





§170.315(b)(13)				
Data segmentation for privacy - receive				
Testing Components:				
				ONC Supplied Test Data
NPRM Draft				

Please consult the Notice of Proposed Rulemaking (NPRM) entitled: *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* for a detailed description of the certification criterion with which these testing steps are associated.

Revision History

Version #	Description of Change	Version Date
1.0	NPRM Draft	04-05-2019

Regulation Text

§170.315 (b)(13) *Data segmentation for privacy — receive—*

Enable a user to:

- (i) Receive a summary record that is formatted in accordance with the standard adopted in § 170.205(a)(4) and (a)(4)(i) that is tagged as restricted at the document, section, and entry (data element) level and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1); and
- (ii) Preserve privacy markings to ensure fidelity to the tagging based on consent and with respect to sharing and re-disclosure restrictions.

Standard(s) Referenced

Paragraph (b)(13)(i)

§ 170.205(a)(4) [HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes \(US Realm\), Draft Standard for Trial Use Release 2.1, August 2015](#)

§ 170.205(a)(4)(i) [HL7 CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R1 Companion Guide, Release 1](#)

§ 170.205(o)(1) [HL7 Implementation Guide: Data Segmentation for Privacy \(DS4P\), Release 1](#)

Required Tests

Paragraph (b)(13)(i)

System Under Test	Test Lab Verification
<p>1. Summary records in accordance with the test steps below, based on the health IT setting(s), are provided by the Edge Testing Tool.</p> <p>2. The health IT developer identifies the policies associated with the handling of the Data Segmentation for Privacy documents.</p> <p>Receive</p> <p>3. Using the Health IT Module, a user receives summary record document(s) formatted in accordance with the standard specified at § 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, Release 2.1 with Errata and § 170.205(a)(4)(i) HL7 CDA® Release 2 Implementation Guide: C-CDA Templates for Clinical Notes Release 1 Companion Guide, Release 1 that is tagged as restricted and subject to restrictions on re-disclosure, according to the standard adopted at § 170.205(o)(1) HL7 Version 3 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1 which may include the following:</p> <ul style="list-style-type: none"> ○ Privacy Segmented Document Template; ○ CDA Mandatory Document Provenance; ○ Mandatory Entry Provenance Template; ○ CDA Mandatory Document Assigned Author Template; ○ If a document contains information protected by specific privacy 	<p>1. The tester creates a human readable version for each of the documents received by SUT to be used for verification.</p> <p>Receive</p> <p>2. The tester verifies that a Health IT Module can receive a summary record document formatted in accordance with the standards specified at § 170.205(a)(4) and § 170.205(a)(4)(i), that is document-level, and potentially section-level and entry-level tagged as restricted and contains restrictions on re-disclosure according to the standard adopted at § 170.205(o)(1) for each health IT setting being certified, using visual inspection.</p> <p>3. The tester verifies that a Health IT Module can receive a summary record document formatted in accordance with the standards specified at § 170.205(a)(4) and § 170.205(a)(4)(i) that is not tagged as restricted for each health IT setting being certified, using visual inspection.</p>

System Under Test	Test Lab Verification
<p>policies, the CDA Privacy and Security Markings Section and Privacy Markings Entr(ies);</p> <ul style="list-style-type: none"> ○ Privacy Segmented Section Template(s); ○ Privacy Annotation Template; and ○ Protected Problem Template. <p>4. The received CCDAs tagged as restricted document includes the following data elements:</p> <ul style="list-style-type: none"> ○ The originating document Individual Author or Organization; and ○ Confidentiality Code constrained in accordance with the standard specified in § 170.205(o)(1). <p>5. Using the Health IT Module, a user receives a summary record document(s) formatted in accordance with the standard specified at § 170.205(a)(4) and § 170.205(a)(4)(i).</p>	

Paragraph (b)(13)(ii)

System Under Test	Test Lab Verification
<ol style="list-style-type: none"> 1. The health IT developer supplies documentation on how the Health IT Module handles a Data Segmentation for Privacy document and preserves the privacy markings as specified in the standard at § 170.205(o)(1) HL7 Version 3 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1. 2. Using the restricted document received in (b)(13)(i), the privacy policies identified in (b)(13)(i), and the Health IT Module, a user demonstrates the ability to appropriately use the restricted document associated with a patient's record based upon the consent and with respect to sharing and re-disclosure restrictions, including the behavior at the document, section, and entry levels in 	<ol style="list-style-type: none"> 1. The tester verifies that the identified documentation completely and accurately describes the method for handling Data Segmentation for Privacy document and privacy markings, along with the preservation of the markings in accordance with the standard specified at § 170.205(o)(1) and the policies outlined in (b)(13)(i). 2. The tester verifies that based upon the policies identified in (b)(13)(i) the Health IT Module correctly handles the restricted document as well as the restricted sections and entries associated in accordance with the privacy and security markings specified at § 170.205(o)(1) within the document and maintains the fidelity of the privacy markings using visual inspection.

System Under Test	Test Lab Verification
<p>accordance with the standard specified at § 170.205(o)(1).</p> <p>3. Using the Health IT Module, a user demonstrates the ability for the document information to be formatted in accordance to the standard specified at § 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, Release 2.1 with Errata and § 170.205(a)(4)(i) HL7 CDA® Release 2 Implementation Guide: C-CDA Templates for Clinical Notes Release 1 Companion Guide, Release 1 that is tagged as restricted and subject to restrictions on re-disclosure, according to the standard adopted at § 170.205(o)(1) while maintaining the re-disclosure restrictions based upon the consent and with respect to sharing and re-disclosure restrictions of the original sender.</p> <p>4. Negative Testing: Using the restricted document received in (b)(13)(i), the privacy policies identified in (b)(13)(i), and the Health IT Module, the user demonstrates that an unauthorized user's access to the restricted document received in (b)(13)(i) is limited based upon the policies provided by the health IT developer in (b)(13)(i) on a document, section, and entry level in accordance with the standard specified at § 170.205(o)(1).</p>	<p>3. The tester verifies that the document created by the Health IT Module is formatted in accordance to the standard specified at § 170.205(a)(4) and § 170.205(a)(4)(i) with restrictions on re-disclosure according to the standard adopted at § 170.205(o)(1) for a specific patient and that the privacy and security markings are maintained with full fidelity using visual inspection.</p> <p>4. Negative Testing: The tester verifies that based upon the policies identified in (b)(13)(i), an unauthorized user access is restricted to the document, sections, and entries according to the policies using visual inspection.</p>

Testing tab

Testing Tool

[Edge Testing Tool \(ETT\)](#): Message Validators

Test Tool Documentation

[Test Tool Supplemental Guide](#)

Test Tool Data

Criterion Subparagraph	Test Data
§170.315 (b)(13)(i)	Inpatient setting: 170.315_b13_ds4p_inp_sample1*.xml Ambulatory setting: 170.315_b13_ds4p_amb_sample1*.xml Inpatient setting: 170.315_b13_ds4p_inp_sample1*.pdf Ambulatory setting: 170.315_b13_ds4p_amb_sample1*.pdf