The Office of the National Coordinator for
Health Information Technology

# 2015 Edition §170.315(e)(1) View, Download, and Transmit to Third Party (VDT)

Testing Components:

| Gap | | | | ONC Supplied Test Data |
|---|---|---|---|---|

Test Procedure Version 1.3 – Last Updated 5/14/16

Please consult the Final Rule entitled: *2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications* for a detailed description of the certification criterion with which these testing steps are associated. We also encourage developers to consult the Certification Companion Guide in tandem with the test procedure as they provide clarifications that may be useful for product development and testing.

*Note: The order in which the test steps are listed reflects the sequence of the certification criterion and does not necessarily prescribe the order in which the test should take place.*

## Required Tests

### (e)(1)(i) View, Download, and Transmit to a Third Party

Patients (and their authorized representatives) must be able to use internet-based technology to view, download, and transmit their health information to a 3rd party in the manner specified below. Such access must be consistent and in accordance with the following standard adopted in § 170.204(a)(1) and may alternatively be demonstrated in accordance with the standard specified in § 170.204(a)(2).

(A) View. Patients (and their authorized representatives) must be able to use health IT to view, at a minimum, the following data:

- (1) The Common Clinical Data Set (which should be in their English (i.e., non-coded) representation if they associate with a vocabulary/code set).
- (2) Ambulatory setting only. Provider's name and office contact information.
- (3) Inpatient setting only. Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization.
- (4) Laboratory test report(s). Laboratory test report(s), including:
  - (i) The information for a test report as specified all the data specified in 42 CFR 493.1291(c)(1) through (7);
  - (ii) The information related to reference intervals or normal values as specified in 42 CFR 493.1291(d); and
  - (iii) The information for corrected reports as specified in 42 CFR 493.1291(k)(2).
- (5) Diagnostic image report(s).

Standards:

§ 170.204(a)(1) Web Content Accessibility Guidelines (WCAG) 2.0, Level A Conformance

§ 170.204(a)(2) Web Content Accessibility Guidelines (WCAG) 2.0, Level AA Conformance

Data Elements and Vocabularies applicable to the Common Clinical Data Set (CCDS) – Outlined in the Common Clinical Data Set Reference Document

42 CFR 493.1291(c) The test report must indicate the following:

- (1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number.
- (2) The name and address of the laboratory location where the test was performed.

(3) The test report date.
(4) The test performed.
(5) Specimen source, when appropriate.
(6) The test result and, if applicable, the units of measurement or interpretation, or both.
(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

42 CFR 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

42 CFR 493.1291(k)(2) When errors in the reported patient test results are detected, the laboratory must do the following: Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results.

§ 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1 (incorporated by reference in § 170.299).

**Test Data Instructions:**

Inpatient setting: 170.315_e1_vdt_inp_sample*.pdf (All samples)

Ambulatory setting: 170.315_e1_vdt_amb_sample*.pdf (All samples)

Test Tool: ETT: Message Validators

| Criteria ¶ | System Under Test | Test Lab Verification |
|---|---|---|
| (i) | Web Content Accessibility<br><br>1. The health IT developer submits test documentation that demonstrates their internet-based technology's compliance with either § 170.204(a)(1), Web Content Accessibility Guidelines (WCAG) 2.0, Level A OR § 170.204(a)(2), Web Content Accessibility Guidelines (WCAG) 2.0, Level AA. | Web Content Accessibility<br><br>1. The tester verifies the level of Web Content Accessibility Guidelines (WCAG) 2.0, Level A as specified in § 170.204(a)(1), or Level AA § 170.204(a)(2), using the submitted test documentation.<br>2. Using the submitted testing results for WCAG Conformance (see http://www.w3.org/TR/2008/REC-WCAG20-20081211/#conformance-reqs) submitted in Step 1, the tester evaluates the documentation of referenced practice, testing tools, tool results, and accompanying documentation to ensure the health IT developer has achieved conformance with Web Content Accessibility Guidelines (WCAG) 2.0 in accordance with § 170.204(a)(1) or § 170.204(a)(2) as applicable.<br>3. The tester verifies that for each internet-based health IT technology, associated with the view, download, or transmit (VDT) capabilities, there is WCAG compliance for associated VDT functions and that all of this information is documented as part of the submitted documentation provided in Step 1. |

| Criteria ¶ | System Under Test | Test Lab Verification |
|---|---|---|
| (i)(A) | <u>View</u><br>1. Using the ETT: Message Validators -C-CDA R2.1 Validator, the health IT developer downloads the ONC-supplied data instructions through the sender download selections of "170.315_e1_VDT_Amb" or "170.315_e1_VDT_Inp" and one of the VDT instruction documents and executes the download.<br>2. Using the internet-based technology health IT function(s), a user, with the role of patient, views the ONC-supplied information downloaded in step 1. At a minimum, the view includes the following data as applicable:<br>• the Common Clinical Data Set (CCDS) as specified in section (e)(1)(i)(A)(1);<br>• For Ambulatory Setting only: the Provider's name and office contact information as specified in section (e)(1)(i)(A)(2);<br>• For Inpatient Setting only: the Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization as specified in section (e)(1)(i)(A)(3);<br>• Laboratory test report(s) as specified in section (e)(1)(i)(A)(4), when available; and<br>• Diagnostic Imaging report(s) as specified in section (e)(1)(i)(A)(5), when available.<br>3. Based upon the health IT setting(s) being certified, a user repeats steps 1-2 for each of the ambulatory and/or inpatient setting(s). All of the VDT summary record instruction documents for a given health IT setting must be viewed. | <u>View</u><br>1. For each view, the tester uses the VDT instruction document downloaded in step 1 of the SUT to perform visual inspection to verify that a patient's view of the patient health data in step 2 of the SUT is accurate and without omission, and at a minimum includes the following data as applicable:<br>• The CCDS as specified in section (e)(1)(i)(A)(1);<br>• For Ambulatory Setting only, the Provider's name and office contact information as specified in section (e)(1)(i)(A)(2);<br>• For Inpatient Setting only, the Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization as specified in section (e)(1)(i)(A)(3);<br>• Laboratory test report(s) as specified in section (e)(1)(i)(A)(4) when available; and<br>• Diagnostic Imaging report(s) as specified in section (e)(1)(i)(A)(5) when available. |

| Criteria ¶ | System Under Test | Test Lab Verification |
|---|---|---|
| (i)(A), continued | Authorized Viewer<br>4. Using one of the ONC-supplied test data instructions from step 1 and the internet-based technology health IT function(s), a user role of authorized patient representative views at a minimum the data referenced in steps 2.<br>5. Negative Test: A user who is neither the patient identified in the patient record nor the patient's authorized representative attempts to access and view patient data and is prevented from doing so. | Authorized Viewer<br>2. The tester verifies that a patient's authorized representative can view the patient health data, and using the VDT instruction document and the view from step 4 of the SUT, performs the same verification as in step 1.<br>3. Negative Test: Using visual inspection, the tester verifies that a user, who is neither the patient identified in the record nor the patient's authorized representative, does not have access to view the patient's health information. |
| (i)(A)(1) | Common Clinical Data Set<br>The data presented in section (e)(1)(i)(A) step 2 includes the Common Clinical Data Set as specified in the CCDS Reference Document as applicable, and is in English (i.e., non-coded) representation, if associated with a vocabulary/code set. | 1. Using Visual Inspection, the tester verifies that the data presented in section (e)(1)(i)(A) step 2 of the SUT includes all of the CCDS data elements as specified in the CCDS Reference Document, as applicable.<br>2. Using Visual Inspection, the tester verifies that the presentation of the Common Clinical Data Set in section (e)(1)(i)(A) step 2 of the SUT, is in human readable format with English terminology (i.e. non-coded representation of vocabulary/code sets), and present where applicable. |
| (i)(A)(2) | Ambulatory Setting Only<br>For Ambulatory Setting only, the data presented in section (e)(1)(i)(A) step 2 will also include:<br>• Provider's Name; and<br>• Office contact information. | Using Visual Inspection, the tester verifies that the data presented in section (e)(1)(i)(A) step 2 of the SUT, in the case of an ambulatory setting, includes the Provider's Name and Office contact information. |
| (i)(A)(3) | Inpatient Setting Only<br>For Inpatient Setting only, the data presented in section (e)(1)(i)(A) step 2 will also include:<br>• Admissions and Discharge dates and locations;<br>• Discharge instructions; and<br>• Reason(s) for hospitalization. | Using Visual Inspection, the tester verifies that the data presented in section (e)(1)(i)(A) step 2 of the SUT, in the case of an inpatient setting, includes the Admissions and Discharge dates and locations, Discharge instructions, and Reason(s) for hospitalization. |

| Criteria ¶ | System Under Test | Test Lab Verification |
|---|---|---|
| (i)(A)(4) | <u>Laboratory Test Report</u><br>The data presented includes the Laboratory test report(s) when available, including the following information:<br>• The test report must indicate the following information as specified in 42 CFR 493.1291(c)(1) through (7):<br>(1) For positive patient identification, either the patient's name and identification number or a unique patient identifier and identification number.<br>(2) The name and address of the laboratory location where the test was performed.<br>(3) The test report date.<br>(4) The test performed.<br>(5) Specimen source, when appropriate.<br>(6) The test result and, if applicable, the units of measurement or interpretation, or both.<br>(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br>• Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results as specified in 42 CFR 493.1291(d); and<br>• The information for corrected reports as specified in 42 CFR 493.1291(k)(2). | 1. Using the ONC-supplied VDT information and visual inspection, the tester verifies that the correct laboratory test report(s) are displayed in human readable format, and that the laboratory test report is complete and accurate.<br>2. Using visual inspection, the tester verifies that the Laboratory test report in step 1 includes:<br>• The Clinical Laboratory Improvement Amendments (CLIA) reporting data requirements specified at 42CFR 493.1291(c)(1) through (c)(7);<br>• The CLIA referenced values 493.1291(d); and<br>• The CLIA corrected report requirements specified at 42CFR 493.1291(k)(2). |
| (i)(A)(5) | <u>Diagnostic Imaging Report</u><br>The data presented includes the Diagnostic image report(s) when available. | Using the ONC-supplied VDT information and visual inspection, the tester verifies that the correct Diagnostic imaging report(s) are displayed in human readable format, and that the Diagnostic imaging report(s) are complete and accurate. |

(B) Download.

(1) Patients (and their authorized representatives) must be able to use technology to download an ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) in the following formats:

(i) Human readable format, and

(ii) The format specified in accordance to the standard specified in § 170.205(a)(4) following the CCD document template.

(2) When downloaded according to the standard specified in § 170.205(a)(4) following the CCD document template, the ambulatory summary or inpatient summary must include, at a minimum, the following data (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set):

(i) Ambulatory setting only. All of the data specified in paragraph (e)(1)(i)(A)(1), (2), (4), and (5).

(ii) Inpatient setting only. All of the data specified in paragraphs (e)(1)(i)(A)(1), and (3) through (5).

(3) Inpatient setting only. Patients (and their authorized representatives) must be able to download transition of care/referral summaries that were created as a result of a transition of care (pursuant to the capability expressed in the certification criterion specified in paragraph (b)(1) of this section).

Standards:

42 CFR 493.1291(c) The test report must indicate the following:

(1) For positive patient identification, either the patient's name and identification number or a unique patient identifier and identification number.

(2) The name and address of the laboratory location where the test was performed.

(3) The test report date.

(4) The test performed.

(5) Specimen source, when appropriate.

(6) The test result and, if applicable, the units of measurement or interpretation, or both.

(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

42 CFR 493.1291(d) Pertinent “reference intervals” or “normal” values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

42 CFR 493.1291(k)(2) When errors in the reported patient test results are detected, the laboratory must do the following: Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results.

§ 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1 (incorporated by reference in § 170.299).

Data Elements and Vocabularies applicable to the CCDS – Outlined in the Common Clinical Data Set Reference Document

§ 170.207(a)(4) International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), U.S. Edition, September 2015 Release,

§ 170.207(i) ICD-10-CM

**Test Data Instructions:**

Inpatient setting: 170.315_e1_vdt_inp_sample*.pdf (All samples)

Ambulatory setting: 170.315_e1_vdt_amb_sample*.pdf (All samples)
Inpatient setting: 170.315_e1_vdt_toc_inp_*_r2.1_sample*.xml (All samples)

Test Tool: ETT: Message Validators

| Criteria ¶ | System Under Test | Test Lab Verification |
|---|---|---|
| (i)(B)(1)(i) | Download in Human Readable Format<br>1. For each data set viewed in section (e)(1)(i)(A) step 2, a user role of patient uses the internet-based technology health IT function(s), to download an ambulatory or inpatient summary document formatted as a human readable document, which at the minimum contains the health information data identified in sections (e)(1)(i)(A)(1-5), as applicable. | Download in Human Readable Format<br>1. For each data set downloaded in step 1 of the SUT, the tester verifies that the data set can be downloaded using visual inspection, and uses the corresponding ONC-supplied VDT summary record information downloaded in (e)(1)(i)(A) step 1 of the SUT to verify that the downloaded ambulatory and/or inpatient summary, in human readable format, is accurate and without omission.<br>2. For the inpatient setting, the tester uses visual inspection to verify that the downloaded inpatient summary document in step 1 includes at a minimum, the following data as applicable:<br>• CCDS as specified in section (e)(1)(i)(A)(1);<br>• The Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization as specified in section (e)(1)(i)(A)(3);<br>• Laboratory test reports(s) as specified in section (e)(1)(i)(A)(4) when available; and<br>• Diagnostic imaging report(s) as specified in section (e)(1)(i)(A)(5) when available. |

| Criteria ¶ | System Under Test | Test Lab Verification |
|---|---|---|
| (i)(B)(1)(i), continued | See above | 3. For the ambulatory setting, the tester uses visual inspection to verify that the downloaded ambulatory summary document in step 1 includes at a minimum, the following data as applicable:<br>• CCDS as specified in section (e)(1)(i)(A)(1);<br>• The Provider's name and office contact information as specified in section (e)(1)(i)(A)(2);<br>• Laboratory test reports(s) when available as specified in section (e)(1)(i)(A)(4); and<br>4. Diagnostic imaging report(s) when available as specified in section (e)(1)(i)(A)(5).<br>5. Using visual inspection, the tester verifies that if included in the downloaded document in step 1, the laboratory report(s) are complete and accurate. The laboratory test report must include the Clinical Laboratory Improvement Amendments (CLIA) reporting data requirements specified at 42CFR 493.1291(c)(1) through (c)(7), the CLIA referenced values 493.1291(d), and the CLIA corrected report requirements specified at 42CFR 493.1291(k)(2).<br>6. Using visual inspection, the tester verifies that if included in the downloaded document in step 1, the diagnostic report is complete and accurate. |
| (i)(B)(1)(i) | <u>Authorized Downloader</u><br>2. For the data set viewed in section (e)(1)(i)(A) step 4, a user role of patient authorized representative uses the internet-based technology health IT function(s), to download an ambulatory or inpatient summary document formatted as a human readable document, which at a minimum contains the health information data identified in section (e)(1)(i)(A)(1-5), as applicable.<br>3. Negative Test: A user who is neither the patient identified in the patient record nor a patient's authorized representative attempts to access and download patient data and is prevented from doing so. | <u>Authorized Downloader</u><br>7. The tester verifies that a patient's authorized representative can download the patient health data in human readable format, and using the VDT instruction document and the download from step 2 of the SUT to perform the same verification as in steps 1-5.<br>8. Negative Test: Using visual inspection, the tester verifies that a user, who is neither the patient identified in the record nor the patient's authorized representative, does not have access to download the patient's health information. |

| Criteria ¶ | System Under Test | Test Lab Verification |
|---|---|---|
| (i)(B)(1)(ii) | <u>Download as a CCD</u><br>1. For each data set viewed in section (e)(1)(i)(A) step 2, a user role of patient uses the internet-based technology health IT function(s), to download an ambulatory or inpatient summary document in section (e)(1)(i)(B) that is formatted as a CCD document according to the standard specified in § 170.205(a)(4), HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU.<br>2. The user submits the downloaded CCD document from step 1 for verification. | <u>Download as a CCD</u><br>1. For each data set downloaded in step 1 of the SUT, the tester verifies that a CCD document has been downloaded using visual inspection.<br>2. For each CCD submitted in step 2 of the SUT, the tester uses the ETT: Message Validators – C-CDA R2.1 Validator to upload the CCD submitted by the SUT as a sender, by selecting "170.315_e1_VDT_Amb" or "170.315_e1_VDT_Inp" criteria and the corresponding ONC-supplied VDT summary record file name, and the tester executes the upload.<br>3. The tester uses the Validation Report produced by the ETT: Message Validators – C-CDA R2.1 Validator in step 2 to verify the validation report indicates passing without error to confirm that the VDT summary record is conformant to the standard adopted in § 170.205(a)(4) using the CCD document format, including: the presentation of the downloaded data is a valid coded document containing: |

| Criteria ¶ | System Under Test | Test Lab Verification |
|---|---|---|
| (i)(B)(1)(ii), continued | See above | • all of the required CCDS data elements as specified in sections (e)(1)(i)(A)(1);<br>• for the ambulatory setting, the Provider's Name and office contact information as specified in section (e)(1)(i)(A)(2);<br>• for the inpatient setting, admission and discharge dates and locations, discharge instructions and reason(s) for hospitalization) as specified in section (e)(1)(i)(A)(3);<br>• laboratory report(s) as specified in section (e)(1)(i)(A)(4), when available; and<br>• diagnostic imaging report(s) as specified in section (e)(1)(i)(A)(5), when available.<br><br>4. As required by the ONC—supplied VDT instruction document, the tester uses the ETT: Message Validators – C-CDA R2.1 Validator Message Content Report, created in step 2, to verify the additional checks for equivalent text the content of all section level narrative text. |

| Criteria ¶ | System Under Test | Test Lab Verification |
|---|---|---|
| (i)(B)(2) | <u>Download CCD - Human Readable Version</u><br>1. For each of the downloaded CCD documents in section (e)(1)(i)(B)(1)(ii), the VDT summary record downloaded must include at a minimum, the following human readable data with applicable standards:<br>• The Common Clinical Data Set;<br>• For the ambulatory setting only: Provider's name and office contact information;<br>• For the inpatient setting only: Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization;<br>• Laboratory test report(s) when available; and<br>• Diagnostic imaging report(s) when available. | <u>Download CCD - Human Readable Version</u><br>5. The tester uses the Message Content Report produced by the ETT: Message Validators – C-CDA R2.1 Validator in step 2 to verify that the submitted CCD document created by the Health IT module includes the following human readable data:<br>• The Common Clinical Data Set as specified in section (e)(1)(i)(A)(1);<br>• For the ambulatory setting only: Provider's name and office contact information as specified in section (e)(1)(i)(A)(2);<br>• For the inpatient setting only: Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization as specified in section (e)(1)(i)(A)(3);<br>• The tester verifies that Laboratory test report(s) are present as specified in section (e)(1)(i)(A)(4) when available; and<br>• The tester verifies that Diagnostic imaging report(s) are present as specified in section (e)(1)(i)(A)(5) when available. |

| Criteria ¶ | System Under Test | Test Lab Verification |
|---|---|---|
| (i)(B)(3) Optional | <u>Download Transition of Care/Referral Summary</u><br>1. For Health IT Modules certified in (b)(1), Transitions of Care, for the <u>inpatient setting only</u>, using the ETT: Message Validators – C-CDA R2.1 Validator, the health IT developer downloads the ONC-supplied transition of care/referral summary records through the sender download selection of "170.315_e1_VDT_Inp" and one of the transition of care/referral summaries files and executes the download. All of the transition of care/referral summary types: Continuity of Care, Referral Note and Discharge Summary are required.<br>2. Using the internet-based technology health IT function(s), the user role of patient downloads each of the VDT transitions of care/referral summary records downloaded from the ETT: Message Validators in step 1 formatted as a:<br>• Continuity of Care;<br>• Referral Note; and<br>• Discharge Summary document. | <u>Setup</u><br>1. For each transition of care/referral summary record document downloaded in step 1 of the SUT, the tester creates a human readable version to be used for verification.<br><u>Download Transition of Care/Referral Summary</u><br>2. Using visual inspection, the tester verifies that each of the VDT transition of care/referral summary records from SUT step 1 is downloaded using the internet-based technology health IT function(s).<br>3. Using visual inspection the tester verifies that each of the VDT transition of care/referral summary records downloaded from SUT step 2 is accurate and complete according to the human readable version in step 1.This includes verification at a minimum the following content as applicable:<br>• Common Clinical Data Set data elements as specified in the CCDS Reference Document;<br>• Encounter Diagnosis;<br>• Cognitive Status;<br>• Functional Status and<br>4. Discharge instructions |

(C) Transmit to third party. Patients (and their authorized representatives) must be able to:

(1) Transmit the ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) created in paragraph (e)(1)(i)(B)(2) of this section in accordance with both of the following ways:

(i) Email transmission to any email address, and

(ii) An encrypted method of electronic transmission.

(2) Inpatient setting only. Transmit transition of care/referral summaries (as a result of a transition of care/referral as referenced by (e)(1)(i)(B)(3)) of this section selected by the patient (or their authorized representative) in both of the ways referenced (e)(1)(i)(C)(1)(i) and (ii) of this section).

Standards:

42 CFR 493.1291(c) The test report must indicate the following:

(1) For positive patient identification, either the patient's name and identification number or a unique patient identifier and identification number.
(2) The name and address of the laboratory location where the test was performed.
(3) The test report date.
(4) The test performed.
(5) Specimen source, when appropriate.
(6) The test result and, if applicable, the units of measurement or interpretation, or both.
(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

42 CFR 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

42 CFR 493.1291(k)(2) When errors in the reported patient test results are detected, the laboratory must do the following: Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results.

§ 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1 (incorporated by reference in § 170.299).

§ 170.210(a)(2) Any encryption algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2, October 8, 2014

**Test Data Instructions:**

Inpatient setting: 170.315_e1_vdt_inp_sample*.pdf (All samples)

Ambulatory setting: 170.315_e1_vdt_amb_sample*.pdf (All samples)

Inpatient setting: 170.315_e1_vdt_toc_inp_*_r2.1_sample*.xml (All samples)

Test Tool: ETT: Message Validators

| Criteria ¶ | System Under Test | Test Lab Verification |
|---|---|---|
| (i)(C)(1)(i) | <u>Unencrypted Email Method</u><br>1. For each data set viewed in section (e)(1)(i)(A), a user role of patient uses the Health IT Module's internet-based technology, to transmit, via email, an ambulatory summary or inpatient summary as created in section (e)(1)(i)(B)(2) as a CCD document according to the standards specified in § 170.205(a)(4), HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, to a valid, third-party email address identified by the health IT developer.<br>2. The health IT developer accesses the third-party email account and verifies that the transmission was received and the correct ambulatory and/or inpatient summary is attached.<br><br><u>Authorized Email Transmission</u><br>3. For the test data set viewed in section (e)(1)(i)(A) step 4, a user role of patient authorized representative uses the Health IT Module's internet-based technology, to transmit, via email, an ambulatory summary or inpatient summary as created in section (e)(1)(i)(B)(2) as a CCD document according to the standards specified in § 170.205(a)(4), HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, to a valid, third-party email address identified by the health IT developer.<br>4. The health IT developer accesses the third-party email account and verifies that the transmission was received and the correct ambulatory and/or inpatient summary is attached.<br>5. Negative Test: A user who is neither the patient identified in the test record nor the patient's authorized representative attempts to access and transmit patient data and is prevented from doing so. | <u>Unencrypted Email Method</u><br>1. Using visual inspection, the tester verifies that each ambulatory or inpatient summary document transmitted in steps 1-2 of the SUT using an email transmission is received successfully by the third-party, developer-identified email address.<br>2. For each CCD document transmitted in step 2 of the SUT, the tester uses ETT: Message Validators – C-CDA R2.1 Validator to upload the CCD transmitted as a sender, by selecting "170.315_e1_VDT_ Amb" or "170.315_e1_VDT_ Inp" criteria and the corresponding ONC-supplied VDT summary record file name, and the tester executes the upload.<br>3. The tester uses the Validation Report produced by the ETT: Message Validators – C-CDA R2.1 Validator in step 2 to verify the validation report indicates passing without error to confirm that the VDT summary record is conformant to the standard adopted in § 170.205(a)(4) using the CCD document format, including: the presentation of the transmitted data is a valid coded document containing:<br>• all of the required CCDS data elements as specified in section (e)(1)(i)(A)(1);<br>• for the ambulatory setting the Provider's Name and office contact information as specified in section (e)(1)(i)(A)(2);<br>• for the inpatient setting Admission and discharge dates and locations, discharge instructions and reason(s) for hospitalization) as specified in section (e)(1)(i)(A)(3), when available;<br>• laboratory report(s) as specified in section (e)(1)(i)(A)(4), when available; and<br>• diagnostic imaging report(s) as specified in section (e)(1)(i)(A)(5) when available. |

| Criteria ¶ | System Under Test | Test Lab Verification |
|---|---|---|
| (i)(C)(1)(i), continued | See above | 4. As required by the corresponding ONC—supplied VDT instruction document, the tester uses the ETT: Message Validators –C-CDA R2.1 Validator Message Content Report created in step 2 to verify the additional checks for equivalent text the content of all section level narrative text.<br>5. The tester uses the ETT: Message Validators –C-CDA R2.1 Validator Message Content Report created in step 2 to verify that if included, the correct laboratory test report is displayed in human readable format, and that the laboratory test report is complete and accurate. The laboratory test report must include the CLIA reporting data requirements specified at 42CFR 493.1291(c)(1) through (c)(7), the CLIA referenced values 493.1291(d), and the CLIA corrected report requirements specified at 42CFR 493.1291(k)(2).<br>6. The tester uses the ETT: Message Validators -C-CDA R2.1 Validator Message Content Report created in step 2 to verify that if included, the correct diagnostic imaging report is displayed in human readable format, and that the diagnostic imaging report is complete and accurate.<br>7. The tester uses the Message Content Report produced by the ETT: Message Validators -C-CDA R2.1 Validator to verify that the transmitted health information in step 2 contains the data in human readable format with English terminology (i.e. non-coded representation of vocabulary/code sets) As specified in section (e)(1)(i)(A). |

| Criteria ¶ | System Under Test | Test Lab Verification |
|---|---|---|
| (i)(C)(1)(i) continued | See above | <u>Authorized Email Transmission</u><br>8. The tester verifies that a patient's authorized representative can transmit the patient health data as a CCD using an unencrypted email method by using the VDT instruction document and the transmission from step 3-4 of the SUT, performs the same verification as in steps 1-7.<br>9. Negative Test: Using visual inspection, the tester verifies that a user who is not the patient identified in the record and is not the patient's authorized representative does not have access to transmit the patient's health information. |

| Criteria ¶ | System Under Test | Test Lab Verification |
|---|---|---|
| (i)(C)(1)(ii) | <u>Encrypted Method</u><br>1. For data set viewed in (e)(1)(i)(A), a user role of patient uses the Health IT Module's internet-based technology to transmit an ambulatory summary or inpatient summary as created in section (e)(1)(i)(B)(2) as a CCD document according to the standards specified in § 170.205(a)(4), HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, to any third party using the developer-identified encrypted method of transmission.<br>2. The health IT developer accesses the account to which the encrypted message has been sent and verifies that the transmission was received with the correct ambulatory and/or inpatient summary.<br><br><u>Authorized Encrypted Transmission</u><br>3. For the data set viewed in section (e)(1)(i)(A) step 4, a user role of patient authorized representative uses the Health IT Module's internet-based technology to transmit an ambulatory summary or inpatient summary as created in section (e)(1)(i)(B)(2) as a CCD document according to the standards specified in § 170.205(a)(4), HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, to any third party using the developer-identified encrypted method of transmission.<br>4. The health IT developer accesses the account to which the encrypted message has been sent and verifies that the transmission was received and the correct ambulatory and/or inpatient summary is attached.<br>5. Negative Test: A user who is neither the patient identified in the test record nor a patient's authorized representative attempts to access and transmit patient data and is prevented from doing so. | <u>Encrypted Method</u><br>1. Using visual inspection, the tester verifies that for each ambulatory or inpatient transmitted in step 2 of the SUT using an encrypted transmission, that the message is received and successfully decrypted.<br>2. For each CCD document transmitted in step 2 of the SUT, the tester uses the ETT: Message Validators -C-CDA R2.1 Validator to upload the CCD transmitted as a sender, by selecting "170.315_e1_VDT_ Amb" or "170.315_e1_VDT_Inp" criteria and the corresponding ONC-supplied VDT summary record file name, and the tester executes the upload.<br>3. The tester uses the Validation Report produced by the ETT: Message Validators -C-CDA R2.1 Validator in step 2 to verify the validation report indicates passing without error to confirm that the VDT summary record is conformant to the standard adopted in § 170.205(a)(4) using the CCD document format and that the presentation of the transmitted data is a valid coded document as specified in(e)(1)(i)(A) containing;<br>• all of the required CCDS data elements as specified in section (e)(1)(i)(A)(1);<br>• for the ambulatory setting, the Provider's Name and office contact information as specified in section (e)(1)(i)(A)(2);<br>• for the inpatient setting, admission and discharge dates and locations, discharge instructions and reason(s) for hospitalization) as specified in section (e)(1)(i)(A)(3);<br>• laboratory report(s) as specified in section (e)(1)(i)(A)(4), when available; and<br>• diagnostic imaging report(s) as specified in section (e)(1)(i)(A)(5) when available. |

| Criteria ¶ | System Under Test | Test Lab Verification |
|---|---|---|
| (i)(C)(1)(ii), continued | See above | 4. As required by the corresponding ONC—supplied VDT instruction document, the tester uses the ETT: Message Validators -C-CDA R2.1 Validator Message Content Report created in step 2 to verify the additional checks for equivalent text for the content of all section level narrative text.<br>5. The tester uses the ETT: Message Validators -C-CDA R2.1 Validator Message Content Report created in step 2 to verify that if included, the correct laboratory test report is displayed in human readable format, and that the laboratory test report is complete and accurate. The laboratory test report must include the Clinical Laboratory Improvement Amendments (CLIA) reporting data requirements specified at 42CFR 493.1291(c)(1) through (c)(7), the CLIA referenced values 493.1291(d), and the CLIA corrected report requirements specified at 42CFR 493.1291(k)(2) using visual inspection.<br>6. The tester uses the ETT: Message Validators -C-CDA R2.1 Validator Message Content Report created in step 2 to verify that if included, the correct diagnostic imaging report is displayed in human readable format, and that the diagnostic imaging report is complete and accurate using visual inspection.<br>7. The tester uses the ETT: Message Validators -C-CDA R2.1 Validator Message Content Report created in step 2 to verify that the transmitted health information contains the data in human readable format with English terminology (i.e. non-coded representation of vocabulary/code sets) as specified in (e)(1)(i)(A), using visual inspection.<br><u>Authorized Encrypted Transmission</u><br>8. The tester verifies that a patient's authorized representative can transmit the patient health data as a CCD using an encrypted method by using the VDT instruction document and the view from step 3-4 of the SUT, performs the same verification as in steps 1-7. |

| Criteria ¶ | System Under Test | Test Lab Verification |
|---|---|---|
| (i)(C)(1)(ii), continued | See above | 9. Negative Test: Using visual inspection, the tester verifies that a user who is not the patient identified in the record and is not the patient's authorized representative does not have access to transmit the patient's health information. |
| (i)(C)(2) Optional | <u>Unencrypted Email Method - ToC</u><br>1. For Health IT Modules certified to (b)(1), Transitions of Care, for the inpatient setting only: a user role of patient uses the Health IT Module's internet-based technology to transmit, via email, to a valid, third-party email address identified by the health IT developer, each of the transitions of care/referral summary as downloaded in section (e)(1)(i)(B)(3) formatted as a:<br>• Continuity of Care;<br>• Referral Note; and<br>• Discharge Summary document.<br>2. The health IT developer accesses the third-party email account and verifies that the transmission was received and the correct ambulatory and/or inpatient summary is attached. | <u>Unencrypted Email Method - ToC</u><br>1. Using visual inspection, the tester verifies that each transitions of care/referral summary document, transmitted in steps 1-2 of the SUT using an email transmission, is received successfully by the third-party, developer-identified email address.<br><br>2. Using visual inspection, the tester verifies that each of the VDT transition of care/referral summary records transmitted in SUT step 2 is accurate and complete according to the human readable version as specified in section (e)(1)(i)(B)(3). |
| (i)(C)(2) Optional | <u>Encrypted Method - ToC</u><br>1. For Health IT Modules certified to (b)(1), Transitions of Care, for the inpatient setting only: a user role of patient uses the Health IT module's internet-based technology to transmit via the developer-identified encrypted method of transmission a transitions of care/referral summary as downloaded in section (e)(1)(i)(B)(3) formatted as a:<br>• Continuity of Care;<br>• Referral Note; and<br>• Discharge Summary document. | <u>Encrypted Method -ToC</u><br>1. Using visual inspection, the tester verifies that each transitions of care/referral summary document transmitted in step 2 of the SUT using an encrypted transmission is received, and the message is successfully decrypted.<br>2. Using visual inspection, the tester verifies that each of the VDT transition of care/referral summary records transmitted in SUT step 2 is accurate and complete according to the human readable version as specified in section (e)(1)(i)(B)(3). |

(D) <u>Timeframe selection.</u> With respect to the data available to view, download, and transmit as referenced paragraphs (e)(1)(i)(A), (B), and (C)), patients (and their authorized representatives) must be able to:

(1) Select data associated with a specific date (to be viewed, downloaded, or transmitted); and
(2) Select data within an identified date range (to be viewed, downloaded, or transmitted).

| Criteria ¶ | System Under Test | Test Lab Verification |
|---|---|---|
| (i)(D)(1) | 1. The user role of patient requests to view, download, and transmit the data in sections (e)(1)(i)(A), (e)(1)(i)(B), and (e)(1)(i)(C) for a specific date.<br>2. The user role of patient authorized representative requests to view, download, and transmit the data in sections (e)(1)(i)(A), (e)(1)(i)(B), and (e)(1)(i)(C) for a specific date. | 1. The tester verifies that the patient and their authorized representative can view the health information as specified in section (e)(1)(i)(A) for a selected date and that the viewed health information data associated with that date is accurate and without omission.<br>2. The tester verifies that the patient and their authorized representative can download the health information as specified in section (e)(1)(i)(B) for a selected date and that the downloaded health information data associated with that date is accurate and without omission.<br>3. The tester verifies that the patient and their authorized representative can transmit the health information to a 3rd party as specified in section (e)(1)(i)(C) for a selected date and that the transmitted health information data associated with that date is accurate and without omission. |

| Criteria ¶ | System Under Test | Test Lab Verification |
|---|---|---|
| (i)(D)(2) | 1. The user role of patient requests to view, download, and transmit the data in sections (e)(1)(i)(A), (e)(1)(i)(B), and (e)(1)(i)(C) for a date range.<br>2. The user role of patient authorized representative requests to view, download, and transmit the data in sections (e)(1)(i)(A), (e)(1)(i)(B), and (e)(1)(i)(C) for a date range. | 1. The tester verifies that the patient and their authorized representative can view the health information as specified in section (e)(1)(i)(A) for a selected date range and that the viewed health information data associated with that date range is accurate and without omission.<br>2. The tester verifies that the patient and their authorized representative can download the health information as specified in section(e)(1)(i)(B) for a selected date range and that the downloaded health information data associated with that date range is accurate and without omission.<br>3. The tester verifies that the patient and their authorized representative can transmit the health information to a 3rd party as specified in section (e)(1)(i)(C) for a selected date range and that the transmitted health information data associated with that date range is accurate and without omission. |

**(e)(1)(ii) Activity History Log**

(A) When any of the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section are used, the following information must be recorded and made accessible to the patient (and their authorized representatives):

(1) The action(s) (i.e., view, download, transmission) that occurred;

(2) The date and time each action occurred in accordance with the standard specified in § 170.210(g);

(3) The user who took the action; and

(4) Where applicable, the addressee to whom an ambulatory summary or inpatient summary was transmitted.

(B) Technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of this section if it is also certified to the certification criterion specified in § 170.315(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) of this section is accessible by the patient (and their authorized representatives).

Standards:

§ 170.210(g): RFC 5905:Network Time Protocol Version 4: Protocol and Algorithms Specification, June 2010

§ 170.210(g): (RFC) 1305: Network Time Protocol (Version 3) Specification, Implementation and Analysis, March 1992Web Site Disclaimers

| Criteria ¶ | System Under Test | Test Lab Verification |
|---|---|---|
| (ii)(A) | 1. When a user utilizes the view, download, or transmit to a third party capabilities as specified in sections (e)(1)(i)(A) through capabilities (e)(1)(i)(C), the Health IT Module record a new activity log entry for the following actions related to electronic health information:<br>• View of patient information;<br>• Download patient information; and<br>• Transmit patient information.<br>2. For each action, the activity log entry includes:<br>• Type of action;<br>• Date and time of event in accordance with the standard specified in § 170.210(g), RFC 5905 or § 170.210(g), RFC 1305<br>• User identification; and<br>• To whom the transmission was sent (if applicable). | 1. The tester verifies that the Health IT Module has certified to the certification criterion specified in § 170.315(d)(2) using Documentation or the tester verifies via visual inspection that for all required actions, an activity log entry related to each action taken has been generated correctly and without omission, containing:<br>• The actions that occurred;<br>• The date/time, specified in accordance to the standard specified in §170.210(g);<br>• User who took the action; and<br>• Addressee to whom the transmission was sent (if applicable). |
| (ii)(B) | The user role of patient **(and their authorized representatives)** accesses the activity history log in the Health IT Module. | The tester verifies that the activity history log created in section (e)(1)(ii)(A) is accessible by a patient **(and their authorized representatives)**, and that it contains all of the activity associated to the patient record. |

## Document History

| Version Number | Description of Change | Date |
|---|---|---|
| 1.0 | Final Test Procedure | January 20, 2016 |

| Version Number | Description of Change | Date |
|---|---|---|
| 1.1 | Updated language in (i) Test Lab Verification step 3 to removed reference to web page.<br>Provided standards link for 170.210(g) (RFC) 1305.<br>Removed the 2 references to the ToC Ambulatory xml files as these are not required for (e)(1) - Inpatient ONLY.<br>Addition of the word "files" to clarify the instructions on what needs to be downloaded for the Inpatient ToC xml files.<br>Updated (i)(B)(3) to optional from conditional | March 21, 2016 |
| 1.2 | In section (e)(1)(ii) Activity History Log authorized representatives was added | April 14, 2016 |
| 1.3 | Updated language in (i) Test Lab Verification step 3 to removed reference to web page.<br>Provided standards link for 170.210(g) (RFC) 1305.<br>Removed the 2 references to the ToC Ambulatory xml files as these are not required for (e)(1) - Inpatient ONLY.<br>Addition of the word "files" to clarify the instructions on what needs to be downloaded and transmitted for the Inpatient ToC xml files.<br>Updated (i)(C)(2) to optional from conditional. | May 7, 2016 |

Dependencies: For all related and required criteria, please refer to the Master Table of Related and Required Criteria.