# Test Criteria: 170.315.b.7 Data Segmentation for Privacy – Send

|  |  |
| --- | --- |
| **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(b)(7)_Data_Segmentation)
* [Test Procedures](#_Test_Procedures)
* [Appendix A: Testing Guide](#_Appendix_A:_Testing)
* [Appendix B: ONC Criteria](#_Appendix_B:_ONC)

### Version of ONC Test Method

1.1

### 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 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

|  |  |
| --- | --- |
| **Test Data Source:** | ONC-Supplied  DG-Supplied:  Developer-Supplied: |
| **Pre-Test Data Setup:**  Test Data is downloaded for the applicable setting from the ETT [C-CDA R2.1 Validator](https://ttpedge.sitenv.org/ttp/#/validators) using the “Sender SUT Test Data” selection. The test data will be loaded prior to test event. | |
| **Test Data:**  Test data derived from Edge Test Tool (ETT). | |
| **Test Tools:**  Edge Test Tool – Message Validators: [C-CDA R2.1 Validator](https://edge.nist.gov/ett/#/validators) | |

# Demonstrate Standards Support

|  |  |
| --- | --- |
| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **Instructions:** Implement standards to demonstrate support for the C-CDA Release 2.1 format with Data Segmentation for Privacy (DS4P) Release tagging. | |

|  |  |  |
| --- | --- | --- |
| **§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). |
|  | §170.205(o)(1) | HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1. |

# 170.315(b)(7) Data Segmentation for Privacy – Send

|  |  |
| --- | --- |
| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **Instructions:** User creates a C-CDA R2.1 summary record that is tagged as restricted and subject to restrictions on re-disclosure according to the DS4P R1. | |
| **Expected Test Result:**   * Enable a user to create a summary record formatted in accordance with the standard adopted in §170.205(a)(4) that is tagged at the document-level as restricted and subject to re-disclosure restrictions according to the standard adopted at §170.205(o)(1). * The generated C-CDA includes the following templates:   + Privacy Segmented Document Template;   + CDA Mandatory Document Provenance;   + CDA Mandatory Document Assigned Author Template; and   + If a document contains information protected by specific privacy policies, CDA Privacy Markings Section * The generated C-CDA includes the following data elements:   + The originating document individual author or organization;   + Confidentiality Code constrained in accordance with the standard specified in DS4P R1; and   + If a document contains information protected by specific privacy policies, the privacy text. * The C-CDA passes the C-CDA R2.1 Edge message validation tool without errors to verify conformance to required standards. | |
| **Points to Remember:**   * Not applicable. | |

### Test Procedures

**1.1 Data Segmentation for Privacy: Send**

|  |  |
| --- | --- |
|  | User creates summary document in accordance with standard adopted in §170.205(a)(4) and indicates that the document is restricted and subject to restrictions on re-disclosure. Resulting document includes the following templates:   * Privacy Segmented Document Template; * CDA Mandatory Document Provenance; * CDA Mandatory Document Assigned Author Template; and * If a document contains information protected by specific privacy policies, CDA Privacy Markings Section.   Summary document must include:   * Originating document individual author or organization; * Confidentiality Code constrained in accordance with the standard specified in §170.205(o)(1); and * If a document contains information protected by specific privacy policies, the privacy text. |
|  | User provides a copy of the summary record to Proctor for validation. |

<INSERT SCREEN SHOTS>

# 1.2 Data Segmentation for Privacy: Validation

|  |  |
| --- | --- |
|  | Proctor validates summary record using Edge Test Tool (ETT) [C-CDA R2.1 Validator](https://edge.nist.gov/ett/#/validators) to verify the Health IT Module passes without error in order to confirm that document is conformant to required standard. |
|  | Using the ETT: Message Validators Message Content Report, Proctor verifies:   * Summary record submitted is accurate and without omission using the Health IT developer-supplied data instructions. * Assigned author information and provides data provenance in accordance with the standard adopted at §170.205(o). * If summary record document contains unstructured text data elements, Proctor uses the Health IT developer-supplied data instructions and the Message Content Report to visually inspect the additional checks for equivalent text for the content of all section level narrative text. |
|  | Proctor performs visual inspection of the following §170.205(o) tags in the Summary Record:   * Privacy Segmented Document Template; * CDA Mandatory Document Provenance; * CDA Mandatory Document Assigned Author Template; * The General Header constraint includes the Author; * If a document contains information protected by specific privacy policies, CDA Privacy Markings Section with text indicating the nature of the explicit notice the provider receiving the disclosed information; and * A Confidentiality Code with the value “R.” |

<INSERT LINK TO FILE – Validation Report>

<INSERT SCREEN SHOTS>

# 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

* This certification criterion at § 170.315(b)(7) focuses on a Health IT Module’s ability to tag a C-CDA document as restricted and subject to re-disclosure restrictions using the HL7 DS4P standard, not on the content of the C-CDA document. As such, this certification criterion is not subject to the Consolidated CDA creation performance certification criterion (§ 170.315(g)(6)) because testing for § 170.315(g)(6) focuses on the content of the C-CDA document. We established a certification criterion for Consolidated CDA creation performance to promote the interoperability of C-CDA documents during exchange by testing conformance of the C-CDA’s content to the variation permitted by the HL7 standard.

# 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(b)(7) *Data segmentation for privacy—send.*** Enable a user to create a summary record formatted in accordance with the standard adopted in § 170.205(a)(4) that is document-level tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1).

**§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).

**(o)(1) Standard.** HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1.

# Change Log

|  |  |
| --- | --- |
| Revision | Change Description |
| 03-Jan-2017 | Removed reference to developer-supplied test data and added ONC-supplied test data under “Test Data and Tools”. |
| 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)

END OF DOCUMENT