

§170.315(b)(8) Data segmentation for privacy – receive

2015 Edition Test Procedure

Version 1.1 Updated on 12-07-2016

Revision History

| Version # | Description of Change | Version Date |
|-----------|---|--------------|
| 1.0 | Final Test Procedure | 01-20-2016 |
| 1.1 | Added supplied test data that includes content validation for DS4P. | 12-07-2016 |

Regulation Text

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§170.315 (b)(8) *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) that is document-level tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted in §170.205(o)(1);
- (ii) Sequester the document-level tagged document from other documents received; and
- (iii) View the restricted document without incorporating any of the data from the document.

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

| | | | | |
|---|---|---|---|---------------------------------|
|  |  |  |  | ONC Supplied Test Data |
|---|---|---|---|---------------------------------|

Paragraph (b)(8)(i)

System Under Test

SUT Instruction

1. Summary records in accordance with the test steps below, based on the health IT setting(s), are provided by the Edge Testing Tool.
2. The health IT developer identifies the policies associated with the handling of the Data Segmentation for Privacy documents.

Receive

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, that is tagged as restricted and subject to restrictions on re-disclosure, according to the standard adopted at § 170.205(o)(1) HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1, which includes the following:
 - 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, the CDA Privacy Markings Section.
4. The document received in step 3 includes the following data elements:
 - The originating document Individual Author or Organization; and
 - Confidentiality Code constrained in accordance with the standard specified in § 170.205(o)(1) HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1.
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) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1, without any restrictions.

Test Lab Verification

Test Lab Instruction

1. The tester creates a human readable version for each of the documents received in steps 3-5 of the SUT to be used for verification.

Receive

2. The tester verifies that a Health IT Module can receive a summary record document formatted in accordance with the standard specified at § 170.205(a)(4) that is document-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.
3. The tester verifies that a Health IT Module can receive a summary record document formatted in accordance with the standard specified at § 170.205(a)(4) that is not document-level tagged as restricted for each health IT setting being certified, using visual inspection.

Paragraph (b)(8)(ii)

System Under Test

1. Using the restricted document received in (b)(8)(i), and the Health IT Module, a user demonstrates the ability to associate the restricted document to a patient's record, but sequester it from other health IT developer supplied summary documents 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 that have been received for that specific patient but are not restricted.
2. Negative Testing: Using the setup from step 1, the user demonstrates that an unauthorized user does not have access to the restricted document received in (b)(8)(i).

Test Lab Verification

1. The tester verifies that based upon the policies identified in (b)(8)(i), the Health IT Module can sequester a document-level tagged document, formatted in accordance to the standard specified at § 170.205(a)(4), with restrictions on re-disclosure according to the standard adopted at § 170.205(o)(1) from other summary documents formatted in accordance to the standard specified at § 170.205(a)(4) for a specific patient, using visual inspection.
2. Negative Testing: The tester verifies that based upon the policies identified in (b)(8)(i), an unauthorized user does not have access to a sequestered document using visual inspection.

Paragraph (b)(8)(iii)

System Under Test

Setup

1. The Health IT Module creates users on the system that are authorized to review sequestered documentation and users that are not authorized to review sequestered documentation.

Viewing

2. Using the sequestered document identified in (b)(8)(ii) and the Health IT Module, authorized users view the document data without incorporating the data into the patient's record as discrete data elements.
3. Negative Testing: The user demonstrates that an unauthorized user cannot view the documents sequestered in (b)(8)(ii).

Test Lab Verification

Viewing

1. The tester verifies that the Health IT Module allows an authorized user to view the data in the restricted document without incorporating it into the patient's record (e.g. medications, medication allergies, problems) using visual inspection.
2. The tester verifies that the Health IT Module view of the document data includes the Data Segmentation for Privacy specific data, and that the data is complete and without omission; including:
 - o The General Header Author; and
 - o If a document contains information protected by specific privacy policies, text indicating the nature of the explicit notice to the provider receiving the disclosed information.
3. If the author of document sections is different than the document author, using the health IT developer-identified health IT function(s), the tester verifies that the Health IT Module provides the correct data provenance.
4. Negative Testing: The tester verifies that the Health IT Module does not allow unauthorized users to access or view restricted data or documents.

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