Test Procedure for §170.304 (h) Clinical Summaries

This document describes the draft 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 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 NIST-supplied test data 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, in human-readable form and using vocabulary coded values
    - 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.	
(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).	

§170.205 Content exchange standards and implementation specifications for exchanging electronic health information.	Regulatory Referenced Standard
(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).	
(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 for each office visit

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 patient clinical information data from NIST-supplied test data in TD170.304.h

TE170.304.h – 1.02: Using 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 – 1.03: Using 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 – 1.04: 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 data in the NIST-supplied Test Data TD170.304.h, Tester shall verify that all of the patient clinical data are entered correctly and without omission

IN170.304.h – 1.02: 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

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 for Each Office Visit 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 data in the NIST-supplied Test Data TD170.304.h, Tester shall verify that the clinical summary has been created in HL7 CDA CCD or ASTM CCR format, in human readable form and using vocabulary coded values correctly and without omission

TEST DATA

Test data is provided by NIST in 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 installed EHR technology 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 exist:

- 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 exercising the 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 technology being evaluated for conformance. The intent is that the Tester fully control 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 the Tester's 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.

The format of the test data below is for readability purposes in this Test Procedure only. It does not represent an implementation of the 'display in human readable format' requirement of this Test Procedure. It is not intended to represent 'human readable' per the Final Rule definition. The format used below does not place any requirements on an EHR module or system. There are no additional requirements for the meaning of 'human readable' beyond those articulated in the definition of 'human readable' referenced above.

TD170.304.h.: Clinical summaries

* indicates alternative standard code per certification criteria

Clinical Summaries Test Data – Set #1 Office Visit #1 for Jonas Barnaby

Patient

Name	Date/Time of Birth	Gender	Identification Number	Identification Number Type	Address/Phone
Jonas Barnaby	07/14/1961 12:30:24	Male	969988999	Medical Record Number	478 Charles Street, Williamsport, Pennsylvania 17701 570-857-8593

"Source" for all data for this patient: Marcus Welby, MD

Problem List

Type	ICD-9 Code	Patient Problem	Status	Date Diagnosed
Diagnosis	250.02	Diabetes Mellitus, Type 2	Active	07/20/2010

Type	SNOMED Code*	Patient Problem	Status	Date Diagnosed
Disorder	44054006	Diabetes Mellitus, Type 2	Active	07/20/2010

Medication List

RxNorm Code	Product	Generic Name	Brand Name	Strength	Dose	Route	Frequency	Date Started	Status
205875	Medication	glyburide	Diabeta	2.5 mg	1 Tablet	PO	Q AM	07/20/2010	Active

Medication Allergy List

Type	SNOMED Code	Medication/Agent	Reaction	Date Recorded
Drug Allergy	293597001	Codeine	Hives	06/27/1996
Drug Allergy	294506009	Ampicillin	Diarrhea, nausea, vomiting	03/15/1994

Diagnostic Test Results

Type	LOINC Code	Test (Normal Range)	Result	Date Performed
Chemistry	14771-0	Fasting Blood Glucose (70–100 mg/dl)	178 mg/dl	07/20/2010

Clinical Summaries Test Data – Set #1 Office Visit #2 for Jonas Barnaby

Problem List

Type	ICD-9 Code	Patient Problem	Status	Date Diagnosed
Condition	272.4	Hyperlipidemia	Active	02/20/2010

Type	SNOMED Code*	Patient Problem	Status	Date Diagnosed
Disorder	55822004	Hyperlipidemia	Active	02/20/2010

Medication List

RxNorm Code	Product	Generic Name	Brand Name	Strength	Dose	Route	Frequency	Date Started	Status
617314	Medication	atorvastatin calcium	Lipitor	10 mg	1 Tablet	PO	Q Day	02/20/2010	Active

Medication Allergy List

Type	SNOMED Code	Medication/Agent	Reaction	Date Recorded
Drug Allergy	293597001	Codeine	Hives	06/27/1996
Drug Allergy	294506009	Ampicillin	Diarrhea, nausea, vomiting	03/15/1994

Diagnostic Test Results

Type	LOINC Code	Test (Normal Range)	Result	Date Performed
Chemistry	14647-2	Total cholesterol (<200 mg/dl)	262 mg/dl	02/20/2010
Chemistry	14646-4	HDL cholesterol (≥40 mg/dl)	78 mg/dl	02/20/2010
Chemistry	2089-1	LDL cholesterol (<100 mg/dl)	184 mg/dl	02/20/2010
Chemistry	14927-8	Triglycerides (<150 mg/dl)	177 mg/dl	02/20/2010

Clinical Summaries Test Data – Set #2 Office Visit #1 for Robert Flint

Patient

Name	Date/Time of Birth	Gender	Identification Number	Identification Number Type	Address/Phone
Robert Flint	04/18/1983 20:18:04	Male	9813624798	Medical Record Number	747 Market Street, Morton, Illinois 61550 309-365-8298

"Source" for all data for this patient: Carl Roberts, MD

Problem List

Type	ICD-9 Code	Patient Problem	Status	Date Diagnosed
Diagnosis	493.00	Asthma, unspecified	Active	07/19/2009

Type	SNOMED Code*	Patient Problem	Status	Date Diagnosed
Disorder	195967001	Asthma	Active	07/19/2009

Medication List

RxNorm Code	Product	Generic Name	Brand Name	Strength	Dose	Route	Frequency	Date Started	Status
206833	Medication	metaproterenol sulfate	Alupent Inhalation Aerosol	15 mg/ml	2 Puffs	Inhaled	Q4h	07/19/2009	Active

Medication Allergy List

Type	SNOMED Code	Medication/Agent	Reaction	Date Recorded
Drug Allergy	91936005	Penicillin	Rash and anaphylaxis	08/10/2008
Drug Allergy	293620004	Indomethacin	Nausea, vomiting, rash, dizziness, headache	03/25/2003

Diagnostic Test Results

Type	LOINC Code	Test (Normal Range)	Result	Date Performed
Imaging	24648-8	Chest X-ray, PA	Increased bronchial wall	07/19/2009

Type	LOINC Code	Test (Normal Range)	Result	Date Performed
			markings, patchy infiltrates	

Clinical Summaries Test Data – Set #2 Office Visit #2 for Robert Flint

Problem List

Type	ICD-9 Code	Patient Problem	Status	Date Diagnosed
Diagnosis	250.02	Diabetes Mellitus, Type 2	Active	03/10/2010

Type	SNOMED Code*	Patient Problem	Status	Date Diagnosed
Disorder	44054006	Diabetes Mellitus, Type 2	Active	03/10/2010

Medication List

RxNorm Code	Product	Generic Name	Brand Name	Strength	Dose	Route	Frequency	Date Started	Status
205875	Medication	glyburide	Diabeta	2.5 mg	1 Tablet	PO	Q AM	03/10/2010	Active

Medication Allergy List

Type	SNOMED Code	Medication/Agent	Reaction	Date Recorded
Drug Allergy	91936005	Penicillin	Rash and anaphylaxis	08/10/2008
Drug Allergy	293620004	Indomethacin	Nausea, vomiting, rash, dizziness, headache	03/25/2003

Diagnostic Test Results

Type	LOINC Code	Test (Normal Range)	Result	Date Performed
Chemistry	14771-0	Fasting Blood Glucose (70–100 mg/dl)	150 mg/dl	03/10/2010
Imaging	24648-8	Chest X-ray, PA	The heart outline is normal and the hilar and mediastinal vessels are of normal appearance	03/10/2010

Clinical Summaries Test Data – Set #3 Office Visit #1 for Barbara Simpson

Patient

Name	Date/Time of Birth	Gender	Identification Number	Identification Number Type	Address/Phone
Barbara Simpson	10/12/1956 19:47:01	Female	9688675266	Medical Record Number	996 Dalton Street, Fargo, North Dakota 58102 701-366-5534

"Source" for all data for this patient: Robert James, MD

Problem List

Type	ICD-9 Code	Patient Problem	Status	Date Diagnosed
Diagnosis	486	Pneumonia	Active	07/02/2010

Type	SNOMED Code*	Patient Problem	Status	Date Diagnosed
Disorder	233604007	Pneumonia	Active	07/02/2010

Medication List

RxNorm Code	Product	Generic Name	Brand Name	Strength	Dose	Route	Frequency	Date Started	Status
308460	Medication	azithromycin	Azithromycin	250 mg	1 Tablet	PO	QD	07/02/2010	Active

Medication Allergy List

Type	SNOMED Code	Medication/Agent	Reaction	Date Recorded
Drug Allergy	91936005	Penicillin	Rash and anaphylaxis	06/10/2009
Drug Allergy	91939003	Sulfonamides	Hives, photosensitivity	04/25/1988

Diagnostic Test Results

Type	LOINC Code	Test (Normal Range)	Result	Date Performed
Imaging	42272-5	Chest X-ray, PA & Lateral	Bilateral Pneumonia	07/02/2010

Type	LOINC Code	Test (Normal Range)	Result	Date Performed
Cardiology	34534-8	Electrocardiogram	Sinus Tachycardia	07/02/2010

Clinical Summaries Test Data – Set #3 Office Visit #2 for Barbara Simpson

Problem List

Type	ICD-9 Code	Patient Problem	Status	Date Diagnosed
Diagnosis	496.0	Chronic Obstructive Pulmonary Disease	Chronic	02/10/2010

Type	SNOMED Code*	Patient Problem	Status	Date Diagnosed
Disorder	13645005	Chronic Obstructive Lung Disease	Chronic	02/10/2010

Medication List

RxNorm Code	Product	Generic Name	Brand Name	Strength	Dose	Route	Frequency	Date Started	Status
836370	Medication	ipratropium bromide monhydrate	Atrovent Inhaler	18 mcg/puff	2 Puffs	Inhaled	QID	02/10/2010	Active
630208	Medication	albuterol sulfate	Albuterol Inhaler	2.5 mg/3ml	2 Puffs	Inhaled	Q 4 hours as needed	02/10/2010	Active

Medication Allergy List

Type	SNOMED Code	Medication/Agent	Reaction	Date Recorded
Drug Allergy	91936005	Penicillin	Rash and anaphylaxis	06/10/2009
Drug Allergy	91939003	Sulfonamides	Hives, photosensitivity	04/25/1988

Diagnostic Test Results

Type	LOINC Code	Test (Normal Range)	Result	Date Performed
Imaging	42272-5	Chest X-ray, PA & Lateral	Hyperinflated lungs with flattened diaphragm and central pulmonary artery enlargement	02/10/2010
Hematology	718-7	Hemoglobin (male: 14-18 g/dl female: 12-16 g/dl)	16 g/dl	02/10/2010

Type	LOINC Code	Test (Normal Range)	Result	Date Performed
Hematology	4544-3	Hematocrit (male: 40-54% female: 36-48%)	45%	02/10/2010

Clinical Summaries Test Data – Set #4 Office Visit #1 for Susan Ellerby

Patient

Name	Date/Time of Birth	Gender	Identification Number	Identification Number Type	Address/Phone
Susan Ellerby	12/08/1963 21:54:24	Female	925377799	Medical Record Number	483 Powell Street, Shawville, Pennsylvania 16873 814-645-9475

"Source" for all data for this patient: Dorcas Wayne, MD

Problem List

Type	ICD-9 Code	Patient Problem	Status	Date Diagnosed
Condition	272.4	Hyperlipidemia	Active	07/06/2010

Type	SNOMED Code*	Patient Problem	Status	Date Diagnosed
Disorder	55822004	Hyperlipidemia	Active	07/06/2010

Medication List

RxNorm Code	Product	Generic Name	Brand Name	Strength	Dose	Route	Frequency	Date Started	Status
617314	Medication	atorvastatin calcium	Lipitor	10 mg	1 Tablet	PO	Q Day	07/06/2010	Active

Medication Allergy List

Type	SNOMED Code	Medication/Agent	Reaction	Date Recorded
Drug Allergy	91936005	Penicillin	Rash and anaphylaxis	05/22/1998
Drug Allergy	293597001	Codeine	Hives	02/17/1992

Diagnostic Test Results

Type	LOINC Code	Test (Normal Range)	Result	Date Performed
Chemistry	14647-2	Total cholesterol (<200 mg/dl)	279 mg/dl	07/06/2010
Chemistry	14646-4	HDL cholesterol (≥40 mg/dl)	89 mg/dl	07/06/2010
Chemistry	2089-1	LDL cholesterol (<100 mg/dl)	190 mg/dl	07/06/2010
Chemistry	14927-8	Triglycerides (<150 mg/dl)	187 mg/dl	07/06/2010

Clinical Summaries Test Data – Set #4 Office Visit #2 for Susan Ellerby

Problem List

Type	ICD-9 Code	Patient Problem	Status	Date Diagnosed
Symptom	401.9	Hypertension, Essential	Active	02/05/2010

Type	SNOMED Code*	Patient Problem	Status	Date Diagnosed
Disorder	59621000	Essential Hypertension	Active	02/05/2010

Medication List

RxNorm Code	Product	Generic Name	Brand Name	Strength	Dose	Route	Frequency	Date Started	Status
200801	Medication	furosemide	Lasix	20 mg	1 Tablet	PO	BID	02/05/2010	Active
628958	Medication	potassium chloride	Klor-Con	10 mEq	1 Tablet	PO	BID	02/05/2010	Active

Medication Allergy List

Type	SNOMED Code	Medication/Agent	Reaction	Date Recorded
Drug Allergy	91936005	Penicillin	Rash and anaphylaxis	05/22/1998
Drug Allergy	293597001	Codeine	Hives	02/17/1992

Diagnostic Test Results

Type	LOINC Code	Test (Normal Range)	Result	Date Performed
Chemistry	2823-3	Potassium (3.5–5.3 mg/dl)	4.5 mg/dl	02/05/2010
Imaging	42272-5	Chest X-ray, PA & Lateral	The heart outline is normal and the hilar and	02/05/2010

Type	LOINC Code	Test (Normal Range)	Result	Date Performed
			mediastinal vessels are of normal appearance	

Clinical Summaries Test Data – Set #5 Office Visit #1 for Johnathan Stone

Patient

Name	Date/Time of Birth	Gender	Identification Number	Identification Number Type	Address/Phone
Johnathan Stone	11/12/1966 08:18:08	Male	988772587	Medical Record Number	937 Sutter Street, Aurora, Colorado 80011 303-544-9988

"Source" for all data for this patient: Samuel Johnston, MD

Problem List

Type	ICD-9 Code	Patient Problem	Status	Date Diagnosed
Diagnosis	250.02	Diabetes Mellitus, Type 2	Active	07/17/2010

Type	SNOMED Code*	Patient Problem	Status	Date Diagnosed
Disorder	44054006	Diabetes Mellitus, Type 2	Active	07/17/2010

Medication List

RxNorm Code	Product	Generic Name	Brand Name	Strength	Dose	Route	Frequency	Date Started	Status
205875	Medication	glyburide	Diabeta	2.5 mg	1 Tablet	PO	Q AM	07/17/2010	Active

Medication Allergy List

Type	SNOMED Code	Medication/Agent	Reaction	Date Recorded
Drug Allergy	294506009	Ampicillin	Diarrhea, nausea, vomiting	03/25/1997
Drug Allergy	91939003	Sulfonamides	Hives, photosensitivity	04/25/1989

Diagnostic Test Results

Type	LOINC Code	Test (Normal Range)	Result	Date Performed
Chemistry	14771-0 LOINC	Fasting Blood Glucose (70–100 mg/dl)	120 mg/dl	07/17/2010

Clinical Summaries Test Data – Set #5 Office Visit #2 for Johnathan Stone

Problem List

Type	ICD-9 Code	Patient Problem	Status	Date Diagnosed
Symptom	401.9	Hypertension, Essential	Active	01/15/2010

Type	SNOMED Code*	Patient Problem	Status	Date Diagnosed
Disorder	59621000	Essential Hypertension	Active	01/15/2010

Medication List

RxNorm Code	Product	Generic Name	Brand Name	Strength	Dose	Route	Frequency	Date Started	Status
200801	Medication	furosemide	Lasix	20 mg	1 Tablet	PO	BID	01/15/2010	Active
628958	Medication	potassium chloride	Klor-Con	10 mEq	1 Tablet	PO	BID	01/15/2010	Active

Medication Allergy List

Type	SNOMED Code	Medication/Agent	Reaction	Date Recorded
Drug Allergy	294506009	Ampicillin	Diarrhea, nausea, vomiting	03/25/1997
Drug Allergy	91939003	Sulfonamides	Hives, photosensitivity	04/25/1989

Diagnostic Test Results

Type	LOINC Code	Test (Normal Range)	Result	Date Performed
Chemistry	2823-3	Potassium (3.5–5.3 mg/dl)	4.5 mg/dl	01/15/2010
Imaging	42272-5	Chest X-ray, PA & Lateral	The heart outline is normal and the hilar and mediastinal vessels are of normal appearance	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

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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