

Test Procedure for § 170.314 (b)(2) Transitions of care – create and transmit summary care records

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 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 <http://www.healthit.gov/certification> (navigation: 2014 Edition Test Method). The 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 Program², 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 issued by the Department of Health and Human Services (HHS) on September 4, 2012.

§ 170.314(b)(2) Transitions of care - create and transmit summary care records.

- i) Create. Enable a user to electronically create a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(3) that 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 specified § 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.
- ii) Transmit. Enable a user to electronically transmit the transition of care/referral summary created in paragraph (b)(2)(i) of this section in accordance with:
- (A) The standard specified in § 170.202(a).
 - (B) Optional. The standards specified in § 170.202(a) and (b).
 - (C) Optional. The standards specified in § 170.202(b) and (c).

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 (September 4, 2012), 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.

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 (September 4, 2012) where the transitions of care – create and transmit summary care records certification criterion is discussed:

- “... based on stakeholder feedback received after the publication of the S&CC July 2010 final rule, we stated our belief that the criterion should be split into two separate certification criteria based on the capabilities required. We explained that this approach would provide developers greater flexibility for certification...”
- “...we have decided to finalize our proposal to allow for the use of ICD-10-CM to represent encounter diagnoses in addition to permitting SNOMED- CT...”
- “...In instances where the EP, EH, or CAH’s CEHRT receives data from an outside source, we acknowledge that requiring the CEHRT to translate the data into an adopted standard vocabulary could alter its intended meaning ... the responsibility of the sending EP or EH/CAH is to send information with standard terms, and in the case when such standard terms are not used, it should not be the responsibility of the receiving EP or EH to translate local or proprietary codes into standard codes ...”
- “...for the purposes of certification, and demonstrating compliance with this certification criterion, EHR technology will need to be tested and certified as being able to apply all of the adopted

standard vocabularies to data required to be included in a Consolidated CDA formatted transition of care/referral summary ...”

- “...Further, we expect that the National Coordinator will approve a test procedure for the transitions of care certification criteria that rigorously assesses EHR technology’s ability to transmit and receive electronic health information according to the adopted transport, content exchange, and vocabulary standards. We anticipate that this test procedure will be specified to ascertain the EHR technology’s ability to engage in standards-based exchange with any other EHR technology that has also implemented the standards we have adopted ...”
- “...We acknowledged that care plan, additional care team members, referring or transitioning provider’s name and contact information as well as certain hospital discharge information are not explicitly required to be captured by separate certification criteria, unlike most other data included in the summary care record. We noted that the ability to capture these data elements is both implicit and necessary to satisfy this certification criterion ...”

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 (September 4, 2012) Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule where the transitions of care – create and transmit summary care records certification criterion is discussed:

- “...we proposed to adopt the Consolidated CDA for this certification criterion because its template structure can accommodate the formatting of a summary care record that includes all of the data elements that CMS proposed be available for inclusion in a summary care record.”
- “We proposed that EHR technology would need to be capable of transmitting a summary care record according to both of the Direct Project’s specifications for secure transport. We also proposed to adopt as an optional standard at § 170.202(a)(3) the SOAP-Based Secure Transport RTM version 1.0³ which was developed under the nationwide health information network Exchange Initiative and to which we stated EHR technology should be able to be certified.”
- “We have adopted, as proposed, that the Applicability Statement for Secure Health Transport specification be a required condition of certification as part of this certification criterion. We have removed the XDR and XDM for Direct Messaging specification as also being required in lieu of a broader range of options for certification.”
- “Additionally..., all EHR technology used by EPs, EHRs, and CAHs and that meets the CEHRT definition will, at a minimum, be capable of SMTP-based exchange.”
- “...we have adopted the updated version of this specification that was established by the stakeholder community during this final rule’s drafting.”
- “...we have adopted two optional certification approaches for transport standards...”

³ <http://modularspecs.siframework.org/NwHIN+SOAP+Based+Secure+Transport+Artifacts>

- The first option would permit EHR technology to be certified as being in compliance with our original proposal: certification to both the Applicability Statement for Secure Health Transport specification and the XDR and XDM for Direct Messaging specification.
- The second option would permit EHR technology to be certified to: the Simple Object Access Protocol (SOAP)-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 standard and the XDR and XDM for Direct Messaging specification.”
- “We have included the XDR and XDM for Direct Messaging specification as a required specification for both of these options.”

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 EHR technology to electronically create and transmit transition of care/referral summary document (summary care record) in conformance with the Consolidated Clinical Document Architecture (C-CDA) standard. The transition of care/referral summary (summary care record) must be transmitted using the Applicability Statement for Secure Health Transport standard. The vendor may optionally elect to be evaluated for the capability to transmit transition of care/referral summaries using the Applicability Statement for Secure Health Transport standard and the ONC XDR and XDM for Direct Messaging Specification standard. The vendor may also optionally elect to be evaluated for the capability to electronically transmit transition of care/referral summaries using the ONC XDR and XDM for Direct Messaging Specification standard and the ONC Transport and Security Specification. (Required: Direct; Optional: Direct + XDR/XDM, SOAP RTM + XDR/XDM).

In evaluating the capability of the EHR technology to transmit information to a third party, this test procedure will test the ability for EHR technology to correctly discover and use address-bound and domain-bound certificates hosted in both DNS and LDAP using the 2014 Direct Certificate Discovery Tool (DCDT).

Using the Edge Testing Tool (ETT), this test procedure will verify that the Direct message is encrypted using the recipient’s Public Key and is signed using the sender’s Private Key. In keeping with the Direct specification, Certified EHR Technology (CEHRT) must maintain an association with a supported address (sender or recipient) and a collection of Trusted Anchors⁴. The ETT requires manual upload of Trust Anchors and certificates for testing purposes and is not linked to the DCDT at this time. The Trust Anchor uploaded to the ETT mimics the certificate discovery capability tested using the DCDT to support testing of transport capabilities. This test procedure will evaluate the capability of EHR technology to create a list of individual Direct recipients that can receive documents sent using Direct.

⁴ Section 4.2.3 of the ONC Applicability Statement for Secure Health Transport: “Each implementation MUST maintain an association with a supported address (sender or recipient) and a collection of Trusted Anchors. The address trusts any valid leaf certificate whose certificate chain contains at least one certificate from the address’s Anchor list.”

ONC provides the test data for this test procedure. This test procedure is organized into two required sections (and two optional sections):

- Create – evaluates the capability to create a transition of care/referral summary from the EHR in C-CDA format. Included in the test procedure is an evaluation of the capability to use specified vocabularies as defined by the referenced standards.
 - For both ambulatory and inpatient settings: 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 ambulatory settings only with named standards as appropriate if they associate with a vocabulary/code set): encounter diagnoses, immunizations, cognitive status, functional status, reason for referral, referring provider’s name and contact information
 - For inpatient settings only with named standards as appropriate if they associate with a vocabulary/code set): encounter diagnoses, immunizations, cognitive status, functional status, and discharge instructions
 - The Vendor creates an existing patient record in the EHR technology with health information based on the ONC-provided test data
 - The Tester logs into the online application as a provider and creates a referral summary/transition of care
- Transmit - Evaluates the capability of EHR technology to allow a provider to electronically transmit the health information created in the “Create” section of the test procedure to another provider or next setting of care.
 - The Tester logs in to the EHR's online technology as the provider who created the information in the “Create” step

- The Tester verifies that the EHR can discover certificates from other parties in DNS CERT records and LDAP servers⁵
- Using the Vendor-identified function(s), the Tester verifies that the EHR is able to create and store a listing of Direct recipients
- Using the Vendor-identified function(s), the Tester causes the health information in C-CDA format to be transmitted to a third party using the Direct transport standard, based on ONC supplied test information
- The Tester verifies successful transmission and receipt of the health information, and that the health information can be successfully decrypted
- The Tester verifies that the information transmitted is in conformance with the C-CDA
 - Using the Validation Report produced by the Edge 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 transition of care/referral summary
- Using the provided test data, the Tester verifies that the data rendered in the transmitted C-CDA are complete and accurate (This may be accomplished by inspection of the C-CDA .xml).
- Optional: Using the Vendor-identified function(s), the Tester causes the health information in C-CDA format to be transmitted to a third party using Direct and the Cross-Enterprise Document Reliable Interchange (XDR) and Cross-Enterprise Document Media Interchange (XDM) for Direct Messaging Specification, based on ONC supplied test information
- Optional: Using the Vendor-identified function(s), the Tester causes the health information in C-CDA format to be transmitted to a third party using the SOAP-Based Secure Transport RTM version 1.0 and XDR, based on ONC supplied test information

⁵ Section 2.3 of the ONC Applicability Statement for Secure Health Transport v1.1: "For universal digital certificate distribution, STAs MUST be able to discover certificates using both the DNS as specified in Section 5 of this applicability statement and LDAP as described by the S&I Framework Certificate Discovery for Direct Project Implementation Guide."

REFERENCED STANDARDS

§ 170.202 Transport standards.	Regulatory Referenced Standard
The Secretary adopts the following transport standards:	
(a) <u>Standard</u> . ONC Applicability Statement for Secure Health Transport (incorporated by reference in § 170.299).	
(b) <u>Standard</u> . ONC XDR and XDM for Direct Messaging Specification (incorporated by reference in § 170.299).	
(c) <u>Standard</u> . ONC Transport and Security Specification (incorporated by reference in § 170.299).	
§ 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) <u>Standard</u> . HL7 Implementation Guide for CDA [®] Release 2: IHE Health Story Consolidation, (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) <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).	
(b)(2) <u>Standard</u> . The code set specified at 45 CFR 162.1002(a)(5).	<p>45 CFR 162.1002 Medical data code sets</p> <p>The Secretary adopts the following code set maintaining organization’s code sets as the standard medical data code sets:</p> <p>(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:</p> <p>(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:</p>

§ 170.207 Vocabulary standards for representing electronic health information.	Regulatory Referenced Standard
(b)(3) <u>Standard</u> . 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) <i>Code on Dental Procedures and Nomenclature</i> , as maintained and distributed by the American Dental Association, for dental services.
(4) <u>Standard</u> . 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) <u>Laboratory tests</u> . (2) <u>Standard</u> . 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) <u>Medications</u> . (2) <u>Standard</u> . 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).	
(e) <u>Immunizations</u> . (2) <u>Standard</u> . HL7 Standard Code Set CVX -- Vaccines Administered, updates through July 11, 2012 (incorporated by reference in § 170.299).	
(f) <u>Race and Ethnicity</u> . <u>Standard</u> . 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 https://obamawhitehouse.archives.gov/omb/fedreg_1997standards).	

§ 170.207 Vocabulary standards for representing electronic health information.
Regulatory Referenced Standard

(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

(i) Encounter diagnoses. Standard. The code set specified at 45 CFR 162.1002(c)(2) for the indicated conditions.

45 CFR 162.1002 Medical data code sets. The Secretary adopts the following maintaining organization's code sets as the standard medical data code sets:

(c)(2) International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) (including The Official ICD-10-CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following conditions:

- (i) Diseases.
- (ii) Injuries.
- (iii) Impairments.
- (iv) Other health problems and their manifestations.
- (v) Causes of injury, disease, impairment, or other health problems.

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.314(b)(2) – 1: Create Transition of Care/Referral Summary

DTR170.314(b)(2) – 2: Transmit Health Information to a Third Party Using Direct

DTR170.314(b)(2) – 3: Transmit Health Information to a Third Party Using Direct and XDM Validation (Optional)

DTR170.314(b)(2) – 4: Transmit Health Information to a Third Party Using SOAP Protocols (Optional)

DTR170.314(b)(2) – 1: Create Transition of Care/Referral Summary

Required Vendor Information

VE170.314(b)(2) – 1.01: 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)(2) – 1: Ambulatory (ambulatory only) or TD170.314(b)(2) – 2: Inpatient (inpatient only)

VE170.314(b)(2) – 1.02: Vendor shall identify a provider with privileges to access the patient's record

VE170.314(b)(2) – 1.03: Vendor shall identify the EHR function(s) that are available for a provider to view health information including the named data elements as well as the Common MU Data Set with associated vocabulary standards and create a transition of care/referral summary document in C-CDA format

Required Test Procedure

TE170.314(b)(2) – 1.01: Using the Vendor-identified EHR function(s), the Tester shall access the ONC-supplied test patient's record as the provider

TE170.314(b)(2) – 1.02: Using the Vendor-identified EHR function(s), the Tester creates the patient encounter and summary care record using the ONC-supplied test data and tester selected values for ranges as indicated in TD170.314(b)(2) – 1: Ambulatory (ambulatory only) or TD170.314(b)(2) – 2: Inpatient (inpatient only) for the patient created in VE170.314(b)(2) – 1.01 that conforms to the minimum requirements for the:

- Ambulatory Summary Care Record: Common MU Data Set and the following data elements: encounter diagnoses, immunizations, cognitive status, functional status, reason for referral, referring provider's name and contact information (Ambulatory EHR Only)
- Inpatient Summary Care Record: Common MU Data Set and encounter diagnoses, immunizations, cognitive status, functional status, and discharge instructions (Inpatient EHR Only)

TE170.314(b)(2) – 1.03: Using the Inspection Test Guide, the Tester shall verify that the created Ambulatory Summary Care Record/Inpatient Summary Care Record is complete and accurate and in accordance with TD170.314(b)(2) – Ambulatory (ambulatory only) or TD170.314(b)(2) – Inpatient (inpatient only)

Inspection Test Guide

IN170.314(b)(2) – 1.01: Using the ONC-provided test data, the Tester shall inspect the content of the C-CDA conformant document is complete and accurate, is equivalent to the provided test data (TD170.314(b)(2)) and equivalent to the information contained in the patient's EHR record

DTR170.314(b)(2) – 2: Transmit Health Information to a Third Party Using Direct

Required Vendor Information

- VE170.314(b)(2) – 2.01: The Vendor shall identify a Direct address and a registered domain for sending of Direct messages for certificate discovery testing for enabling of testing using the 2014 Direct Certificate Discovery Tool
- VE170.314(b)(2) – 2.02: The Vendor shall identify a non-Direct email address to be used for delivery of results of certificate discovery testing for enabling of testing using the 2014 Direct Certificate Discovery Tool
- VE170.314(b)(2) – 2.03: The Vendor shall identify a Contact Email address to be used for receipt of the validation report generated by the Edge Testing Tool
- VE170.314(b)(2) – 2.04: The Vendor shall identify the Direct address for registering within the Edge Testing Tool
- VE170.314(b)(2) – 2.05: The Vendor shall obtain the Edge Testing Tool's Public Key and Trust Anchor from the Edge Testing Tool and store it within the EHR technology function/location for encrypting Direct message(s) to be sent to another setting of care or provider of care⁶
- VE170.314(b)(2) – 2.06: The Vendor shall identify its signing certificate to sign message content with its Private Key and include the Public Key in messages sent to the Edge Testing Tool
- VE170.314(b)(2) – 2.07: The Vendor shall identify the C-CDA conformant document(s) created in TE170.314(b)(2) – 1.02

Required Test Procedures

- TE170.314(b)(2) – 2.01: The Tester shall download the 2014 Direct Certificate Discovery Tool's Trust Anchor and import it into the EHR technology's trust store
- TE170.314(b)(2) – 2.02: The Tester shall use the Direct (From) address provided in VE170.314(b)(2) - 2.01 to execute the test using the 2014 Direct Certificate Discovery Tool
- TE170.314(b)(2) – 2.03: The Tester shall use the non-Direct email address provided in VE170.314(b)(2) - 2.02 for receipt and validation of results of certificate discovery testing
- TE170.314(b)(2) – 2.04: The Tester shall execute all test cases available within the 2014 Direct Certificate Discovery Tool
- TE170.314(b)(2) – 2.05: Using the Inspection Test Guide, the Tester shall verify that the EHR technology is able to correctly discover and use address-bound and domain-bound certificates hosted in both DNS and LDAP
- TE170.314(b)(2) – 2.06: The Tester shall cause the EHR to register the Direct (To) address(es) specified in the Edge Testing Tool (to be available as a recipient for sending of Direct messages within the EHR)

⁶ When the test procedure refers to the Edge Testing Tool's trust anchor and certificates, this refers to ONC hosted version on healthit.gov/ett. If your organization is hosting its own version of Edge Testing Tool (ETT), then you will need to create your own trust anchor certificates and use these instead. For example, the trust anchor for hit-testing@ttpedge.sitenav.org may change to "ett.yourdomain.com".

TE170.314(b)(2) – 2.07: The Tester shall cause the EHR to transmit Consolidated CDA conformant document(s) using ONC Applicability Statement for Secure Health Transport (Direct) standard to the Direct (To) address(es) specified in the Edge Testing Tool that are available within the EHR following TE170.314(b)(2) – 2.06. The Direct message shall be encrypted using the recipient's (Edge Testing Tool) Public Key obtained in VE170.314(b)(2) – 2.05 and signed using the sender's (Vendor) Private Key for the Referral Summary/Transition of Care document created in TE170.314(b)(2) – 1.02

TE170.314(b)(2) – 2.08: Using the Inspection Test Guide, the Tester shall verify that the transmitted Transition of Care/Referral Summary is transmitted according to the ONC Applicability Statement for Secure Health Transport (Direct) standard and formatted according to the Consolidated CDA standard tested and the named vocabulary standards, and is complete and accurate

Inspection Test Guide

IN170.314(b)(2) – 2.01: Using the 2014 Direct Certificate Discovery Tool, the Tester shall inspect the results received via email to verify that all test cases for discovery of certificates hosted in DNS and LDAP were successful

IN170.314(b)(2) – 2.02: The Tester shall verify the appropriate Direct (To) address(es) (provided within the Edge Testing Tool) have been registered within the EHR technology and are visible Direct addresses for transmitting of health information to the Edge Testing Tool according to the ONC Applicability Statement for Secure Health Transport (Direct) standard

IN170.314(b)(2) – 2.03: Using the Edge Testing Tool Direct Message Validator, the Tester shall verify that the transmitted C-CDA conformant document has been transmitted and received successfully according to the ONC Applicability Statement for Secure Health Transport (Direct) standard, and the Edge Testing Tool validation report indicates successful decryption validation

IN170.314(b)(2) – 2.04: Using the provided test data, the documents identified in VE170.314(b)(2) – 2.07 and the Validation Report produced by the Edge Testing Tool Message Validators CCDA R1.1 Validator 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 (Ambulatory/Inpatient) Transition of Care/Referral Summary
- The standards for the named vocabularies for the Common MU Data Set, Encounter diagnoses, and Immunizations are met by the electronically generated Transition of Care/Referral Summary

IN170.314(b)(2) – 2.05: The Tester shall identify the C-CDA conformant .xml files within the transmitted documents (This may involve reviewing EHR logs to access the transmitted

documents, parsing files and inspecting the header to identify the C-CDA conformant document .xml (vs. style sheet, human readable document, etc.))

IN170.314(b)(2) – 2.06: Using the ONC-provided test data, the Tester shall verify that the content of the transmitted C-CDA conformant document (by inspecting .xml) is complete and accurate and includes, at a minimum:

- 1) Encounter diagnoses
- 2) Immunizations
- 3) Cognitive status
- 4) Functional status
- 5) Reason for referral
- 6) Referring or transitioning provider's name
- 7) Provider name
- 8) Provider office contact information
- 9) 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)(2) – 2.07: Using the ONC-provided test data, the Tester shall verify that the content of the transmitted C-CDA conformant document (by inspecting .xml) is complete and accurate and includes, at a minimum, the following data elements:

- 1) Encounter diagnoses
- 2) Immunizations
- 3) Cognitive status
- 4) Functional status
- 5) Discharge instructions
- 6) 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)

DTR170.314(b)(2) –3: Transmit Health Information Using Direct and XDM Validation (Optional)

Required Vendor Information

- VE170.314(b)(2) – 3.01: The Vendor shall identify a Contact Email address to be used for receipt of the validation report generated by the Edge Testing Tool if the Contact email address for XDM Validation differs from the one identified in VE170.314(b)(2) – 2.03
- VE170.314(b)(2) – 3.02: The Vendor shall identify the Direct address for registering within the Edge Testing Tool that shall send the direct message if the Direct address for XDM Validation differs from the one identified in VE170.314(b)(2) – 2.04

Required Test Procedures

- TE170.314(b)(2) – 3.01: The Tester shall cause the EHR to register the Direct (To) addresses specified in the Edge Testing Tool to be available for Direct messaging with XDM Validation within the EHR
- TE170.314(b)(2) – 3.02: The Tester shall cause the EHR to transmit Consolidated CDA conformant document(s) identified in VE170.314(b)(2) – 2.07 using ONC Applicability Statement for Secure Health Transport (Direct) standard with XDM Validation to the Direct (To) address(es) specified in the Edge Testing Tool that are available within the EHR following TE170.314(b)(2) – 3.01. The Direct message shall be encrypted using the recipient's (Edge Testing Tool) Public Key obtained in VE170.314(b)(2)– 2.05 and signed using the sender's (Vendor) Private Key for the Referral Summary/Transition of Care document created in VE170.314 (b)(2)– 1.02
- TE170.314 (b)(2) – 3.03: Using the Inspection Test Guide, the Tester shall verify that the Transition of Care/Referral Summary is transmitted according to the ONC Applicability Statement for Secure Health Transport (Direct) standard with XDM Validation and formatted according to the Consolidated CDA standard tested and the named vocabulary standards, and is complete and accurate

Inspection Test Guide

- IN170.314(b)(2) – 3.01: The Tester shall verify the appropriate Direct (To) address(es) (provided within the Edge Testing Tool) have been registered within the EHR technology and are visible Direct addresses for transmitting of health information to the Edge Testing Tool according to the ONC Applicability Statement for Secure Health Transport (Direct) standard with XDM Validation
- IN170.314(b)(2) – 3.02: Using the Edge Testing Tool Direct Message Validator, the Tester shall verify that the transmitted C-CDA conformant document has been transmitted and received successfully according to the ONC Applicability Statement for Secure Health Transport (Direct) standard with XDM Validation, and the Edge Testing Tool validation report indicates successful decryption validation and trust anchor validation

IN170.314(b)(2) – 3.03: Using the provided test data, and the Validation Report produced by the Edge Testing Tool Message Validators XDM Validator 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 (Ambulatory/Inpatient) Transition of Care/Referral Summary
- The standards for the named vocabularies for the Common MU Data Set, Encounter diagnoses, and Immunizations are met by the electronically generated Transition of Care/Referral Summary

IN170.314(b)(2) – 3.04: The Tester shall identify the C-CDA .xml files within the transmitted documents (This may involve parsing files and inspecting the header to identify the C-CDA conformant documents (vs. style sheet, human readable document, etc.))

IN170.314(b)(2) – 3.05: Using the ONC-provided test data, the Tester shall verify that the content of the transmitted C-CDA conformant document is complete and accurate and includes, at a minimum, the following data elements (Ambulatory Only):

- 1) Encounter diagnoses
- 2) Immunizations
- 3) Cognitive status
- 4) Functional status
- 5) Reason for referral
- 6) Referring or transitioning provider's name
- 7) Provider name
- 8) Provider office contact information
- 9) 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(b)(2) – 3.06: Using the ONC-provided test data, the Tester shall verify that the content of the transmitted C-CDA conformant document is complete and accurate and includes, at a minimum, the following data elements (Inpatient Only):

- 1) Encounter diagnoses
- 2) Immunizations
- 3) Cognitive status
- 4) Functional status
- 5) Discharge instructions
- 6) 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(b)(2) – 4: Transmit Health Information Using SOAP Protocols (Optional)

Required Vendor Information

VE170.314(b)(2) – 4.01: The Vendor shall generate a SOAP endpoint for XDR for each C-CDA conformant document that will be sent to the ETT Message Validators XDR Validator and provide a Name for each ETT connection,

Required Test Procedures

TE170.314(b)(2) – 4.01: The Tester shall cause the EHR to transmit the Consolidated CDA conformant document(s) for Referral Summary/Transition of Care created in TE170.314(b)(2) – 1.02 using SOAP Protocols with XDR Validation to the SOAP endpoint generated in VE 170.314(b)(2) – 4.01 in the Edge Testing Tool

TE170.314(b)(2) – 4.02: Using the Inspection Test Guide, the Tester shall verify that the Transition of Care/Referral Summary is transmitted using SOAP Protocols with XDR Validation and formatted according to the Consolidated CDA standard tested and the named vocabulary standards, and is complete and accurate

Inspection Test Guide

IN170.314(b)(2) – 4.01: Using the Edge Testing Tool Message Validators XDR Validator, the Tester shall verify that the transmitted C-CDA conformant document(s) have been transmitted and received successfully according to SOAP Protocols with XDR Validation

IN170.314(b)(2) – 4.02: Using the ONC-provided test data, the Tester shall verify that the content of the transmitted C-CDA conformant document is complete and accurate and includes, at a minimum, the following data elements (Ambulatory Only):

- 1) Encounter diagnoses
- 2) Immunizations
- 3) Cognitive status
- 4) Functional status
- 5) Reason for referral
- 6) Referring or transitioning provider's name
- 7) Provider name
- 8) Provider office contact information
- 9) 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(b)(2) – 4.03: Using the ONC-provided test data, the Tester shall verify that the content of the transmitted C-CDA conformant document is complete and accurate and includes, at a minimum, the following data elements (Inpatient Only):

- 1) Encounter diagnoses
- 2) Immunizations
- 3) Cognitive status
- 4) Functional status
- 5) Discharge instructions
- 6) 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)

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)(2) Transitions of care - create and transmit summary care records is 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:

- 2014 Direct Certificate Discovery Tool (2014 DCDT) – ONC provides a web application certificate discovery testing tool to support this test procedure. This tool was created to support automated testing of systems that plan to enact the Certificate Discovery and Provider Directory Implementation Guide, approved as normative specification by the Direct community, as of July 9, 2012. It is based on the written test package and requirement traceability matrix created by the Modular Specifications project.
 - This application can be installed and deployed locally.

- The Direct Certificate Discovery Tool, User's Guide, configuration instructions, and other documentation are available at: <https://sitenv.org/direct-certificate-discovery-tool>
- Edge Testing Tool (ETT) – the Edge Testing Tool is designed to support this test procedure.
 - The Edge Testing Tool Direct Testing (Sections: Register Direct, Send Direct Message and Message Validator) includes the capability to verify the ability to exchange Consolidated CDA (C-CDA) conformant documents using Direct transport standards (e.g., Direct and Direct + XDM).
 - The Edge Testing Tool Message Validators (Section: XDR Validator) includes the capability to verify the ability to exchange Consolidated CDA (C-CDA) conformant documents using ONC XDR and XDM for Direct Messaging.
 - The Edge Testing Tool Message Validators (Section: CCDA R1.1 Validator) includes the capability to verify the conformance of the CDA (C-CDA R1.1) documents.
 - The Edge Testing Tool Edge Testing (Sections: Homepage, SMTP Test Cases, IMAP Test Cases, POP3 Test Cases, XDR Test Cases) includes the capability to verify the ability to exchange Consolidated CDA (C-CDA) conformant documents using transport standards (e.g. SOAP).
 - The Edge Testing Tool HISP Testing and Delivery Notification (Section: Message Tracking) includes the capability to verify the receipt of messages.
 - This application can be installed and deployed locally.
 - The Edge Testing Tool (ETT) is available at: healthit.gov/ett

Multiple browsers may be used to access this tool. As the tool has been testing using both Chrome and Firefox browsers, these are the recommended browsers. The Edge Testing Tool 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 Edge Testing Tool (ETT):

The Edge Testing Tool (ETT), 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 of Change	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	Posted Updated Approved Test Procedure Updates: <ul style="list-style-type: none"> ▪ Added note in Informative Test Procedure clarifying purpose of strikethrough text ▪ Removed Normative Test Procedure steps to upload trust anchor to TTT and validate the trust anchor, and removed references to these steps in the Informative Test Description ▪ Strikethrough DTR 170.314(b)(2) – 3 and 170.314(b)(2) – 4 in Normative Test Procedure and reference to these test steps in the Informative Test Description ▪ Inserted footnote in Normative Test Procedure clarifying Transport Testing Tool Trust Anchor and Certificates for local installation of TTT ▪ Inserted VE170.314(b)(2) – 2.06 and 2.07 ▪ Inserted references to visually inspect .xml to verify content/values are acceptable ▪ Changed VE170.314(b)(2) – 1.02 to TE170.314(b)(2) – 1.02 in TE170.314(b)(2) – 2.07 ▪ Updated step numbers in Normative Test Procedure to be consecutive 	February 1, 2013
1.4	Updated Test Procedure Updates: <ul style="list-style-type: none"> ▪ Removed strikethrough of DTR 170.314(b)(2) – 3 and 170.314(b)(2) – 4 in Normative Test Procedure and strikethrough of reference to these test steps in the Informative Test Description ▪ Updated DTR170.314(b)(2) – 4 to reflect current functionalities available in the Transport Testing tool ▪ Removed bullet in Informative Test Description describing import of health information to the TTT ▪ Updated TE170.314(b)(2) – 2.08, TE170.314(b)(2) – 3.03, and TE170.314(b)(2) – 4.02 to include verification of conformance to transmission and content standards ▪ Added steps in DTR 170.314(b)(2) – 3 to indicate that vendor may provide separate email addresses for DTR170.314(b)(2) – 2 and DTR 170.314(b)(2) – 3 ▪ Removed requirement in Inspection Test Guide of DTR170.314(b)(2) – 3 and DTR170.314(b)(2) – 4 that C-CDA data elements must appear in their English representation ▪ Updated Diagram for DTR170.314(b)(2) - 4 ▪ Provided clarification in TE170.314(b)(2) – 2.07 regarding access of registered address in tool following prior step 	March 1, 2013

Version Number	Description of Change	Date Published
1.5	<p>Removed Note regarding TTT functionality that has not been implemented.</p> <p>Addition of version for the Direct Certificate Discovery Tool (DCDT) – 2014.</p> <p>Changed all references Transport Testing Tool (TTT) to Edge Testing Tool (ETT). The TTT tool has been retired. The Message Validator within the ETT tool is found in the Message Validators CCDA R1.1 Validator section. Sections impacted include the:</p> <ul style="list-style-type: none"> ▪ Informative Test Description ▪ DTR170.314(b)(2) – 2: Transmit Health Information to a Third Party Using Direct <ul style="list-style-type: none"> ○ Informative Test Description ○ VE170.314(b)(2) – 2.01, VE170.314(b)(2) – 2.02, VE170.314(b)(2) – 2.03, VE170.314(b)(2) – 2.04, VE170.314(b)(2) – 2.05, TE170.314(b)(2) – 2.01, TE170.314(b)(2) – 2.04, TE170.314(b)(2) – 2.06, TE170.314(b)(2) – 2.07, IN170.314(b)(2) – 2.01, IN170.314(b)(2) – 2.02, IN170.314(b)(2) – 2.03, IN170.314(b)(2) – 2.04 • DTR170.314(b)(2) – 3: Transmit Health Information Using Direct and XDM Validation Conformance Test Tools <ul style="list-style-type: none"> ○ VE170.314(b)(2) – 3.01, VE170.314(b)(2) – 3.02, TE170.314(b)(2) – 3.01, TE170.314(b)(2) – 3.02, IN170.314(b)(2) – 3.01, IN170.314(b)(2) – 3.02, IN170.314(b)(2) – 3.03 • DTR170.314(b)(2) – 4: Transmit Health Information Using SOAP Protocols VE170.314(b)(2) – 4.01, TE170.314(b)(2) – 4.01, IN170.314(b)(2) – 4.01 • DTR170.314(b)(2) – 2: Transmit Health Information to a Third Party Using Direct Removal of Figure 1 • DTR170.314(b)(2) – 4: Transmit Health Information Using SOAP Protocols removal of Figure 2 • Modified the Conformance Test Tools section to reflect the use of the Edge Testing Tool. 	January 27, 2017