HealthIT.gov

§170.315(b)(9) Care plan

2015 Edition CCGs

Updated on 06-15-2020

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	10-30-2015
1.1	Added clarifications that Consolidated CDA creation performance is required for this certification criterion per the 2015 Edition final rule Correction Notice. Added clarification about the data expected in the “Goals” and “Health Concerns” Sections. Added clarification that Health IT Modules are not required to enable a user to reconcile received care plan data.	01-05-2016
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	09-21-2018

	2018 Validator Update of C-CDA 2.1 Corrections adoption and compliance requirements for the entire criterion.	
1.5	Updated the Security requirements per 21st Century Cures Act.	06-15-2020

Regulation Text

Regulation Text

§ 170.315 (b)(9) *Care plan*—

Enable a user to record, change, access, create, and receive care plan information in accordance with the Care Plan document template, including the Health Status Evaluations and Outcomes Section and Interventions Section (V2), in the standard specified in § 170.205(a)(4).

Standard(s) Referenced

Applies to entire criterion

§ 170.205(a)(4) Health Level 7 (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

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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Testing

Testing Tool

Edge Testing Tool (ETT): Message Validators

Test Tool Documentation

Test Tool Supplemental Guide

Certification Companion Guide: Care plan

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
Link to Correction Notice 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)(9). 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.
- § 170.315(d)(2)(i)(C) is not required if the scope of the Health IT Module does not have end-user device encryption features.

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))
- Encrypt authentication credentials (§ 170.315(d)(12))
- Multi-factor authentication (MFA) (§ 170.315(d)(13))

- If choosing Approach 2:
  - For each applicable privacy and security certification criterion not certified for 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 the Health IT Module to access external services necessary to meet the requirements of the privacy and security certification criterion. Please see the *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* 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.
- Consolidated Clinical Document Architecture (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 CCG for more details.

Table for Design and Performance

- 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

Technical outcome – A user can record, change, access, create, and receive care plan information according to the Care Plan document template in the HL7® Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1, including the Health Status Evaluations and Outcomes Section and Interventions Section (V2).

Clarifications:

- The Care Plan document template supports broader information about the patient, including education, physical therapy/range of motion, and social interventions not commonly found in other parts of the C-CDA standard and is also distinct from the 'Plan of Treatment Section' in Version 2.1 of the C-CDA. (The Plan of Care Section in C-CDA 1.1 was renamed Plan of Treatment Section in C-CDA 2.0 and 2.1). [see also 80 FR 62648]
- The Care Plan document template is distinct from the "Plan of Care Section" in previous versions of the C-CDA. [see also 80 FR 62648]

- Consistent with ONC policy, health IT must enable a user to record, change, access, create, and receive information for those sections of the C-CDA Care Plan template that are required, including the “Goals” and “Health Concerns” Sections. [see also 80 FR 62648] ONC would expect that these sections could contain patient-expressed information, including patient-expressed goals and health concerns. Because of this, the information contained within the “Goals” and “Health Concerns” Sections of the care plan document could differ from the information contained within those same sections in a transition of care/referral summary document.
- Health IT must enable a user to record, change, access, create, and receive information for the “Health Status Evaluations and Outcomes Section” and “Interventions Section (V2)”. Although these sections are deemed optional in the C-CDA standard, they are required for certification. [see also 80 FR 62649]
- Although a system will need to be able to receive a care plan in accordance with C-CDA Release 2.1, the system is not required to enable a user to reconcile the care plan data. [see also 80 FR 62649]
- 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 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]

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