§170.315(b)(7) Data segmentation for privacy – send

2015 Edition Test Procedure

Version 1.2 Updated on 01-10-2017

Revision History		
Version #	**Description of Change**	**Version Date**
1.0	Final Test Procedure	01-20-2016
1.1	Added supplied test data and respective steps. Removed step 6 under TLV to remove redundancy. The General Header constraint bullet from TLV step 5 was removed.	12-07-2016
1.2	Updated TLV step 3 and 4 from 'Health IT developer-supplied data' to 'ONC-supplied data'.	01-10-2017

Regulation Text

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§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).

Standard(s) Referenced

Applies to entire criterion

§ 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(o)(1) HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1

Please consult the Final Rule entitled: 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications for a detailed description of the certification criterion with which these testing steps are associated. We also encourage developers to consult the Certification Companion Guide in tandem with the test procedure as they provide clarifications that may be useful for product development and testing.

Note: The order in which the test steps are listed reflects the sequence of the certification criterion and does not necessarily prescribe the order in which the test should take place.

Testing components

Gap				ONC Supplied Test Data

Paragraph (b)(7)

System Under Test

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_b7_DS4P Amb" or "170.315_b7_DS4P_Inp" criteria and one of the DS4P instruction documents and executes the download.
2. Using the ONC-supplied DS4P instruction document downloaded in step 1, 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:
   - Document Level Confidentiality Code constrained in accordance with the standard specified in § 170.205(o)(1) HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1;
   - Document Level Author Element;
   - Document Level Provenance Element; and
   - Privacy and Security Markings Section with Re-disclosure notice.
4. A summary record document must be submitted for each health IT setting being certified.

Test Lab Verification

1. Using the ETT: Message Validators – C-CDA R2.1 Validator, the tester uploads the submitted summary record(s) with restrictions (xml file) from step 4 of 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.

2. The tester uses the Validation Report(s) created by the ETT: Message Validators in step 1 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).

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. The resulting document retains these tags according to the standard adopted at § 170.205(o)(1):
   - Privacy Segmented Document Template;
   - CDA Mandatory Document Provenance;
   - CDA Mandatory Document Assigned Author Template;
   - If a document 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; and
   - A Confidentiality Code with the value "R."

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