



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

2015 Edition CCGs

Updated on 09-21-2018

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	12-30-2015
1.1	Provides notification of March 2017 Validator Update of C-CDA 2.1 Corrections adoption and compliance requirements within paragraph (b)(8)(i).	09-29-2017
1.2	Provides notification of April 2018 Validator Update of C-CDA 2.1 Corrections adoption and compliance requirements within paragraph (b)(8)(i). Note: Due to an error in calculation ONC is also updating the dates for compliance with the March 2017 Validator Update of C-CDA 2.1 Corrections that were adopted September 29, 2017.	05-02-2018
1.3	Provides notification of August 2018 Validator Update of C-CDA 2.1 Corrections adoption and compliance requirements within paragraph (b)(8)(i).	09-21-2018

Regulation Text

Regulation Text

§ 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](#)

Resource Documents

Resource Document

- [Privacy and Security Certification Companion Guide \[PDF - 281 KB\]](#)
- [2015 Edition Network Time Protocol \(NTP\) \[PDF - 157 KB\]](#)
- [CHPL SED Guide \[PDF - 690 KB\]](#)
- [Master Table of Related and Required Criteria \[PDF-251 KB\]](#)

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compliance requirements within paragraph (b)(8)(i).

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§ 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](#)

Testing

Testing Tool

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

Test Tool Documentation

[Test Tool Supplemental Guide](#)

Certification Companion Guide: Data segmentation for privacy - receive-

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the 2015 Edition final regulation. It extracts key portions of the rule's preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the 2015 Edition final rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

[Link to Final Rule Preamble](#)

Edition Comparision	Gap Certification Eligible	Base EHR Definition	In Scope for CEHRT Definition
New	No	Not Included	No

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(b)(8). As a result, an ONC Authorized Certification Body (ONC-ACB) must ensure that a product presented for certification to a § 170.315(b) criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (b) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be tested once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, exceptions exist for § 170.315(e)(1) “View, download, and transmit to 3rd party (VDT)” and (e)(2) “Secure messaging,” which are explicitly stated.

Table for Privacy and Security

- If choosing Approach 1:
 - [Authentication, access control, and authorization \(§ 170.315\(d\)\(1\)\)](#)
 - [Auditable events and tamper-resistance \(§ 170.315\(d\)\(2\)\)](#)
 - [Audit reports \(§ 170.315\(d\)\(3\)\)](#)
 - [Amendments \(§ 170.315\(d\)\(4\)\)](#)
 - [Automatic access time-out \(§ 170.315\(d\)\(5\)\)](#)
 - [Emergency access \(§ 170.315\(d\)\(6\)\)](#)
 - [End-user device encryption \(§ 170.315\(d\)\(7\)\)](#)
 - [Integrity \(§ 170.315\(d\)\(8\)\)](#)
- If choosing Approach 2:
 - For each applicable privacy and security certification criterion not certified using Approach 1, the health IT developer may certify using system documentation which is sufficiently detailed to enable integration such that the Health IT Module has implemented service interfaces to access external services necessary to meet the requirements of the privacy and security certification criterion. Please see the ONC Cures Act Final Rule at [85 FR 25710](#) for additional clarification.

Design and Performance: The following design and performance certification criteria (adopted in § 170.315(g)) must also be certified in order for the product to be certified.

- When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, the QMS’ need to be identified for every capability to which it was applied.
- When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied; or, alternatively, the developer must state that no accessibility-centered design was used.

Table for Design and Performance

- [Quality management system \(§ 170.315\(g\)\(4\)\)](#)
- [Accessibility-centered design \(§ 170.315\(g\)\(5\)\)](#)

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:

- No additional clarifications.

Paragraph (b)(8)(i)

Technical outcome – The health IT must be able to receive a summary record (formatted to Consolidated CDA Release 2.1) that is document-level tagged as restricted and subject to re-disclosure restrictions using the HL7® Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1.

Clarifications:

- The DS4P standard does not have a service discovery mechanism to determine if a potential recipient is able to receive a tagged document. ONC expects that providers will have to determine the receiving capabilities of their exchange partners, similar to how they have to work with their exchange partners today when they are manually exchanging sensitive health information via fax. [see [80 FR 62648](#)]
- In order to mitigate potential interoperability errors and inconsistent implementation of the HL7® Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1, ONC assesses, approves, and incorporates corrections as part of required testing and certification to this criterion. [see [ONC Health IT Certification Program Overview](#)] Certified health IT adoption and compliance with the following corrections are necessary because they implement updates to vocabularies, update rules for cardinality and conformance statements, and promote proper exchange of C-CDA documents. There is a 90-day delay from the time the CCG has been updated with the ONC-approved corrections to when compliance with the corrections will be required to pass testing (i.e., C-CDA 2.1 Validator). Similarly, there will be an 18-month delay before a finding of a correction's absence in certified health IT during surveillance would constitute a non-conformity under the Certification Program.
 - [March 2017 Validator Update of C-CDA 2.1 Corrections](#) [Effective for testing on December 28, 2017; Surveillance compliance date is March 29, 2019]
 - [April 2018 Validator Update of C-CDA 2.1 Corrections](#) [Effective for testing on July 31, 2018; Surveillance compliance date is November 2, 2019]
 - [August 2018 Validator Update of C-CDA 2.1 Corrections](#) [Effective for testing on December 20, 2018; Surveillance compliance date is March 21, 2020]

Paragraph (b)(8)(ii)

Technical outcome – A user must be able to separate the document-level tagged document from other documents received.

Clarifications:

- “Sequester” in this case means that only authorized users will have the ability to view the document. Once document-level tagged documents are received and stored in the Health IT Module they must only be accessible and viewable by authorized users and separated from other documents. The developer has full design and development discretion to implement a solution that handles this capability properly. Specific functionality other than authorized user access is not required, but if a developer opts to implement a more complex solution than described that is permissible and acceptable.

Paragraph (b)(8)(iii)

Technical outcome – A user must be able to view the restricted document without having to incorporate any of the data from the document.

Clarifications:

- No additional clarifications.

Content last reviewed on June 15, 2022