§170.315(b)(2) Clinical information reconciliation and incorporation

2015 Edition CCGs

Version 1.4 Updated on 09-21-2018

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	10-29-2015
1.1	Added the links to the test tool and test tool user guide.	01-29-2016
1.2	Provides notification of March 2017 Validator Update of C-CDA 2.1 Corrections adoption and compliance requirements for the entire criterion.	09-29-2017
1.3	Provides notification of April 2018 Validator Update of C-CDA 2.1 Corrections adoption and compliance requirements for the entire criterion. 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
1.4	Provides notification of August 2018 Validator Update of C-CDA 2.1 Corrections adoption and	09-21-2018

	compliance requirements for the entire criterion.	

Regulation Text

Regulation Text

§170.315 (b)(2) *Clinical information reconciliation and incorporation*—

(i) *General requirements.* Paragraphs (b)(2)(ii) and (iii) of this section must be completed based on the receipt of a transition of care/referral summary formatted in accordance with the standards adopted in §170.205(a)(3) and §170.205(a)(4) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates.

(ii) *Correct patient.* Upon receipt of a transition of care/referral summary formatted according to the standards adopted §170.205(a)(3) and §170.205(a)(4), technology must be able to demonstrate that the transition of care/referral summary received can be properly matched to the correct patient.

(iii) *Reconciliation.* Enable a user to reconcile the data that represent a patient's active medication list, medication allergy list, and problem list as follows. For each list type:

(A) Simultaneously display (i.e., in a single view) the data from at least two sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date.

(B) Enable a user to create a single reconciled list of each of the following: Medications; medication allergies; and problems.

(C) Enable a user to review and validate the accuracy of a final set of data.

(D) Upon a user's confirmation, automatically update the list, and incorporate the following data expressed according to the specified standard(s):

(1) Medications. At a minimum, the version of the standard specified in §170.207(d)(3);

(2) Medication allergies. At a minimum, the version of the standard specified in §170.207(d)(3); and

(3) Problems. At a minimum, the version of the standard specified in §170.207(a)(4).

(iv) *System verification.* Based on the data reconciled and incorporated, the technology must be able to create a file formatted according to the standard specified in §170.205(a)(4) using the Continuity of Care Document document template.

Standard(s) Referenced

Paragraphs (b)(2)(i) and (ii)

§ 170.205(a)(3) HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012

§ 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

Paragraphs (b)(2)(iii)(B) – (D)

§ 170.207(a)(4) International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), U.S. Edition, September 2015 Release

§ 170.207(d)(3) RxNorm, September 8, 2015 Full Release Update

Paragraph (b)(2)(iv)

§ 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

Additional Resources

§ 170.207(a)(3) International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) International Release July 31, 2012 and US Extension to SNOMED CT® March 2012

§ 170.207(d)(2) RxNorm, August 6, 2012 Full Release Update

Certification Companion Guide: Clinical information reconciliation and incorporation

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
Revised	No	Not Included	Yes

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(b)(2). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(b) "paragraph (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) "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))
  - 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 P&S certification criterion not certified for approach 1, the health IT developer may certify for the criterion using system documentation which provides a clear description of how the external services necessary to meet the P&S criteria would be deployed and used. Please see the 2015 Edition final rule correction notice at 80 FR 76870 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.

- Safety-enhanced design (§ 170.315(g)(3)) must be explicitly demonstrated for this criterion.
- 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.
- C-CDA creation performance (§ 170.315(g)(6)) does not need to be explicitly tested with this criterion unless it is the only criterion within the scope of the requested certification that includes C-CDA creation capabilities. Note that the application of § 170.315(g)(6) depends on the C-CDA templates explicitly required by the C-CDA-referenced criterion or criteria included within the scope of the certificate sought. Please refer to the C-CDA creation performance Certification Companion Guide for more details.

Table for Design and Performance

- Safety-enhanced design (§ 170.315(g)(3))
- Quality management system (§ 170.315(g)(4))
- Accessibility-centered design (§ 170.315(g)(5))
- Consolidated CDA creation performance (§ 170.315(g)(6))

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:

- The scope of this criterion is limited to the Consolidated CDA (C-CDA) Continuity of Care Document (CCD), Referral Note, and (inpatient setting only) Discharge Summary document templates. [see also 80 FR 62639]
- "Incorporation" means to electronically process structured information from another source such that it is combined (in structured form) with information maintained by health IT and is subsequently available for use within the health IT system by a user. [see also 77 FR 54168 and 77 FR 54218]
- 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 FAQ #51] 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. Consistent with FAQ 51, 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 consistent with FAQ 51, 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 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)(2)(i)

Clarifications:

- We are requiring Health IT Modules to be able to reconcile and incorporate information from C-CDAs formatted to both C-CDA Releases 1.1 and 2.1. While Release 2.1 largely ensures compatibility between C-CDA Release 1.1 and 2.0, it does not guarantee compatibility without further development effort. [see also 80 FR 62639]

Paragraph (b)(2)(ii)

Technical outcome – The health IT can properly match a received transition of care (ToC)/referral summary (for both Releases 1.1 and 2.1) to the correct patient.

Clarifications:

- Health IT Modules do not have to auto-match the patient. Manual patient match is acceptable as long as the received C-CDA can be matched to the correct patient. [see also 80 FR 62640 and 77 FR 54219]

Paragraph (b)(2)(iii)(A)

Technical outcome – A user can simultaneously display a patient's active data and the data attributes from two sources, for each of a patient's medication list, medication allergy list, and problem list. The data display must include the source and the last modification date.

Clarifications:

- A vendor must enable a user to electronically and simultaneously display (that is in a single view) the data from at least two list sources. If the two lists cannot be displayed in the tool at the same time this does not constitute a single view and does not meet the requirements for the certification criterion.

Paragraphs (b)(2)(iii)(B) - (D)

Technical outcome – A user can review, validate, and incorporate a patient's medication list (using RxNorm), medication allergy list (using RxNorm), and problem list (using SNOMED CT®).

Clarifications:

- The health IT can enable a user to review, validate, and incorporate medications, medication allergies, and problems in distinct functions, or combined, as long as all three can be demonstrated. [see also 80 FR 62639]
- Testing will evaluate health IT ability to incorporate data from C-CDA documents with variations in the data elements to be reconciled to test real-world variation that may be found in C-CDA documents. [see also 80 FR 62639]
- ONC encourages developers to incorporate data in a structured format. [see also 77 FR 54219]
- Incorporation does not have to be automated. [see also 77 FR 54219]
- Health IT Modules can present for certification to a more recent version of RxNorm than the September 8, 2015 Release per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62620]
- Health IT Modules can present for certification to a more recent version of SNOMED CT®, U.S. Edition than the September 2015 Release per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62620]
- We provide the following OIDs to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards.
  - RxNorm OID: 2.16.840.1.113883.6.88.
  - SNOMED CT® OID: 2.16.840.1.113883.6.96. [see also 80 FR 62612]

Paragraph (b)(2)(iv)

Technical outcome – The health IT can create a C-CDA document (using the CCD template in C-CDA Release 2.1) that includes the reconciled and incorporated data.

Clarifications:

- No additional clarifications available.

Content last reviewed on May 20, 2020