

2015 Edition §170.315(b)(7) Data Segmentation for Privacy - send					
Testing Components:					
					
Test Procedure Version 1.1 – Last Updated 10/30/15					

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.

Required Tests

(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 tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted at §170.205(o)(1).

Standards:

§170.205(o)(1): [Standard. HL7 Implementation Guide: Data Segmentation for Privacy \(DS4P\), Release 1](#) (incorporated by reference in § 170.299).

§170.205(a)(4): [HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1](#) (incorporated by reference in § 170.299).

Test Tool: [C-CDA Validator within the Edge Testing Tool](#)

Criteria ¶	System Under Test	Test Lab Verification
(b)(7)	<p>1. The user creates a summary record document in accordance with the standard adopted in §170.205(a)(4), HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1, and indicates that the document is restricted or subject to restrictions on re-disclosure. The resulting document retains these tags according to the standard adopted at §170.205(o)(1), Standard, HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1, when it is sent to a third party, and includes the following templates:</p> <ul style="list-style-type: none"> • 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 <p>And the following data elements:</p> <ul style="list-style-type: none"> • The 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. 	<ol style="list-style-type: none"> 1. Validation of a summary record with document restrictions is done using the top-level C-CDA Validator, one of the tool selections within the Edge Testing Tool. To validate the summary record with restrictions (xml file) created by the Health IT module, the tester uses the C-CDA Validator Tool within the Edge Testing Tool to select a C-CDA R2 Release 2.1 document as the criteria, uploads the summary record with restrictions (xml file), and selects validate. 2. The tester uses the Validation Report created by the C-CDA Validator in step 2 to verify the Health IT module passes without error in order to confirm that document is conformant to each of the standards adopted in §170.205(a)(4), 3. If the summary record submitted in step 2 includes unstructured text data elements, the tester uses the Health IT developer-supplied instruction to verify through visual inspection the additional checks for equivalent text for content for all section level narrative text. 4. The tester verifies that the summary record submitted in step 2 is accurate and without omission using visual inspection. 5. The tester verifies that the summary record in step 2 indicates that the document is restricted or subject to restrictions on re-disclosure. The resulting document retains these tags according to the standard adopted at §170.205(o) using visual inspection of the following within the summary record for the presence of the following: <ul style="list-style-type: none"> • 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 to the provider receiving the disclosed information; and • A Confidentiality Code with the value “R.” 6. The tester verifies that the summary record in step 2 includes the assigned author information within the document and provides data provenance in accordance with the standard adopted at §170.205(o) using visual inspection.

Document History

Version Number	Description of Change	Date
1.0	Released for Comment - NPRM	March 31, 2015
1.1	Released for Comment - FR	October 30, 2015

Dependencies: For all related and required criteria, please refer to the [Master Table of Related and Required Criteria](#).