

2015 Edition §170.315(b)(6) Data Export					
Testing Components:					
				Data	
Test Procedure Version 1.1 – Last Updated 10/30/15					

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.*

## Required Tests

### (b)(6)(i) General Requirements for Export Summary Configuration

- (A) Enable a user to set the configuration options specified in paragraph (b)(6)(ii) through (iv) of this section when creating an export summary as well as a set of export summaries for patients whose information is stored in the technology. A user must be able to execute these capabilities at any time the user chooses and without subsequent developer assistance to operate.
- (B) Limit the ability of users who can create export summaries in at least one of these two ways:
  - (1) To a specific set of identified users
  - (2) As a system administrative function.

**Standards:** None

Criteria ¶	System Under Test	Test Lab Verification
(i)	<ol style="list-style-type: none"> <li>1. The user demonstrates the ability to configure the following data export configuration options at any time: <ul style="list-style-type: none"> <li>• Document creation configuration as specified in (b)(6)(ii);</li> <li>• Timeframe configuration as specified in (b)(6)(iii); and</li> <li>• Location Configuration as specified in (b)(6)(iv).</li> </ul> </li> <li>2. The user demonstrates the ability to limit the set of users who can create export summaries, either: <ul style="list-style-type: none"> <li>• by specifying an identified set of users; or</li> <li>• providing this functionality as an administrative function.</li> </ul> </li> <li>3. The user demonstrates that a user who has not been granted the ability to create export summaries cannot create export summaries.</li> </ol>	<ol style="list-style-type: none"> <li>1. The tester verifies that an authorized user can modify the following configuration options any time without assistance from a developer: <ul style="list-style-type: none"> <li>• Document creation configuration;</li> <li>• Timeframe configuration; and</li> <li>• Location Configuration.</li> </ul> </li> <li>2. Negative test: The tester verifies that an unauthorized user cannot modify any of the configuration options associated with the data export including: <ul style="list-style-type: none"> <li>• Document creation configuration;</li> <li>• Timeframe configuration; and</li> <li>• Location Configuration.</li> </ul> </li> <li>3. The tester verifies that an authorized user can limit the set of users who can create export summaries either: <ul style="list-style-type: none"> <li>• by specifying an identified set of users; or</li> <li>• providing this functionality as an administrative function.</li> </ul> </li> <li>4. Negative test: The tester verifies that an unauthorized user cannot modify which users can create export summaries.</li> </ol>

**(ii) Creation configuration**

Enable a user to configure the technology to create export summaries formatted in accordance with the standard specified in § 170.205(a)(4) using the Continuity of Care Document template that includes, at a minimum:

- (A) The Common Clinical Data Set.
- (B) Encounter diagnoses. Formatted according to at least one of the following standards:
  - (1) The standard specified in § 170.207(i)
  - (2) At a minimum, the version of the standard specified in § 170.207(a)(4).
- (C) Cognitive status.
- (D) Functional status.
- (E) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information.
- (F) Inpatient setting only. Discharge instructions.

**Standards:** § 170.205(a)(4) [HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1](#) (incorporated by reference in § 170.299).

§ 170.207(b)(3) [CDT](#)

§ 170.207(b)(2) [CPT-4](#)

§ 170.207(f)(2) [“Race & Ethnicity – CDC” code system in the PHIN Vocabulary Access and Distribution System \(VADS\), Release 3.3.9](#)

§ 170.207(e)(4) [National Drug Code Directory– Vaccine Codes, updates through August 3, 2015](#)

§ 170.207(b)(4) [ICD-10-PCS](#)

§ 170.207(i) [ICD-10-CM](#)

§ 170.207(e)(3) [HL7 Standard Code Set CVX—Vaccines Administered, updates through June 18, 2015](#)

§ 170.207(f)(1) [The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997](#)

§ 170.207(c)(3) [Logical Observation Identifiers Names and Codes \(LOINC®\) Database version 2.52](#)

§ 170.207(m)(1) [The Unified Code of Units of Measure, Revision 1.9](#)

§ 170.207(g)(2) [Request for Comments \(RFC\) 5646: Tags for Identifying Languages](#)

§ 170.207(q)(1) [International Telecommunication Union E.123:Notation for national and international telephone numbers, e-mail addresses and web addresses and International](#) and [Telecommunication Union E. 164: The international public telecommunication numbering plan](#)

§ 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 [http://www.nlm.nih.gov/research/umls/Snomed/us\\_edition.html](http://www.nlm.nih.gov/research/umls/Snomed/us_edition.html),

§ 170.207(d)(3) [RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release](#)

§ 170.207(h) Smoking status must be coded in one of the following SNOMED CT® codes:

- (1) Current every day smoker. 449868002
- (2) Current some day smoker. 428041000124106
- (3) Former smoker. 8517006
- (4) Never smoker. 266919005
- (5) Smoker, current status unknown. 77176002
- (6) Unknown if ever smoked. 266927001
- (7) Heavy tobacco smoker. 428071000124103
- (8) Light tobacco smoker. 428061000124105

§ 170.207(n)(1) Birth sex must be coded in accordance with HL7 Version 3 attributed as follows:

- (i) Male. M
- (ii) Female. F
- (iii) Unknown. UNK

**Test Data:** [C-CDA Validator within the Edge Testing Tool.](#)

Inpatient Settings: 170.315\_b6\_de\_inp\_sample\*.pdf (All Samples)

Ambulatory Settings: 170.315\_b6\_de\_amb\_sample\*.pdf (All Samples)

**Test Tool:** [C-CDA Validator within the Edge Testing Tool](#).

Criteria ¶	System Under Test	Test Lab Verification
(ii)	<p>1. An authorized user creates export summary documents formatted as a Continuity of Care (CCD) document template in accordance with the standard specified in § 170.205(a)(4), HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, Release 2.1 including at minimum the following data elements:</p> <ul style="list-style-type: none"> <li>• Common Clinical Data Set (CCDS) including: <ul style="list-style-type: none"> <li>○ Patient Name</li> <li>○ Sex constrained including birth sex</li> <li>○ Date of Birth.</li> <li>○ Race and Ethnicity</li> <li>○ Preferred language</li> <li>○ Smoking Status</li> <li>○ Problems constrained</li> <li>○ Medications constrained</li> <li>○ Medication Allergies</li> <li>○ Laboratory Tests constrained</li> <li>○ Laboratory Values(s)/Result(s)</li> <li>○ Vital Signs</li> <li>○ Procedures constrained</li> <li>○ Care Team Member(s)</li> <li>○ Immunizations constrained</li> <li>○ Unique Device Identifier(s) for a Patient’s Implantable Device(s)</li> <li>○ Assessment and Plan of Treatment</li> <li>○ Goals</li> <li>○ Health Concerns</li> </ul> </li> </ul> <p>The complete list of the Common Clinical Data Set and associated standards can be referenced in <a href="#">Table 8</a> of the Final Rule.</p>	<ol style="list-style-type: none"> <li>1. The tester verifies an authorized user can create export summary documents using the ONC test data instructions on the export summary document templates formatted in accordance with the standard specified in § 170.205(a)(4) and including at a minimum the following applicable data elements defined in the Common Clinical Data Set and (6)(ii)(B)-(F).</li> <li>2. Negative Test: Using the Health IT module, the tester verifies an unauthorized user cannot create export summary document templates.</li> <li>3. Validation of an export data summary record is done using the top-level C-CDA Validator, one of the tool selections within the Edge Testing Tool. To validate the data export summary record (xml file) created by the Health IT module, the tester uses the C-CDA Validator Tool within the Edge Testing Tool to select the criteria to be verified based upon the originally downloaded test case document and uploads the data export summary record (xml file) created by the Health IT module.</li> </ol> <ol style="list-style-type: none"> <li>2. For each test case, the tester uploads the data export summary record xml file into the top-level C-CDA Validator Tool within the Edge Testing Tool and uses the Validation Report produced by the test tool to verify the Health IT module passes without error to confirm that the data export summary record is a CCD document conformant to the standard adopted in § 170.205(a)(4).</li> <li>3. As required by the test case, the tester uses the ONC-supplied data export summary record instructions and the data export summary record xml file from step 3 to verify through Visual Inspection the additional checks for equivalent text for content for all section level narrative text.</li> </ol>

Criteria ¶	System Under Test	Test Lab Verification
(ii)	<ul style="list-style-type: none"> <li>• Encounter diagnoses in the standard specified at §170.207(i), code set specified at 45 CFR 162.1002(c)(2) for the indicated conditions ICD-10-CM as maintained and distributed by HHS, for the following conditions:               <ul style="list-style-type: none"> <li>(i) Diseases.</li> <li>(ii) Injuries.</li> <li>(iii) Impairments.</li> <li>(iv) Other health problems and their manifestations.</li> <li>(v) Causes of injury, disease, impairment, or other health problems</li> </ul>               or at a minimum the version of the standard specified at §170.205(a)(4) (ICD-10-CM or SNOMED CT®)             </li> <li>• Cognitive status;</li> <li>• Functional Status;</li> <li>• For ambulatory settings only: reason for referral, referring or transitioning provider’s name, and office contact information;</li> <li>• For inpatient settings only: discharge instructions as applicable.</li> </ul> <p>4. Based upon the health IT setting(s) ambulatory and/or inpatient, a user enters the data export information for each of the ambulatory and/or inpatient test cases referenced from the data export sample documents into the Health IT module. All test cases for a given health IT setting are required. The user retrieves the required Data Export instructions for entering data into the Health IT module from the top-level C-CDA Validator, one of the tool selections within the Edge Testing Tool.</p> <p>5. Using the C-CDA Validator, the user selects the ambulatory and/or inpatient Data Export documents (pdf) and selects</p>	

Criteria ¶	System Under Test	Test Lab Verification
(ii)	<p>download to download the required Data Export information documents.</p> <ul style="list-style-type: none"> <li>The user creates summary records to export based on Data Export information entered into the Health IT module and on the export summary document templates created in Step 1.</li> </ul>	

(iii) Timeframe configuration

(A) Enable a user to set the date and time period within which data would be used to create the export summaries. This must include the ability to enter in a start and end date and time range.

(B) Consistent with the date range specified in paragraph (b)(6)(iii)(A) of this section, enable a user to do each of the following:

- (1) Create export summaries in real-time;
- (2) Create export summaries based on a relative date and time (e.g., the first of every month at 1:00am); and
- (3) Create export summaries based on a specific date and time (e.g., on 10/24/2015 at 1:00am).

**Standards:** None

Criteria ¶	System Under Test	Test Lab Verification
(iii)(A)	<ol style="list-style-type: none"> <li>1. An authorized user demonstrates that the time period within which data would be used to create the export summary or set of export summaries can be configured with a start and end date and time range so that the export can occur: <ul style="list-style-type: none"> <li>• In real-time, and include data from the start date and time until now;</li> <li>• Based upon a relative date and time (e.g., the first of every month at 1:00am) from the entered start and end dates and times; and</li> <li>• Based upon a specific date (e.g., on 10/24/2015 at 1:00am) from the entered start and end dates and times.</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>1. The tester verifies that the timeframe configuration start and end dates and times can be modified for a: <ul style="list-style-type: none"> <li>• real-time export,</li> <li>• export based upon a relative date; and</li> <li>• export based upon a specific date.</li> </ul> </li> </ol>

Criteria ¶	System Under Test	Test Lab Verification
(iii)(B)	<p>1. The user exports a summary based upon the export summary document template created in (6)(b)(ii) for each of the types of export summaries or set of export summaries:</p> <ul style="list-style-type: none"> <li>• A real-time export;</li> <li>• A relative date export; and</li> <li>• A specific date export.</li> </ul>	<p>1. The tester verifies that the data in the export summaries cover the correct time periods and the data contained within the export is complete and without omission.</p>

#### (iv) Location Configuration

Enable a user to set the storage location to which the export summary or export summaries are intended to be saved.

**Standards:** None

Criteria ¶	System Under Test	Test Lab Verification
(iv)	<p>1. An authorized user is able to set the location where the export summaries are to be saved.</p> <p>2. An authorized user is able to store export summaries to a configured location.</p>	<p>1. The tester verifies that an authorized user can set the location where the export summaries are to be saved to the local disk or a network disk.</p> <p>2. The tester verifies that export summaries can be saved to the configured export location.</p>

#### Document History

Version Number	Description of Change	Date
1.0	Released for Comment - NPRM	March 20, 2015
1.1	Released for Comment - FR	October 30, 2015

Dependencies: For all related and required criteria, please refer to the [Master Table of Related and Required Criteria](#).