089-1	LDL cholesterol	184 mg/dl	Vendor-supplied (e.g., above high normal)	Vendor-supplied (e.g., 02/20/2010)
14927-8	Triglycerides	177 mg/dl	Vendor-supplied (e.g., above high normal)	Vendor-supplied (e.g., 02/20/2010)

Clinical Summaries - Data Set #2

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

Patient

Name	Date of Birth	Gender	Identification Number	Identification Number Type	Address/Phone
Vendor-supplied (e.g., Robert Flint)	Vendor-supplied (e.g., 04/18/1983)	Vendor-supplied (e.g., Male)	Vendor-supplied (e.g., 9813624798)	Vendor-supplied (e.g., Medical Record Number)	Vendor-supplied (e.g., 747 Market Street, Morton, Illinois 61550 309-365-8298)

Problem List

ICD-9 Code	Patient Problem	Status	Date Diagnosed
493.00	Asthma, unspecified	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 07/19/2009)
250.02	Diabetes Mellitus, Type 2	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 03/10/2010)

SNOMED Code	Patient Problem	Status	Date Diagnosed
195967001	Asthma	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 07/19/2009)
44054006	Diabetes Mellitus, Type 2	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 03/10/2010)

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., 07/19/2009)	Vendor-supplied (e.g., Active)

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., 03/10/2010)	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, 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	150 mg/dl	Vendor-supplied (e.g., above high normal)	Vendor-supplied (e.g., 03/10/2010)

Clinical Summaries - Data Set #3

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

Patient

Name	Date of Birth	Gender	Identification Number	Identification Number Type	Address/Phone
Vendor-supplied (e.g., Barbara Simpson)	Vendor-supplied (e.g., 10/12/1956)	Vendor-supplied (e.g., Female)	Vendor-supplied (e.g., 9688675266)	Vendor-supplied (e.g., Medical Record Number)	Vendor-supplied (e.g., 996 Dalton Street, Fargo, North Dakota 58102 701-366-5534)

Problem List

ICD-9 Code	Patient Problem	Status	Date Diagnosed

ICD-9 Code	Patient Problem	Status	Date Diagnosed
486	Pneumonia	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 07/02/2010)
496.0	Chronic Obstructive Pulmonary Disease	Vendor-supplied (e.g., Chronic)	Vendor-supplied (e.g., 02/10/2010)

SNOMED Code	Patient Problem	Status	Date Diagnosed
233604007	Pneumonia	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 07/02/2010)
13645005	Chronic Obstructive Lung Disease	Vendor-supplied (e.g., Chronic)	Vendor-supplied (e.g., 02/10/2010)

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
308460	Medication	azithromycin	Azithromycin	250 mg	Vendor-supplied (e.g., 1 Tablet)	PO	Vendor-supplied (e.g., Q Day)	Vendor-supplied (e.g., 07/02/2010)	Vendor-supplied (e.g., 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., 02/10/2010)	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., Q 4 hours PRN for shortness of breath)	Vendor-supplied (e.g., 02/10/2010)	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

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, 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., 02/10/2010)
4544-3	Hematocrit	45%	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 02/10/2010)

Clinical Summaries - Data Set #4

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

Patient

Name	Date of Birth	Gender	Identification Number	Identification Number Type	Address/Phone
Vendor-supplied (e.g., Susan Ellerby)	Vendor-supplied (e.g., 12/08/1963)	Vendor-supplied (e.g., Female)	Vendor-supplied (e.g., 925377799)	Vendor-supplied (e.g., Medical Record Number)	Vendor-supplied (e.g., 483 Powell Street, Shawville, Pennsylvania 16873 814-645-9475)

Problem List

ICD-9 Code	Patient Problem	Status	Date Diagnosed
272.4	Hyperlipidemia	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 07/06/2010)
401.9	Hypertension, Essential	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 02/05/2010)

SNOMED Code	Patient Problem	Status	Date Diagnosed
55822004	Hyperlipidemia	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 07/06/2010)

SNOMED Code	Patient Problem	Status	Date Diagnosed
59621000	Essential Hypertension	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 02/05/2010)

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., 07/06/2010)	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., 02/05/2010)	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., 02/05/2010)	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, 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
14647-2	Total cholesterol	279 mg/dl	Vendor-supplied (e.g., above high normal)	Vendor-supplied (e.g., 07/06/2010)
14646-4	HDL cholesterol	89 mg/dl	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 07/06/2010)
2089-1	LDL cholesterol	190 mg/dl	Vendor-supplied (e.g., above high normal)	Vendor-supplied (e.g., 07/06/2010)

LOINC Code	Test	Result	Abnormal Flag	Date Performed
14927-8	Triglycerides (<150 mg/dl)	187 mg/dl	Vendor-supplied (e.g., above high normal)	Vendor-supplied (e.g., 07/06/2010)
2823-3	Potassium	4.5 mEq/L	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 02/05/2010)

Clinical Summaries - Data Set #5

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

Patient

Name	Date of Birth	Gender	Identification Number	Identification Number Type	Address/Phone
Vendor-supplied (e.g., Johnathan Stone)	Vendor-supplied (e.g., 11/12/1966)	Vendor-supplied (e.g., Male)	Vendor-supplied (e.g., 988772587)	Vendor-supplied (e.g., Medical Record Number)	Vendor-supplied (e.g., 937 Sutter Street, Aurora, Colorado 80011 303-544-9988)

Problem List

ICD-9 Code	Patient Problem	Status	Date Diagnosed
401.9	Hypertension, Essential	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 01/15/2010)
250.02	Diabetes Mellitus, Type 2	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 07/17/2010)

SNOMED Code	Patient Problem	Status	Date Diagnosed
44054006	Diabetes Mellitus, Type 2	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 07/17/2010)
59621000	Essential Hypertension	Vendor-supplied (e.g., Active)	Vendor-supplied (e.g., 01/15/2010)

Medication List (Use RxNorm code or the Vendor-supplied code that is mapped to the RxNorm code listed in the test data)

RxNorm Code	Product	Generic Name	Brand Name	Strength	Dose	Route	Frequency	Date Started	Status

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., 07/17/2010)	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., 01/15/2010)	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., 01/15/2010)	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	120 mg/dl	Vendor-supplied (e.g., above high normal)	Vendor-supplied (e.g., 07/17/2010)
2823-3	Potassium	4.5 mEq/L	Vendor-supplied (e.g., normal)	Vendor-supplied (e.g., 01/15/2010)

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-accessable 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 (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 inspection test data values derived from required vocabularies and code sets.

Document History

Version Number	Description	Date Published
0.5	Original draft version	April 9, 2010
1.0	Updated to reflect Final Rule	July 21, 2010
1.0	Updates include: • removed “Pending” in header • updated zip codes in test data	August 13, 2010
1.1	• Removed “draft” from introductory paragraph In the Informative Test Description section • Changed verbiage "using vocabulary coded values" to "using the specified vocabularies" In the Normative Test Procedure section • Added verbiage instructing Tester to select only one data set from the Test Data In the Test Data section • 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 o 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) o Deleted any medications for which an RxNorm code could no longer be found o Replaced any RxNorm codes that did not apply to both the brand and generic medication names o 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 o 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) o Changed heading from “SNOMED Allergy Code” to “SNOMED Allergy Type Code” o Replaced all previous SNOMED allergy code data with SNOMED allergy type code data "416098002 – Drug Allergy (disorder)" o Changed the Medication/Agent Allergy data to "Vendor-supplied (including medication/agent allergy and associated RxNorm code)" o Changed heading from "Date Recorded" to "Adverse Event Date" o Deleted all but one row of Medication Allergy List data in each data set	September 24, 2010