

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

This document describes the test procedure for evaluating conformance of Complete EHRs or EHR Modules 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 document¹ is organized by test procedure and derived test requirements with traceability to the normative certification criteria as described in the Overview document located at [available when final]. 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. Testing of EHR technology in the Permanent Certification Program, henceforth referred to as the ONC HIT Certification Program², is carried out by National Voluntary Laboratory Accreditation Program-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 issued by the Department of Health and Human Services (HHS) on 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):

- (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);

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

- (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.

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 CCDAs formatted document."

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 electronically export current patient data into a set of Consolidated CDA documents for all patients in the EHR technology.

The test data are supplied by ONC and the Vendor.

The test procedure is organized into one section:

- Create – evaluates the capability for the EHR technology to enable a user to create a set of export summaries for all patients in EHR technology 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)
- For the ambulatory setting:
 - The Vendor creates one test patient and records the minimum test data required for an ambulatory setting export summary
 - Using ONC-supplied test data for a 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 data and enters the Tester-selected data
- Using the Vendor-identified EHR function(s), the Tester causes the EHR to electronically generate a set of exports summaries including the Vendor-supplied test patient and the ONC-supplied test patient in Consolidated CDA standard
- For the inpatient setting:
 - The Vendor creates one test patient and records the minimum test data required for an inpatient setting export summary
 - Using ONC-supplied test data for a 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 data and enters the Tester-selected data
 - Using the Vendor-identified EHR function(s), the Tester causes the EHR to electronically generate a set of exports summaries, including the Vendor-supplied test patient and the ONC-supplied test patient in Consolidated CDA standard
- Using the Vendor-identified EHR function(s), the Tester imports the generated Consolidated CDA export summaries into the NIST Transport Test Tool to test for Consolidated CDA conformance (i.e., 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

The test data includes a minimum of five Vendor-supplied test patients and at least one ONC-supplied test patient.

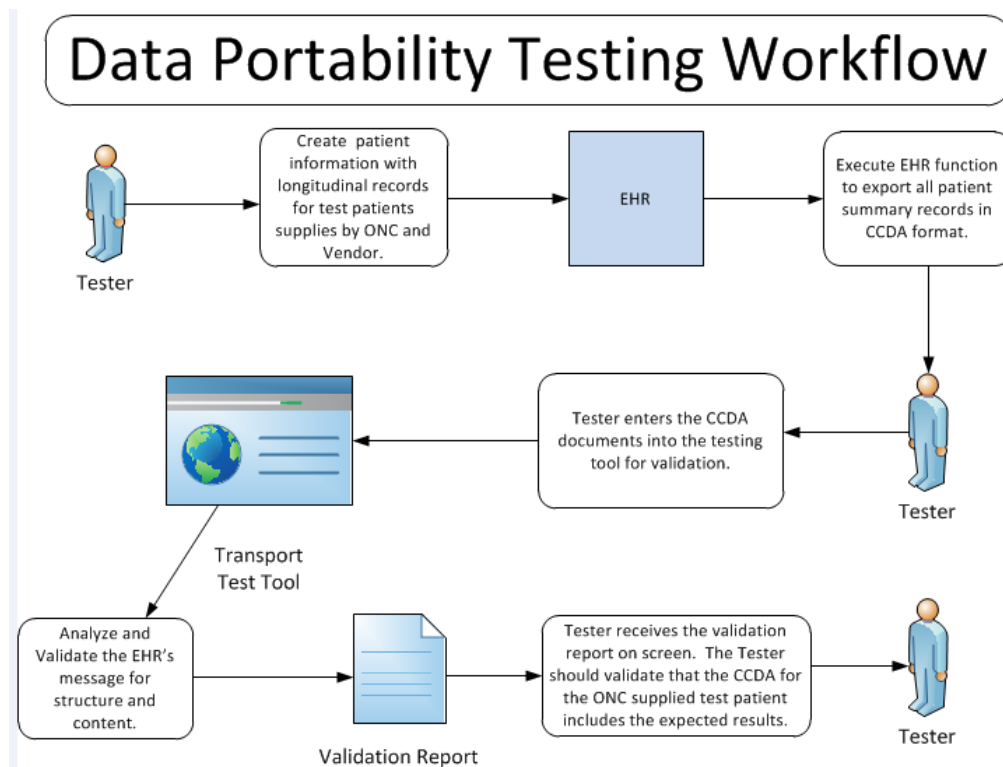
One ONC-supplied test patient will be included in the ONC-supplied test data for this test procedure. The ONC-supplied test data will include two prior encounters for a patient to be included by the Vendor in the EHR technology presented for testing. During the test, the Tester will select test data from a range of provided values to create a third additional encounter to be included in EHR technology using the current date/time of the test.

This test evaluates the ability for EHR technology to create a set of export summaries (in Consolidated CDA format) for all patients (e.g. batch export) contained within the EHR technology presented for testing. The Vendor will instruct the Tester on the method to access individual Consolidated CDAs for the individual test patients selected for evaluation during this test.

The Tester will select one or more Vendor-supplied test patient Consolidated CDAs at random and evaluate Consolidated CDA conformance and use of named standard vocabularies for applicable data elements using the NIST Transport Testing Tool.

For the ONC-supplied test patient(s), the Tester will:

- evaluate Consolidated CDA conformance and use of named standard vocabularies for applicable data elements using the NIST Transport Testing Tool
- evaluate that the Consolidated CDA contains 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)



REFERENCED STANDARDS

§170.205 Content exchange standards and implementation specifications for exchanging electronic health information.	Regulatory Referenced Standard
<p>The Secretary adopts the following content exchange standards and associated implementation specifications:</p>	
<p>(a)(3) <u>Standard</u>. 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.</p>	
§170.207 Vocabulary standards for representing electronic health information.	Regulatory Referenced Standard
<p>The Secretary adopts the following code sets, terminology, and nomenclature as the vocabulary standards for the purpose of representing electronic health information:</p>	
<p>(a)(3) <u>Standard</u>. 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).</p>	
§170.207 Vocabulary standards for representing electronic health information.	Regulatory Referenced Standard
<p>(b)(2) <u>Standard</u>. The code set specified at 45 CFR 162.1002(a)(5).</p>	<p>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:</p> <ul style="list-style-type: none">(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:<ul style="list-style-type: none">(5) The combination of <i>Health Care Financing Administration Common Procedure Coding System (HCPCS)</i>, as maintained and distributed by HHS, and <i>Current Procedural Terminology, Fourth Edition (CPT-4)</i>, as maintained and distributed by the American Medical Association, for physician services and other health care services. These services include, but are not limited to, the following:

(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.whitehouse.gov/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).

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- (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
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1.1.1 NORMATIVE TEST PROCEDURES – INPATIENT SETTING

Derived Test Requirements

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 EHR shall be populated with test patients

VE170.314.b.7 – 1.02: 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 – 1.03: Using ONC-supplied test data, the Vendor shall create a test patient with an existing record in the EHR to be used for this test as indicated in TD170.314.b.7 – Inpatient Encounter 1 and TD170.314.b.7 – Inpatient Encounter 2

VE170.314.b.7 – 1.04: Vendor shall identify the EHR function(s) that are available to 1) select the Vendor and ONC provided test patients, 2) electronically generate an export summary according to the Consolidated CDA, including the named data elements as well as the Common MU Data Set with associated vocabulary standards, for all test patients, and 3) export the set of export summaries

Required Test Procedure

TE170.314.b.7 – 1.01: Using the Vendor-identified EHR function(s), the Tester shall select the ONC-supplied test patient

TE170.314.b.7 – 1.02: Using the Vendor-identified EHR function(s), the Tester shall verify that the patient encounter in accordance with TD170.314 – Inpatient Encounter 1 is contained within the EHR

TE170.314.b.7 – 1.03: Using the Vendor-identified EHR function(s), the Tester shall verify that the patient encounter in accordance with TD170.314 – Inpatient Encounter 2 is contained within the EHR

TE170.314.b.7 – 1.04: Using the ONC-provided test data provided in TD170.314.b.7 – Inpatient Encounter 3, 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

TE170.314.b.7 – 1.05: Using the Vendor-identified EHR function(s), the Tester shall verify that at least one patient, and up to five patients, indicated in VE170.314.b.7 – 1.02 are contained within the EHR presented for testing

- TE170.314.b.7 – 1.06: Using the Vendor-identified EHR function(s), the Tester shall cause the EHR to electronically generate a set of export summaries for the set of test patients contained in the EHR 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 – 1.07: The Tester shall select the Consolidated CDA export summary for the ONC-supplied test patient and import it 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 – 1.08: The Tester shall randomly select the Consolidated CDA export summary for at least one patient identified in TE170.314.b.7 – 1.05 and import it 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 a Consolidated CDA export summary for a patient that is not selected TE170.314.b.7 – 1.07 or TE170.314.b.7 – 1.08 and import it 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: Using the Inspection Test Guide, the Tester shall analyze the Consolidated CDA content for the patient in TE170.314.b.7 – 1.08 is complete and accurate and includes the expected results as indicated in TD170.314.b.7 – 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 imported in TE170.314.b.7 – 1.07 for the ONC-supplied test patient in TE170.314.b.7 – 1.08 and TE170.314.b.7 – 1.09 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 CDAs imported in TE170.314.b.7 – 1.07 for the ONC-supplied test patient and TE170.314.b.7 – 1.08 and TE170.314.b.7 – 1.09 for randomly selected Vendor-supplied test patients
- IN170.314.b.7 – 1.02: Using the ONC-supplied provided test data and TD170.314.b.7 – Expected Results, the Tester shall analyze the Consolidated CDA content for the patient in TE170.314.b.7 – 1.01 and include, at a minimum: immunizations; encounter diagnoses; discharge instructions; cognitive status; functional status; 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)

1.1.2 NORMATIVE TEST PROCEDURES – AMBULATORY SETTING

Derived Test Requirements

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 EHR shall be populated with test patients

VE170.314.b.7 – 2.02: 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 – 2.03: Using ONC-supplied test data, the Vendor shall create a test patient with an existing record in the EHR to be used for this test as indicated in TD170.314.b.7 – Ambulatory Encounter 1 and TD170.314.b.7 – Ambulatory Encounter 2

VE170.314.b.7 – 2.04: Vendor shall identify the EHR function(s) that are available to 1) select the Vendor and ONC provided test patients, 2) electronically generate an export summary according to the Consolidated CDA, including the named data elements as well as the Common MU Data Set with associated vocabulary standards, for all test patients, and 3) export the set of export summaries

Required Test Procedure

TE170.314.b.7 – 2.01: Using the Vendor-identified EHR function(s), the Tester shall select the ONC-supplied test patient

TE170.314.b.7 – 2.02: Using the Vendor-identified EHR function(s), the Tester shall verify that the patient encounter in accordance with TD170.314 – Ambulatory Encounter 1 is contained within the EHR

- TE170.314.b.7 – 2.03: Using the Vendor-identified EHR function(s), the Tester shall verify that the patient encounter in accordance with TD170.314 – Ambulatory Encounter 2 is contained within the EHR
- TE170.314.b.7 – 2.04: Using the ONC-provided test data provided in TD170.314.b.7 – Ambulatory Encounter 3, 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
- TE170.314.b.7 – 2.05: Using the Vendor-identified EHR function(s), the Tester shall verify that at least one patient, and up to five patients, indicated in VE170.314.b.7 – 2.02 are contained within the EHR presented for testing
- TE170.314.b.7 – 2.06: Using the Vendor-identified EHR function(s), the Tester shall cause the EHR to electronically generate a set of export summaries for the set of test patients contained in the EHR 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; the reason for referral; and referring or transitioning provider's name and office contact information
- TE170.314.b.7 – 2.07: The Tester shall select the Consolidated CDA export summary for the ONC-supplied test patient and import it 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 – 2.08: The Tester shall randomly select the Consolidated CDA export summary for at least one patient identified in TE170.314.b.7 – 2.05 and import it 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 a Consolidated CDA export summary for a patient that is not selected TE170.314.b.7 – 2.07 or TE170.314.b.7 – 2.08 and import it 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: Using the Inspection Test Guide, the Tester shall analyze the Consolidated CDA content for the patient in TE170.314.b.7 – 2.07 is complete and accurate and includes the expected results as indicated in TD170.314.b.7 – Expected Results

Inspection Test Guide

- IN170.314.b.7 – 2.01: 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 imported in TE170.314.b.7 – 2.07 for the ONC-supplied test patient and TE170.314.b.7 – 2.08 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 CDAs imported in TE170.314.b.7 – 2.07 for the ONC-supplied test patient and TE170.314.b.7 – 2.08 and TE170.314.b.7 – 2.09 for randomly selected Vendor-supplied test patients

IN170.314.b.7 – 2.02: Using the ONC-supplied provided test data and TD170.314.b.7 – Expected Results, the Tester shall analyze the Consolidated CDA content for the patient in TE170.314.b.7 – 2.01 and include, at a minimum: immunizations; encounter diagnoses; discharge instructions; cognitive status; functional status; 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)

TEST DATA

Test data is provided with the 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 National Voluntary Laboratory Accreditation Program-Accredited Testing Laboratories (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 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 provided test data during the test, without exception, unless one of the following conditions exists:

- The Tester determines that the Vendor-selected message format requires some modification to the test data.

- 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 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 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 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 – NIST provides a Transport Testing Tool designed to support this test procedure. This test will not involve transport testing, however the Transport Testing Tool has a stand-alone ability to verify Consolidated CDA documents. This component of the Transport Testing Tool relies on Model Driven Health Tools (MDHT) for Consolidated CDA validation. The tool is a Web Application:
 - The application can be downloaded for local installation
 - NIST is making available the web-site for pre-testing
 - The Transport Testing Tool is available at: <http://hit-testing.nist.gov:9100/ttt>
 - Documentation for the MDHT project used for C-CDA validation is available at: <https://www.projects.openhealthtools.org/sf/projects/mdht/>

Support for these tools is available by contacting:

Kevin Brady (Kevin.Brady@nist.gov)
Leader, Systems Interoperability Group
Acting Leader, Cyber Infrastructure Group
National Institute of Standards and Technology (NIST)

Information Technology Laboratory

The NIST Transport Testing Tool, 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 inspection test data values derived from required vocabularies and code sets.

Document History

Version Number	Description	Date Published
1.0	Released for Public Comment	September 28, 2012