Test Procedure for §170.314(e)(2) Ambulatory setting only – clinical summary

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 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 [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 Program[2], 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(e)(2) Ambulatory setting only – clinical summary

(i) Create. Create. Enable a user to create a clinical summary for a patient in human readable format and formatted according to the standards adopted at § 170.205(a)(3).

(ii) Customization. Enable a user to customize the data included in the clinical summary.

[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

(iii) Minimum data from which to select. EHR technology must permit a user to select, at a minimum, the following data when creating a clinical summary:

(A) Common MU Data Set (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set)

(B) The provider's name and office contact information; date and location of visit; reason for visit; immunizations and/or medications administered during the visit; diagnostic tests pending; clinical instructions; future appointments; referrals to other providers; future scheduled tests; and recommended patient decision aids.

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 revised from the 2011 Edition. This certification criterion meets at least one of the three factors of revised certification criteria: (1) the certification criterion includes changes to capabilities that were specified in the previously adopted certification criterion, (2) the certification criterion has a new mandatory capability that was not included in the previously adopted certification criterion, or (3) the certification criterion was previously adopted as "optional" for a particular setting and is subsequently adopted as "mandatory" for that 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 clinical summary certification criterion is discussed:

- "This certification criterion requires EHR technology to be capable of enabling a user to electronically create a clinical summary in human readable format and formatted according to the Consolidated CDA."
- "This certification criterion focuses on capabilities that EHR technology would have to demonstrate for certification that would support an EP's ability to provide a clinical summary to a patient, including electronically. It is not focused on the exchange of a patient's health information."
- "…to make this certification criterion easier to read and to clearly express the capabilities that EHR technology must include in order to support MU, we have broken the certification criterion into three separate specific capabilities.
    - The first echoes the requirement that EHR technology must be able to create a clinical summary in both human readable format and according to the Consolidated CDA.
    - The second would require EHR technology to enable a user to customize (e.g., be able to edit) the data they include in the clinical summary. This capability supports CMS's policy for this MU objective and measure that permits EPs excluding certain data from a clinical summary and clarifies as well as makes explicit the customization capability other commenters mentioned should be present. And, overall we believe this capability will

assist EPs in determining how to best structure the clinical summary they want to provide their patients based on the data their CEHRT is able to produce.
    - The third specific capability identifies the minimum data EHR technology must permit a user to select for inclusion in a clinical summary."

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 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

CHANGES FROM 2011 TO 2014 EDITION

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 clinical summary certification criterion is discussed:

- "We proposed to revise the "clinical summaries" certification criterion for the 2014 Edition EHR certification criteria to reflect the proposed new and revised standards for problem lists and other vocabulary standards."
- "…the "transitions of care–create and transmit transition of care/referral summaries" certification criterion (§ 170.314(b)(2)) requires EHR technology to be capable of formatting a patient's transition of care/referral summary in accordance with the Consolidated CDA and capable of using transport standards."
- "We are adopting this certification criterion as proposed with Release 2.0 (July 2012) of the Consolidated CDA standard…"
- "The second [certification criterion capability] would require EHR technology to enable a user to customize (e.g., be able to edit) the data they include in the clinical summary. This capability supports CMS's policy for this MU objective and measure that permits EPs excluding certain data from a clinical summary and clarifies as well as makes explicit the customization capability other commenters mentioned should be present."

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

- Enable a user to create a clinical summary, according to the HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation (without use of the "unstructured document" document-level template), and including, at a minimum, the following data elements:
  1) Provider's name and office contact information
  2) Date and location of visit
  3) Reason for visit
  4) Immunizations and/or medications administered during the visit
  5) Diagnostic tests pending
  6) Clinical Instructions
  7) Future appointments
  8) Referrals to other providers
  9) Future schedule tests
  10) Recommended patient decision aids

  and the Common MU Data set, which includes the following data elements with the specified standard(s):
  1) Patient name
  2) Sex
  3) Date of birth

4) Race according to, at minimum, 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.
5) Ethnicity according to, at minimum, 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.
6) Preferred language according to, a minimum, ISO 639-2 alpha-3 codes limited to those that also have a corresponding alpha-2 code in ISO 639-1
7) Smoking status according to, the codes 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
8) Problems according to, at a minimum, the International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) International Release July 2012 and US Extension to SNOMED CT® March 2012 Release.
9) Medications according to, at a minimum, RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release
10) Medication allergies according to, at a minimum, RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release
11) Laboratory test(s) according to, at a minimum, Logical Observation Identifiers Names and Codes (LOINC®) version 2.40, June 2012
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 –
   (i) at a minimum, International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) International Release July 2012 and US Extension to SNOMED CT® March 2012 Release

   OR

   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:
      (i) Physician services.

(ii) Physical and occupational therapy services.
(iii) Radiologic procedures.
(iv) Clinical laboratory tests.
(v) Other medical diagnostic procedures.
(vi) Hearing and vision services.
(vii) Transportation services including ambulance.

(ii) Optional. The *Code on Dental Procedures and Nomenclature,* as maintained and distributed by the American Dental Association, for dental services.

(iii) Optional. For the indicated procedures or other actions taken according to The 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.

16) Care team member(s)
- Permit a user to customize the data included in the clinical summary at the time it is being created by editing. (This may be accomplished at the data element level or editing of information within a data element).

ONC provides the test data for this test procedure.

This test procedure is organized into two sections:

- Create – evaluates the capability for the EHR technology to enable a user to generate a clinical summary for a patient in human readable format and according to the Implementation Guide for CDA® Release 2.0, Consolidated CDA Templates; and including, at a minimum, the provider's name and office contact information; date and location of visit; reason for visit; immunizations and/or medications administered during the visit; diagnostic tests pending; clinical instructions; future appointments; referrals to other providers; future scheduled tests; recommended patient decision aids; and the Common MU Data Set data with named standards as appropriate (in their English representation if they associate with a vocabulary/code 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)

- Using the Vendor-identified EHR function(s), the Tester inputs the provided test data into a Vendor-identified patient's record in the EHR
- Using the Vendor-identified EHR function(s) and the provided test data, the Tester causes the EHR to electronically generate a clinical summary in Consolidated CDA standard
- Using the Vendor-identified EHR function(s) and the provided test data, the Tester causes the EHR to electronically generate a clinical summary in a human readable format (this may be accomplished by creating a separate human readable file or supporting human readable capability with the C-CDA by applying a style sheet, access to a C-CDA viewer etc.)
- Using the Vendor-identified EHR function(s), the Tester imports the generated C-CDA clinical summary into the NIST C-CDA Conformance Test Tool
- Using the Validation Report produced by the NIST C-CDA Conformance Test Tool, the Tester verifies that the Implementation Guide conformance requirements tested are met, and that the named standard vocabularies have been used where applicable for data in the Common MU Data Set
- Using the provided test data, the Tester verifies that the data rendered in the generated clinical summary are complete and accurate, are in human readable format, and that the data in the Common MU Data Set are shown in their English representation if they associate with a vocabulary/code set

- Customize – evaluates the capability for a user to customize the data included in the clinical summary
  - Using the Vendor-identified EHR function(s) and the provided test data, the Tester selects certain data for exclusion from the clinical summary (e.g. Excluding an entire data element, or removing text within certain data elements (e.g. patient instructions))
  - Using the Vendor-identified EHR function(s) and the provided test data, the Tester selects data for inclusion into the clinical summary. (Examples of this may include, but are not limited to, selecting data elements to include in the clinical summary, or modifying text
  - Using the Vendor-identified EHR function(s), the Tester causes the EHR to electronically generate the clinical summary in a human readable format
  - Using the Vendor-identified EHR function(s) and the provided test data, the Tester causes the EHR to electronically generate a clinical summary according to the Consolidated CDA standard
  - Using the Vendor-identified EHR function(s), the Tester imports the clinical summary into the NIST C-CDA Conformance Test Tool

- Using the Validation Report produced by the NIST C-CDA Conformance Test Tool, the Tester verifies that the Implementation Guide conformance requirements tested are met, and that the named standard vocabularies have been used where applicable for data in the Common MU Data Set
- Using the provided test data, the Tester verifies that the data selected for exclusion are omitted in the generated clinical summary, and that the remaining data are in human readable format and are complete and accurate
- Using the provided test data, the Tester verifies that the data selected for inclusion are incorporated in the clinical summary in human readable format and are complete and accurate
- Using the provided test data, the Tester verifies that the data selected for exclusion are omitted in the generated clinical summary according to the Consolidated CDA standard, and that data in the Common MU Data Set are shown in their English representation if they associate with a vocabulary/code set the remaining and data and are complete and accurate
- Using the provided test data, the Tester verifies that the data selected for inclusion are incorporated in the clinical summary according to the Consolidated CDA standard, and that the data in the Common MU Data Set are shown in their English representation if they associate with a vocabulary/code set and are complete and accurate

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.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).
(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

Derived Test Requirements

DTR170.314.e.2 – 1: Create a Patient Clinical Summary

DTR170.314.e.2 – 2: Customize Data in the Patient Clinical Summary

DTR170.314.e.2 – 1: Create a Patient Clinical Summary

Required Vendor Information

VE170.314.e.2 – 1.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test

VE170.314.e.2 – 1.02: Vendor shall identify the EHR function(s) that are available to 1) select the patient, 2) electronically generate a clinical summary in human readable format 3) electronically generate a clinical summary according to the Consolidated CDA, including the named data elements as well as the Common MU Data Set with

associated vocabulary standards, 4) import the clinical summary into the NIST C-CDA Conformance Test Tool, and 5) customize the patient information within the clinical summary

Required Test Procedure

TE170.314.e.2 – 1.01: Tester shall select the provided test data

TE170.314.e.2 – 1.02: Using the Vendor-identified EHR function(s), the Tester shall select the Vendor-identified test patient

TE170.314.e.2 – 1.03: Using the provided test data selected in TE170.314.e.2 – 1.01 and the Vendor-identified EHR function(s), the Tester shall input the test data into the Vendor-identified patient's record in the EHR

TE170.314.e.2 – 1.04: Using the Vendor-identified EHR function(s) and the test data selected in TE170.314.e.2 – 1.01, the Tester shall

- Cause the EHR to electronically generate a clinical summary for the test patient according to the Consolidated CDA standard and named vocabulary standards for the Common MU Data Set and the following data elements: The provider's name and office contact information; date and location of visit; reason for visit; immunizations and/or medications administered during the visit; diagnostic tests pending; clinical instructions; future appointments; referrals to other providers; future scheduled tests; and recommended patient decision aids
- Cause the EHR to electronically generate a clinical summary for the test patient in human readable format including elements from the Common MU Data set and the following data elements: The provider's name and office contact information; date and location of visit; reason for visit; immunizations and/or medications administered during the visit; diagnostic tests pending; clinical instructions; future appointments; referrals to other providers; future scheduled tests; and recommended patient decision aids
- Import the C-CDA clinical summary into the NIST C-CDA Conformance Test Tool identified in the Conformance Test Tools section of this test procedure

TE170.314.e.2 – 1.05: Using the Inspection Test Guide, the Tester shall verify that the clinical summary is created in human readable format, and is complete and accurate

TE170.314.e.2 – 1.06: Using the Inspection Test Guide, the Tester shall verify that the clinical summary is created according to the Consolidated CDA standard tested and the named vocabulary standards, and is complete and accurate

Inspection Test Guide

IN170.314.e.2 – 1.01: Using the provided test data and the Validation Report produced by the NIST C-CDA Conformance Test Tool identified in the Conformance Test Tools section of this test procedure**,** the Tester shall verify that

- The C-CDA Implementation Guide conformance requirements tested are met by the electronically generated clinical summary
- The standards for the named vocabularies for the Common MU Data Set are met by the electronically generated clinical summary

IN170.314.e.2 – 1.02: Using the provided test data, the Tester shall verify that the patient's clinical summary is created in human readable format, and including, at a minimum, the following data elements:

1) Provider's name and office contact information
2) Date and location of visit
3) Reason for visit
4) Immunizations and/or medications administered during the visit
5) Diagnostic tests pending
6) Clinical Instructions
7) Future appointments
8) Referrals to other providers
9) Future schedule tests
10) Recommended patient decision aids

and the Common MU Data Set (in their English representation if they associate with a vocabulary/code 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.e.2 – 1.03: Using the provided test data, the Tester shall verify that the patient's clinical summary is created according to the Consolidated CDA standard, and including, at a minimum, the following data elements:

1) Provider's name and office contact information
2) Date and location of visit
3) Reason for visit

4) Immunizations and/or medications administered during the visit
5) Diagnostic tests pending
6) Clinical Instructions
7) Future appointments
8) Referrals to other providers
9) Future schedule tests
10) Recommended patient decision aids

and the Common MU Data Set (in their English representation if they associate with a vocabulary/code 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)

DTR170.314.e.2 – 2: Customize Data in the Patient Clinical Summary

Required Vendor Information

- Information as defined in DTR170.314.e.2 - 1, no additional information is required

Required Test Procedure

TE170.314.e.2 – 2.01: Using the Vendor-identified EHR function(s), the existing patient record, the patient data entered in DTR170.314.e.2 – 1: Create a Patient Clinical Summary, and Vendor-supplied test data, the Tester shall select data for inclusion in the clinical summary

TE170.314.e.2 – 2.02: Using the Vendor-identified EHR function(s), the existing patient record, the patient data entered in DTR170.314.e.2 – 1: Create a Patient Clinical Summary, and Vendor-supplied test data, the Tester shall select data for exclusion from the clinical summary

TE170.314.e.2 – 2.03: Using the Vendor-identified EHR function(s), the Tester shall

- Cause the EHR to generate the clinical summary for the test patient in human readable format for the Common MU Data Set and the following data elements: The provider's name and office contact information; date and location of visit; reason for visit; immunizations and/or medications administered during the visit; diagnostic tests pending; clinical instructions; future appointments; referrals to other providers; future scheduled tests; and recommended patient decision aids
- Cause the EHR to generate the clinical summary for the test patient according to the Consolidated CDA standard and named vocabulary standards for the Common MU Data Set and the following data elements: The provider's name and office contact information; date and location of visit; reason for visit; immunizations and/or medications administered during the visit; diagnostic tests pending; clinical instructions; future appointments; referrals to other providers; future scheduled tests; and recommended patient decision aids
- Import the clinical summary to the NIST C-CDA Conformance Test Tool identified in the Conformance Test Tools section of this test procedure

TE170.314.e.2 – 2.04: Using the Inspection Test Guide, the Tester shall verify that the electronically generated clinical summary is created in human readable format and excludes the data selected for exclusion in TE170.314.e.2 – 2.01

TE170.314.e.2 – 2.05: Using the Inspection Test Guide, the Tester shall verify that the electronically generated clinical summary is created in human readable format, and includes the data selected for inclusion in TE170.314.e.2 – 2.01

TE170.314.e.2 – 2.06: Using the Inspection Test Guide, the Tester shall verify that the electronically generated clinical summary is created according to the Consolidated CDA standard and the named vocabulary standards, and excludes the data selected for exclusion in TE170.314.e.2 – 2.01

TE170.314.e.2 – 2.07: Using the Inspection Test Guide, the Tester shall verify that the electronically generated clinical summary is created according to the Consolidated CDA standard and the named vocabulary standards, and includes the data selected for inclusion in TE170.314.e.2 – 2.01

Inspection Test Guide

IN170.314.e.2 – 2.01: Using the provided test data and the Validation Report produced by the NIST C-CDA Conformance Test Tool identified in the Conformance Test Tools section of this test procedure**,** the Tester shall verify that

- The C-CDA Implementation Guide conformance requirements tested are met by the electronically generated clinical summary
- The standards for the named vocabularies for the Common MU Data Set are met by the electronically generated clinical summary

IN170.314.e.2 – 2.02: Using the provided test data, the Tester shall verify that the patient's clinical summary is electronically generated in human readable format that the data

selected for exclusion in TE170.314.e.2 – 2.01 are omitted from the generated clinical summary, and that the remaining data are accurate and complete

IN170.314.e.2 – 2.03: Using the provided test data, the Tester shall verify that the patient's clinical summary is electronically generated in human readable format that the data selected for inclusion in TE170.314.e.2 – 2.01 are incorporated within the generated clinical summary, and that the remaining data are accurate and complete

IN170.314.e.2 – 2.04: Using the provided test data, the Tester shall verify that the patient's clinical summary is electronically generated according to the Consolidated CDA standard that the data selected for exclusion in TE170.314.e.2 – 2.01 are omitted from the generated clinical summary, that the remaining data are accurate and complete, and that the data in the Common MU Data Set are shown in their English representation if they associate with a vocabulary/code set

IN170.314.e.2 – 2.05: Using the provided test data, the Tester shall verify that the patient's clinical summary is electronically generated according to the Consolidated CDA standard that the data selected for inclusion in TE170.314.e.2 – 2.01 are incorporated within the generated clinical summary, that the remaining data are accurate and complete, and that the data in the Common MU Data Set are shown in their English representation if they associate with a vocabulary/code set

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 web application validation service 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/

Release Notes/Disclaimer:

September 20, 2012 - NIST Transport Testing Tool is alpha software that is still under development. Currently the only functionality supported is CCDA validation. The DIRECT and SOAP based functionally is still under development and is unlikely to work at this time. Please check back for updates.

Known CCDA validation issues in the version of TTT include:

- The test data contains conformance errors
- When using the CCDA validation tool, there have been sporadic exceptions thrown by the system causing it to fail at the validation attempt

Support for these tools is available by contacting:

Bill Majuski (Bill.Majurski@nist.gov)
Computer Scientist
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 21, 2012