# Test Criteria: 170.315.g.6 Consolidated CDA Creation Performance

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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)
* [Standards Support](#_Demonstrate_Standards_Support)
* [Drummond Test Report (Instructions, Expected Results, Points to Remember)](#_170.315(g)(6)_Consolidated_CDA)
* [Test Procedures](#_Test_Procedures)
* [Appendix A: Testing Guide](#_Appendix_A:_Testing)
* [Appendix B: ONC Criteria](#_Appendix_B:_ONC)

### Version of ONC Test Method

1.0

### 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 Participant under Test 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:**  Not applicable. | |
| **Test Data:**  The C-CDA data set to be used corresponds to the C-CDA related criteria for which the Health IT module is certifying. | |
| **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 support for standards to demonstrate compliance for C-CDA Creation Performance. | |

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| **§170.205 Content Exchange Standards – Patient Summary Record** | | |
|  | §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 Vocabulary standards for representing electronic health information** | | |
|  | §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(b)(4) | 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 |

**CCDS Reference Table**

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|  | **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)** |
|  | BMI (Optional) |  |
|  | Procedures | **§170.207 (a)(4)**  **§170.207 (b)(2)** |
|  | Procedures (Optional: for dental systems) | **§170.207 (b)(3)** |
|  | Procedures (Optional) | **§170.207 (b)(4)** |
|  | 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 | **Goals Section” of the 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.** |

# 170.315(g)(6) Consolidated CDA Creation Performance

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| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **Instructions:** User generates C-CDA R2.1 documents based on the criteria set forth for each module(s) that requires C-CDA creation and is being sought for certification. No additional testing is required to satisfy §170.315(g)(6). | |
| **Expected Test Result:**   * The verification of the §170.315(g)(6) Consolidated CDA Creation Performance criteria for a given criterion is performed in-conjunction with the specific criteria. No additional tests need to be executed to certify for §170.315(g)(6) Consolidated CDA Creation Performance. The §170.315(g)(6) Consolidated CDA Creation Performance Test Procedure is provided to illustrate the tests which are performed as part of certifying for §170.315(g)(6) Consolidated CDA Creation Performance. * Specific criteria requiring (g.6) certification include: * (b.1) Transitions of Care * (b.2) Clinical Reconciliation * (b.4) Common Clinical Data Set – Create * (b.6) Data Export * (b.9) Care Plan * (e.1) View, Download, and Transmit * (g.9) Application Access – All Data Request * Health IT module creates documents formatted in accordance with the C-CDA R2.1 §170.205(a)(4) standard. * Each C-CDA document submitted for testing passes the ETT validation, and the Proctor’s visual inspection for C-CDA R2.1 template, vocabulary, and section narrative text conformance. | |
| **Points to Remember:**   * **All health IT modules presented for certification that includes C-CDA creation capabilities within its scope will simultaneously be certified to §170.315(g)(6) if C-CDAs pass validation using the Edge Test Tool Message Validators and have undergone visual inspection by Proctor.** * Drummond Group will submit all C-CDA files created and validated during testing as sample gold standard C-CDAs to the [ONC-maintained repository](https://github.com/siteadmin/2015-C-CDA-Certification-Samples) for the public to review and provide comment. * C-CDA creation performance should be demonstrated for the C-CDA Release 2.1 document templates required by the 2015 Edition certification criteria presented for certification. For example, if a Health IT Module only included §170.315(e)(1) within its certificate's scope, then only the Continuity of Care Document (CCD) document template would be applicable within this criterion. Conversely, if a Health IT Module designed for the inpatient setting included § 170.315(b)(1) within its certificate's scope, then all three document templates referenced by that criterion would need to evaluated as part of this certification criterion. * Birth sex must be located somewhere in the CCDA, preferably in the Social History Observation section of the CCDA following HL7 Best Practice Example for Birth Sex that includes an approved Birth Sex template. Birth Sex **cannot** be documented in the administrativeGenderCode field in the header section of the CCDA, as that field does not represent the birth sex of the patient, but their gender identification. (Ref: [https://groups.google.com/forum/#!topic/edge-test-tool/7SmOtqRA60Y](https://groups.google.com/forum/%23!topic/edge-test-tool/7SmOtqRA60Y)). | |

### Test Procedures

**1.1 Edge Test Tool Validation**

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|  | For any module being sought for certification that requires C-CDA creation, the generated C-CDA(s) must pass the Edge Test Tool (ETT) validation without any errors to verify that a C-CDA Release 2.1 document can be created, that each document type is conformant to the standard specified in §170.205(a)(4), and contains the applicable data elements for the certifying criteria. |

<INSERT LINK TO VALIDATION REPORTS>

**2.1 Visual Inspection by Proctor**

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| --- | --- |
|  | For any module being sought for certification that requires C-CDA creation, Proctor performs validation of section level narrative text. |

<INSERT SCREEN SHOTS OR LINK TO ORIGINAL FILE>

# 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

* <NONE>

# 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(g)(6) *Consolidated CDA creation performance.*** The following technical and performance outcomes must be demonstrated related to Consolidated CDA creation. The capabilities required under paragraphs (g)(6)(i) through (iv) of this section can be demonstrated in tandem and do not need to be individually addressed in isolation or sequentially. This certification criterion's scope includes only data expressed within the Common Clinical Data Set definition.

(i) *Reference C-CDA match.* Create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that matches a gold-standard, reference data file.

(ii) *Document-template conformance.* Create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that demonstrates a valid implementation of each document template applicable to the certification criterion or criteria within the scope of the certificate sought. The scope of this certification criterion will not exceed the evaluation of the CCD, Referral Note, and Discharge Summary document templates.

(iii) *Vocabulary conformance.* Create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that demonstrates the required vocabulary standards (and value sets) are properly implemented.

(iv) *Completeness verification.* Create a data file for each of the applicable document templates referenced in paragraph (g)(6)(ii) of this section without the omission of any of the data included in the Common Clinical Data Set definition.

**§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(b)(4).

(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).

**§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.**

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

**(a)(3) *Standard.*** HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012.

**(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).

**(p) *XDM package processing*—(1) *Standard.*** IHE IT Infrastructure Technical Framework Volume 2b (ITI TF-2b) (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.

**(b)(4) *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).

# Change Log

|  |  |
| --- | --- |
| Revision | Change Description |
| 03-Apr-2017 | Added Birth Sex guidance to “Points to Remember” section. |
| 01-Oct-2016 | Removed (b.7) and added (b.2) as related criteria for this module. Updated hyperlink for ONC-hosted ETT. |
| 01-July-2016 | Added hyperlink for “ONC-maintained repository”. |
| 01-Jun-2016 | Removed inapplicable standards from “Demonstrate Standards Support” section. Added specific criteria which requires (g.6) certification. |
| 01-May-2016 | Corrected Race and Ethnicity entries on “CCDS Reference Table” to clarify 170.207(f)(2) should be mapped to 170.207(f)(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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