



Office of the National Coordinator
for Health Information Technology

HTI-1 Insights Condition and Maintenance of Certification Requirements with Question & Answer

Health Data, Technology, and Interoperability: Certification Program Updates,
Algorithm Transparency, and Information Sharing

Information Session
February 8, 2024



Please Note:

- The materials contained in this presentation about the "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing" (HTI-1) Final Rule are based on the document that has been published in the Federal Register on January 9, 2024, which amends provisions contained in 45 C.F.R. Parts 170 and 171. While every effort has been made to ensure the accuracy of this restatement of those provisions, this presentation is not a legal document. The official provisions are contained in the final rule and 45 C.F.R. Parts 170 and 171. Please note that other Federal, state and local laws may also apply.
- This communication is produced and disseminated at U.S. taxpayer expense.



Insights Condition and Maintenance of Certification



EHR Reporting Program

Insights Condition

The Cures Act laid the foundation for transparent reporting:

- Established the requirement to create an Electronic Health Record (EHR) Reporting Program to provide transparent reporting to measure the performance of certified health IT
- Specified its implementation as part of a Condition and Maintenance of Certification for developers of certified health IT

Insights Condition provides transparent reporting that:

- Addresses information gaps in the health IT marketplace
- Provides insights on the use of specific certified health IT functionalities
- Provides information about consumers' experience with certified health IT

How Were the Measures Developed?



- ONC contracted with the Urban Institute, and its subcontractor, HealthTech Solutions, to identify measures that developers of certified health IT would be required to report under the Program based on:
 - Extensive research including literature review, market research;
 - Input from stakeholders and health IT measurement experts; and
 - Input from feasibility and validity testing
- Public feedback was obtained on the draft measures, including from the [2021 EHR Reporting Program Task Force](#) of the HITAC.
- The measures were refined and modified based on HITAC and public feedback, along with additional research and expert consultations, and proposed in the HTI-1 Proposed Rule.
- Based on feedback received during the HTI-1 Proposed Rule public comment period, we further refined the measures, which are finalized in the HTI-1 Final Rule.

Insights Condition: Measures and Related Criteria



AREA	MEASURE	RELATED CRITERION/CRITERIA
Individuals' Access to EHI	Individuals' Access to Electronic Health Information Through Certified Health IT	§§ 170.315(e)(1) and (g)(10)
Clinical Care Information Exchange	C-CDA Problems, Medications, and Allergies Reconciliation and Incorporation Through 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 Through Certified Health IT	§ 170.315(g)(10)
Standards Adoption & Conformance	Use of FHIR Bulk Data Access Through Certified Health IT	§ 170.315(g)(10)
Public Health Information Exchange	Immunization Administrations Electronically Submitted to Immunization Information Systems Through Certified Health IT	§ 170.315(f)(1)
Public Health Information Exchange	Immunization History and Forecasts Through Certified Health IT	§ 170.315(f)(1)

Note: Metrics associated with the measures are described in the measure specification sheets published on ONC's website.

Who Will Be Reporting on These Measures and How?

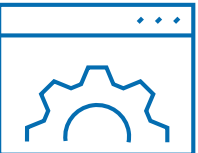


- Developers of certified health IT must submit responses if the developer meets each of the following criteria:
 - Has at least 50 hospital sites or 500 individual clinician users across their certified health IT;
 - Has any health IT certified to the certification criteria specified in each measure; and
 - 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.
- Developers of certified health IT will provide percentage of total customers (e.g., hospital sites, individual clinician users) represented in provided data for each response.



How Will These Measures Be Reported?

- Responses will be aggregated and reported at the product level (across versions) in the format specified by the measure.
 - 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).
 - Health IT developers 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.
- Insights Condition responses may also be used for Real World Testing plans and results.
- Developers of certified health IT will submit documentation on the data sources and methodology used to generate submitted data/responses.
- Responses and required documentation will be made publicly available via ONC website.
- Health IT developers to 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.



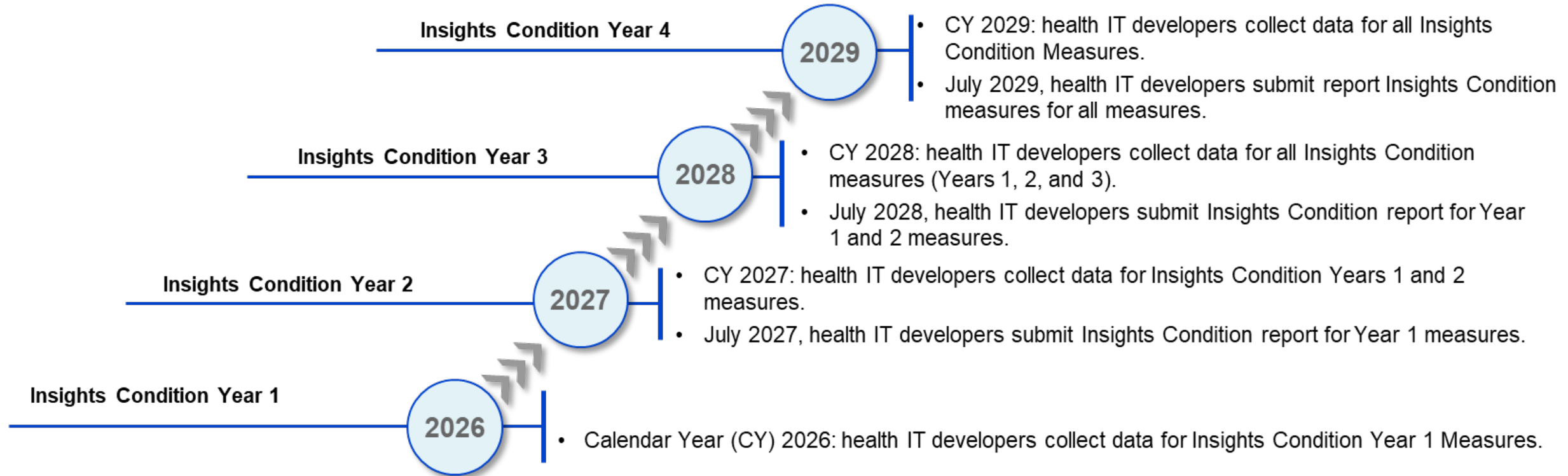
What Is the Reporting Frequency?

The reporting period is one calendar year with developers having 6 months to collate the responses.

Responses due annually, each July.

Year 1												Year 2											
Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Collect Data for Year 1 measures/metrics												Assemble Data						Report					
												Collect Data for Year 1 and 2 measures/metrics											

What Is the Reporting Timeline?



What is the Reporting Timeline?

The measures are implemented over three years, gradually phasing in more complex aspects.

Measure	Program Year Data Collection Begins
Individual's Access to EHI Through Certified Health IT	Year 1
Consolidated Clinical Document Architecture (C-CDA) Problems, Medications, and Allergies Reconciliation and Incorporation Through Certified Health IT	Years 2 and 3
Applications Supported Through Certified Health IT	Year 1
Use of FHIR in Apps Through Certified Health IT	Years 1 and 2
Use of FHIR Bulk Data Access Through Certified Health IT	Year 2
Immunization Administrations Electronically Submitted to Immunization Information Systems Through Certified Health IT	Years 1 and 2
Immunization History and Forecasts Through Certified Health IT	Years 2 and 3



We listened! Your feedback led to changes to the reporting process...

More Time and Reduced Reporting

- Delayed start date for collecting and reporting measures
- Spreading the implementation of the measures across 3 years instead of 2 years
- Reduced reporting from twice a year to annually
- Insights measures can be re-used for meeting RWT reporting requirements



Measures and Metrics in Detail

Resources to Understand Measures and Metrics

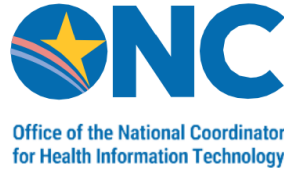
Current Resource: Measure Specification Sheets

- Each measure has a set of metrics associated with it that will be reported.
- Measure specification sheets detail the metrics, provide definitions and provide guidance on implementing the measure.
- The specification sheets can be found here:
 - <https://healthIT.gov/HTI-1>
 - Let's walk through a measure specification together...



Measure Topic Area: Individual Access to EHI

Measure: Individual Access to EHI



Final Rule: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing

ONC Health IT Certification Program Insights Condition

Updated December 13, 2023

Measure ID and Version: Interop_Individual Access_1_v2

Measure Title: Individuals' Access to Electronic Health Information through certified health IT

Measure Description

- *Regulatory Reference:* § 170.407(a)(3)(i)
- *Associated Certification Criteria:* §§ 170.315(e)(1) & (g)(10)
- This measure provides insights into the number of unique individuals who access their electronic health information (EHI) overall and by different methods of access through certified health IT.

Metrics and Reporting Timeline

Metric	Program Year
Number of unique individuals who accessed their EHI using technology certified to the “standardized API for patient population services” certification criterion under § 170.315(g)(10)	Year 1
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)	Year 1
Number of unique individuals who accessed their EHI using any method	Year 1

Note: “Program Year” refers to the implementation year of the Insights Condition. “Year 1” measures start data collection in calendar year 2026 (January 1st, 2026 - December 31st, 2026), with responses due in July 2027 (and annually thereafter).

Measure: Individual Access to EHI

Definitions

Access

- Access to EHI via patient portal using technology certified to the "view, download, and transmit to 3rd party" certification criterion under § 170.315(e)(1) is counted as a patient log-in with the access credential belonging to the individual at least once during the reporting period.
- Access to EHI via technology certified to the "standardized API for patient population services" certification criterion under § 170.315(g)(10) is counted as the individual's authorization, as indicated by an access token, at least once during the reporting period.
- Any method is not limited to third-party apps using technology certified to "standardized API for patient population services" certification criterion under § 170.315(g)(10) or patient portals using technology certified to the "view, download, and transmit to 3rd-party " certification criterion under § 170.315(e)(1) during the reporting period.

Unique Individual

- Unique individuals must be deduplicated within each instance of certified health IT.
- The measure counts individual's accessing their EHI and does not include authorized representatives.

Measure: Individual Access to EHI

Supplemental Reporting Information

- **Required:** Measure and related metrics are due annually. The reporting period is one calendar year.
- **Required:** measures must be aggregated at the product level (across versions).
 - 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).
- **Required:** Developers must provide percentage of total customers (e.g., hospital sites, individual clinician users) represented in the provided data for each metric response.
- **Required:** Developers will submit documentation on the data sources and methodology, including how access to EHI via the different methods was collected and reported.
- **Optional:** Developers may also submit descriptive or qualitative information to provide context, including a description of the other methods beyond patient portals and third-party apps used to enable patient access to EHI.

Implementation Information

- The measure does not distinguish between third-party apps selected by individuals vs. Third-party apps offered by health care providers.
- The measure should report on whether individuals accessed their data during the reporting period.
- Access to EHI is based upon an individual logging into a system (whether that be a portal or third-party app or other system) within the reporting period and is not based on accessing any specific piece of information or performing any specific action within the system itself such as view, download, and transmit activities.

Exclusions

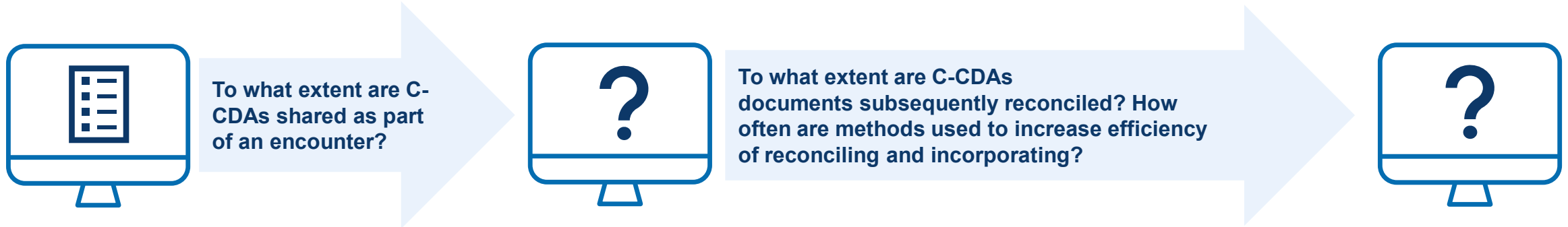
- Products not certified to §§ 170.315(e)(1) or (g)(10) are excluded from this measure



Measure Topic Area: Clinical Care Information Exchange

Insights Into C-CDA Exchange and Use

Finalized Measure: Consolidated clinical document architecture (C-CDA) problems, medications, and allergies reconciliation and incorporation through certified health IT



Removed Measure:

Consolidated Clinical Document Architecture (C-CDA) Documents Obtained Using Certified Health IT by Exchange Mechanism

Measure: Consolidated clinical document architecture (C-CDA) problems, medications, and allergies reconciliation and incorporation through certified health IT

Year
1

Year
2

Year
3

Year 2	Year 3
Number of encounters	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 unique patients with an encounter	
Number of unique patients with an associated C-CDA document	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	
Number of unique C-CDA documents obtained	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
Number of total C-CDA documents obtained that were pre-processed	
Number of total C-CDA documents obtained that were not pre-processed	

Refer to the Measure Specification Sheet for definitions, supplemental reporting information, and implementation information

Measure: Consolidated clinical document architecture (C-CDA) problems, medications, and allergies reconciliation and incorporation through certified health IT

Year
1

Year
2

Year
3

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

- Encounter definition aligned with CMS measurement approaches and ONC certification criteria
- Unique patient identified within one instance of a certified health IT
- Count any valid C-CDA template
- Patient matched to at least one C-CDA within the certified Health IT Module

Refer to the Measure Specification Sheet for definitions, supplemental reporting information, and implementation information

Measure: Consolidated clinical document architecture (C-CDA) problems, medications, and allergies reconciliation and incorporation through certified health IT

Year
1

Year
2

Year
3

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

- Count any valid C-CDA templates.
- Unique C-CDAs identified by document identifier only.
- Must identify unique C-CDAs for the Insights Condition even when not identified by health IT product

Measure: Consolidated clinical document architecture (C-CDA) problems, medications, and allergies reconciliation and incorporation through certified health IT

Year
1

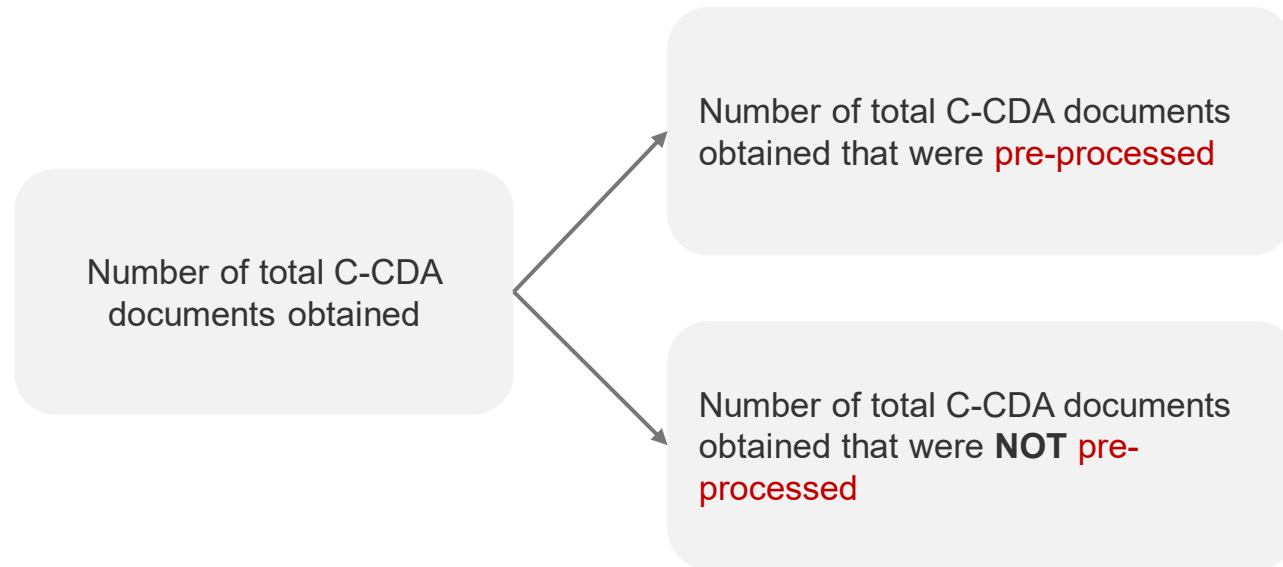
Year
2

Year
3

Year 2	Year 3
Number of encounters	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 unique patients with an encounter	
Number of unique patients with an associated C-CDA document	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	
Number of unique C-CDA documents obtained	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
Number of total C-CDA documents obtained that were pre-processed	
Number of total C-CDA documents obtained that were not pre-processed	

Refer to the Measure Specification Sheet for definitions, supplemental reporting information, and implementation information

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

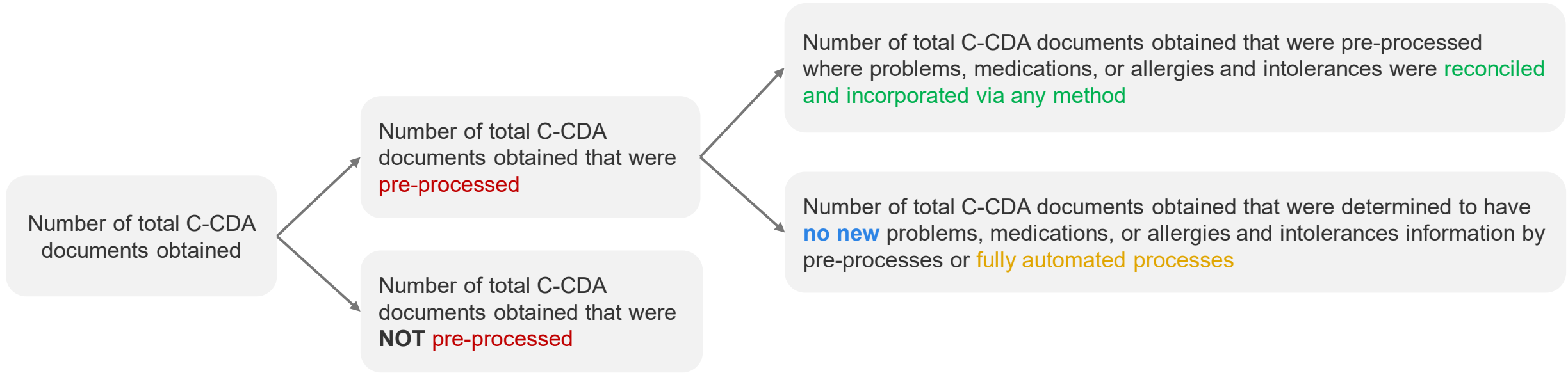


Pre-process:

Automated process that facilitates reconciliation and incorporation. For example:

1. deduplication (by document ID or information within C-CDA)
2. removal of information already in Health IT Module;
3. aggregation across documents

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



Pre-process:

Automated process that facilitates reconciliation and incorporation. For example:

1. deduplication (by document ID or information within C-CDA)
2. removal of information already in Health IT Module;
3. aggregation across documents

Any method:

Manual, automated processes or a mix.

Affirmative action to:

1. reconcile new information or
2. indicate that no new information needs to be incorporated

No new problems, medications or allergies and intolerances:

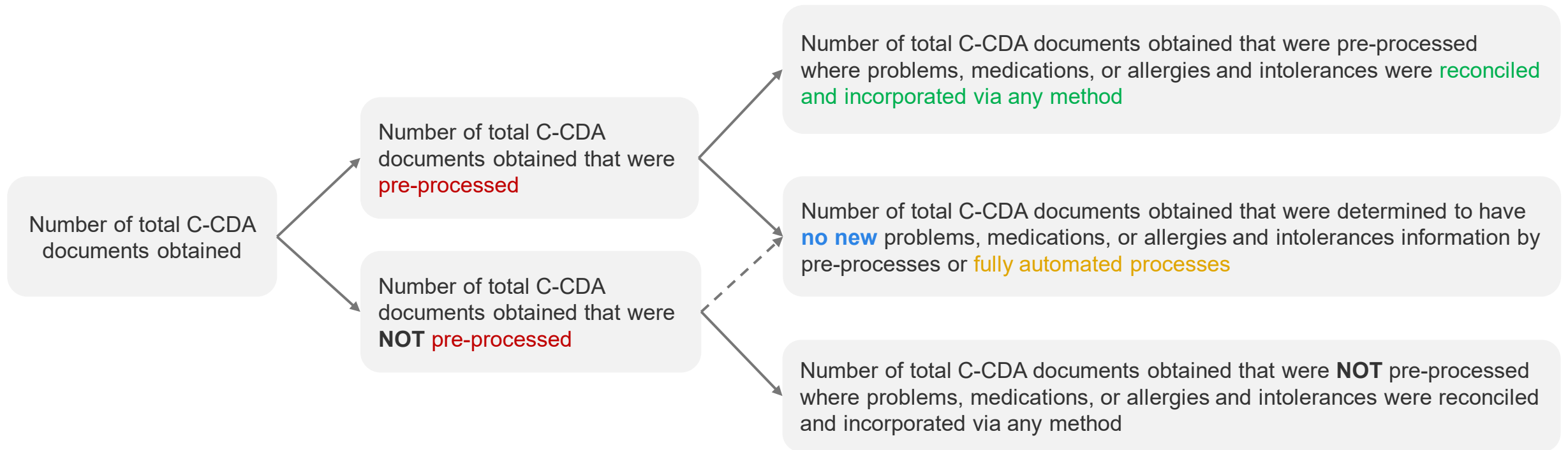
Any pre-process or fully automated process that determines that the C-CDA contains no new information.

Fully automated process:

Reconciliation and incorporation without an action by a clinician end-user or their delegate

1. reconcile new information or
2. determine that no new information needs to be incorporated

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



Pre-process:

Automated process that facilitates reconciliation and incorporation. For example:

1. deduplication (by document ID or information within C-CDA)
2. removal of information already in Health IT Module;
3. aggregation across documents

Any method:

Manual, automated processes or a mix. Affirmative action to:

1. reconcile new information or
2. indicate that no new information needs to be incorporated

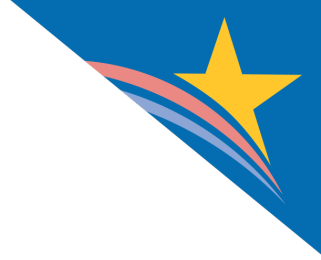
No new problems, medications or allergies and intolerances:

Any pre-process or fully automated process that determines that the C-CDA contains no new information.

Fully automated process:

Reconciliation and incorporation without an action by a clinician end-user or their delegate

1. reconcile new information or
2. determine that no new information needs to be incorporated

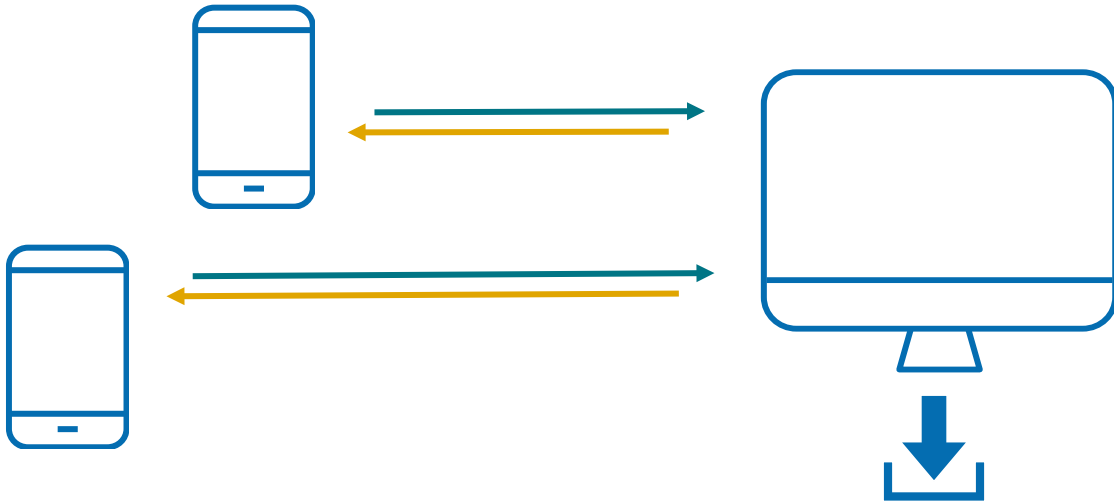


Measure Topic Area: Standards Adoption & Conformance

Insights Into the App Ecosystem and Use of FHIR to support the movement of data

Applications Supported Through Certified Health IT

What apps are connected to certified health IT products? What are the apps' features?



Use of FHIR in Apps Through Certified Health IT

How is FHIR used to support the transfer of data from certified health IT to apps?

Use of FHIR bulk data access through certified health IT

To what extent are Bulk FHIR capabilities being used to support the movement of data from certified health IT?

Removed Measure:

Electronic Health Information (EHI) Export through Certified Health IT

Measure: Applications Supported Through Certified Health IT



Year
1

Year
2

Year
3

Year 1 Metrics	Intended Purpose(s) of Application:	Intended Application User(s):
Application Name(s)	Administrative Tasks (e.g., scheduling & check-in, billing & payment)	Individual/Caregiver
Application Developer Name(s)		Clinical Team
Intended Purpose(s) of Application: (See Middle Table)	Clinical Tools (e.g., clinical decision support, risk calculators, remote patient monitoring)	Healthcare Administrator/Executive
Intended Application User(s): (See Far Right Table)	Individuals' Access to their EHI (e.g., enables patients to access their health information, medications, test results, vaccine records)	Payer
Application Status: • Actively Used • Not Actively Used	Research (e.g., used to perform clinical research)	Researcher
	Population Data (e.g., bulk transfer of data, population analytics & reporting)	Other Intended User
	Public Health (e.g., electronic case reporting)	Unknown (e.g., missing)
	Patient-Provider Communication (e.g., secure messaging, telehealth)	
	Educational Resources (e.g., patient and provider educational resources)	
	Other Intended Purpose	
	Unknown (e.g., missing)	

Measure: Use of FHIR in Apps Through Certified Health IT

Year
1

Year
2

Year
3

Year 1 Metrics	Year 2 Metric
Number of distinct certified health IT deployments (across clients) associated with at least one FHIR resource returned, overall and by user type	Number of distinct certified health IT deployments (across clients) associated with at least one FHIR resource returned by US Core Implementation Guide version
Number of requests made to distinct certified health IT deployments (across clients) that returned at least one FHIR resource by FHIR resource type	
Number of distinct certified health IT deployments (across clients) active at any time during the reporting period, overall and by user type	

Measure: Use of FHIR Bulk Data Access Through Certified Health IT



Year 2 Metrics

Number of bulk data access requests completed (across clients) to export all data requested for patients within a specified group

Number of distinct certified health IT deployments (across clients) that completed at least one bulk data access request



Measure Topic Area: Public Health Information Exchange

Insights Into Exchange of Immunization Data

Immunization Administrations Electronically Submitted to an Immunization Information System through Certified Health IT

To what extent are immunization administrations successfully submitted to an IIS using certified health IT?



Immunization History and Forecasts through Certified Health IT

To what extent are immunization queries made of an IIS successfully responded to/received via certified health IT?

Measure: Immunization Administrations Electronically Submitted to an Immunization Information System Through Certified Health IT

Year
1

Year
2

Year
3

Year 1 Metrics	Year 2 Metrics
The number of administrations administered overall	The number of administrations administered overall by age category and IIS
The number of immunizations administered that were electronically submitted successfully to IISs overall	The number of immunizations administered that were electronically submitted successfully to IISs overall by age category and IIS

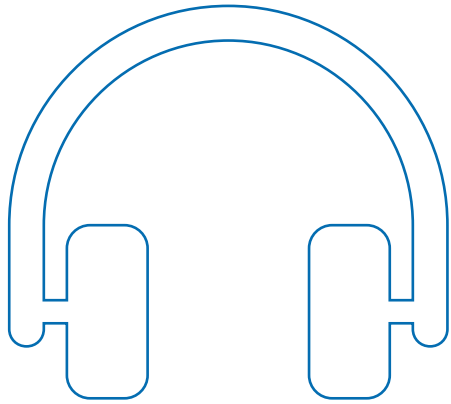
Refer to the Measure Specification Sheet for definitions, supplemental reporting information, and implementation information

Measure: Immunization History and Forecasts Through Certified Health IT



Year 2 Metrics	Year 3 Metrics
The number of immunization queries sent to IISs overall	The number of immunization queries sent to IISs overall by IIS
The number of query responses received successfully from IISs overall	The number of query responses received successfully from IISs overall by IIS

Refer to the Measure Specification Sheet for definitions, supplemental reporting information, and implementation information



We listened! Your feedback led to the proposed measures and related metrics

- Clarified or added definitions to help explain the metrics
- Removed terms that were confusing
- Streamlined and constrained measures and related metrics, including removing certain measures and metrics



Looking Ahead



Insights Condition: Future Resources

- ONC will continue to educate and support the health IT community with the following resources:
 - Webinars that delve further into the measures and program requirements
 - Resource Guide for health IT developers for reporting measures
 - FAQs about the program, measures and related metrics



Evolution of the Insights Condition Program

- Through future notice and rulemaking, ONC may propose modifications to the Insights Condition
- ONC may consider modifications based on:
 - Revisions to the regulatory baselines associated with metrics – such as changes to certification criteria—could potentially prompt changes to the measure specifications to ensure alignment
 - Analysis of metrics reported by health IT developers
 - Feedback from the health IT community
 - Additional Cures Act measurement categories (e.g., security, usability and user-centered design, conformance to certification testing, and other categories)

Current Resources Available on HealthIT.gov!

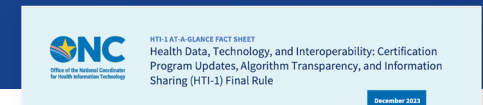
Visit <https://healthIT.gov/HTI-1> for additional information.

Fact Sheets

- General Overview
- Final Rule At-a-Glance
- Decision Support Interventions and Predictive Models
- Insights Condition
- HTI-1 Information Blocking
- HTI-1 Key Dates

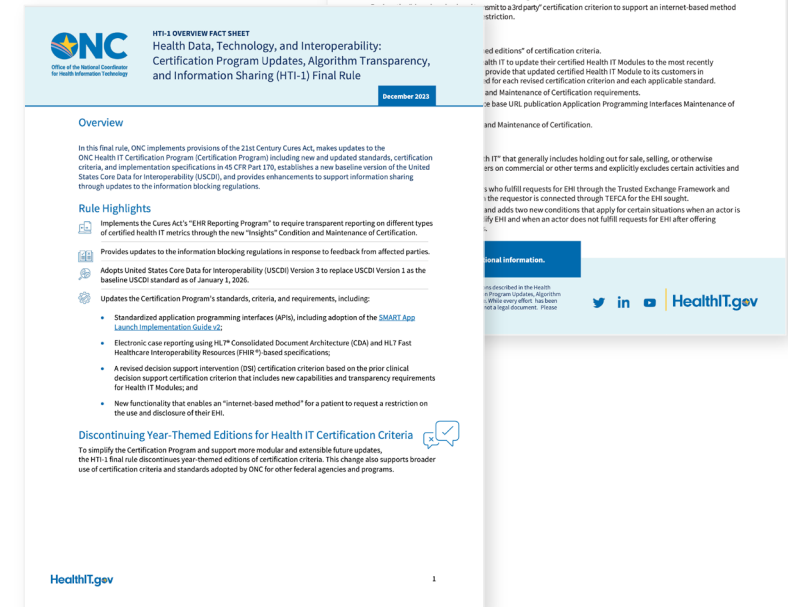
Measurement Spec Sheets

- For each of the Insights Condition Measures



Standards and Certification Criteria

- Adopts United States Core Data for Interoperability Version 3 (USCDI v3) as the new data set baseline across applicable certification criteria.
- Adopts the proposed versions of "minimum standards" code sets that serve as the baseline for Program certification.
- Revises the "electronic case reporting" certification criterion to be based on consensus-based, industry developed electronic standards and implementation guides by HL7.
- Adopts a "decision support interventions" (DSI) certification criterion as a revised version of the "clinical decision support" (CDS) certification criterion. The DSI certification criterion includes, among other changes, new transparency requirements.
- Adds new requirements for the "standardized API for patient and population services" certification criterion, including requirements for issuing refresh tokens and revoking access privileges.
- Adds new data elements and revises the demographics certification criterion.
- Adds new data elements and revises the demographics certification criterion to support an internet based method restriction.





Office of the National Coordinator
for Health Information Technology

Contact ONC



Phone: 202-690-7151



Health IT Feedback Form:

<https://www.healthit.gov/form/healthit-feedback-form>



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