Test Procedure for §170.314(b)(7) Data portability

This document describes the test procedure for evaluating conformance of EHR technology to the certification criteria defined in 45 CFR Part 170 Subpart C of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule. The document[1] 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://www.healthit.gov/certification(navigation: 2014 Edition Test Method). Test procedures may be updated to reflect on-going feedback received during the certification activities.

The Department of Health and Human Services (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. Testing of EHR technology in the Permanent Certification Program, henceforth referred to as the ONC Health Information Technology (HIT) Certification Program[2], is carried out by National Voluntary Laboratory Accreditation Program (NVLAP)-Accredited Testing Laboratories (ATLs) as set forth in the final rule establishing the Permanent Certification Program (*Establishment of the Permanent Certification Program for Health Information Technology, 45 CFR Part 170; February 7, 2011*).

Questions or concerns regarding the ONC HIT Certification Program should be directed to ONC at ONC.Certification@hhs.gov.

CERTIFICATION CRITERIA

This Certification Criterion is from the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule (September 4, 2012)

§170.314(b)(7) Data portability. Enable a user to electronically create a set of export summaries for all patients in EHR technology formatted according to the standard adopted at §170.205(a)(3) that represents the most current clinical information about each patient and includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):

[1] Disclaimer: Certain commercial products may be identified in this document. Such identification does not imply recommendation or endorsement by ONC.

[2] Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule

(A) Encounter diagnoses. The standard specified in §170.207(i) or, at a minimum, the version of the standard at §170.207(a)(3);
(B) Immunizations. The standard specified in §170.207(e)(2);
(C) Cognitive status;
(D) Functional status; and
(E) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information.
(F) Inpatient setting only. Discharge instructions.

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule, the 2014 Edition of this Certification Criterion is classified as new from the 2011 Edition. This certification criterion meets at least one of the factors of new certification criteria: (1) the certification criterion only specifies capabilities that have never been included in previously adopted certification criteria, or (2) the certification criterion was previously adopted as "mandatory" for a particular setting and subsequently adopted as "mandatory" or "optional" for a different setting.

2014 EDITION PREAMBLE LANGUAGE

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule where the data portability certification criterion and Consolidated CDA is discussed:

- "We intend for this certification criterion to be a starting point and have framed it in such a way as to leverage capabilities that will already be included in an EP, EH, and CAH's CEHRT."
- "…the data portability certification criterion expressly limits the scope of the data to the most current clinical information about each patient for which an export summary is created."
- "For the purposes of certification and for all of the patients on which an EP's, EH's, or CAH's CEHRT maintains data, the EHR technology must enable a user to electronically create a set of export summaries for all patients in EHR technology formatted according to the Consolidated CDA that includes each patient's most recent clinical information."
- "While this is the minimum capability required for certification, we encourage EHR technology developers to include patients' longitudinal information for laboratory test results, immunizations, and procedures, and intend to consider including this broader requirement in the next edition of this certification criterion. We believe this initial capability provides a strong starting point for the fluid transition from one EHR technology to another."
- "…we decline to require as a condition of certification that EHR technology natively record medication allergies directly into RxNorm. We have, however, in response to these comments and other comments received on other certification criteria that reference medication allergies, adopted RxNorm for instances where this data would be included in a CCDA formatted document."

- "Accordingly, we clarify that, with respect to the Consolidated CDA, certification will not focus on a specific document-level template because none are particularly suited to support MU's policy objectives and the data elements specified across the different certification criteria that reference the Consolidated CDA. Rather, certification will focus on an EHR technology's ability to properly implement the US Realm header and the associated section-level templates necessary to support each certification criterion in which the Consolidated CDA is referenced and for the appropriate data specified in each of those certification criteria."

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 an EHR technology to electronically create a set of export summaries, formatted according to the Consolidated CDA standard, for all patients in the EHR technology (a minimum of one C-CDA for each patient in the EHR, for all patients in the EHR).

ONC supplies the test data for this test procedure.

The test procedure is organized into one section:

- Create – evaluates the capability for the EHR technology to enable a user to electronically create a set of export summaries that contain the most current clinical information for all patients in EHR technology and that are formatted according to the Implementation Guide for CDA® Release 2.0, Consolidated CDA Templates; and including, at a minimum:
  - Encounter diagnoses in the named standard;
  - Immunizations in the named standard;
  - Cognitive status;
  - Functional status;
  - In ambulatory settings only, reason for referral and referring or transitioning provider's name and office contact information;
  - In inpatient settings only, discharge instructions; and
  - The Common MU Data Set data with named standards as appropriate:

    1) Patient name
    2) Sex
    3) Date of birth
    4) Race
    5) Ethnicity
    6) Preferred language
    7) Smoking status
    8) Problems
    9) Medications
    10) Medication allergies

11) Laboratory test(s)
12) Laboratory value(s)/result(s)
13) Vital signs – height, weight, blood pressure, BMI
14) Care plan field(s), including goals and instructions
15) Procedures
16) Care team member(s)

The test procedure follows the steps described below for ambulatory and inpatient settings:

- For the ambulatory setting:
    - Using Vendor-supplied test data, the Vendor creates the first test patient and records the minimum test data required for an ambulatory setting export summary
    - Using ONC-supplied test data for a second test patient with three encounters, the Vendor creates a patient record and preloads the provided data for Ambulatory Encounter 1 and Ambulatory Encounter 2
    - For the ONC-supplied test patient, the Tester designates a value within the range of ONC-supplied test data for Ambulatory Encounter 3
    - The Vendor creates Ambulatory Encounter 3 for the ONC-supplied test patient and enters the Tester-selected values
    - Using the Vendor-identified EHR function(s), the Tester causes the EHR to electronically generate a set of exports summaries for all patients in the EHR, including the first Vendor-supplied test patient and the second ONC-supplied test patient, according to the Consolidated CDA standard

- For the inpatient setting:
    - Using Vendor-supplied test data, the Vendor creates the first test patient and records the minimum test data required for an inpatient setting export summary
    - Using ONC-supplied test data for a second test patient with three encounters, the Vendor creates a patient record and preloads the provided data for Inpatient Encounter 1 and Inpatient Encounter 2
    - For the ONC-supplied test patient, the Tester designates a value within the range of ONC-supplied test data for Inpatient Encounter 3
    - The Vendor creates Inpatient Encounter 3 for the ONC-supplied test patient and enters the Tester-selected values
    - Using the Vendor-identified EHR function(s), the Tester causes the EHR to electronically generate a set of exports summaries for all patients in the EHR, including the first Vendor-supplied test patient and the second ONC-supplied test patient, according to the Consolidated CDA standard

- For the ambulatory and inpatient settings:
    - Using the Vendor-identified EHR function(s), the Tester imports the generated export summaries into the NIST Transport Test Tool to test for Consolidated CDA conformance (that is, the tool is used only to test conformance, not transport or exchange)

- Using the Consolidated CDA Validation Report produced by the NIST Transport Test Tool, the Tester verifies that the Implementation Guide conformance requirements tested are met in the generated export summaries
- Using the Consolidated CDA Validation Report produced by the NIST Transport Test Tool, the Tester verifies that the named standard vocabularies have been used where applicable for data in the Common MU Data Set, encounter diagnoses, and immunizations in the generated export summaries
- Using the Vendor-supplied test data and the Inspection Test Guide, the Tester verifies that the data rendered in the generated export summaries are complete and accurate
- Using the ONC-supplied test patient and the Inspection Test Guide, the Tester verifies that the most current clinical information is represented in ONC-supplied test patient export summary document(s)

The test data includes a minimum of five Vendor-supplied test patients and one ONC-supplied test patient for the purpose of creating the test patients for which a set of export summaries will be generated during the test and, for the Vendor-supplied test patients, selected at random to test conformance to the Consolidated CDA standard and named vocabulary requirements.

Three ONC-supplied test patients are included in the ONC-supplied test data for this test procedure. The ONC-supplied test data will include two prior encounters for a patient to be entered by the Vendor in the EHR technology presented for testing. During the test, the Tester will select test data from a range of provided values to create the test patient's third additional encounter, which will be entered in EHR technology at the current date/time of the test. The Vendor-supplied test patients will have a minimum of two encounters to be entered by the Vendor in the EHR technology presented for testing.

This test evaluates the ability for EHR technology to create a set of export summaries (according to Consolidated CDA format) for all patients (for example, a batch export) contained within the EHR technology presented for testing, including, at a minimum, one ONC-supplied test patient and five or more Vendor-supplied test patients. The Vendor will instruct the Tester on the method to access the individual export summaries for the individual test patients selected for evaluation during this test.

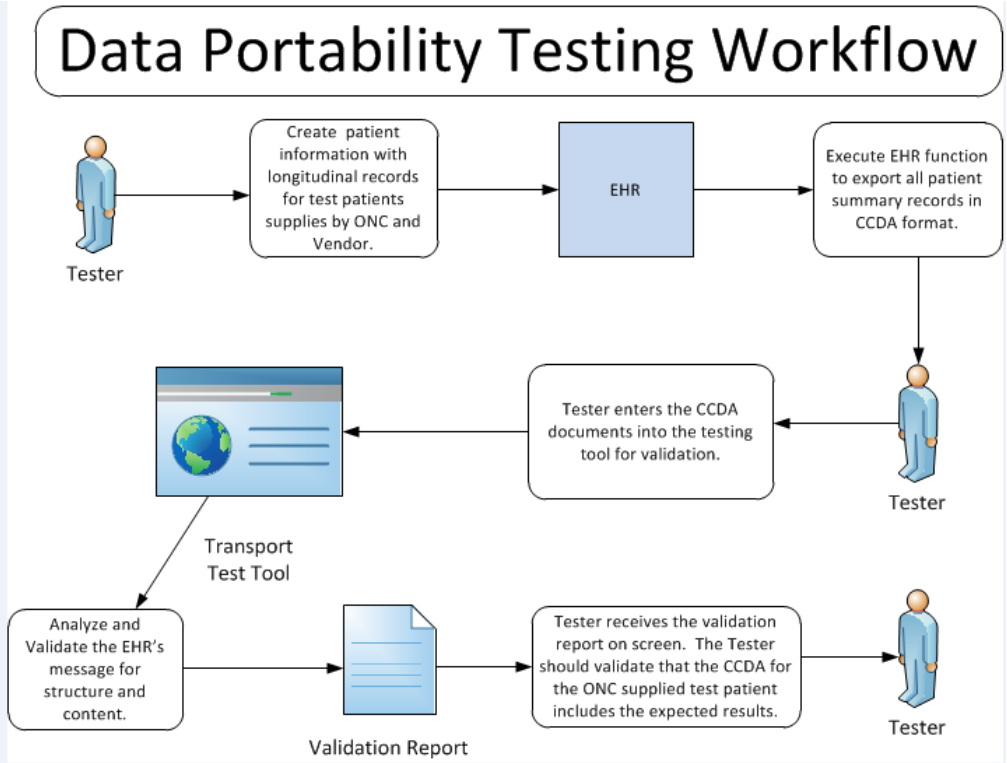
The Tester will select the ONC-supplied test patient and one or more Vendor-supplied test patient's export summaries, formatted according to the Consolidated CDA standard at random and evaluate Consolidated CDA conformance and use of named standard vocabularies for applicable data elements using the Transport Testing Tool. The 2014 Standards and Certification Criteria provide data elements to be included in the C-CDA conformant document but do not specify the location in a C-CDA conformant document where the data should be located. The Vendor may determine the appropriate location for this information in the C-CDA conformant document provided it conforms to the C-CDA Implementation Guide. If no information is available, a null flavor may be placed in a given section provided it is permitted by the C-CDA Implementation Guide.

For the ONC-supplied test patient, the Tester will:

- evaluate Consolidated CDA conformance and use of named standard vocabularies for applicable data elements using the NIST Transport Testing Tool; and
- evaluate that the Consolidated CDA conformant document(s) contain the expected results for the minimum information contained in the export summary representation across all three encounters (the expected results does not preclude additional longitudinal information that exceeds the minimum for data portability). The expected results may be contained in one or several C-CDA conformant documents provided that all documents conform to the requirements outlined in the certification criterion.

Figure 1 describes the workflow for testing conformance to the C-CDA standard.

Figure 1



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)(3) Standard. HL7 Implementation Guide for CDA® Release 2.0, Consolidated CDA Templates (US Realm), July 2012 (incorporated by reference in § 170.299). The use of the "unstructured document" document-level template is prohibited.	

§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)(3) Standard. IHTSDO SNOMED CT® International Release July 2012 (incorporated by reference in § 170.299) and US Extension to SNOMED CT® March 2012 Release (incorporated by reference in § 170.299).	

§170.207 Vocabulary standards for representing electronic health information.	Regulatory Referenced Standard
(b)(2) Standard. The code set specified at 45 CFR 162.1002(a)(5).	45 CFR 162.1002 Medical data code sets The Secretary adopts the following code set maintaining organization's code sets as the standard medical data code sets: (a) 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: (5) The combination of *Health Care Financing Administration Common Procedure Coding System (HCPCS),* as maintained and distributed by HHS, and *Current Procedural Terminology, Fourth Edition (CPT–4),* as maintained and distributed by the American Medical Association, for physician services and other health care services. These services include, but are not limited to, the following:

(b)(3) Standard. The code set specified at 45 CFR 162.1002(a)(4).	45 CFR 162.1002 Medical data code sets The Secretary adopts the following code set maintaining organization's code sets as the standard medical data code sets: (a) 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: (4) *Code on Dental Procedures and Nomenclature,* as maintained and distributed by the American Dental Association, for dental services.
(4) Standard. The code set specified at 45 CFR 162.1002(c)(3) for the indicated procedures or other actions taken.	45 CFR 162.1002 Medical data code sets The Secretary adopts the following code set maintaining organization's code sets as the standard medical data code sets: (c)(3) International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) (including The Official ICD–10–PCS Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals: (i) Prevention. (ii) Diagnosis. (iii) Treatment. (iv) Management.
(c) Laboratory tests. (2) Standard. Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc. (incorporated by reference in § 170.299).	
(d) Medications. (2) Standard. RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release (incorporated by reference in § 170.299).	
(f) Race and Ethnicity. Standard. The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997 (see "Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity," available at http://www.whitehousFor exampleov/omb/fedreg_1997standards).	
(g) Preferred language. Standard. As specified by the Library of Congress, ISO 639-2 alpha-3 codes limited to those that also have a corresponding alpha-2 code in ISO 639-1. (incorporated by reference in § 170.299).	

(h) Smoking status. Standard. Smoking status must be coded in one of the following SNOMED CT® codes:
(1) Current every day smoker. 449868002
(2) Current some day smoker. 428041000124106
(3) Former smoker. 8517006
(4) Never smoker. 266919005
(5) Smoker, current status unknown. 77176002
(6) Unknown if ever smoked. 266927001
(7) Heavy tobacco smoker. 428071000124103
(8) Light tobacco smoker. 428061000124105

NORMATIVE TEST PROCEDURES – INPATIENT SETTING

Derived Test Requirements

DTR170.314(b)(7) – 1: Create Set of Export Summaries

DTR170.314(b)(7) – 1: Create Set of Export Summaries

Required Vendor Information

VE170.314(b)(7) – 1.01: Using Vendor-supplied test data, the Vendor shall create five or more test patients with existing records in the EHR to be used for this test that each include the minimum test data for an inpatient setting export summary and that each include two or more encounters

VE170.314(b)(7) – 1.02: Using ONC-supplied test data for TD170.314(b)(7) – 1, TD170.314(b)(7) – 2, and TD170.314(b)(7) – 3, the Vendor shall create three test patients with an existing record in the EHR to be used for this test as indicated in Inpatient Encounter 1 and Inpatient Encounter 2

VE170.314(b)(7) – 1.03: The Vendor shall identify the EHR function(s) that are available to 1) select the Vendor and ONC-provided test patients, 2) electronically generate a set of export summaries according to the Consolidated CDA standard, including the named data elements as well as the Common MU Data Set with associated vocabulary standards, for all test patients, and 3) access the generated set of export summaries

Required Test Procedure

TE170.314(b)(7) – 1.01: Using the Vendor-identified EHR function(s), the Tester shall select one of three ONC-supplied test patients: TD170.314(b)(7) – 1, TD170.314(b)(7) – 2, or TD170.314(b)(7) – 3

TE170.314(b)(7) – 1.02: Using the Vendor-identified EHR function(s) and the test patient selected in TE170.314(b)(7) – 1.01, the Tester shall verify that Inpatient Encounter 1 is contained within the EHR

TE170.314(b)(7) – 1.03: Using the Vendor-identified EHR function(s) and the test patient selected in TE170.314(b)(7) – 1.01, the Tester shall verify that Inpatient Encounter 2 is contained within the EHR

TE170.314(b)(7) – 1.04: Using the test patient selected in TE170.314(b)(7) – 1.01, the Tester shall designate a value within the range for Inpatient Encounter 3, where ranges for clinical data are indicated

TE170.314(b)(7) – 1.05: Using the ONC-provided test data provided for the test patient selected in TE170.314(b)(7) – 1.01, and the Vendor-identified EHR function(s), the Tester shall create a new encounter for the selected patient and input the test data for the encounter, including the values designated by the Tester in TE170.314(b)(7) – 1.04

TE170.314(b)(7) – 1.06: Using the Vendor-identified EHR function(s), the Tester shall verify that a minimum of five Vendor-supplied test patients, indicated in VE170.314(b)(7) – 1.01, are contained within the EHR presented for testing

TE170.314(b)(7) – 1.07: Using the Vendor-identified EHR function(s), the Tester shall cause the EHR to electronically generate a set of export summaries for all patients in the EHR, including the set of ONC and Vendor-supplied test patients presented for testing, according to the Consolidated CDA standard format and named vocabulary standards for immunizations, encounter diagnoses, and the Common MU Data Set; and discharge instructions, cognitive status, and functional status

TE170.314(b)(7) – 1.08: The Tester shall select the individual export summary document(s) in Consolidated CDA format for the ONC-supplied test patient selected in TE170.314(b)(7) – 1.01 and import the document(s) into the NIST Transport Testing Tool identified in the Conformance Test Tools section of this test procedure to verify Consolidated CDA conformance and conformance with the named vocabulary standards

TE170.314(b)(7) – 1.09: The Tester shall randomly select the individual export summary document(s) in Consolidated CDA format for one of the five Vendor-supplied test patients identified in TE170.314(b)(7) – 1.06 and import the document(s) into the NIST Transport Testing Tool identified in the Conformance Test Tools section of this test procedure to verify Consolidated CDA conformance and conformance with the named vocabulary standards

TE170.314(b)(7) – 1.10: The Tester shall randomly select Consolidated CDA export summary document(s) for a patient that is not selected TE170.314(b)(7) – 1.08 or TE170.314(b)(7) – 1.09 and import the document(s) into the NIST Transport Testing Tool identified in the Conformance Test Tools section of this test procedure to verify Consolidated CDA conformance and conformance with the named vocabulary standards

TE170.314(b)(7) – 1.11: Using the Inspection Test Guide and the test data for the patient selected in TE170.314(b)(7) – 1.01, the Tester shall analyze the Consolidated CDA content for the patient in TE170.314(b)(7) – 1.08 and verify it is complete and accurate and includes the expected results .

Inspection Test Guide

IN170.314(b)(7) – 1.01: Using the Validation Report produced by the NIST Transport Test Tool identified in the Conformance Test Tools section of this test procedure, the Tester shall verify that

- The Consolidated CDA Implementation Guide conformance requirements tested are met by the Consolidated CDA conformant document(s) imported in TE170.314(b)(7) – 1.08 for the ONC-supplied test patient in TE170.314(b)(7) – 1.09 and TE170.314(b)(7) – 1.10 for randomly selected Vendor-supplied test patients
- The standards for the named vocabularies for the Common MU Data Set, encounter diagnoses and immunizations are met by the Consolidated CDA conformant document(s) imported in TE170.314(b)(7) – 1.08 for the ONC-supplied test patient and TE170.314(b)(7) – 1.09 and TE170.314(b)(7) – 1.10 for randomly selected Vendor-supplied test patients

IN170.314(b)(7) – 1.02: Using the Expected results from the ONC-supplied test data for the patient selected in TE170.314(b)(7) – 1.01, the Tester shall analyze the Consolidated CDA content for the patient in TE170.314(b)(7) – 1.01 and verify it includes, at a minimum: encounter diagnoses, immunizations, cognitive status, functional status, discharge instructions, and the Common MU Data Set:

1) Patient name
2) Sex
3) Date of birth
4) Race
5) Ethnicity
6) Preferred language
7) Smoking status
8) Problems
9) Medications
10) Medication allergies
11) Laboratory test(s)
12) Laboratory value(s)/result(s)
13) Vital signs – height, weight, blood pressure, BMI
14) Care plan field(s), including goals and instructions
15) Procedures
16) Care team member(s)

IN170.314(b)(7) – 1.03: The Tester may need to parse the .xml and use the MIME part to inspect the header to identify the C-CDA conformant documents (vs. style sheet)

NORMATIVE TEST PROCEDURES – AMBULATORY SETTING

Derived Test Requirements

DTR170.314(b)(7) – 2: Create Set of Export Summaries

DTR170.314(b)(7) – 2: Create Set of Export Summaries

Required Vendor Information

VE170.314(b)(7) – 2.01: Using Vendor-supplied test data, the Vendor shall create five or more test patients with existing records in the EHR to be used for this test that each include the minimum test data for an ambulatory setting export summary and that each include two or more encounters

VE170.314(b)(7) – 2.02: Using ONC-supplied test data for TD170.314(b)(7) – 4, TD170.314(b)(7) – 5, and TD170.314(b)(7) – 6, the Vendor shall create three test patients with an existing record in the EHR to be used for this test as indicated in Ambulatory Encounter 1 and Ambulatory Encounter 2

VE170.314(b)(7) – 2.03: The Vendor shall identify the EHR function(s) that are available to 1) select the Vendor and ONC-provided test patients, 2) electronically generate a set of export summaries according to the Consolidated CDA standard, including the named data elements as well as the Common MU Data Set with associated vocabulary standards, for all test patients, and 3) access the generated set of export summaries

Required Test Procedure

TE170.314(b)(7) – 2.01: Using the Vendor-identified EHR function(s), the Tester shall select one of three ONC-supplied test patients: TD170.314(b)(7) – 4, TD170.314(b)(7) – 5, or TD170.314(b)(7) – 6

TE170.314(b)(7) – 2.02: Using the Vendor-identified EHR function(s) and the test patient selected in TE170.314(b)(7) – 2.01, the Tester shall verify that Ambulatory Encounter 1 is contained within the EHR

TE170.314(b)(7) – 2.03: Using the Vendor-identified EHR function(s) and the test patient selected in TE170.314(b)(7) – 2.01, the Tester shall verify that Ambulatory Encounter 2 is contained within the EHR

TE170.314(b)(7) – 2.04: Using the test patient selected in TE170.314(b)(7) – 2.01, the Tester shall designate a value within the range for Ambulatory Encounter 3, where ranges for clinical data are indicated

TE170.314(b)(7) – 2.05: Using the ONC-provided test data provided for the test patient selected in TE170.314(b)(7) – 2.01, and the Vendor-identified EHR function(s), the Tester shall create a new encounter for the selected patient and input the test data for

the encounter, including the values designated by the Tester in TE170.314(b)(7) – 2.04

TE170.314(b)(7) – 2.06: Using the Vendor-identified EHR function(s), the Tester shall verify that a minimum of five Vendor-supplied test patients, indicated in VE170.314(b)(7) – 2.01, are contained within the EHR presented for testing

TE170.314(b)(7) – 2.07: Using the Vendor-identified EHR function(s), the Tester shall cause the EHR to electronically generate a set of export summaries for all patients in the EHR, including the set of ONC and Vendor-supplied test patients presented for testing, according to the Consolidated CDA standard format and named vocabulary standards for immunizations, encounter diagnoses, and the Common MU Data Set; and cognitive status, functional status, reason for referral and referring or transitioning provider's name and office contact information

TE170.314(b)(7) – 2.08: The Tester shall select the individual export summary document(s) in Consolidated CDA format for the ONC-supplied test patient selected in TE170.314(b)(7) – 2.01 and import the document(s) into the NIST Transport Testing Tool identified in the Conformance Test Tools section of this test procedure to verify Consolidated CDA conformance and conformance with the named vocabulary standards

TE170.314(b)(7) – 2.09: The Tester shall randomly select the individual export summary document(s) in Consolidated CDA format for one of the five Vendor-supplied test patients identified in TE170.314(b)(7) – 2.06 and import the document(s) into the NIST Transport Testing Tool identified in the Conformance Test Tools section of this test procedure to verify Consolidated CDA conformance and conformance with the named vocabulary standards

TE170.314(b)(7) – 2.10: The Tester shall randomly select Consolidated CDA export summary document(s) for a patient that is not selected TE170.314(b)(7) – 2.08 or TE170.314(b)(7) – 2.09 and import the document(s) into the NIST Transport Testing Tool identified in the Conformance Test Tools section of this test procedure to verify Consolidated CDA conformance and conformance with the named vocabulary standards

TE170.314(b)(7) – 2.11: Using the Inspection Test Guide and the test data for the patient selected in TE170.314(b)(7) – 2.01, the Tester shall analyze the Consolidated CDA content for the patient in TE170.314(b)(7) – 2.08 and verify it is complete and accurate and includes the expected results .

Inspection Test Guide

IN170.314(b)(7) – 2.01: Using the Validation Report produced by the Transport Testing Tool identified in the Conformance Test Tools section of this test procedure, the Tester shall verify that

- The Consolidated CDA Implementation Guide conformance requirements tested are met by the Consolidated CDA conformant document(s) imported in the Transport Testing Tool TE170.314(b)(7) – 2.08 for the ONC-supplied test

patient and TE170.314(b)(7) – 2.09 and TE170.314(b)(7) – 2.10 for randomly selected Vendor-supplied test patients

- The standards for the named vocabularies for the Common MU Data Set, encounter diagnoses and immunizations are met by the Consolidated CDA conformant document(s) imported in TE170.314(b)(7) – 2.08 for the ONC-supplied test patient and TE TE170.314(b)(7) – 2.09 and TE170.314(b)(7) – 2.10 for randomly selected Vendor-supplied test patients

IN170.314(b)(7) – 2.02: Using the Expected Results from the ONC-supplied test data for the patient selected in TE170.314(b)(7) – 2.01, the Tester shall analyze the Consolidated CDA content for the patient in TE170.314(b)(7) – 2.01 and verify it includes, at a minimum: encounter diagnoses; immunizations; cognitive status; functional status; reason for referral and referring or transitioning provider's name and office contact information; and the Common MU Data Set:

1) Patient name
2) Sex
3) Date of birth
4) Race
5) Ethnicity
6) Preferred language
7) Smoking status
8) Problems
9) Medications
10) Medication allergies
11) Laboratory test(s)
12) Laboratory value(s)/result(s)
13) Vital signs – height, weight, blood pressure, BMI
14) Care plan field(s), including goals and instructions
15) Procedures
16) Care team member(s)

IN170.314(b)(7) – 2.03: The Tester may need to parse the .xml and use the MIME part to inspect the header to identify the C-CDA conformant documents (vs. style sheet)

TEST DATA

ONC-supplied test data are provided with the test procedure to ensure that the applicable requirements identified in the criteria can be adequately evaluated for conformance, as well as to provide consistency in the testing process across multiple National Voluntary Laboratory Accreditation Program-(NVLAP) Accredited Testing Labs (ATLs). The provided test data focus on evaluating the basic capabilities of required EHR technology, rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support. The test data are 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 provided 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 provided test data needs to be modified in order to conduct an adequate test. Having made the determination that some modification to the provided 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 applicable requirements identified in the criterion can be adequately evaluated for conformance and that the test data provides a comparable level of robustness. Having made the determination that some modification to the provided test data is necessary, the Tester shall record the modifications made as part of the test documentation.

Test Data for §170.314(b)(7) Data Portability available at http://www.healthit.gov/certification (navigation: 2014 Edition Test Method)

Any departure from the provided 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 applicable test data into the EHR technology 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 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.

CONFORMANCE TEST TOOLS

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

- Transport Testing Tool (TTT) C-CDA/Direct/SOAP – the web application Transport Testing Tool is designed to support this test procedure
  - The application can be downloaded for local installation
  - The Transport Testing Tool is available at: http://transport-testing.nist.gov

Support for these tools is available by submitting questions to the following user's group: https://groups.google.com/d/forum/transport-testing-tool

Multiple browsers may be used to access this tool; if the tool does not load completely using Internet Explorer 8 or Internet Explorer 9, alternative browsers such as Firefox, Google Chrome, or Safari are recommended. The Transport Testing Tool (TTT) C-CDA/Direct/SOAP uses non-standard ports. If your firewall blocks HTTP traffic on non-standard ports, this tool may not be accessible. Please retry access from a location without a firewall that blocks non-standard ports. Alternatively users may download and run a local version of the tool.

The following information is provided to assist the Tester in interpreting the conformance reports generated by the Transport Testing Tool (TTT) C-CDA/Direct/SOAP:

The Transport Testing Tool (TTT) C-CDA/Direct/SOAP, via MDHT, evaluates individual conformance statements which have been derived from the standards and the "HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012" identified in the Final Rule and the test data provided in this test procedure. The validation tools evaluate the submitted HL7 message 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. ATLs 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	Date Published
1.0	Released for Public Comment	November 19, 2012
1.1	Delivered for National Coordinator Approval	December 3, 2012
1.2	Posted Approved Test Procedure	December 14, 2012
1.3	Updated Approved Test Procedure Updates: • Added “document(s)” after “export summary” in bullet point on page 4 of the Informative Test Description and in TE170.314(b)(7) – 1.08, TE170.314(b)(7) – 1.09, TE170.314(b)(7) – 1.10, TE170.314(b)(7) – 2.08, TE170.314(b)(7) – 2.09, TE170.314(b)(7) – 2.10 of the Normative Test Procedure • Changed “One ONC-supplied test patient is included” to “Three ONC-supplied test patients are included” in the second paragraph on Page 5 of the Informative Test Description • Added “conformant document(s)” after Consolidated C-CDA on last bullet on Page 5 of the Informative Test Description and in first and second bullet in IN170.314(b)(7) – 1.01 and IN170.314(b)(7) – 2.01 of the Normative Test Procedure • Note added to the Informative Test Description at the bottom of Page 5: “The expected results may be contained in one or several C-CDA conformant documents provided that all documents conform to the requirements outlined in the certification criterion.” • Changed “generate the set of export summaries” to “access the generated set of export summaries” in VE170.314(b)(7) – 1.03 and VE170.314(b)(7) – 2.03 of the Normative Test Procedure • Changed “import it into the NIST Transport Testing Tool” to “import the document(s) into the NIST Transport Testing Tool” in TE170.314(b)(7) – 1.08, TE170.314(b)(7) – 1.09, TE170.314(b)(7) – 1.10, TE170.314(b)(7) – 2.08, TE170.314(b)(7) – 2.09, and TE170.314(b)(7) – 2.10 • Changed “and include, at a minimum” to “and verify it includes, at a minimum” in IN170.314(b)(7) – 1.02 and IN170.314(b)(7) – 2.02 • Added “conformant” after C-CDA in IN170.314(b)(7) –1.03 and IN170.314(b)(7) – 2.03	March 29, 2013
1.4	Updated Approved Test Procedure Update: • Provided clarification in informative test description on 2014 Standards and Certification Criteria reference to C-CDA Implementation Guide (page 5)	May 8, 2013