

# 2015 Edition Certification Companion Guide

## Care Plan - 45 CFR 170.315(b)(9)

Links will be updated as available: [Final Rule Preamble](#) – [Correction Notice Preamble](#) – [Test Procedure](#) – [Test Tool/Data](#) – [Test Tool User Guide](#)

Version 1.1 – Last Updated 1/5/2016

New/Revised/Unchanged Compared to 2014 Edition	Gap Certification Eligible	Base EHR Definition	In Scope for Certified EHR Technology Definition	Associated EHR Incentive Program Objective(s)
New	No	No	No	N/A

### Certification Requirements

**Privacy and Security:** This certification criterion was adopted at § 170.315(b)(9). 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.

**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.
- 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.

Privacy and Security (§ 170.315(d))	Design and Performance (§ 170.315(g))
<ul style="list-style-type: none"> <li>• If choosing Approach 1: <ul style="list-style-type: none"> <li>○ <a href="#">Authentication, access control, and authorization (§ 170.315(d)(1))</a></li> <li>○ <a href="#">Auditable events and tamper-resistance (§ 170.315(d)(2))</a></li> <li>○ <a href="#">Audit reports (§ 170.315(d)(3))</a></li> <li>○ <a href="#">Automatic access time-out (§ 170.315(d)(5))</a></li> <li>○ <a href="#">Emergency access (§ 170.315(d)(6))</a></li> <li>○ <a href="#">End-user device encryption (§ 170.315(d)(7))</a></li> <li>○ <a href="#">Integrity (§ 170.315(d)(8))</a></li> </ul> </li> <li>• If choosing Approach 2: <ul style="list-style-type: none"> <li>○ For each applicable P&amp;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&amp;S criteria would be deployed and used. Please see the 2015 Edition final rule correction notice at <a href="#">80 FR 76870</a> for additional clarification.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">Quality management system (§ 170.315(g)(4))</a></li> <li>• <a href="#">Accessibility-centered design (§ 170.315(g)(5))</a></li> <li>• <a href="#">Consolidated CDA creation performance (§ 170.315(g)(6))</a></li> </ul>

**Regulation Text**

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).

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion	<p>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).</p> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>• 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 <a href="#">80 FR 62648</a>]</li> <li>• The Care Plan document template is distinct from the “Plan of Care Section” in previous versions of the C-CDA. [see also <a href="#">80 FR 62648</a>]</li> <li>• 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 <a href="#">80 FR 62648</a>] We 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.</li> <li>• 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 <a href="#">80 FR 62649</a>]</li> <li>• 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 <a href="#">80 FR 62649</a>]</li> </ul>	<p>§ 170.205(a)(4) <a href="#">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</a></p>

**Note:** 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.

## Version History

Version #	Change(s) Summary	Date Made
1.0	Initial Publication	Oct 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.	Jan 5, 2016