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| 2015 Edition §170.315(e)(1) View, Download, and Transmit to Third Party (VDT) | | | | | |
| Testing Components: | | | | | |
|  |  |  |  | Data |  |
| Test Procedure Version 1.1 – Last Updated 10/30/15 | | | | | |

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](#)

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).

§ 170.207(b)(3) [CDT](#)

§ 170.207(b)(2) [CPT-4](#)

§ 170.207(f)(2) [“Race & Ethnicity – CDC” code system in the PHIN Vocabulary Access and Distribution System \(VADS\), Release 3.3.9](#)

§ 170.207(e)(4) [National Drug Code Directory– Vaccine Codes, updates through August 3, 2015](#)

§ 170.207(b)(4) [ICD-10-PCS](#)

§ 170.207(i) [ICD-10-CM](#)

§ 170.207(p)(1) [IHE IT Infrastructure Technical Framework Volume 2b \(ITI TF-2b\)](#)

§ 170.207(e)(3) [HL7 Standard Code Set CVX—Vaccines Administered, updates through June 18, 2015](#)

§ 170.207(f)(1) [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](#)

§ 170.207(c)(3) [Logical Observation Identifiers Names and Codes \(LOINC®\) Database version 2.52](#)

§ 170.207(m)(1) [The Unified Code of Units of Measure, Revision 1.9](#)

§ 170.207(g)(2) [Request for Comments \(RFC\) 5646: Tags for Identifying Languages](#)

§ 170.207(q)(1) [International Telecommunication Union E.123:Notation for national and international telephone numbers, e-mail addresses and web addresses and International and Telecommunication Union E. 164: The international public telecommunication numbering plan](#)

§ 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(d)(3) [RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release](#)

§ 170.207(h) 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

§ 170.207(n)(1) Birth sex must be coded in accordance with HL7 Version 3 attributed as follows:

- (i) Male. M
- (ii) Female. F
- (iii) Unknown. UNK

§ 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](#)

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

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_b1_toc_inp_sample*.pdf (All samples)
- Ambulatory setting: 170.315_b1_toc_amb_sample*.pdf (All samples)

| Criteria ¶ | System Under Test | Test Lab Verification |
|------------|---|---|
| (i)(A) | <p><u>Web Content Accessibility</u></p> <ol style="list-style-type: none"> 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. | <p><u>Web Content Accessibility</u></p> <ol style="list-style-type: none"> 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 testing results documentation. 2. Using the submitted testing results for WCAG Conformance (see http://www.w3.org/WAI/WCAG2-Conformance) 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. 3. The tester verifies that for each internet-based Health IT technology associated with the view, download, or transmit capabilities, the correct scope has been defined along with the use of web pages for testing; and that all of this information is documented as part of the submitted documentation provided in Step 1. |

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| (i)(A)(1)-(3) | <ol style="list-style-type: none"> 1. Based upon the health IT setting(s) (i.e. ambulatory and/or inpatient), a user enters the VDT summary record information for each of the ambulatory and/or inpatient test cases referenced from the VDT summary record documents into the Health IT module. All test cases for a given health IT setting are required. The user retrieves the required VDT instructions for entering data into the Health IT module from the top-level C-CDA Validator, one of the tool selections within the Edge Testing Tool. 2. Using the C-CDA Validator, the user selects the ambulatory and/or inpatient VDT documents (pdf) and selects download to download the required VDT information documents. 3. Using ONC-supplied test data instructions and the internet-based technology Health IT function(s), a user role of patient views at a minimum the Common Clinical Data Set in a non-coded representation (i.e. English) when applicable, including: <ul style="list-style-type: none"> • Patient Name • Sex constrained including birth sex • Date of Birth • Race and Ethnicity • Preferred language • Smoking Status • Problems constrained • Medications constrained • Medication Allergies • Laboratory Tests constrained • Laboratory Values(s)/Result(s). • Vital Signs • Procedures constrained • Care Team Member(s) • Immunizations constrained • Unique Device Identifier(s) for a Patient’s Implantable Device(s) • Assessment and Plan of Treatment | <ol style="list-style-type: none"> 1. For each test case, using visual inspection, the tester verifies that the patient health data that has been entered into the Health IT module is accurate and without omission. 2. For each test case, using visual inspection and the corresponding VDT summary record document, the tester verifies that accurate patient health information can be viewed by the patient using the internet-based technology Health IT function(s) without omission. 3. Using Visual Inspection, the tester verifies that the presentation of the Common Clinical Data Set in step 2 is in human readable format with English terminology (i.e. non-coded representation of vocabulary/code sets), and present where applicable. 4. Using Visual Inspection, the tester verifies that the view presented in step 2 in the case of an <u>ambulatory setting</u> includes the Provider’s Name and Office contact information is present. 5. Using Visual Inspection, the tester verifies that the view presented in step 2 in the case of an <u>inpatient setting</u> includes the Admissions and Discharge dates and locations, Discharge instructions and Reason(s) for hospitalization are present. 6. 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 view the patient’s health information. |

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| | <ul style="list-style-type: none"> • Goals • Health Concerns • The complete list of the Common Clinical Data Set and associated standards can be referenced in Table 8 of the Final Rule. <p>4. For Ambulatory Setting only, non-coded representation (i.e. English) will also include:</p> <ul style="list-style-type: none"> • Provider’s Name; and • Office contact information. <p>5. For Inpatient Setting only, non-coded representation (i.e. English) will also include:</p> <ul style="list-style-type: none"> • Admissions and Discharge dates and locations; • Discharge instructions; and • Reason(s) for hospitalization. <p>6. Using ONC-supplied test data instructions 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 3, 4, and 5.</p> <p>7. Negative Test: A user who is neither the patient identified in the test record nor the patient’s authorized representative attempts to access and view patient data and is prevented from doing so.</p> | |

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| (i)(A)(4) | <ol style="list-style-type: none"> 1. Using ONC-supplied VDT information which has been previously downloaded and the internet-based technology Health IT function(s), a user role of patient views Laboratory test report(s) when available, including the following information: <ul style="list-style-type: none"> • The test report must indicate the following information as specified in 42 CFR 493.1291(c)(1) through (7): <ol style="list-style-type: none"> (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. • 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 • The information for corrected reports as specified in 42 CFR 493.1291(k)(2). 2. A user role of authorized representative views the Laboratory test report(s), from step 1. | <ol style="list-style-type: none"> 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. 2. Using visual inspection, the Laboratory test report in step 1 includes: <ul style="list-style-type: none"> • 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). |

| Criteria ¶ | System Under Test | Test Lab Verification |
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| (i)(A)(5) | <ol style="list-style-type: none"> 1. Using ONC-supplied VDT information which has been previously download and the internet-based technology Health IT function(s), a user role of patient views Diagnostic image report(s) when available. 2. A user role of authorized representative view the Diagnostic image report from step 1. | <ol style="list-style-type: none"> 1. 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).
- § 170.207(b)(3) [CDT](#)
- § 170.207(b)(2) [CPT-4](#)
- § 170.207(f)(2) [“Race & Ethnicity – CDC” code system in the PHIN Vocabulary Access and Distribution System \(VADS\), Release 3.3.9](#)
- § 170.207(e)(4) [National Drug Code Directory– Vaccine Codes, updates through August 3, 2015](#)
- § 170.207(b)(4) [ICD-10-PCS](#)
- § 170.207(i) [ICD-10-CM](#)
- § 170.207(p)(1) [IHE IT Infrastructure Technical Framework Volume 2b \(ITI TF-2b\)](#)
- § 170.207(e)(3) [HL7 Standard Code Set CVX—Vaccines Administered, updates through June 18, 2015](#)
- § 170.207(f)(1) [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](#)
- § 170.207(c)(3) [Logical Observation Identifiers Names and Codes \(LOINC®\) Database version 2.52](#)
- § 170.207(m)(1) [The Unified Code of Units of Measure, Revision 1.9](#)
- § 170.207(g)(2) [Request for Comments \(RFC\) 5646: Tags for Identifying Languages](#)
- § 170.207(q)(1) [International Telecommunication Union E.123:Notation for national and international telephone numbers, e-mail addresses and web addresses and International and Telecommunication Union E. 164: The international public telecommunication numbering plan](#)
- § 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(d)(3) [RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release](#)
- § 170.207(h) 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
- § 170.207(n)(1) Birth sex must be coded in accordance with HL7 Version 3 attributed as follows:
- (i) Male. M
 - (ii) Female. F
 - (iii) Unknown. UNK
- § 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](#)

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

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_b1_toc_inp_sample*.pdf (All samples)

Ambulatory setting: 170.315_b1_toc_amb_sample*.pdf (All samples)

| Criteria ¶ | System Under Test | Test Lab Verification |
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| (i)(B)(1)(i) | <ol style="list-style-type: none"> 1. The VDT summary record information entered into the Health IT Module in (e)(1)(i)(A) must be used. All test cases for a given health IT setting are required. 2. For each test case identified in (e)(1)(i)(A), 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 (e)(1)(i)(A). 3. For each test case identified in (e)(1)(i)(A), 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 the minimum contains the health information data identified in (e)(1)(i)(A). 8. Negative Test: A user who is neither the patient identified in the test record nor a patient’s authorized representative attempts to access and download patient data and is prevented from doing so. | <ol style="list-style-type: none"> 1. For each test case, using the ONC-supplied VDT summary record information downloaded in (e)(1)(i)(A) the tester verifies that the downloaded ambulatory and/or inpatient summary(ies) are accurate and without omission using visual inspection. The Common Clinical Data Set presents in human readable format with English terminology (i.e. non-coded representation of vocabulary/code sets), where applicable, as specified in (e)(1)(i)(A). 2. Using visual inspection, the tester verifies that the downloaded document in step 1 includes the Provider’s Name and Office contact information as specified in (e)(1)(i)(A) for the ambulatory summary records. 3. Using visual inspection, the tester verifies that the downloaded document in step 1 includes the Admissions and Discharge dates and locations, Discharge instructions and Reason(s) for hospitalization as specified in (e)(1)(i)(A) for the inpatient summary records. 4. Using visual inspection, the tester verifies that if included in the downloaded document in step 1, the laboratory report(s) are complete and accurate, and is present as specified in (e)(1)(i)(A), and includes |

| Criteria ¶ | System Under Test | Test Lab Verification |
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| (i)(B)(1)(i) | | <ul style="list-style-type: none"> • The Laboratory Improvement Amendments (CLIA) reporting data requirements specified at 42CFR 493.1291(c)(1) through (c)(7): <ol style="list-style-type: none"> (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. • 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 • The information for corrected reports as specified at 42CFR 493.1291(k)(2). <ol style="list-style-type: none"> 5. Using Visual Inspection, the tester verifies that if included in the downloaded document in step 1, the diagnostic report is complete and accurate. 6. 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 download the patient’s health information. |

| Criteria ¶ | System Under Test | Test Lab Verification |
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| <p>(i)(B)(1)(ii)</p> | <ol style="list-style-type: none"> 1. The VDT summary record information entered into the Health IT Module in (e)(1)(i)(A) must be used. All test cases for a given health IT setting are required. 2. For each test case identified in (e)(1)(i)(A), a user role of patient uses the internet-based technology Health IT function(s), to download an ambulatory or inpatient summary document in (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. 3. For each test case identified in (e)(1)(i)(A), a user role of patient authorized representative uses the internet-based technology Health IT function(s), to download an ambulatory or inpatient summary document in (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. | <ol style="list-style-type: none"> 1. For each test case, using the ONC-supplied VDT summary record information downloaded in (e)(1)(i)(A), the tester verifies that for each test case the VDT summary records are downloaded using the internet-based technology Health IT function(s), using visual inspection. 2. Validation of a VDT CCD document is done using the C-CDA Validator, one of the tool selections within the Edge Testing Tool. To validate the VDT CCD (xml file) downloaded by the Health IT module, the tester uses the C-CDA Validator Tool within the Edge Testing Tool to select the criteria to be verified based upon the originally downloaded test case document and upload the VDT summary record created by the Health IT module. 3. For each test case, the tester uploads the VDT summary record xml file downloaded by the Health IT Module into the C-CDA Validator Tool within the Edge Testing Tool for validation based on each test case listed, and uses the Validation Report produced by the test tool 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. 4. As required by the test case, the tester uses the ONC-supplied VDT summary record instructions and the VDT summary record document uploaded in step 3 to verify through visual inspection the additional checks for equivalent text for content for all section level narrative text. |

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| (i)(B)(2) | <p>1. For each of the test cases in (e)(1)(B)(ii), the VDT summary record downloaded in (i)(B)(1)(ii) must include at a minimum, the following data with applicable standards:</p> <ul style="list-style-type: none"> • The Common Clinical Data Set • For the ambulatory setting only: Provider’s name and office contact information • For the inpatient setting only: Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization • Laboratory test report(s) when available. • Diagnostic imaging report(s) when available. | <p>5. For each test case in (e)(1)(B)(ii), the tester verifies using the C-CDA Validator, one of the tool selections within the Edge Testing Tool. To validate the VDT CCD (xml file) downloaded by the Health IT module, the tester uses the C-CDA Validator Tool within the Edge Testing Tool to select the criteria to be verified based upon the originally downloaded test case document and upload the VDT summary record created by the Health IT module to verify that the following data is included:</p> <ul style="list-style-type: none"> • The Common Clinical Data Set • For the ambulatory setting only: Provider’s name and office contact information • For the inpatient setting only: Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization • Laboratory test report(s) when available. • Diagnostic imaging report(s) when available. |

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| (i)(B)(3) | <ul style="list-style-type: none"> • The VDT summary record information entered into the Health IT Module in (e)(1)(i)(A) must be used. All test cases for a given health IT setting are required. • For Health IT Modules certified in (b)(1), Transitions of Care, for the inpatient setting only; using the internet-based technology Health IT function(s), the patient and their authorized representatives download a transitions of care/referral summary created in accordance with § 170.315(b)(1) Transitions of Care (Criteria (b)(1)(iii), formatted as one of the documents created by § 170.315(b)(1) according to the standard specified in § 170.205(a)(4), HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU: <ul style="list-style-type: none"> • Continuity of Care; • Referral Note; and • Discharge Summary document. | <ol style="list-style-type: none"> 1. The tester verifies that for each test case the VDT transition of care/referral summary records are downloaded using the internet-based technology Health IT function(s) using visual inspection. 2. Validation of a VDT Transition of Care/Referral summary document is done using C-C-CDA Validator Tool within the Edge Testing Tool. To validate the VDT Transition of Care/Referral summary document (xml file) the tester uses the C-CDA Validator Tool within the Edge Testing Tool to select the criteria to be verified based upon the originally downloaded test case document and uploads the VDT summary record created by the Health IT module. 3. For each test case, the tester uploads the corresponding VDT Transition of Care/Referral summary xml file from step 2, and selects validate. 4. The tester uses the Validation Report produced by the test tool to verify the validation report indicates passing without error to confirm that the transition of care/referral summary record is conformant as specified by § 170.315(b)(1). This includes verification that the downloaded document is: <ul style="list-style-type: none"> • Formatted as an accurate transitions of care/referral summary document in accordance with the standard specified at minimum § 170.205(a)(4). • The content of the transitions of care/referral summary document includes at a minimum the Common Clinical Data Set which is in accordance to § 170.315(b)(1) Transitions of Care (Criteria iii). • Encounter Diagnoses as specified in § 170.315(b)(1) Transitions of Care (Criteria (iii)(B)). • Cognitive status as specified in § 170.315(b)(1) Transitions of Care (Criteria (iii)(C)). |

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| | <ul style="list-style-type: none"> • | <ul style="list-style-type: none"> • Functional status as specified in § 170.315(b)(1) Transitions of Care (Criteria (iii)(D)). • Discharge instructions as specified in § 170.315(b)(1) Transitions of Care (Criteria (iii)(F)). • Patient match data as specified in § 170.315(b)(1) Transitions of Care (Criteria (iii)(G)). <p>As required by the test case, the tester uses the ONC-supplied transition of care/referral summary record instructions and the transition of care/referral summary record document downloaded in step 1 to verify through visual inspection the additional checks for equivalent text for content for all section level narrative text.</p> |

(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).
- § 170.207(b)(3) [CDT](#)
- § 170.207(b)(2) [CPT-4](#)
- § 170.207(f)(2) [“Race & Ethnicity – CDC” code system in the PHIN Vocabulary Access and Distribution System \(VADS\), Release 3.3.9](#)
- § 170.207(e)(4) [National Drug Code Directory– Vaccine Codes, updates through August 3, 2015](#)
- § 170.207(b)(4) [ICD-10-PCS](#)
- § 170.207(i) [ICD-10-CM](#)
- § 170.207(p)(1) [IHE IT Infrastructure Technical Framework Volume 2b \(ITI TF-2b\)](#)
- § 170.207(e)(3) [HL7 Standard Code Set CVX—Vaccines Administered, updates through June 18, 2015](#)
- § 170.207(f)(1) [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](#)
- § 170.207(c)(3) [Logical Observation Identifiers Names and Codes \(LOINC®\) Database version 2.52](#)
- § 170.207(m)(1) [The Unified Code of Units of Measure, Revision 1.9](#)
- § 170.207(g)(2) [Request for Comments \(RFC\) 5646: Tags for Identifying Languages](#)
- § 170.207(q)(1) [International Telecommunication Union E.123:Notation for national and international telephone numbers, e-mail addresses and web addresses and International and Telecommunication Union E. 164: The international public telecommunication numbering plan](#)
- § 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(d)(3) [RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release](#)
- § 170.207(h) 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
- § 170.207(n)(1) Birth sex must be coded in accordance with HL7 Version 3 attributed as follows:
- (i) Male. M
 - (ii) Female. F
 - (iii) Unknown. UNK
- § 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](#)

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

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_b1_toc_inp_sample*.pdf (All samples)

Ambulatory setting: 170.315_b1_toc_amb_sample*.pdf (All samples)

| Criteria ¶ | System Under Test | Test Lab Verification |
|--------------|---|---|
| (i)(C)(1)(i) | <p><u>Unsecure Email Method</u></p> <ol style="list-style-type: none"> For each test case identified in (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 (e)(1)(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. 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. For each test case identified in (e)(1)(i)((A) 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 (e)(1)(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. | <p><u>Unsecure Email Method</u></p> <ol style="list-style-type: none"> Using visual inspection, the tester verifies that for the appropriate setting(s) (i.e. ambulatory or inpatient setting), the patient and their authorized representative can transmit the appropriate summary document using an email transmission and that the email is received successfully by the third-party developer-identified email address. Validation of a VDT CCD document is done using the C-CDA Validator, one of the tool selections within the Edge Testing Tool. To validate the VDT CCD (xml file) transmitted by the Health IT Module, the tester uses the C-CDA Validator Tool within the Edge Testing Tool to select the criteria to be verified based upon the originally transmitted test case document and upload the VDT summary record created by the Health IT Module in (e)(1)(i)(A). For each test case, the tester uploads the transmitted VDT summary record xml file transmitted into the C-C-CDA Validator into the C-C-CDA Validator Tool within the Edge Testing Tool for validation based on each test case listed, and uses the Validation Report produced by the test tool to verify the Health IT module passes without error to confirm that the VDT summary record is conformant to the standard adopted in § 170.205(a)(4) using the |

| Criteria ¶ | System Under Test | Test Lab Verification |
|------------|---|---|
| | <p>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.</p> <p>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.</p> | <p>CCD document format including: the presentation of the transmitted data is a valid coded document containing</p> <ul style="list-style-type: none"> • all of the required CCDS data elements • for the ambulatory setting the Provider's Name and office contact information, • for the inpatient setting Admission and discharge dates and locations, discharge instructions and reason(s) for hospitalization) • laboratory report(s) • diagnostic imaging report(s) • data elements specified in (e)(1)(A). <p>4. The tester verifies 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 (e)(1)(i)(A) using visual inspection.</p> <p>5. As required by the test case, the tester uses the ONC-supplied VDT summary record instructions and the VDT summary record document transmitted in step 3 to verify through visual inspection the additional checks for equivalent text for content for all section level narrative text.</p> <p>6. Using visual inspection, the tester verifies 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).</p> <p>7. The tester verifies that if included the correct diagnostic imaging report is displayed in human readable format, and that the</p> |

| Criteria ¶ | System Under Test | Test Lab Verification |
|------------|-------------------|--|
| | | <p>6. diagnostic imaging report is complete and accurate using Visual Inspection.</p> <p>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.</p> |

| Criteria ¶ | System Under Test | Test Lab Verification |
|---------------|---|---|
| (i)(C)(1)(ii) | <p><u>Encrypted Method</u></p> <ol style="list-style-type: none"> 1. For each test case identified 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 (e)(1)(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. 2. The Health IT developer accesses the account to which the encrypted message has been sent verifies that the transmission was received and the correct ambulatory and/or inpatient summary is attached. 3. For each test case identified in (e)(1)(i)(A), 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 (e)(1)(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. 4. The Health IT developer accesses the account to which the encrypted message has been sent verifies that the transmission was received and the correct ambulatory and/or inpatient summary is attached. 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. | <p><u>Encrypted Method</u></p> <ol style="list-style-type: none"> 1. Using visual inspection, the tester verifies that for the appropriate setting(s) (i.e. ambulatory or inpatient setting), the patient and their authorized representative can transmit the appropriate summary document using an encrypted transmission and that the message is received and successfully decrypted. 2. Validation of a VDT CCD document is done using the C-CDA Validator, one of the tool selections within the Edge Testing Tool. To validate the VDT CCD (xml file) created by the Health IT Module, the tester uses the C-CDA Validator Tool within the Edge Testing Tool to select the criteria to be verified based upon the originally transmitted test case document and upload the VDT summary record created by the Health IT module. 3. For each test case, the tester uploads the VDT summary record xml file created by the Health IT module into the C-CDA Validator Tool within the Edge Testing Tool for validation based on each test case listed, and uses the Validation Report produced by the test tool to verify the Health IT module passes 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; <ul style="list-style-type: none"> • all of the required CCDS data elements; • for the ambulatory setting the Provider's Name and office contact information; • for the inpatient setting Admission and discharge dates and locations, discharge instructions and reason(s) for hospitalization); • laboratory report(s); • diagnostic imaging report(s); • data elements specified in (e)(1)(A). |

| Criteria ¶ | System Under Test | Test Lab Verification |
|------------|-------------------|---|
| | | <ol style="list-style-type: none"> 4. The tester verifies that the transmitted health information in step 3 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 the visual inspection. 5. As required by the test case, the tester uses the ONC-supplied VDT summary record instructions and the VDT summary record document transmitted in step 3 to verify through visual inspection the additional checks for equivalent text for content for all section level narrative text. For Inpatient Setting only: Discharge Instructions 6. The tester verifies 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. 7. The tester verifies 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. <p>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.</p> |

| Criteria ¶ | System Under Test | Test Lab Verification |
|------------|--|--|
| (i)(C)(2) | <p><u>Unsecure Email Method</u></p> <ol style="list-style-type: none"> For Health IT Modules certified in (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, a transitions of care/referral summary as downloaded in (e)(1)(i)(B)(3) and created in accordance to § 170.315(b)(1) Transitions of Care (Criteria (b)(1)(iii)), formatted as one of the document created by§ 170.315(b)(1) according to the standard specified in § 170.205(a)(4), HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU: <ul style="list-style-type: none"> Continuity of Care; Referral Note; and Discharge Summary document. 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. For Health IT Modules certified in (b)(1), Transitions of Care, for the inpatient setting only: a user role of patient authorized representative 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, a transitions of care/referral summary as downloaded in (e)(1)(i)(B)(3) and created in accordance to § 170.315(b)(1) Transitions of Care (Criteria (b)(1)(iii)), formatted as one of the document created by§ 170.315(b)(1) according to the standard specified in § 170.205(a)(4), HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU: <ul style="list-style-type: none"> Continuity of Care; Referral Note; and | <p><u>Unsecure Email Method</u></p> <ol style="list-style-type: none"> Using visual inspection, the tester verifies that for the transitions of care/referral summary document, the patient and their authorized representative can transmit the appropriate summary document using an email transmission and that the email is received successfully by the third-party developer-identified email address. Validation of a VDT transition of care/referral summary document is done using the C-CDA Validator, one of the tool selections within the Edge Testing Tool. To validate the VDT transition of care/referral summary (xml file) created by the Health IT Module, the tester uses the C-CDA Validator Tool within the Edge Testing Tool to select the criteria to be verified based upon the originally transmitted test case document and upload the VDT transition of care/referral record created by the Health IT module in (e)(1)(i)(A). For each test case, the tester uploads the transmitted VDT Transition of care/referral summary xml into the C-CDA Validator within the Edge Testing Tool for validation based on each test case listed, and uses the Validation Report produced by the test tool to verify the Health IT module passes without error to confirm that the transition of care/referral summary record is conformant to the standard as specified in (e)(1)(i)(B)(3). As required by the test case, the tester uses the ONC-supplied VDT summary record instructions and the VDT summary record document transmitted in step 1 to verify through visual inspection the additional checks for equivalent text for content for all section level narrative text. 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 |
|------------|--|-----------------------|
| | <ul style="list-style-type: none"> • Discharge Summary document. <ol style="list-style-type: none"> 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. 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. | |

| Criteria ¶ | System Under Test | Test Lab Verification |
|------------|--|---|
| (i)(C)(2) | <p><u>Encrypted Method</u></p> <ol style="list-style-type: none"> For Health IT modules certified in (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 (e)(1)(i)(B)(3) and created in accordance to § 170.315(b)(1) Transitions of Care (Criteria (b)(1)(iii)), formatted as one of the document created by § 170.315(b)(1) according to the standards specified in § 170.205(a)(4), HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU: <ul style="list-style-type: none"> Continuity of Care; Referral Note; and Discharge Summary document. For Health IT modules certified in (b)(1), Transitions of Care, for the inpatient setting only: a user role of patient authorized user 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 (e)(1)(i)(B)(3) and created in accordance to § 170.315(b)(1) Transitions of Care (Criteria (b)(1)(iii)), formatted as one of the document created by § 170.315(b)(1) according to the standards specified in § 170.205(a)(4), HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU: <ul style="list-style-type: none"> Continuity of Care; Referral Note; and Discharge Summary document. 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. | <p><u>Encrypted Method</u></p> <ol style="list-style-type: none"> Using visual inspection, the tester verifies that for transitions of care/referral summary document, the patient and their authorized representative can transmit the appropriate summary document using an encrypted transmission and that the message is received and successfully decrypted. Validation of a VDT transition of care/referral summary document is done using the C-CDA Validator, one of the tool selections within the Edge Testing Tool. To validate the VDT transition of care/referral summary (xml file) created by the Health IT module, the tester uses the C-CDA Validator Tool within the Edge Testing Tool to select the criteria to be verified based upon the originally transmitted test case document and upload the VDT transition of care/referral summary created by the Health IT Module in (e)(1)(i)(A). For each test case, the tester uploads the transmitted VDT Transition of care/referral summary xml into the C-CDA Validator within the Edge Testing Tool for validation based on each test case listed, and uses the Validation Report produced by the test tool to verify the Health IT module passes without error to confirm that the transition of care/referral summary record is conformant to the standard as specified in (e)(1)(i)(B)(3).. As required by the test case, the tester uses the ONC-supplied VDT summary record instructions and the VDT summary record document transmitted in step 1 to verify through visual inspection the additional checks for equivalent text for content for all section level narrative text using visual inspection: 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. |

(D) Timeframe selection. 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) | <ol style="list-style-type: none"> 1. The user role of patient requests to view, download, and transmit the data in (e)(1)(i)(A), (B), and (C) for a specific date. 2. The user role of patient authorized representative requests to view, download, and transmit the data in (e)(1)(i)(A), (B), and (C) for a specific date. | <ol style="list-style-type: none"> 1. The tester verifies that the patient and their authorized representative can view the health information as specified in (e)(1)(A) for a selected date and that the viewed health information data associated with that date is accurate and without omission. 2. The tester verifies that the patient and their authorized representative can download the health information as specified in (e)(1)(B) for a selected date and that the downloaded health information data associated with that date is accurate and without omission. 3. The tester verifies that the patient and their authorized representative can transmit the health information to a 3rd party as specified in (e)(1)(C) for a selected date and that the transmitted health information data associated with that date is accurate and without omission. |
| (i)(D)(2) | <ol style="list-style-type: none"> 1. The user role of patient requests to view, download, and transmit the data in (e)(1)(i)(A), (B), and (C) for a date range. 2. The user role of patient authorized representative requests to view, download, and transmit the data in (e)(1)(i)(A), (B), and (C) for a date range. | <ol style="list-style-type: none"> 1. The tester verifies that the patient and their authorized representative can view the health information as specified in (e)(1)(A) for a selected date range and that the viewed health information data associated with that date range is accurate and without omission. 2. The tester verifies that the patient and their authorized representative can download the health information as specified in (e)(1)(B) for a selected date range and that the downloaded health information data associated with that date range is accurate and without omission. 3. The tester verifies that the patient and their authorized representative can transmit the health information to a 3rd party as specified in (e)(1)(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:

- (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.

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

| Criteria ¶ | System Under Test | Test Lab Verification |
|----------------|--|--|
| (ii)(A) | <p>1. When a user uses the view, download, or transmit to a third party capabilities as specified in (e)(1)(i)(A) through capabilities (e)(1)(i)(C), the Health IT module records a new activity log entry for the following actions related to electronic health information:</p> <ul style="list-style-type: none"> • View of patient information; • Download patient information; and • Transmit patient information. <p>2. For each action, the activity log entry includes:</p> <ul style="list-style-type: none"> • Type of action; • Date and time of event in accordance with the standard specified in § 170.210(g), RFC 5905: Network Time Protocol Version 4: Protocol and Algorithms Specification; • User identification; and • To whom the transmission was sent (if applicable). | <p>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:</p> <ul style="list-style-type: none"> • The actions that occurred; • The date/time, specified in accordance to the standard specified in §170.210(g); • User who took the action; and • Addressee to whom the transmission was sent (if applicable). |
| (ii)(B) | <p>The user role of patient accesses the activity history log in the Health IT module.</p> | <p>The tester verifies that the activity history log created in (e)(1)(ii)(A) is accessible by a patient, and that it contains all of the activity associated to the patient record.</p> |

Document History

| Version Number | Description of Change | Date |
|----------------|-----------------------------|-------------------------------|
| 1.0 | Released for Comment - NPRM | March 20 th , 2015 |
| 1.1 | Released for Comment - FR | October 30, 2015 |

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