HealthIT.gov

# §170.315(b)(9) Care plan

2015 Edition Test Procedure

**Updated on 01-20-2016**

## Revision History

| Version # | Description of Change | Version Date |
|---|---|---|
| 1.0 | Final Test Procedure | 01-20-2016 |

## 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**

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.

# Testing components

| | | | | |
|---|---|---|---|---|
| Gap | | | | ONC Supplied Test Data |

### Paragraph (b)(9) - Record

#### System Under Test

**Record**

1. Using the ETT: Message Validators – C-CDA R2.1 Validator, the health IT developer downloads the ONC-supplied data instructions through the sender download selections of the “170.315_b9_CP_Amb” or “170.315_b9_CP_Inp” criteria and one of the care plan instruction documents and executes the download.
2. Using the ONC-supplied care plan instruction document returned in step 1, a user enters the care plan information into the Health IT Module.
3. The user records care plan information that includes the following:
   - Patient Name;
   - Goals;
   - Health Concerns;
   - Health Status Evaluations and Outcomes; and
   - Interventions.
4. Based on the health IT setting(s) to be certified, a user repeats steps 1-3, for each of the ambulatory and/or inpatient care plan instruction documents found in the ETT: Message Validators. The recording of a care plan is required for all the care plan instruction documents for a given health IT setting.

#### Test Lab Verification

**Record**

1. For each care plans recorded by the SUT, the tester verifies the outlined care plan information has been recorded correctly and without omission through visual inspection of the SUT using the ONC-supplied care plan instruction document associated with the recorded care plan.

### Paragraph (b)(9) - Change and Access

#### System Under Test

**Change and Access**

Using the Health IT Module, the user accesses and changes the care plan information for a specific patient that includes the following:

- Patient Name;
- Goals;
- Health Concerns;
- Health Status Evaluations and Outcomes; and
- Interventions.

#### Test Lab Verification

**Change and Access**

The tester verifies care plan information can be accessed and changed using visual inspection of the SUT.

### Paragraph (b)(9) - Create

#### System Under Test

**Create**

1. For each care plan recorded by the Health IT Module, the user creates a care plan document formatted in accordance with the Care Plan document template in the standard adopted at § 170.205(a)(4) HL7® Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1, and includes the Health Status Evaluations and Outcomes Section and Interventions Section (V2), which at a minimum includes:
   - Patient Name
   - Goals
   - Health Concerns
   - Health Status Evaluations and Outcomes
   - Interventions.
2. For each care plan document created in step 1, the user submits the care plan document to the tester for verification.

#### Test Lab Verification

**Create**

1. Using the ETT: Message Validators – C-CDA R2.1 Validator, the tester uploads the submitted care plan (xml file) created by the Health IT Module in step 1, of the SUT, through the sender upload selection of the “170.315_b9_CP_Amb” or “170.315_b9_CP_Inp” criteria and file name of the care plan recorded by the SUT, and executes the upload of the submitted file to the ETT: Message Validators.
2. The tester uses the Validation Report produced by the ETT: Message Validators in step 1 to verify the validation report indicates passing without error to confirm that the care plan is a C-CDA R2 Release 2.1, document conformant to the standard specified at § 170.205(a)(4) and includes the Health Status Evaluations and Outcomes Section and Interventions Section (V2).
3. As required by the ONC-supplied care plan instructions with the corresponding file names as uploaded in step 1, the tester uses the ONC-supplied care plan document and the ETT: Message Validators Message Content Report to verify the additional checks for equivalent text for the content of all section level narrative text.

## Paragraph (b)(9) - Receive

### System Under Test

**Receive**

1. Using the ETT: Message Validators - C-CDA R2.1 Validator, the health IT developer downloads the ONC-supplied care plan xml documents through the receiver download selections of the “170.315_CP_Amb” or “170.315_CP_Inp” criteria and care plan xml file and executes the download of the care plan xml file.
2. Using the Health IT Module, a user receives the care plan (xml files) downloaded from the ETT: Message Validators in step 1, which is formatted in accordance with the Care Plan document template in the standard adopted at § 170.205(a)(4) HL7® Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1, and includes the Health Status Evaluations and Outcomes Section and Interventions Section (V2), which at a minimum includes:
   - Patient Name;
   - Goals;
   - Health Concerns;
   - Health Status Evaluations and Outcomes; and
   - Interventions.
3. Based upon the health IT setting(s) to be certified, a user repeats steps 1-2, for each ambulatory and/or inpatient care plan (xml) document in the ETT: Message Validators. All of the care plan (xml) documents for a given health IT setting must be received.

**Negative Test**

4. Using the ETT: Message Validators – C-CDA R2.1 Validator, the health IT developer downloads the ONC-supplied care plan negative test xml documents through the receiver download selections of the “NegativeTesting CarePlan” criteria and one of the invalid C-CDA documents and executes the download of the invalid C-CDA xml file.
5. Using the Health IT Module, the user receives the applicable C-CDA document types containing errors in the corresponding “document-templates,” “section-templates,” and “entry-templates” including invalid vocabulary standards and codes not specified in the standards adopted in at § 170.205(a)(4) HL7® Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1, and reports the errors.
6. A user repeats steps 4 and 5, for each of the negative test samples in ETT: Message Validators “NegativeTesting_CarePlan.” All of the negative test care plan (xml) documents must be received.

### Test Lab Verification

**Receive**

1. The tester creates a human readable version of the care plan document downloaded in step 1, of the SUT to be used for verification.
2. For each care plan document received, the tester verifies that the Health IT Module can receive a care plan document formatted in accordance with the standard specified at § 170.205(a)(4) and includes the Health Status Evaluations and Outcomes Section and Interventions Section (V2) using visual inspection.
3. Using the Health IT Module, the tester verifies that the care plan document received in step 2, is accurate and without omission through the visual inspection.

**Negative Test**

4. For each invalid C-CDA document received, the tester uses visual inspection to verify that the Health IT Module can successfully identify errors in the C-CDA documents not specified in accordance with the standards adopted in § 170.205(a)(4) including:
   - “document-templates;”
   - “section-templates;”
   - “entry-templates;”
   - Invalid vocabulary standards; and
   - Invalid codes.

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