

§ 170.315(b)(10) Electronic Health Information (EHI) Export

Health IT developers that participate in the ONC Health IT Certification Program are subject to [Condition and Maintenance of Certification](#) requirements as part of the [2015 Edition Cures Update](#). Included in these requirements is the [Assurances Maintenance of Certification](#) which requires Certified Health IT that electronically stores Electronic Health Information (EHI) to certify to the Cures Update [§ 170.315\(b\)\(10\) EHI Export](#) criterion. Health IT developers certifying to this criterion must provide their customers with the capability to efficiently export single and multi-patient EHI in a secure and timely manner. The Direct Review process promotes accountability, ensuring Certified Health IT conforms to Certification Program requirements when it is implemented and used in real world settings.

What Is EHI?

Electronic Health Information (EHI) refers to “electronic protected health information” (ePHI) to the extent that it would be included in a designated record set as defined in [45 CFR 164.501](#). EHI does not include psychotherapy notes as defined in 45 CFR 164.501 or information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding. The EHI definition represents the same ePHI that an individual would have the right to access under the [HIPAA Privacy Rule](#) (For additional information about the definition of EHI, we refer readers to the [Understanding Electronic Health Information \(EHI\) fact sheet](#)).

Who is required to certify to the new § 170.315(b)(10) EHI export criterion and when is the deadline?

Developers must certify any Health IT Module that is part of a product that electronically stores EHI to the § 170.315(b)(10) EHI export criterion, and it must be available to their customers by December 31, 2023.

What is required under the new § 170.315(b)(10) EHI export criterion?

Developers must certify any Health IT Module that is part of a product that electronically stores EHI to the § 170.315(b)(10) EHI export criterion, and it must be available to their customers by December 31, 2023.

Single Patient EHI Export:

- Export EHI for a single patient at any time the user chooses without Developer assistance
- The export must be created in a timely fashion
- Must include all EHI for a single patient
- Must be electronic and in a computable format
- Must include a publicly accessible hyperlink of the export's format
- Certified Health IT Module must be able to limit users who can perform an EHI export

Patient Population EHI Export:

- Must include all EHI for a patient population
- Must be electronic and in a computable format
- Must include a publicly accessible hyperlink of the export's format

These requirements are designed to offer Certified Health IT developers flexibility in their approach to conformance and to foster innovation, transparency, and best practices for data sharing. A developer of Certified Health IT can implement any type of export capability they choose, as long as it supports the two use cases of single patient and patient population EHI export functionalities identified above. There are no requirements for specific transport methods, or for data standards, however the EHI export file must be in an electronic and computable format.

“User” of EHI export functionality is a health care professional or their office staff; or a software program or service that can interact directly with the Certified Health IT.

What if the Certified Health IT Module stores the EHI somewhere else, or if the Certified Health IT Module is part of a larger software product?

Developers must certify any Health IT Module that is part of a product that electronically stores EHI to the § 170.315(b)(10) EHI export criterion. By “product,” ONC means the listing on the [Certified Health IT Product List \(CHPL\)](#) of which the certified Health IT Module is a part. This would include both EHI stored by functionality certified under the ONC Health IT Certification Program and EHI stored by non-certified health IT functionality also contained within the named product. Such “stored” data applies to all EHI and is agnostic as to whether the EHI is stored in or by the certified Health IT Module or in or by any of the other “non-certified” capabilities of the health IT product of which the certified Health IT Module is a part. Additionally, developers must support the export of EHI stored by the product and not limit the export only to EHI stored within the product. For example, if the CHPL-listed product of which the certified Health IT Module is a part of causes EHI to be stored in one or more connected databases at the time the product is presented for certification, the developer’s product must be certified to § 170.315(b)(10).

What are the requirements for the EHI export file format?

All EHI export files are required to include an accessible and up-to-date hyperlink that allows any user to directly access the EHI export file format information without preconditions or additional steps. Users of the export files will use the export format documentation to process EHI after it has been exported by a product. The EHI export file format should describe the structure and syntax of how the EHI is exported, but not the EHI itself. For example, EHI exported in formats such as [Consolidated-Clinical Data Architecture \(C-CDA\)](#) documents or a data dictionary for comma-separated values (CSV) files satisfies the EHI export file format requirements. If the developer had previously specified C-CDA as the export format for meeting the criterion, but subsequently updated their Certified Health IT product to use a different format (e.g., FHIR XML or JSON) and stopped supporting the C-CDA export format, then the documentation for the export format must be updated to ensure users are able to continue to accurately process all EHI exported by the product.

How is the newer § 170.315(b)(10) EHI export criterion different from the older § 170.315(b)(6) Data Export criterion?

The 2015 Edition Cures Update includes the § 170.315(b)(10) EHI export criterion that replaces [§170.315\(b\)\(6\) Data Export](#). This newer criterion will enable a clinician, or their staff, to export all EHI stored in the Certified Health IT product for a single patient or the EHI for the clinician's entire patient population. This supports individual patients' access to their electronic data, and also empowers providers and provider organizations to migrate all the EHI from one Certified Health IT product to any health IT system of their choosing. ONC Authorized Certification Bodies (ONC-ACBs) will be permitted to issue certificates for § 170.315(b)(6) as a standardized means of exporting discrete data specified in the [2015 Edition Common Clinical Data Set \(CCDS\)](#) during the transition period to § 170.315(b)(10), which ends May 1, 2023.

How do developers certify to the § 170.315(b)(10) EHI export criterion and what is the conformance method?

This certification criterion does not require testing by an ONC Authorized Test Lab (ONC-ATL). Developers are required to submit an attestation to their ONC-ACB for certification to the EHI export criterion. Before granting certification, ONC-ACBs review the attestations and determine if the Module(s) conform to all requirements. For more information on the attestation process, please visit the [ONC Attestations](#) webpage or the [§ 170.315\(b\)\(10\) EHI Export Certification Companion Guide \(CCG\)](#).