# Test Criteria: 170.315.e.1 View, Download, and Transmit to Third Party (VDT)

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| --- | --- |
| **Testing Result** |  |
| Participant and Product-with-version |  |
| Setting (Ambulatory or Inpatient) |  |
| Test Proctor |  |
| Test Date |  |
| Test Result | Pass:  Fail:  No Attempt: |
| Error Description (if applicable) |  |
| Modifications to Product Under Test |  |
| Additional Software Used |  |
| Additional Proctor Notes |  |

### Overview

In this document you will find:

* [Test Data and Test Tools](#_Test_Data_and_1)
* [Standards Support](#_Demonstrate_Standards_Support)
* [Drummond Test Report (Instructions, Expected Results, Points to Remember)](#_170.315(a)(1)(i)_Record,_Change,)
* [Test Procedures](#_Test_Procedures)
* [Appendix A: Testing Guide](#_Appendix_A:_Testing)
* [Appendix B: ONC Criteria](#_Appendix_B:_ONC)
* [Appendix C: CCDS Reference Table](#_Appendix_C:_CCDS)

### Version of ONC Test Method

1.3

### Scope of Proctoring Sheet

The ONC test method associated with this criterion is the only approved test method for EHR Meaningful Use certification. This Proctoring Sheet is not a replacement test method but a test procedure document for performing the ONC test method and recording the results. Proctoring Sheet describe test data, test criteria and expected results. It is assumed the Health IT Developer or Participant UnderTest is familiar with the associated ONC test method.

# Robustness and Reliability Requirement

To satisfy the module criteria, it is expected that the Product-Under-Test is able to complete the testing requirements reliably, including repeat testing with the same result without error, and with a satisfactory level of robustness. This includes unexpected error messages produced through normal operation, multiple unintended restarts of the application or any other “buggy” facets of the product displayed while testing. These errors are record in the Additional Proctor Notes of the proctor sheet. Lack of reliability and robustness of design will result in failure of the module.

# Test Data and Tools

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| **Test Data Source:** | ONC-Supplied  DG-Supplied:  Developer-Supplied: |
| **Pre-Test Data Setup:**  Health IT developer pre-loads the 170.315(e)(1) ONC test data specified below based on health care setting. | |
| **Test Data:**  Test data is downloaded from the ETT [C-CDA R2.1 Validator](https://ttpedge.sitenv.org/ttp/#/validators) using the “Sender SUT Test Data” selection:   * + Ambulatory setting: 170.315\_e1\_vdt\_amb\_sample\*.pdf (All samples)   + Inpatient setting: 170.315\_e1\_vdt\_inp\_sample\*.pdf (All samples)   + Inpatient setting: 170.315\_e1\_vdt\_toc\_inp\_sample\*.xml (All samples) | |
| **Test Tools:**  Edge Test Tool – Message Validators: [C-CDA R2.1 Validator](https://ttpedge.sitenv.org/ttp/#/validators) | |

# Demonstrate Standards Support

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| --- | --- |
| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **Instructions:** Implement standards to satisfy the View, Download, and Transmit requirements. For additional references, click [here](https://www.healthit.gov/policy-researchers-implementers/meaningful-use-stage-2-0/standards-hub) for the ONC Standards Hub. | |

|  |  |  |
| --- | --- | --- |
|  | **Standard** |  |
|  | 42 CFR 493.1291 | [493.1291 Standard: Test Report](https://www.law.cornell.edu/cfr/text/42/493.1291). (c)(1) through (c)(7) *Standard.* Required test report data.  (d) *Standard.* Reference intervals or normal values.  (k)(2) *Standard.* Correct report requirements. |
|  | §170.204(a)(1) | Web Content Guidelines (WCAG), Level A Conformance |
|  | §170.204(a)(2) | Web Content Guidelines (WCAG), Level AA Conformance |
|  | §170.205(a)(4) | HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 1—Introductory Material, Release 2.1 and HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 2—Templates and Supporting Material, Release 2.1 (incorporated by reference in § 170.299). |
|  | §170.207(a)(4) | IHTSDO SNOMED CT®, U.S. Edition, September 2015 Release. |
|  | §170.207(b)(2) | 45 CFR 162.1002(a)(5)—combination of HCPCS and CPT-4 |
|  | §170.207(b)(3) | 45 CFR 162.1002(a)(4)—Code on Dental Procedures and Nomenclature. |
|  | §170.207(e)(1) | 45 CFR 162.1002(c)(3)—ICD-10-PCS |
|  | §170.207(c)(3) | LOINC® Database version 2.52. |
|  | §170.207(d)(3) | RxNorm, September 8, 2015 Release. |
|  | §170.207(e)(3) | HL7 CVX—Vaccines Administered, updates through August 17, 2015. |
|  | §170.207(e)(4) | National Drug Code Directory—Vaccine Codes, updates through August 17, 2015. |
|  | §170.207(f)(1) | OMB as revised, October 30, 1997. |
|  | §170.207(f)(2) | CDC Race and Ethnicity Code Set Version 1.0 (March 2000) (incorporated by reference in § 170.299). |
|  | §170.207(g)(2) | Request for Comments (RFC) 5646 (incorporated by reference in § 170.299). |
|  | §170.207(h) | Smoking status constrained codes from SNOMED CT®. |
|  | §170.207(k)(1) | LOINC® version 2.51 (minimum codes: 8480-6, 8462-4, 8302-2, 3141-9, 8867-4, 9279-1, 8310-5, 59408-5, 39156-5, and 8478-0) |
|  | §170.207(m) | Numerical references—(1) Standard. The Unified Code of Units of Measure, Revision 1.9 (incorporated by reference in § 170.299). |
|  | §170.207(n)(1) | Birth sex must be coded in accordance with HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor (incorporated by reference in § 170.299), attributed as follows:  (i) Male. M  (ii) Female. F  (iii) Unknown. nullFlavor UNK |
|  | §170.210(g) | Synchronized clocks. The date and time recorded utilize a system clock that has been synchronized following (RFC 1305) Network Time Protocol, (incorporated by reference in §170.299) or (RFC 5905) Network Time Protocol Version 4, (incorporated by reference in §170.299). ***Refer to the “170.210.g – Network Time Protocol Test” proctor sheet. The test steps must be performed to prove compliance with the 170.210(g) standard.*** |

# 170.315.e.1 View, Download, and Transmit to Third Party (VDT)(i)(A) – View, (i)(B) – Download, (VDT)(i)(C) – Transmit to Third Party, (ii) – Activity History Log

# 170.315.e.1 View, Download, and Transmit to Third Party (VDT)(i)(D) - Timeframe Selection

|  |  |
| --- | --- |
| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **WCAG Conformance** | Level A:  Level AA: |
| **Instructions:**  **View**  Patient (and their authorized representatives) use internet-based technology to view the patient’s health information. Health IT module also demonstrates synchronization to a configured NTP server and web conformance accessibility (WCAG).  **Download**  Patient (and their authorized representatives) use internet-based technology to download the patient’s health information.  **Transmit**  Patient (and their authorized representatives) use internet-based technology to transmit the patient’s health information.  **Activity Log**  Health IT module enables the patient to view the activity history log for all view, download, and transmit actions performed within the patient’s record.  **Notes regarding Patient Portal products:**  The ONC has added a requirement that patient portals must now create the CCDA. A stand-alone patient portal product has two options:   * Create the CCDA utilizing their own native functionality. In this approach, the patient portal is tested/certified independently of any associated EHR. * Receive the CCDA from an EHR. The EHR will need to be tested with the portal and therefore the portal will list the EHR as relied upon software. The portal is required to test with one EHR but is permitted to list multiple EHR products as relied upon software.   A primary EHR that lists a portal as relied upon software is not affected by this ruling. | |
| **Expected Test Result:**  **View**   * Enable patients (and their authorized representatives) to view, at a minimum, the Common Clinical Data Set; laboratory test report(s); and diagnostic image reports in addition to:   + Ambulatory setting only. The provider's name and office contact information.   + Inpatient setting only. The admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization. * Enable patient (and their authorized representative) to view for health information filtered by a specific date and date range. * Health IT module system time is synchronized within five seconds of the NTP configured ITS server. * If applicable, the EHR time is within five seconds of the health IT module system time or the NTP configured ITS server.   **Download**   * Enable patient (and their authorized representatives) to download an ambulatory or inpatient summary (as applicable to setting) in the following formats:  1. human readable format; 2. format specified at §170.205(a)(4) CCD document template  * When downloaded, the ambulatory or inpatient summary must include, at a minimum, the Common Clinical Data Set; laboratory test report(s); diagnostic image reports; and:   + 1. Ambulatory setting only. The provider's name and office contact information.     2. Inpatient setting only. The admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization. Additionally, 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.     3. Enable patient (and their authorized representative) to download for health information filtered by a specific date and date range.   **Transmit**   * For both settings, patients (and their authorized representatives) must be able to transmit the CCD summary through both:  1. email transmission to any email address; and 2. an encrypted method of electronic transmission  * When transmitted, the ambulatory or inpatient summary must include, at a minimum, the Common Clinical Data Set; laboratory test report(s); diagnostic image reports; and:   + 1. Ambulatory setting only. The provider's name and office contact information.     2. Inpatient setting only. The admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization. Additionally, patients (and their authorized representatives) must be able to transmit transition of care/referral summaries that were created as a result of a transition of care through both (1) email transmission to any email address; and (2) an encrypted method of electronic transmission. * Enable patient (and their authorized representative) to download for health information filtered by a specific date and date range. * C-CDA files must successfully validate with the C-CDA message validator.   **Activity Log**   * For all view, download, and transmit capabilities, the following information must be recorded and made accessible to the patient (and authorized representative):  1. the action that occurred; 2. the date and time each action occurred using either Network Time Protocol RFC 1305 or 5905; 3. the user who took the action; and the addressee to whom the summary was transmitted. | |
| **Points to Remember:**  **View**   * Prior to the test event, the Health IT Developer shall perform and document WCAG compliance testing using the Drummond Group **WCAG 2.0A/AA Report Template**. This report template can be downloaded from the Zendesk Knowledgebase or request a copy from your Test Proctor. * Testing assumes the operating system synchronizes to the NTP server and the Health IT Module then synchronizes to the operating system; however, the Heath IT Module could synchronize directly to the NTP server. The Health IT Module may use either method to demonstrate that the synchronization has occurred. Use of internal NTP servers are allowed, but the Health IT Module must demonstrate that the internal servers are synced to a NIST timeserver for accuracy.   **Download**   * Downloaded summary files will be validated using the [C-CDA R2.1 Validator](https://ttpedge.sitenv.org/ttp/#/validators) within the Edge Test Tool (ETT). * Inpatient Setting Only - For health IT module certified in Transition of Care (b.1), patients must be able to download transition of care/referral summaries that were created as result of a transition of care.   **Transmit**   * Direct project is recommended for the encrypted method. * Transmitted summary files will be validated using the [C-CDA R2.1 Validator](https://ttpedge.sitenv.org/ttp/#/validators) within the Edge Test Tool (ETT). * Inpatient Setting Only - For health IT module certified in Transition of Care (b.1), patients must be able to transmit the transition of care/referral summaries that were created as result of a transition of care.   **Activity Log**   * Refer to the “170.210.g – Network Time Protocol Test” proctor sheet. The test steps must be performed to prove compliance with the 170.210(g) standard. * Health IT may meet this requirement if it is certified to the 2015 Edition “auditable events and tamper-resistance” certification criterion (§ 170.315(d)(2)) and these data are accessible by the patient. * The time period for which the activity log should be available is a policy determination that the organization who implements the health IT should make. Testing and certification will only test for the health IT ability to create such a log. * The date and time recorded utilize a system clock that has been synchronized following (RFC 1305) Network Time Protocol, or (RFC 5905) Network Time Protocol Version 4. | |

### Test Procedures

**1.1 NTP Test**

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|  | Configure the HIT module’s operating system NTP server to an ITS server:  NIST Timer Server: <NIST Time Server> |
|  | Synchronize the HIT module operating system NTP server to the ITS server. |
|  | Verify that NTP server never queries the time server more than once every 4 seconds. |
|  | The HIT module operating system display time is accurate within 5 seconds of the NIST time server. |
|  | HIT module display time is accurate within 5 seconds of the operating system time. (Alternative)  HIT module display time is accurate within 5 seconds of the NIST time server. (Alternative) |
|  | Time Service (ITS):  NTP version:  NTPv3  NTPv4 |

<INSERT SCREEN SHOTS - NTP Configuration>

<INSERT SCREEN SHOTS - NTP Logs>

**1.2 Web Content Accessibility**

|  |  |
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|  | Prior to test event, health IT developer submits **WCAG 2.0 Compliance Template Report** documenting the health IT module’s compliance with either:   * Web Content Accessibility Guidelines (WCAG) 2.0, Level A (§170.204(a)(1))   **OR**   * Web Content Accessibility Guidelines (WCAG) 2.0, Level AA (§170.204(a)(2)) |
|  | Proctor evaluates the report including 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. |
|  | Proctor verifies that for each internet-based health IT technology, associated with the VDT capabilities, there is WCAG compliance for associated VDT functions using the selected conformance testing tool based on Level (A or AA) as attested by Health IT developer. |

<INSERT LINK to WCAG Report and SCREENSHOTS of WCAG Conformance Validation Tool Reports>

**1.3 View Health Information: Unauthorized User**

**1.4 Download Health Information: Unauthorized User**

**1.5 Transmit Health Information (Unencrypted): Unauthorized User**

**1.6 Transmit Health Information (Encrypted): Unauthorized User**

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| --- | --- |
|  | Unauthorized user logs in and attempts to view, download, and transmit patient health information. |
|  | Access denied to unauthorized user. |

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**\*\*\* The following test procedures are repeated for one patient and one authorized patient representative. \*\*\***

# PATIENT

**1.7 View Health Information**

|  |  |
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|  | Using the **ETT: Message Validators -C-CDA R2.1 Validator**, the health IT developer downloads the ONC-supplied test data file (2015-Certification-C-CDA-Test-Data-master.zip ) and pre-loads one version of Sample 1 and Sample 2 Sender SUT Test Data according to the applicable setting. Drummond recommends using the latest version of each test data.  Ambulatory setting (170.315\_e1\_VDT\_Amb folder):   * 170.315\_e1\_vdt\_amb\_sample1\_v\*.pdf * 170.315\_e1\_vdt\_amb\_sample2\_v\*.pdf   Inpatient setting (170.315\_e1\_VDT\_Inp folder):   * 170.315\_e1\_vdt\_inp\_sample1\_v\*.pdf * 170.315\_e1\_vdt\_inp\_sample2\_v\*.pdf |
|  | **Patient** logs in to the health IT module based on the first sample file for the applicable setting. **Patient** views the following health data completely and accurately in human-readable form:   * **Common Clinical Data Set** (*see* [Appendix C](#_Appendix_C:_Reference) *for CCDS Reference*); * **Diagnostic Image Report(s)** when available; * **Laboratory Test Report(s)** based on the Clinical Laboratory Improvement Amendments (CLIA) reporting data requirements:   (1) Patient 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. (8) 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  (9) The information for corrected reports as specified in 42 CFR 493.1291(k)(2).   * ***Ambulatory setting:*** Provider’s Name and Office Contact Information; * ***Inpatient setting:*** Admission and Discharge Dates and Locations, Discharge Instructions, and Reason(s) for Hospitalization |

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**1.8 Download Health Information**

**1.9 Transmit Health Information: Unencrypted E-mail Method**

**1.10 Transmit Health Information: Encrypted Method**

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| --- | --- |
|  | Using ONC-supplied test data:  Ambulatory setting (170.315\_e1\_VDT\_Amb folder):   * 170.315\_e1\_vdt\_amb\_sample1\_v\*.pdf (CCD) * 170.315\_e1\_vdt\_amb\_sample2\_v\*.pdf (CCD)   Inpatient setting (170.315\_e1\_VDT\_Inp folder):   * 170.315\_e1\_vdt\_inp\_sample1\_v\*.pdf (CCD) * 170.315\_e1\_vdt\_inp\_sample2\_v\*.pdf (CCD)   *If Inpatient certifying to 170.315(b.1) include:*   * 170.315\_e1\_vdt\_toc\_inp\_ccd\_r21\_sample\*.xml * 170.315\_e1\_vdt\_toc\_ds\_r21\_sample\*.xml * 170.315\_e1\_vdt\_toc\_inp\_rn\_r21\_sample\*.xml   Patient logs in to portal and performs:   * Download; * transmit unencrypted e-mail; and * transmit encrypted method;   Actions should include both a **human readable form** and **CCD format** (xml) except for the three (3) Inpatient Transition of Care “toc” files. These files only require a CCD format (xml).Vendor provides a copy of each of these tested documents to the Proctor. |
|  | Proctor validates the documents using the ETT:  **Human Readable.** Using the Message Content Report from the ETT, Proctor verifies the **human-readable** summary copies downloaded, transmitted unencrypted, and transmitted encrypted by the patient is accurate and includes:   * **Common Clinical Data Set** (*see* [Appendix C](#_Appendix_C:_Reference) *for CCDS Reference*); * **Diagnostic Image Report(s)**; * **Laboratory Test Report(s)** based on CLIA data requirements; and * ***Ambulatory setting:*** Provider’s Name and Office Contact Information; * ***Inpatient setting (CCD):*** Admission and Discharge Dates and Locations, Discharge Instructions, and Reason(s) for Hospitalization * ***Inpatient setting (ToC):*** * **Common Clinical Data Set:** as specified in the CCDS Reference Document (*see* [Appendix C](#_Appendix_C:_Reference) *for CCDS Reference*); * **Encounter Diagnosis**; * **Cognitive Status**; * **Functional Status**; and * **Discharge Instructions**   **XML.** Proctor validates the CCD document (xml) files downloaded, transmitted unencrypted, and transmitted encrypted by the patient using the **ETT Message Validator – C-CDA R2.1 Validator**. |

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**1.11 Activity History Log**

|  |  |
| --- | --- |
|  | Patient logs in to health IT module and accesses the Activity History Log. |
|  | Proctor verifies the activity log is accessible by patient and contains all of the activity associated to the patient record for each *view, download*, and *transmit* action. Entries should include:   * **Action that occurred**; * **Date/time** in accordance to standard specified at §170.210(g); * **User who took the action**; and * **Addressee to whom transmission was sent** |

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**1.12 View Health Information: Timeframe Selection**

**1.13 Download Health Information: Timeframe Selection**

**1.14 Transmit Health Information (Unencrypted): Timeframe Selection**

**1.15 Transmit Health Information (Encrypted): Timeframe Selection**

|  |  |
| --- | --- |
|  | Using same patient account above, demonstrate functionality to view, download, transmit unencrypted, and transmit encrypted health information for:   * **a specific date**; and * **a specific date range** |

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# AUTHORIZED PATIENT REPRESENTATIVE

**1.16 View Health Information**

|  |  |
| --- | --- |
|  | Using the **ETT: Message Validators -C-CDA R2.1 Validator**, the health IT developer downloads the ONC-supplied test data file (2015-Certification-C-CDA-Test-Data-master.zip ) and pre-loads one version of Sample 1 and Sample 2 Sender SUT Test Data according to the applicable setting. Drummond recommends using the latest version of each test data.  Ambulatory setting (170.315\_e1\_VDT\_Amb folder):   * 170.315\_e1\_vdt\_amb\_sample1\_v\*.pdf * 170.315\_e1\_vdt\_amb\_sample2\_v\*.pdf   Inpatient setting (170.315\_e1\_VDT\_Inp folder):   * 170.315\_e1\_vdt\_inp\_sample1\_v\*.pdf * 170.315\_e1\_vdt\_inp\_sample2\_v\*.pdf |
|  | **Authorized Patient Representative** logs in to the health IT module based on the first sample file for the applicable setting. **Authorized Patient Representative** views the following health data completely and accurately in human-readable form:   * **Common Clinical Data Set** (*see* [Appendix C](#_Appendix_C:_Reference) *for CCDS Reference*); * **Diagnostic Image Report(s)** when available; * **Laboratory Test Report(s)** based on the Clinical Laboratory Improvement Amendments (CLIA) reporting data requirements:   (1) Patient 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. (8) 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  (9) The information for corrected reports as specified in 42 CFR 493.1291(k)(2).   * ***Ambulatory setting:*** Provider’s Name and Office Contact Information; * ***Inpatient setting:*** Admission and Discharge Dates and Locations, Discharge Instructions, and Reason(s) for Hospitalization |

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**1.17 Download Health Information**

**1.18 Transmit Health Information: Unencrypted E-mail Method**

**1.19 Transmit Health Information: Encrypted Method**

|  |  |
| --- | --- |
|  | Using ONC-supplied test data:  Ambulatory setting (170.315\_e1\_VDT\_Amb folder):   * 170.315\_e1\_vdt\_amb\_sample1\_v\*.pdf (CCD) * 170.315\_e1\_vdt\_amb\_sample2\_v\*.pdf (CCD)   Inpatient setting (170.315\_e1\_VDT\_Inp folder):   * 170.315\_e1\_vdt\_inp\_sample1\_v\*.pdf (CCD) * 170.315\_e1\_vdt\_inp\_sample2\_v\*.pdf (CCD) * 170.315\_e1\_vdt\_toc\_inp\_ccd\_r21\_sample\*.xml * 170.315\_e1\_vdt\_toc\_ds\_r21\_sample\*.xml * 170.315\_e1\_vdt\_toc\_inp\_rn\_r21\_sample\*.xml   Authorized Representative logs in to portal and performs:   * Download; * transmit unencrypted e-mail; and * transmit encrypted method;   Actions should include both a **human readable form** and **CCD format** (xml) except for the three (3) Inpatient Transition of Care “toc” files. These files only require a CCD format (xml).Vendor provides a copy of each of these tested documents to the Proctor. |
|  | Proctor validates the documents using the ETT:  **Human Readable.** Using the Message Content Report from the ETT, Proctor verifies the **human-readable** summary copies downloaded, transmitted unencrypted, and transmitted encrypted by the patient is accurate and includes:   * **Common Clinical Data Set** (*see* [Appendix C](#_Appendix_C:_Reference) *for CCDS Reference*); * **Diagnostic Image Report(s)**; * **Laboratory Test Report(s)** based on CLIA data requirements; and * ***Ambulatory setting:*** Provider’s Name and Office Contact Information; * ***Inpatient setting (CCD):*** Admission and Discharge Dates and Locations, Discharge Instructions, and Reason(s) for Hospitalization * ***Inpatient setting (ToC):*** * **Common Clinical Data Set:** as specified in the CCDS Reference Document (*see* [Appendix C](#_Appendix_C:_Reference) *for CCDS Reference*); * **Encounter Diagnosis**; * **Cognitive Status**; * **Functional Status**; and * **Discharge Instructions**   **XML.** Proctor validates the CCD document (xml) copies downloaded, transmitted unencrypted, and transmitted encrypted by the patient using the **ETT Message Validator – C-CDA R2.1 Validator**. |

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**1.20 Activity History Log**

|  |  |
| --- | --- |
|  | Authorized Patient Representative logs in to health IT module and accesses the Activity History Log. |
|  | Proctor verifies the activity log is accessible by authorized patient representative and contains all of the activity associated to the authorized patient representative account for each *view, download*, and *transmit* action. Entries should include:   * **Action that occurred**; * **Date/time** in accordance to standard specified at §170.210(g); * **User who took the action**; and * **Addressee to whom transmission was sent** |

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**1.21 View Health Information: Timeframe Selection**

**1.22 Download Health Information: Timeframe Selection**

**1.23 Transmit Health Information (Unencrypted): Timeframe Selection**

**1.24 Transmit Health Information (Encrypted): Timeframe Selection**

|  |  |
| --- | --- |
|  | Using same authorized patient representative account above, demonstrate functionality to view, download, transmit unencrypted, and transmit encrypted health information for:   * **a specific date**; and * **a specific date range** |

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# Appendix A: Testing Guide

*This appendix contains more details and background on the testing requirements, including explanation on underlying standards, notable issues and best practice suggestions.*

Rev 01-Mar-2016 Additions

* The scope of this criterion is limited to the Consolidated CDA (C-CDA) Release 2.1 Continuity of Care Document (CCD) document template. Health IT developers may choose to offer VDT capabilities for other C-CDA templates as appropriate for different care and practice settings, but the CCD document template is the mandatory minimum that must be supported for this criterion.
* “Patients (and their authorized representatives)” is defined as any individual to whom the patient has granted access to their health information.
* The technology specifications should be designed and implemented in such a way as to provide maximum clarity to a patient (and their authorized representative) about what data exists in the system and how to interpret it, and we expect that health IT developers will make choices following design and usability best practices that will make it easier and clearer for patients to find and use their records.
* A Health IT Module must demonstrate compliance with the Web Content Accessibility Guideline (WCAG) 2.0 Level A at minimum, and may alternatively demonstrate compliance in accordance with the standard specified in Level AA protocols. This information will be listed with the product as part of its Certified Health IT Product List (CHPL) listing. A Health IT Module does not need to support both WCAG 2.0 Levels.
* Documentation from a third party or self-attestation that provides independent evidence of conformance to WCAG Levels A or AA can expedite a NVLAP accredited testing laboratory’s review, but health IT still needs to be independently assessed by the testing laboratory for conformance according to the ONC test procedure.
* To meet the “view” requirement, the Common Clinical Data Set information should be made available in its human readable/English (i.e., non-coded) representation.
* Throughout this criterion, this requirement pertains to the diagnostic image report, not the image(s) itself. A diagnostic image report contains the consulting specialist’s interpretation of image data conveying the interpretation to the referring/ordering physician and should become a part of the patient’s medical record. Unstructured data for the interpretation text is acceptable for certification. [see also 80 FR 62659]
* Although Health IT Modules must allow the patient to download and transmit corrected reports in accordance with 42 CFR 493.1291(k)(2), there is no need to separately test for this capability to achieve certification for this criterion. The laboratory test report requirement is satisfied if the Health IT Module demonstrates that it can send a test report.
* The “human readable” aspect for “download” can be satisfied using a style sheet associated with a document formatted according to the C-CDA. [see also 77 FR 54180]. A hyperlink to the data alone cannot satisfy this provision.
* Health IT Modules may include laboratory test reports and diagnostic image reports in the “Results” section of the CCD.
  + For laboratory test reports, the C-CDA can support this information in a structured way using the “Result Observation Template” in the “Results” section.
    - There is no need to test for sending a corrected laboratory report; this requirement is satisfied if the Health IT Module can demonstrate that it can send a laboratory test report. [see also 80 FR 62660]
  + The C-CDA can support the laboratory test reports data in a structured way using the “Result Observation Template” in the “Results” section. We recommend developers follow the best practices for use of the Result Observation Template per HL7 (e.g., HL7 Task Force Examples: http://wiki.hl7.org/index.php?title=CDA\_Example\_Task\_Force).
* We recommend developers code laboratory test report data where possible and appropriate in anticipation that future certification will require more extensively coded laboratory test report data. [see also 80 FR 62660]For diagnostic image reports, unstructured data for the interpretation text is acceptable.
* Timeframe selections: There is no need to allow for selection of a specific time within in each date range. For example, “9/1/2015 to 10/1/2015” is sufficient, rather than “9/1/2015 at 9:00am to 10/1/2015 at 5:00pm.” However, health IT developers may choose to include additional functionality to make it easy for patients to locate the information they need.
* Please see the OCR frequently asked questions for best practices regarding the use of email for transmitting health information: <http://www.hhs.gov/ocr/privacy/hipaa/faq/health_information_technology/570.html>.
* For the email option, the approach is to provide patients with a readily understood and convenient option to send their health information via email. Under current HIPAA regulations (45 CFR 164.524 and related guidance), patients may presently ask that their data be disclosed to them via unencrypted email.
* For the encrypted “transmit” option, we encourage developers to provide innovative options for individuals to easily and efficiently protect their health information based on generally available mechanisms for security and new advances in this area.
  + The second “transmit” option is subject to the 2015 Edition privacy and security certification framework, particularly the “trusted connection” certification criterion (§ 170.315(d)(9)).
  + Health IT developers have the flexibility to either establish an encrypted connection between two end points or, alternatively, secure the payload via encryption.
  + The Direct protocol remains an encouraged and viable method to meet the requirements of the encrypted “transmit” requirement.
* Transferring data to an electronic media like a USB drive or DVD does not constitute “electronic transmission” to meet this criterion.

# Appendix B: ONC Criteria and Standards

*This appendix contains copy of the relevant ONC criteria and standards for this proctor sheet as a reference. In the event of a discrepancy with the ONC Final Rule, the ONC Final Rule takes precedence.*

**§170.315(e)(1) 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).

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

The Common Clinical Data Set (which should be in their English (i.e., non-coded) representation if they associate with a vocabulary/code set).

Ambulatory setting only. Provider's name and office contact information.

Inpatient setting only. Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization.

Laboratory test report(s). Laboratory test report(s), including:

The information for a test report as specified all the data specified in 42 CFR 493.1291(c)(1) through (7);

The information related to reference intervals or normal values as specified in 42 CFR 493.1291(d); and

The information for corrected reports as specified in 42 CFR 493.1291(k)(2).

Diagnostic image report(s).

Download.

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:

Human readable format, and

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

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 seE

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

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

Inpatient setting only. Patients (and their authorized representatives) must be able to download transition of care/referral summaries that were created

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

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:

(Email transmission to any email address, and

An encrypted method of electronic transmission.

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).

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:

Select data associated with a specific date (to be viewed, downloaded, or transmitted); and

Select data within an identified date range (to be viewed, downloaded, or transmitted).

Activity History Log

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.

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.

**§170.102 – Definitions**

***Common Clinical Data Set*** means the following data expressed, where indicated, according to the specified standard(s):

(1) *Patient name.*

(2) *Sex.* (ii) The standard specified in § 170.207(n)(1).

(3) *Date of birth.*

(4) *Race.* (ii) For certification to the 2015 Edition health IT certification criteria:

(A) The standard specified in § 170.207(f)(2);

(B) The standard specified in § 170.207(f)(1) for each race identified in accordance § 170.207(f)(2).

(5) *Ethnicity.* (ii) For certification to the 2015 Edition health IT certification criteria:

(A) The standard specified in § 170.207(f)(2);

(B) The standard specified in § 170.207(f)(1) for each ethnicity identified in accordance § 170.207(f)(2).

(6) *Preferred language.* (ii) The standard specified in § 170.207(g)(2).

(7) *Smoking status.* The standard specified in § 170.207(h).

(8) *Problems.* (ii) At a minimum, the standard specified in § 170.207(a)(4).

(9) *Medications.* (ii) At a minimum, the standard specified in § 170.207(d)(3).

(10) *Medication allergies.* (ii) At a minimum, the standard specified in § 170.207(d)(3).

(11) *Laboratory test(s).* (ii) At a minimum, the standard specified in § 170.207(c)(3).

(12) *Laboratory value(s)/result(s).*

(13) *Vital signs.* (ii) For certification to the 2015 Edition Health IT certification criteria:

(A) The patient's diastolic blood pressure, systolic blood pressure, body height, body weight, heart rate, respiratory rate, body temperature, pulse oximetry, and inhaled oxygen concentration must be exchanged in numerical values only; and

(B) In accordance with the standard specified in § 170.207(c)(3) and with the associated applicable unit of measure for the vital sign measurement in the standard specified in § 170.207(m)(1).

(C) *Optional.* The patient's BMI percentile per age and sex for youth 2-20 years of age, weight for age per length and sex for children less than 3 years of age, and head occipital-frontal circumference for children less than 3 years of age must be recorded in numerical values only in accordance with the standard specified in § 170.207(c)(3) and with the associated applicable unit of measure for the vital sign measurement in the standard specified in § 170.207(m)(1). For BMI percentile per age and sex for youth 2-20 years of age and weight for age per length and sex for children less than 3 years of age, the reference range/scale or growth curve should be included as appropriate.

(15) *Procedures*—(i)(A) At a minimum, the version of the standard specified in § 170.207(a)(4), or § 170.207(b)(2); or

(B) For technology primarily developed to record dental procedures, the standard specified in § 170.207(b)(3).

(ii) *Optional.* The standard specified in § 170.207(e)(1).

(16) *Care team member(s).*

(17) *Immunizations.* In accordance with, at a minimum, the standards specified in § 170.207(e)(3) and (4).

(18) *Unique device identifier(s) for a patient's implantable device(s).* In accordance with the “Product Instance” in the “Procedure Activity Procedure Section” of the standard specified in § 170.205(a)(4).

(19) *Assessment and plan of treatment.* (i) In accordance with the “Assessment and Plan Section (V2)” of the standard specified in § 170.205(a)(4); or

(ii) In accordance with the “Assessment Section (V2)” and “Plan of Treatment Section (V2)” of the standard specified in § 170.205(a)(4).

(20) *Goals.* In accordance with the “Goals Section” of the standard specified in § 170.205(a)(4).

(21) *Health concerns.* In accordance with the “Health Concerns Section” of the standard specified in § 170.205(a)(4).

**CFR 493.1291 Laboratory Requirements – Standard: Test Report.**

**(c)(1) through (7) *Standard.*** Required test report data.

**(d) *Standard.*** Reference intervals or normal values.

**(k)(2) *Standard.*** Correct report requirements.

**§170.204 Functional Standards.**

**(a)(1) *Standard.*** Web Content Guidelines (WCAG), Level A Conformance

**(a)(2) *Standard.*** Web Content Guidelines (WCAG), Level AA Conformance

**§170.205 Content Exchange Standards – Patient Summary Record.**

**(a)(4) *Standard.*** HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 1—Introductory Material, Release 2.1 and HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 2—Templates and Supporting Material, Release 2.1 (incorporated by reference in § 170.299).

**§170.207 Vocabulary standards for representing electronic health information.**

**(a)(4) *Standard*.** IHTSDO SNOMED CT®, U.S. Edition, September 2015 Release.

**(b)(2) *Standard*.** 45 CFR 162.1002(a)(5)—combination of HCPCS and CPT-4

**(b)(3) *Standard.*** 45 CFR 162.1002(a)(4)—Code on Dental Procedures and Nomenclature.

**(e)(1) *Standard.*** 45 CFR 162.1002(c)(3)—ICD-10-PCS

**(c)(3) *Standard.*** LOINC® Database version 2.52.

**(d)(3) *Standard.*** RxNorm, September 8, 2015 Release.

**(e)(3) *Standard.*** HL7 CVX—Vaccines Administered, updates through August 17, 2015.

**(e)(4) *Standard.*** National Drug Code Directory—Vaccine Codes, updates through August 17, 2015.

**(f)(1) *Standard.*** OMB as revised, October 30, 1997.

**(f)(2) *Standard.*** CDC Race and Ethnicity Code Set Version 1.0 (March 2000) (incorporated by reference in § 170.299).

**(g)(2) *Standard.*** Request for Comments (RFC) 5646 (incorporated by reference in § 170.299).

**(h) *Standard.*** Smoking status constrained codes from SNOMED CT®.

**(k)(1) *Standard.*** LOINC® version 2.51 (minimum codes: 8480-6, 8462-4, 8302-2, 3141-9, 8867-4, 9279-1, 8310-5, 59408-5, 39156-5, and 8478-0)

***(m) Numerical references—(1) Standard.*** The Unified Code of Units of Measure, Revision 1.9 (incorporated by reference in § 170.299).

**(n)(1) *Standard*.** Birth sex must be coded in accordance with HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor (incorporated by reference in § 170.299), attributed as follows:

(i) Male. M

(ii) Female. F

(iii) Unknown. nullFlavor UNK

**§170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.**

(g) Synchronized clocks. The date and time recorded utilize a system clock that has been synchronized following (RFC 1305) Network Time Protocol, (incorporated by reference in §170.299) or (RFC 5905) Network Time Protocol Version 4, (incorporated by reference in §170.299).

# Appendix C: CCDS Reference Table

# *This appendix contains a reference guide to evaluate the Common Clinical Data Set, Diagnostic Image Report, Laboratory Test Result, and additional elements are populated accurately and without omission.*

**CCDS Reference Table**

**Common Clinical Data Set (CCDS), Diagnostic Image Reports, and Laboratory Test Results**

|  |  |  |
| --- | --- | --- |
|  | **CCDS** | **Standard** |
|  | Patient Name | **<Not applicable>** |
|  | Sex; including Birth sex | **§170.207 (n)(1)** |
|  | Date of Birth | **<Not applicable>** |
|  | Race | **§170.207 (f)(2)** Mapped to **§170.207 (f)(1);**  **§170.207 (f)(2)** |
|  | Ethnicity | **§170.207 (f)(2)** Mapped to **§170.207 (f)(1);**  **§170.207 (f)(2)** |
|  | Preferred Language | **§170.207 (g)(2)** |
|  | Smoking Status | **§170.207 (h)** |
|  | Problems | **§170.207 (a)(4)** |
|  | Medications | **§170.207 (d)(3)** |
|  | Allergies | **§170.207 (d)(3)** |
|  | Lab Tests | **§170.207 (m)(1)** |
|  | Lab Values(s)/Results | **<Not applicable>** |
|  | Vital Signs | **§170.207 (k)(1), §170.207 (m)(1)** |
|  | BMI (Optional) | **§170.207 (c)(3), §170.207 (m)(1)** |
|  | Procedures | **§170.207 (a)(4) , §170.207 (b)(2)** |
|  | Procedures (Optional: for dental systems) | **§170.207 (b)(3)** |
|  | Procedures (Optional) | **§170.207 (b)(5)** |
|  | Care Team Member(s) | **<Not applicable>** |
|  | Immunizations | **§170.207 (e)(3), §170.207 (e)(4)** |
|  | Unique Device Identifier(s) for a Patient’s Implantable Device(s) | **“Product Instance” in the “Procedure Activity Procedure Section” of the standard specified in § 170.205(a)(4)** |
|  | Assessment and Plan of Treatment | **In accordance with the “Assessment and Plan Section (V2)” of the standard specified in § 170.205(a)(4); or**  **In accordance with the “Assessment Section (V2)” and “Plan of Treatment Section (V2)” of the standard specified in § 170.205(a)(4).** |
|  | Goals | **In accordance with “Goals Section” of standard specified in § 170.205(a)(4) for certification to the 2015 Edition health IT certification criteria.** |
|  | Health Concerns | **In accordance with the “Health Concerns Section” of the standard specified in § 170.205(a)(4) for certification to the 2015 Edition health IT certification criteria.** |
| **DIAGNOSTIC IMAGE REPORT** | | |
| **Data Element** | | **Standard** |
|  | Diagnostic image report narrative interpretation in human readable format, complete and accurate. | **<Not applicable>** |
| **LABORATORY TEST REPORT** | | |
| **Data Element** | | **Standard** |
|  | Patient's name and identification number or a unique patient identifier and identification number. | **42 CFR 493.1291(c)(1)** |
|  | The name and address of the laboratory location where the test was performed. | **42 CFR 493.1291(c)(2)** |
|  | The test report date. | **42 CFR 493.1291(c)(3)** |
|  | The test performed. | **42 CFR 493.1291(c)(4)** |
|  | Specimen source, when appropriate. | **42 CFR 493.1291(c)(5)** |
|  | The test result and, if applicable, the units of measurement or interpretation, or both. | **42 CFR 493.1291(c)(6)** |
|  | Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability | **42 CFR 493.1291(c)(7)** |
|  | CLIA “reference values” or “normal” values. | **42 CFR 493.1291(d)** |
|  | CLIA corrected report requirements | **42 CFR 493.1291(k)(2)** |
| **AMBULATORY ONLY** | | |
|  | **Data Element** | **Standard** |
|  | Providers name and office contact information | **<Not applicable>** |
| **INPATIENT ONLY** | | |
|  | **Data Element** | **Standard** |
|  | Admission dates and location | **<Not applicable>** |
|  | Reason for hospitalization | **<Not applicable>** |
|  | Discharge dates | **<Not applicable>** |
|  | Discharge Instructions | **<Not applicable>** |

# Change Log

|  |  |
| --- | --- |
| Revision | Change Description |
| 15-Sep-2017 | Added ONC clarification that portals must create the CCDA. |
| 05-Jun-2017 | Clarified test step for Inpatient TOC files. |
| 03-May-2017 | Consolidated test procedure sections to streamline testing. |
| 10-Feb-2017 | Updated references to ONC supplied test data. |
| 01-Dec-2016 | Corrections made to section 1.5 (changed ‘download’ to ‘view’); section 2.1 (corrected section title). |
| 01-Nov-2016 | Added transmit actions for unauthorized user and timeframe selection under encrypted method (sections 3.5 and 3.6) |
| 01-Oct-2016 | Clarified authorized representative access to activity log. Updated hyperlinks for ONC-hosted ETT. Updated test procedures in each section to optimize efficiency in testing. |
| 01-May-2016 | Added authorized representative role for accessing Activity History Log (section 5.1). Removed (b.1) certification requirement and revised Referral Note and Discharge Summary as optional under Transition of Care Download for Inpatient setting (section 3.5). Corrected Race and Ethnicity entries on “CCDS Reference Table” to clarify 170.207(f)(2) should be mapped to 170.207(f)(1). Added NTP Test (1.1). Updated section numbering. |
| 01-Apr-2016 | Clarified Proctor validation of health IT technology WCAG conformance under section 1.1. |
| 01-Mar-2016 | Initial Release. |

**About Drummond Group LLC**

Drummond Group LLC is a global software test and certification lab that serves a wide range of vertical industries.  In healthcare, Drummond Group tests and certifies Controlled Substance Ordering Systems (CSOS), Electronic Prescription of Controlled Substances (EPCS) software and processes, and Electronic Health Records (EHRs) – designating the trusted test lab as the only third-party certifier of all three initiatives designed to move the industry toward a digital future. Founded in 1999, and accredited for the Office of the National Coordinator Health IT Certification Program as an Authorized Certification Body (ACB) and an Authorized Test Lab (ATL), Drummond Group continues to build upon its deep experience and expertise necessary to deliver reliable and cost-effective services. For more information, please visit <http://www.drummondgroup.com> or email [ehr@drummondgroup.com](mailto:ehr@drummondgroup.com)

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