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

April 2023

ONC's HTI-1 proposed rule proposes to create 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 would implement the "EHR Reporting Program" called for by the 21st Century Cures Act.

What Is the Cures Act EHR Reporting Program Provision?

The **21st Century Cures Act of 2016 (Cures Act)** requires 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 specifies 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.

What Are the Goals of the Insights Condition?

We intend to refer to the Condition and Maintenance of Certification associated with the "EHR Reporting Program" as the "Insights Condition." The Insights Condition would provide transparent reporting that aims to: (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 end-users' experience with certified health IT. This first set of proposed measures would provide insights on the interoperability category specified in the Cures Act.

To Whom Does the Insights Condition Apply?

ONC proposes that developers of certified health IT would be expected to report on a measure if the developer has:

1. At least 50 hospital users or 500 clinician users across their certified health IT products; and

2. Any applicable Health IT Modules certified to criteria associated with a given measure; and

3. Any users of the applicable criterion/criteria associated with the measure.

We propose to implement the Insights Condition in a way that does not unduly disadvantage small and startup developers of certified health IT. Developers of certified health IT who do not meet the minimum reporting qualifications (as specified under each measure), would submit a response to indicate that they do not meet the minimum reporting qualifications for the measure under the Insights Condition measure.

What Reporting Measures Are Being Proposed?

ONC proposes to adopt nine measures across four topic areas related to interoperability: individuals' access to EHI, public health information exchange, clinical care information exchange, and standards adoption and conformance.

AREA	MEASURE	RELATED CRITERION/ CRITERIA
Individual Access to EHI	Individuals' Access to Electronic Health Information Supported by Certified API Technology	§§ 170.315(e)(1); 170.315(g)(10)
Clinical Care Information Exchange	C-CDA Documents Obtained Using Certified Health IT by Exchange Mechanism	§ 170.315(b)(2)
Clinical Care Information Exchange	C-CDA Medications, Allergies, and Problems Reconciliation and Incorporation Using Certified Health IT	§ 170.315(b)(2)
Standards Adoption & Conformance	Applications Supported Through Certified Health IT	§ 170.315(g)(10)
Standards Adoption & Conformance	Use of FHIR in Apps Supported by Certified API Technology	§ 170.315(g)(10)
Standards Adoption & Conformance	Use of FHIR Bulk Data Access through Certified Health IT	§ 170.315(g)(10)
Standards Adoption & Conformance	Electronic Health Information Export through Certified Health IT	§ 170.315(b)(10)
Public Health Information Exchange	Immunization Administrations Electronically Submitted to Immunization Information System Registries through Certified Health IT	§ 170.315(f)(1)
Public Health Information Exchange	Immunization History and Forecasts	§ 170.315(f)(1)

- **Individuals' access to electronic health information (EHI)** – consists of one measure that will help ONC monitor the implementation of policies designed to enhance individuals' access to their EHI.
  - Individual Access to EHI captures individuals' use of different methods to access their EHI, including third-party app technology, apps offered by the health IT developer or health care provider, and/or patient portals. Each of these methods relates to specific certification criteria as shown in the table above.
- **Public health information exchange** – consists of 2 proposed measures that would provide insights into the use of certified health IT to exchange vaccination/immunization data with an Immunization Information System (IIS). See the table above for the specific certification criteria.
  - Immunization Administrations Electronically Submitted to an IIS would capture the use of certified health IT to send information on vaccination and immunization administrations to an IIS.
  - Immunization History and Forecasts captures the use of certified health IT to query information from an IIS.

- **Clinical care information exchange** – consists of 2 proposed measures that would assess how certified health IT supports the exchange and use of external information by clinicians across exchange scenarios, not limited to transitions of care/referrals. These measures would provide insights on the use and utility of C-CDA-based exchange. See the table above for the specific certification criteria.

  - C-CDA Documents Obtained Using Certified Health IT by Exchange Mechanism captures the volume of Consolidated C-CDA documents obtained by exchange mechanism relative to patient volume.

  - C-CDA Problems, Allergies and Medications Reconciliation and Incorporation Using Certified Health IT captures the number of C-CDA documents that are reconciled and incorporated as part of patients' records by clinicians or their delegates.

- **Standards adoption and conformance** – consists of 4 proposed measures that would shed light on how FHIR and EHI Export are used in certified health IT and how certified health IT is supporting a nationwide app ecosystem. See the table above for the specific certification criteria.

  - Applications Supported Through Certified Health IT is a listing of apps that are connected to certified health IT products and provides information about each app (e.g., intended purpose of the app, intended user of the app).

  - Use of FHIR in Apps Supported by Certified API Technology captures the volume of FHIR resources transferred in response to API calls from apps connected to certified API technology by FHIR resource type.

  - Use of FHIR Bulk Data Access Through Certified Health IT captures the number of bulk data downloads relative to the number of certified health IT deployments.

  - Electronic Health Information Export Through Certified Health IT captures the use of certified health IT to export single patient and patient population EHI.

Visit healthit.gov/proposedrule for additional information. More updates will be added over time.

HealthIT.gov