

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule

December 2023

Background

The [21st Century Cures Act of 2016 \(Cures Act\)](#) required ONC to establish the Electronic Health Records (EHR) Reporting Program to provide transparent reporting on certified health IT in the categories of interoperability, usability and user-centered design, security, conformance to certification testing, and more. The Cures Act also specified that a health IT developer be required to submit responses to the reporting criteria developed with respect to all certified technology offered by the health IT developer.

ONC's HTI-1 final rule created the Insights Condition and Maintenance of Certification ("Insights Condition") within the ONC Health IT Certification Program to provide transparent reporting on certified health IT. The Insights Condition's reporting will: (1) Address information gaps in the health IT marketplace; (2) Provide insights on the use of specific certified health IT functionalities; and (3) Provide information about use of certified functionalities by end users.

Applicability to Health IT Developers

The Insights Condition's reporting requirements were structured so as not to unduly disadvantage small and startup developers of certified health IT. The finalized Insights Condition requires a health IT developer participating in the ONC Health IT Certification Program to report responses for a measure and related metrics if the developer meets each of the following criteria:

- 1) Has at least 50 hospital sites or 500 individual clinician users across their certified health IT;
- 2) Has any health IT certified to the certification criteria specified in each measure; and
- 3) Has any users using the certified health IT associated with the measure.

Developers of certified health IT who do not meet the qualifications above will submit a response (attestation) to indicate that they do not meet the minimum reporting qualifications for a measure.

Insights Condition Measures

The HTI-1 final rule adopts seven measures across four areas related to interoperability: individuals' access to electronic health information (EHI), clinical care information exchange, standards adoption and conformance and public health information exchange.

- **Individuals' access to electronic health information (EHI)** – consists of one measure that captures the number of unique individuals who access their electronic health information (EHI) overall and by different methods.
 - Individuals' access to EHI through certified health IT captures individuals' use of different methods to access their EHI including, apps offered by the health IT developer or health care provider, and/or patient portals, as well as any other method.
- **Public health information exchange** – consists of two measures that provide insights into the use of certified health IT to exchange immunization information with immunization information systems (IIS).

- Immunization administrations electronically submitted to immunization information systems through certified health IT captures the use of certified health IT to send information on vaccination and immunization administrations to an IIS.
- Immunization history and forecasts through certified health IT captures the use of certified health IT to query information from an IIS.
- **Clinical care information exchange** – consists of one measure that provides insights on the exchange and use of certified health IT to support C-CDA-based exchange.
 - Consolidated clinical document architecture (C-CDA) problems, medications, and allergies reconciliation and incorporation through certified health IT captures the use of health IT to obtain, reconcile, and incorporate C-CDA documents including those reconciled and incorporated through manual and automated processes.
- **Standards adoption and conformance** – consists of three measures that shed light on how certified health IT supports the app ecosystem as well as how FHIR enables the exchange of data through certified health IT.
 - Applications supported through certified health IT captures information about apps that are connected to certified health IT products, including intended purpose of the app, intended user of the app and whether the app is actively used.
 - Use of FHIR in apps through certified health IT captures the volume and type of FHIR resources transferred to apps from certified health IT relative to the number of active certified API technology deployments.
 - Use of FHIR bulk data access through certified health IT captures the number of bulk data access requests completed through certified health IT relative to the number of certified health IT deployments.

Each of the measures have metrics which developers of certified health IT are required to report on (see Table 1 below). Please visit the [HTI-1 Final Rule landing page](#) to view the measure specification sheets and the HTI-1 final rule which provide further details on the specific metrics associated with the Insights Condition measures.

Reporting Frequency and Timeline

The reporting period is one calendar year, with 6 months provided for collating the data. Responses will be submitted annually, during the month of July. The measures and metrics are phased in over three years according to the schedule shown in the table below. “Year 1” data collection starts in calendar year (CY) 2026 (January 1st, 2026-December 31st, 2026), with response submissions due in July 2027. Reporting is on an annual basis thereafter. “Year 2” measures and related metrics will begin data collection CY 2027, with reporting July 2028 (and annually thereafter). The “Year 3” measures and related metrics start data collection CY 2028, with reporting July 2029 (and annually thereafter).

Table 1: Insights Condition Measures, Metrics, and Program Year

Individuals' Access to Electronic Health Information Through Certified Health IT

Year 1

- Number of unique individuals who accessed their EHI using technology certified to “standardized API for patient population services” certification criterion under § 170.315(g)(10)
- Number of unique individuals who accessed their EHI using technology certified to the “view, download, and transmit to 3rd party” certification criterion under § 170.315(e)(1)
- Number of unique individuals who accessed their EHI using any method.

Consolidated Clinical Document Architecture (C-CDA) Problems, Medications, and Allergies Reconciliation and Incorporation Through Certified Health IT

Year 2

- Number of encounters
- Number of unique patients with an encounter
- Number of unique patients with an associated C-CDA document
- Number of total C-CDA documents obtained
- Number of unique C-CDA documents obtained
- Number of total C-CDA documents obtained that were pre-processed
- Number of total C-CDA documents obtained that were not pre-processed

Year 3

- Number of total C-CDA documents obtained that were pre-processed where problems, medications, or allergies and intolerances were reconciled and incorporated via any method
- Number of total C-CDA documents obtained that were not pre-processed where problems, medications, or allergies and intolerances were reconciled and incorporated via any method
- Number of total C-CDA documents obtained that were determined to have no new problems, medications, or allergies and intolerances information by pre-processes or fully automated processes

Applications Supported Through Certified Health IT

Year 1

- Application name(s)
- Application developer Name(s)
- Intended purpose(s) of application using categories set out in measurement specification sheets
- Intended application user(s) using categories set out in measurement specification sheets
- Application Status

Use of FHIR in Apps Through Certified Health IT

Year 1

- Number of distinct certified health IT deployments (across clients) active at any time during the reporting period, overall and by user type
- Number of requests made to distinct certified health IT deployments that returned at least one FHIR resource by FHIR resource type
- Number of distinct certified health IT deployments (across clients) associated with at least one FHIR resource returned overall and by user type

Year 2

- Number of distinct certified health IT deployments (across clients) associated with at least one FHIR resource returned by US Core Implementation Guide version

Use of FHIR Bulk Data Access Through Certified Health IT

Year 2

- Number of distinct certified health IT deployments (across clients) that completed at least one bulk data access request
- Number of bulk data access requests completed (across clients) to export all data requested for patients within a specified group

Immunization Administrations Electronically Submitted to Immunization Information Systems Through Certified Health IT

Year 1

- Number of immunizations administered overall

Year 2

- Number of immunizations administered overall by IIS and by age category

Year 1

- Number of immunizations administered electronically submitted successfully to IISs overall

Year 2

- Number of immunizations administered electronically submitted successfully to IISs overall by IIS and by age category

Immunization History and Forecasts Through Certified Health IT

Year 2

- Number of immunization queries sent to IISs overall

Year 3

- Number of immunization queries sent to IISs overall by IIS

Year 2

- Number of query responses received successfully from IISs overall

Year 3

- Number of query responses received successfully from IISs overall by IIS

Note: “Program Year” refers to the implementation year of the Insights Condition, with the start of the data collection.

Response Submission Process

Measure and related metric responses will be aggregated and reported at the product level (across versions) in the format specified by the measure.

- Note that health IT developers with integrated certified health IT products will only have to report one response for each metric for those products (rather than two or more individual responses).
- Developers must provide percentage of total customers (e.g., hospital sites, individual clinician users) represented in the provided data for each metric response.
- Health IT developer using relied upon software to meet the certification requirements is responsible to report on Insights Condition measure. The health IT developer may work with its relied upon software vendor, if necessary, to report on the metrics.

To help ensure the responses/data are interpreted correctly, health IT developers will submit documentation on the data sources and methodology used to generate submitted data.

- Optionally, health IT developers may also submit descriptive or qualitative information to provide context as applicable.

The responses and required documentation will be made publicly available via an ONC website.

Health IT developers will submit responses and documentation for the Insights Condition using a web-based form and method. ONC will provide templates that enable submitting the data in a structured, electronic format for this purpose, consistent with the requirement in § 3009A(c) of the Public Health Service Act (PHSA)



Visit healthit.gov/HTI-1 for additional information.

