The Office of the National Coordinator for
Health Information Technology

§170.315(b)(12) Data segmentation for privacy - send
Testing Components:
Gap · (document) · (magnifier) · (wand) · 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

Proposed Regulation Text

§170.315 (b)(12) *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) 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).

Standard(s) Referenced

Paragraph (b)(12)

§ 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)(12)

System Under Test	Test Lab Verification

1. Using the ETT: Message Validators – C-CDA R2.1 Validator, the health IT developer downloads the ONC-supplied data instructions through the sender download selections of the "170.315_b12_DS4P Amb" or "170.315_b12_DS4P_Inp" criteria and one of the DS4P instruction documents and executes the download.
2. Using the downloaded ONC-supplied DS4P instruction document(s), a user enters the information as appropriate into the Health IT Module including the DS4P tags and notices.
3. The user will generate a summary record document(s) from the Health IT Module and submit the document(s) to the tester for verification. The generated summary record includes the following data elements:
   o Document Level Confidentiality Code constrained in accordance with the standard specified in § 170.205(o)(1) HL7 Version 3 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1;
   o Document Level Author Element;
   o Document Level Provenance Element;
   o Privacy and Security Markings Section with Re-disclosure notice;
   o Privacy Segmented Section(s);
   o Privacy Markings Entr(ies); and
   o Mandatory Entry Provenance Element(s).
4. A summary record document must be submitted for each health IT setting being certified.
	1. Using the ETT: Message Validators – C-CDA R2.1 Validator, the tester uploads the submitted summary record(s) with restrictions (xml file) created by the SUT, through the sender upload selection of the "Data Segmentation for Privacy –send – Ambulatory" or "Data Segmentation for Privacy –send – Inpatient" criteria, and executes the upload of the submitted file(s) to the ETT: Message Validators in order to create Validation Report(s).
	2. The tester uses the Validation Report(s) created by the ETT: Message Validators to verify the Health IT Module passes without error in order to confirm that the document is conformant to each of the standards adopted in § 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2 Consolidation CDA Templates for Clinical Notes, DSTU Release 2.1 and § 170.205(a)(4)(i) HL7 CDA® Release 2 Implementation Guide: C-CDA Templates for Clinical Notes R1 Companion Guide, Release 1.
	3. If the summary record(s) submitted includes unstructured text data elements, the tester uses the ONC-supplied data instructions and the Message Content Report to verify the additional checks for equivalent text for the content of all section level narrative text.
	4. Using the ETT: Message Validators Message Content Report, the tester verifies that the summary record(s) submitted is accurate and without omission using the ONC-supplied data instructions.
	5. Using the ETT: Message Validators Message Content Report, the tester verifies that the summary record(s) indicates that the document(s) is restricted and subject to restrictions on re-disclosure.

System Under Test	Test Lab Verification
	The resulting document retains these tags according to the standard adopted at § 170.205(o)(1):
	o Privacy Segmented Document Template;
	o Privacy Segmented Section Template(s);
	o Privacy Markings Entry Template(s);
	o Mandatory Entry Provenance Template(s);
	o CDA Mandatory Document Provenance;
	o CDA Mandatory Document Assigned Author Template;
	o If a document, section, or entry contains information protected by specific privacy policies, CDA Privacy Markings Section with text indicating the nature of the explicit notice to the provider receiving the disclosed information;
	o If the metadata for a section is different than the overall document, the confidentiality levels and provenance information should be maintained; and
	o A Confidentiality Code with the value "R".

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)(12)	170.315_b12_DS4P_Amb 170.315_b12_DS4P_Inp