






§170.315(b)(10) Electronic health information export				
Testing Components:				
				
NPRM Draft				

Please consult the Notice of Proposed Rulemaking (NPRM) entitled: *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* for a detailed description of the certification criterion with which these testing steps are associated.

### Revision History

Version #	Description of Change	Version Date
1.0	NPRM Draft	April 5, 2019

### Regulation Text

§170.315 (b)(10) *Electronic health information export*—

- (i) *Single patient electronic health information export.*
  - (A) Enable a user to timely create an export file(s) with all of a single patient’s electronic health information the health IT produces and electronically manages on that patient.
  - (B) A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.
  - (C) Limit the ability of users who can create such export file(s) in at least one of these two ways:
    - (1) To a specific set of identified users.
    - (2) As a system administrative function.
  - (D) The export file(s) created must be electronic and in a computable format.
  - (E) The export file(s) format, including its structure and syntax, must be included with the exported file(s).
- (ii) *Database export.* Create an export of all the electronic health information the health IT produces and electronically manages.
  - (A) The export created must be electronic and in a computable format.

(B) The export’s format, including its structure and syntax must be included with the export.

- (iii) *Documentation.* The export format(s) used to support single patient electronic health information export as specified in paragraph (b)(10)(i) of this section and database export as specified in paragraph (b)(10)(ii) of this section must be made available via a publicly accessible hyperlink.

## Standard(s) Referenced

None

## Required Tests

Paragraph (b)(10)(i)(A)

System Under Test	Test Lab Verification
<p><b><u>Export of a Single Patient’s Electronic Health Information</u></b></p> <ol style="list-style-type: none"> <li>1. The health IT developer provides documentation on the content of the patient electronic health information to be exported per (b)(10)(iii).</li> <li>2. Using the Health IT Module, an authorized user demonstrates the export of the entire electronic health record for a single patient.</li> </ol>	<p><b><u>Export of a Single Patient’s Electronic Health Information</u></b></p> <ol style="list-style-type: none"> <li>1. The tester verifies that the content of the electronic health information exported by the SUT for the single patient is complete and without omission using the documentation provided by the health IT developer.</li> <li>2. The tester verifies that the length of time to export the patient electronic health information from the time of the request to the availability of the export file is timely.</li> </ol>

Paragraph (b)(10)(i)(B) – (D)

System Under Test	Test Lab Verification
<p><b><u>Export At Any Time</u></b></p> <ol style="list-style-type: none"> <li>1. Using the Health IT Module, the user demonstrates that a user can export all of the electronic health information for a single patient at any time without health IT development involvement.</li> </ol>	<p><b><u>Export At Any Time</u></b></p> <ol style="list-style-type: none"> <li>1. The tester verifies that the user can export all of the electronic health information associated with a single patient at any time without any intervention or support from health IT development.</li> </ol>

System Under Test	Test Lab Verification
<p><b><u>Export By Authorized Users Only</u></b></p> <ol style="list-style-type: none"> <li>2. The health IT developer demonstrates that the ability to create an export file containing patient electronic health information is limited to a set of authorized users.</li> <li>3. Using the Health IT Module, the user demonstrates that an authorized user can export all of the electronic health information for a single patient.</li> <li>4. Negative Test: Using the Health IT Module, the user demonstrates that an unauthorized user cannot export a patient's electronic health information.</li> </ol>	<p><b><u>Export By Authorized Users Only</u></b></p> <ol style="list-style-type: none"> <li>2. The tester verifies that access to the creation of an export file containing patient electronic health information is limited to a specific set of identified users or is a system administration function.</li> <li>3. The tester verifies that an authorized user can export all of the electronic health information for a patient.</li> <li>4. Negative Test: The tester verifies that an unauthorized user cannot export all of the electronic health information for a patient.</li> </ol> <p><b><u>Export is an Electronic and Computable Format</u></b></p> <ol style="list-style-type: none"> <li>5. The tester verifies that the export file created in section (b)(10)(i) is in an electronic and computable format meaning:               <ul style="list-style-type: none"> <li>○ Human-readable and computable representations are supported;</li> <li>○ If required set operations and relational algebra is implemented;</li> <li>○ Structured rules are used to represent Phenotype criteria (e.g. nested logical structure, Boolean logic);</li> <li>○ Temporal relations between clinical events are defined and</li> <li>○ Standardized controlled clinical terminologies are utilized including the facilitation of value set reuse.</li> </ul> </li> </ol>

Paragraph (b)(10)(ii)

System Under Test	Test Lab Verification
<ol style="list-style-type: none"> <li>1. The health IT developer provides documentation on the content of health IT Module.</li> <li>2. Using the Health IT Module, an authorized user demonstrates the export of all the electronic health information the health IT produces and electronically manages.</li> </ol>	<ol style="list-style-type: none"> <li>1. The tester verifies that the content of the electronic health information exported by the SUT (database export) is complete and without omission using the documentation provided by the health IT developer. Furthermore the tester verifies that the number of patient records exported matches the number of records in the</li> </ol>

System Under Test	Test Lab Verification
	<p>health IT Module.</p> <ol style="list-style-type: none"> <li>2. The tester verifies that the content of the electronic health information exported by the SUT (database export) is complete and without omission using the documentation provided by the health IT developer. Furthermore the tester verifies that the number of patient records exported matches the number of records in the health IT Module.</li> <li>3. using the documentation provided by the health IT developer, the tester verifies that the database export created is in an electronic and computable format meaning: <ul style="list-style-type: none"> <li>○ Human-readable and computable representations are supported;</li> <li>○ If required set operations and relational algebra is implemented;</li> <li>○ Structured rules are used to represent Phenotype criteria (e.g. nested logical structure, Boolean logic);</li> <li>○ Temporal relations between clinical events are defined and</li> <li>○ Standardized controlled clinical terminologies are utilized, including the facilitation of reuse value.</li> </ul> </li> <li>4. The tester verifies that the export created for the database export, as specified in the documentation provided by the health IT developer, includes information on the export format, including the structure and syntax of the information contained within the export of all of the patient health information.</li> </ol>

Paragraph (b)(10)(iii)

System Under Test	Test Lab Verification
<ol style="list-style-type: none"> <li>1. The health IT developer supplies documentation describing the export format for a single patient’s health information as performed in (b)(10)(i), with the intended audience of developers, and includes at a minimum:               <ul style="list-style-type: none"> <li>○ Structure;</li> <li>○ Syntax; and</li> <li>○ Information to facilitate the interpretation of the electronic health information.</li> </ul> </li> <li>2. The health IT developer supplies documentation describing the export format for a database export as performed in (b)(10)(ii), with the intended audience of developers, and includes at a minimum:               <ul style="list-style-type: none"> <li>○ Structure;</li> <li>○ Syntax; and</li> <li>○ Information to facilitate the interpretation of the electronic health information.</li> </ul> </li> <li>3. The documentation used to meet paragraph (b)(10)(i) and (b)(10)(ii) of this section must be available via a publicly accessible hyperlink.</li> </ol>	<ol style="list-style-type: none"> <li>1. The tester verifies that the identified documentation for the Health IT Module’s export of a single patient’s health information is accurate and without omission and that it matches the version of the software release.</li> <li>2. The tester verifies that the identified documentation for the Health IT Module’s export of all patient’s health information as a database export is accurate and without omission and that it matches the version of the software release.</li> <li>3. The tester verifies that the supplied documentation is publicly accessible by hyperlink.</li> </ol>