

§170.315(b)(6) Data export

2015 Edition Test Procedure

Version 1.0 Updated on 01-20-2016

Revision History

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

Regulation Text

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§170.315(b)(6) *Data export*—

- (i) *General requirements for export summary configuration.*
 - (A) Enable a user to set the configuration options specified in paragraphs (b)(6)(iii) and (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.
- (ii) *Creation.* Enable a user to create export summaries formatted in accordance with the standard specified in §170.205(a)(4) using the Continuity of Care Document 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.
- (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 and time period 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 1:00 a.m.); and
 - (3) Create export summaries based on a specific date and time (e.g., on 10/24/2015 at 1:00 a.m.).
- (iv) *Location configuration.* Enable a user to set the storage location to which the export summary or export summaries are intended to be saved.

Standard(s) Referenced

Paragraph (b)(6)(ii)

§ 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](#)

§ 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(i) [ICD-10-CM](#)

Please refer to the Data Elements and Vocabularies applicable to the Common Clinical Data Set (CCDS) as outlined in the Common Clinical Data Set Reference Document

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

				ONC Supplied Test Data
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Paragraph (b)(6)(i)

System Under Test

Configuration

1. The user demonstrates the ability to configure the following data export configuration options at any time:
 - o Timeframe configuration as specified in (b)(6)(iii); and
 - o Location Configuration as specified in (b)(6)(iv).
2. The user demonstrates the ability to limit the set of users who can create export summaries, either:
 - o by specifying an identified set of users; or
 - o providing this functionality as an administrative function.
3. Negative Test: The user demonstrates that a user who has not been granted the ability to create export summaries cannot create export summaries.

Export Any Time

4. A user can execute the export summary configuration capability described in (b)(6)(i) steps 1 and 2 any time the user chooses and without subsequent developer assistance to operate.

Test Lab Verification

Configuration

1. The tester verifies that an authorized user can modify the following configuration options without assistance from a developer:
 - o Timeframe configuration; and
 - o Location Configuration.
2. Negative test: The tester verifies that an unauthorized user cannot modify any of the configuration options associated with the data export including:
 - o Document creation configuration;
 - o Timeframe configuration; and
 - o Location Configuration.
3. The tester verifies that an authorized user can limit the set of users who can create export summaries either:
 - o by specifying an identified set of users; or
 - o providing this functionality as an administrative function.
4. The tester verifies an authorized user can create export summary documents.
5. Negative test: The tester verifies that an unauthorized user cannot create export summaries.

Export Any Time

6. Via documentation submitted by the health IT developer, the tester verifies that a user can configure an export summary as specified in (b)(6)(i) any time the user chooses and without subsequent developer assistance to operate.

Paragraph (b)(6)(ii)

System Under Test

Create

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_DE_Amb” or “170.315_DE_Inp” criteria and one of the data export instruction documents, and executes the download.
2. Using the ONC-supplied data export data instruction document returned in step 1, the user creates patient records in the Health IT Module.
3. Using the Health IT Module and the downloaded instruction document from step 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:
 - Common Clinical Data Set (CCDS);
 - Encounter diagnoses;
 - Cognitive status;
 - Functional status;
 - *Ambulatory setting only*: reason for referral, and referring or transitioning provider's name and office contact information; and
 - *Inpatient setting only*: the discharge instructions.
4. The user submits the data export summary created in step 3 to be verified.
5. Based on the health IT setting(s) to be certified, a user repeats steps 1-4 for each of the ambulatory and/or inpatient data export instruction document found in the ETT: Message Validators. The data export is required for all of the data export instruction documents for a given health IT setting.

All Patient Data Export

6. Using the Health IT Developer-supplied data, the user creates records for multiple patients which can be used for data export in the Health IT Module.
7. An authorized user creates a set of export summaries which includes data from all of the patients in the Health IT Module.

Sub-Set of Patients Data Export

8. Using the Health IT Developer-supplied selection criteria, an authorized user creates a set of export summaries which includes a sub-set of the patients in the Health IT Module.

Test Lab Verification

Create

1. Using the ETT: Message Validators – C-CDA R2.1 Validator, the tester uploads the submitted data export summary record (xml file) created by the Health IT module, through the sender upload selection of the “170.315_DE_Amb” or “170.315_DE_Inp” criteria and file name, and executes the uploads of the submitted file to the ETT: Message Validators.

Note: In the case where the data export summary contains multiple xml files, the xml files must be submitted to the ETT: Message Validators one at a time.

2. For each submitted data export summary document, the tester uses the Validation Report produced by the ETT: Message Validators 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) and including at a minimum the following applicable data elements defined in the Common Clinical Data Set and (b)(6)(ii)(A)-(F).
3. As required by the ONC-supplied data export summary record instructions, the tester uses the ONC-supplied data export summary record instructions and ETT: Message Validators Message Content Report to verify the additional checks for equivalent text for the content of all section level narrative text.

All Patient Data Export

4. Using the Health IT Developer-supplied data from the SUT in step 6 and the data export summaries with all of the patients created from the SUT in step 7, the tester verifies that the number of data export documents is correct.
5. The tester creates a human readable version of the data export summaries from step 4 and verifies that the all of the patients in the Health It Module are present in the data export summaries.

Sub-Set of Patients Data Export

6. Using the Health IT Developer-supplied data from the SUT in step 6, and the selection criteria and the data export summaries with a sub-set of the patients created from the SUT in step 8, the tester verifies that the number of data export documents is correct.
7. The tester creates a human readable version of the data export summaries from step 6 and verifies that the correct patients are present in the set of data export summaries.

Paragraphs (b)(6)(ii)(A)–(F)

System Under Test

The Data Export Summary CCD Document created in section (b)(6)(ii) at a minimum contains the following data elements:

- (A) CCDS as specified in the 2015 Edition of the CCDS Reference Document, as applicable.
- (B) Encounter diagnoses in the standard specified at a minimum the version of the standard specified at § 170.207(a)(4) SNOMED CT® or the standard specified at § 170.207(i) ICD-10-CM for the following conditions:
 - (i) Diseases.
 - (ii) Injuries.
 - (iii) Impairments.
 - (iv) Other health problems and their manifestations.
 - (v) Causes of injury, disease, impairment, or other health problems.
- (C) Cognitive status when present in the Health IT Module;
- (D) Functional Status when present in the Health IT Module;
- (E) *Ambulatory setting only*: reason for referral, and referring or transitioning provider's name and office contact information; and
- (F) *Inpatient setting only*: the discharge instructions.

Test Lab Verification

The verification of the minimum required data elements and the associated standards is performed as part of the Create verification in (b)(6)(ii). This includes the following verification:

- (A) CCDS data elements are in accordance with the CCDS Reference Document for a document specified in accordance with § 170.205(a)(4).
- (B) Encounter diagnoses data element is specified in accordance with the constrained standard specified at § 170.207(i) or at a minimum the version of the standard specified at § 170.207(a)(4).
- (C) Cognitive Status data element, when present in the Health IT Module.
- (D) Functional Status data element, when present in the Health IT Module.
- (E) *Ambulatory setting only*, the following data elements: reason for referral, and referring or transitioning provider's name and office contact information.
- (F) *Inpatient setting only*, the following data elements: the discharge instructions.

Paragraph (b)(6)(iii)(A)**System Under Test**

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:

- In real-time, and include data from the entered start date and time until now;
- 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
- Based upon a specific date (e.g., on 10/24/2015 at 1:00am) from the entered start and end dates and times.

Test Lab Verification

The tester verifies that the timeframe configuration start and end dates and times can be modified for a:

- real-time export;
- export based upon a relative date; and
- export based upon a specific date.

Paragraph (b)(6)(iii)(B)**System Under Test**

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:

- A real-time export;
- A relative date export; and
- A specific date export.

Test Lab Verification

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.

Paragraph (b)(6)(iv)**System Under Test**

1. An authorized user is able to set the location where the export summaries are to be saved.
2. An authorized user is able to store export summaries to a configured location.

Test Lab Verification

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.
2. The tester verifies that export summaries can be saved to the configured export location.

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