
ONC 170.315.b.10 Electronic Health Information Export

Point and Click Solutions has attested certification to the ONC 170.315.b.10 Electronic Health Information Export criteria. This document details the processes adopted by the PNC system to meet this standard.

What is the ONC b.10 criteria requirement?

The ONC b.10 criteria is another step toward being able to electronically export entire medical records in a computable format from one medical system in a format that can then be imported into another FHIR capable application, as a way of increasing the interoperability of health information.

As detailed in the ONC documentation found at

<https://www.healthit.gov/test-method/electronic-health-information-export> a certified EHR is required to allow a user of the EHR who has specific permissions to perform an export of an entire medical record in a computable format without developer assistance. It also requires that the medical records of a specific population of patients can all be exported in a computable format. Exporting records for a population of patients can be done with the help of a developer. This is a computable file format and is not intended to be a human readable file. This file export is designed to be imported by another system or application capable of ingesting and displaying the data in human readable format. This file would not be released to a patient expecting that they could read the files unless they were utilizing an application able to open and incorporate the file. The b.10 criteria involves creating the file; future engineering will allow medical records to be sent to patients via an interface.

What format is used for the computable file export?

ONC does not currently specify the electronic format required for the records export. However, there is an increasing push toward medical record intraoperability utilizing the HL7 FHIR interface. See this site for HL7 FHIR details, <https://www.hl7.org/fhir/>. PNC has developed HL7 FHIR capabilities to meet the b.10 requirement as part of a road map to utilizing this interface for a variety of medical information exchange needs going forward. The medical record file export for b.10 created by PNC utilizes the FHIR file interface creating JSON files for each FHIR resource that is utilized.

What is included and not included in the export?

ONC requires that Electronic Health Information (EHI) that falls under the definition of a “Designated Record Set” should all be included in the export with exceptions for psychotherapy notes and records involved in legal proceedings. Here is some information and definitions of terms concerning medical record content and some helpful reference links:

Defining health Information:

Health information means any information, including genetic information, whether oral or recorded in any form or medium, that:

- (1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and
- (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Defining electronic health information:

EHI is electronic protected health information (ePHI) to the extent that it would be included in a designated record set (DRS) (other than psychotherapy notes or information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding), regardless of whether the group of records is used or maintained by or for a HIPAA covered entity.

Health information means any information, including genetic information, whether oral or recorded in any form or medium, that:

- (1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and
- (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

<https://www.healthit.gov/topic/information-blocking/understanding-electronic-health-information-ehi>

<https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-160/subpart-A/section-160.103>

Defining a designated record set:

Individuals have a right to access PHI in a "designated record set." A "designated record set" is defined at 45 CFR 164.501 as a group of records maintained by or for a covered entity that comprises the:

- Medical records and billing records about individuals maintained by or for a covered health care provider;
- Enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or
- Other records that are used, in whole or in part, by or for the covered entity to make decisions about individuals. This last category includes records that are used to make decisions about any individuals, whether or not the records have been used to make a decision about the particular individual requesting access.

The term "record" means any item, collection, or grouping of information that includes PHI and is maintained, collected, used, or disseminated by or for a covered entity.

Thus, individuals have a right to a broad array of health information about themselves maintained by or for covered entities, including: medical records; billing and payment records; insurance information; clinical laboratory test results; medical images, such as X-rays; wellness and disease management program files; and clinical case notes; among other information used to make decisions about individuals. In responding to a request for access, a covered entity is not, however, required to create new information, such as explanatory materials or analyses, that does not already exist in the designated record set.

Information Excluded from the Right of Access:

An individual does not have a right to access PHI that is not part of a designated record set because the information is not used to make decisions about individuals. This may include certain quality assessment or improvement records, patient safety activity records, or business planning, development, and management records that are used for business decisions more generally rather than to make decisions about individuals. For example, a hospital's peer review files or practitioner or provider performance evaluations, or a health plan's quality control records that are used to improve customer service or formulary development records, may be generated from and include an individual's PHI but might not be in the covered entity's designated record set and subject to access by the individual.

In addition, two categories of information are expressly excluded from the right of access:

- Psychotherapy notes, which are the personal notes of a mental health care provider documenting or analyzing the contents of a counseling session, that are maintained separate from the rest of the patient's medical record. See 45 CFR 164.524(a)(1)(i) and 164.501.
- Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding. See 45 CFR 164.524(a)(1)(ii).

However, the underlying PHI from the individual's medical or payment records or other records used to generate the above types of excluded records or information remains part of the designated record set and subject to access by the individual.

<https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html>

Information included and not included in the PNC FHIR b.10 export:

PNC has made every attempt to include all of the information required for this export by ONC. The HL7 FHIR export uses 'resources' to define subsets of data from a medical record into discrete fields of known formatting to facilitate import into another FHIR capable system. HL7 FHIR is well known to be a work in progress and updated resources are being released periodically. PNC is using the R4 FHIR release. Data fields from PNC do not always match one to one with the FHIR format resources. PNC has worked diligently to match the data fields as closely as possible to create a complete data export. In some cases there have been extensive challenges to map the PNC patient data to the existing R4 FHIR resources. We will soon have the FHIR R5 version available and will be refining the data mapping to the new and improved F5 resources. Mapping challenges were especially true for the financial data. This promises to be much better in FHIR version R5.

Here is a summary of PNC system components and the FHIR resources included in the export. As detailed above, this file is computable by a system prepared to handle FHIR files and is not human readable until it is processed by such a system. The files are exported in JSON format.

PNC Patient Data	FHIR Resource
Entire Chart	https://www.hl7.org/fhir/patient-operation-everything.html
Registration	https://www.hl7.org/fhir/patient.html
Allergies	https://www.hl7.org/fhir/allergyintolerance.html
Diagnoses	https://www.hl7.org/fhir/condition.html
Problems/Issues	https://www.hl7.org/fhir/condition.html
Family History	https://www.hl7.org/fhir/familymemberhistory.html
Vitals	https://www.hl7.org/fhir/observation.html
Procedures	https://www.hl7.org/fhir/procedure.html
Plan	https://www.hl7.org/fhir/careplan.html
Care Team	https://www.hl7.org/fhir/careteam.html
Immunizations	https://www.hl7.org/fhir/immunization.html
Medications (Rx)	https://www.hl7.org/fhir/medicationrequest.html
Medications (Historic)	https://www.hl7.org/fhir/medicationstatement.html
ECG/PFT	https://www.hl7.org/fhir/documentreference.html
Encounter Notes	https://www.hl7.org/fhir/documentreference.html
Lab Reports	https://www.hl7.org/fhir/documentreference.html
Letters	https://www.hl7.org/fhir/documentreference.html
Messages	https://www.hl7.org/fhir/documentreference.html
Outside Notes	https://www.hl7.org/fhir/documentreference.html
Radiology Reports	https://www.hl7.org/fhir/documentreference.html
Surveys	https://www.hl7.org/fhir/documentreference.html
Scanned Documents	https://www.hl7.org/fhir/documentreference.html
Photos (Scanned Docs)	https://www.hl7.org/fhir/documentreference.html
Advanced Directive (Scanned Docs)	https://www.hl7.org/fhir/documentreference.html
Transcription (Scanned Documents)	https://www.hl7.org/fhir/documentreference.html
Compliance Forms (Scanned Documents)	https://www.hl7.org/fhir/documentreference.html
Consent Forms (Scanned Documents)	https://www.hl7.org/fhir/documentreference.html
Discharge Summaries/CCDs	https://www.hl7.org/fhir/documentreference.html
Appointments	https://www.hl7.org/fhir/appointment.html
Financial Statements	https://www.hl7.org/fhir/invoice.html

Data intentionally excluded from the export:

The PNC system uses the 'Sequestered Chart' option in the PncRegistration to designate charts involved in a legal process. Information for charts marked in this manner will not be released via this export.

To comply with the Cures Act Open Notes rule PNC developed a system to mark specific records (note, lab result, radiology results) as 'Hidden' which kept these records from being displayed in the medical records section of the patient portal. The 'Hidden' flag could be placed on these items either by visit type, lab order or radiology order placed by the system administrator or could be based on the decision of a user of the system to 'hide' an individual test/note. PNC feels that these notes were hidden from the patient/client for a specific reason and therefore will not include these records in the b.10 FHIR record release.

Creating the FHIR export file in PNC:

The PncChart/Facility view contains an option in the right hamburger menu for 'Export Patient Documents'. Access is controlled by permissions. There are 2 administrative permissions that allow a user to export EHIR files.

1- ChartExportPatientDocuments (This is permission to use Export Patient Documents for a single patient.)

2-ChartExportPopulationDocuments (This is permission to use Export Patient Documents for a population of patients.)

The FHIR JSON files are exported to a file folder that is specified in the Export patient Documents setup. PNC strongly encourages the export file folder to be a secure drive due to the extreme sensitivity of the PHI contained in these files.

As discussed above, this is not intended to be a release of records for a patient to read. These are computable, electronic format, non-human readable files meant for consumption by another HL7 FHIR capable system. For any questions about this process please contact PNC support.