ASTP Assistant Secretary for Technology Policy

Insights Condition Information Session

September 25, 2025

Disclaimers and Public Comment Guidance

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Agenda

- Overview of the Insights Condition and Maintenance of Certification and Submission Requirements
- Overview of the Percentage of Customers and updated Certification Companion Guide (CCG) Guidance
- Further Information

Overview

Insights Condition and Maintenance of Certification

Insights Condition and Maintenance of Certification

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 end users' experience with certified health IT

Who Is Required to Submit Insights Responses?

CONDITION OF CERTIFICATION

A Certified Health IT developer **must submit** one of the following annually **for each applicable measure**:

Measure responses including:

- Product-level aggregated data
- Data sources and methodology
- Percentage of customers represented

OR

Attestation that they:

- Do not have at least 50 hospital sites or 500 clinician users across their certified health IT
- Do not have certified technology for a measure
- Do not have users for that certified functionality

MAINTENANCE OF CERTIFICATION

Developers must submit responses (data or attestation) **annually**

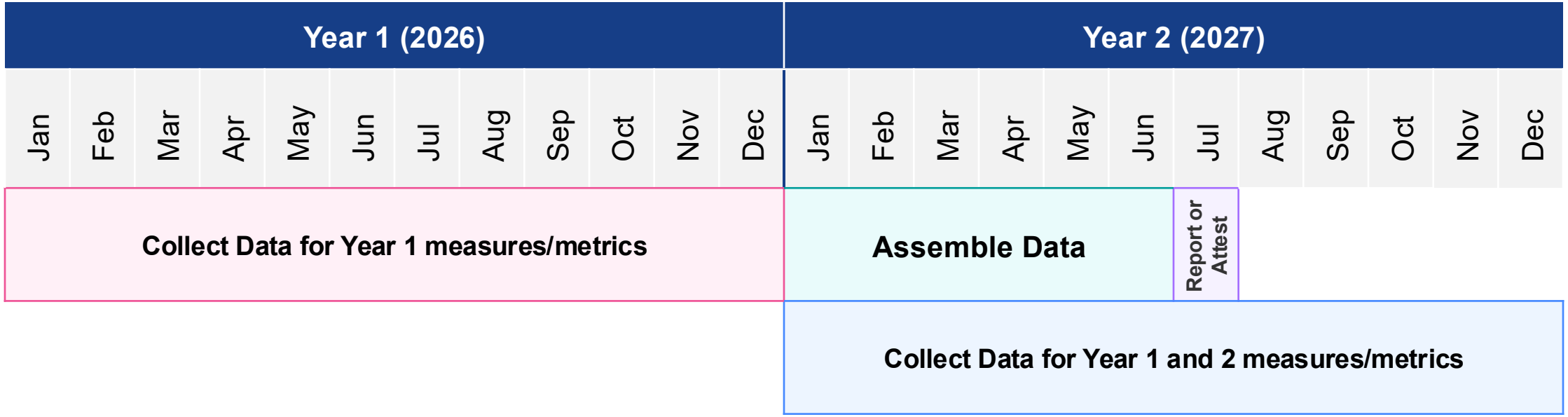
- **First data collection starts:** January 1, 2026
- **First response window opens:** July 1, 2027

Insights CCG: https://www.healthit.gov/condition-ccg/insights

What is the Reporting Frequency?

- The reporting period is one calendar year with developers having 6 months to collate the responses. These responses are due annually, each July.

- If not providing a data response, attest that do not meet the minimum reporting qualifications and provide reason why they do not meet the criteria for reporting.



How Will These Measures Be Reported?

- Responses will be **aggregated and reported <u>at the product level</u>** (across versions) in the format specified by the measure.
  - Certified 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)
  - Certified Health IT developers using **relied upon software** to meet the certification requirements are responsible to report on Insights Condition measure
    - Developers may work with their relied upon software vendor, if necessary, to report on the metrics
- Certified Health IT developers shall make the required and optional documentation available via a **publicly accessible hyperlink** that allows any person to directly access the information **without any preconditions or additional steps**
- Responses will be made **publicly available** via an ASTP/ONC website
- **Note:** Insights Condition responses may also be used for **Real World Testing**

Submission Process

- Submission Process – Year 1 Reporting or Attestation due July 2027

- Developers will access the Insights submission system by logging in through the Certified Health IT Product List (CHPL)

- The system is expected to provide multiple options for submitting results, including:
  - Directly entering results in a web-form
  - Using a CSV template to input results and then load to submission system
  - Using provided JSON template to input results and then load to submission system

Resources to help developers determine reporting eligibility are planned and will be shared when available.

Insights Measure Reporting
Enforcement Discretion

- At this time, Certified Health IT developers will not be required to comply with data collection and reporting beyond the "use of FHIR in apps through certified health IT" measure

- ASTP/ONC only expects Certified Health IT developers to report on, if applicable:

  "Use of FHIR in apps through certified health IT" measure
  - 45 CFR 170.407(a)(3)(iv)(A) and (B): beginning July 1, 2027 (Year 1)
  - 45 CFR 170.407(a)(3)(iv)(C): beginning July 1, 2028 (Year 2)

- For all other measures under 45 CFR 170.407, ASTP/ONC is demonstrating enforcement discretion

UPDATE: Enforcement Discretion

Required under Enforcement Discretion	Domain	Measure	Related 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 ASTP/ONC's website.

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	

Refer to the Measure Specification Sheets (v2,v4) for definitions, supplemental reporting information, and implementation information

Insights Measure Specifications: v2/v4 Flexibility

- Certified Health IT developers must submit data using at least the version of the Insights measure specifications finalized in the HTI-1 Final Rule (Version 2)

- Developers may submit data using either:
  - Version 2 (HTI-1 Final Rule), or
  - Version 4 (effective January 17, 2025)
    - Updated definition of "user type" to include one additional category (patient-facing AND non-patient facing).

- Applies only to the **"use of FHIR in apps through certified health IT"** measure (45 CFR 170.407(a)(3)(iv)), which is the only measure currently subject to reporting under enforcement discretion

Insights Measure Specifications Version 4: Clarifications Fact Sheet

https://www.healthit.gov/sites/default/files/2025-04/Insights_Measure_Spec_Sheet_4_Fact_Sheet.pdf

Use of FHIR in apps through certified health IT V2 versus V4

Metrics	Version
Number of distinct Certified Health IT deployments (across clients) associated with at least one FHIR resource returned, overall	2 and 4
Number of distinct Certified Health IT deployments (across clients) associated with at least one FHIR resource returned, patient-facing	2 and 4
Number of distinct Certified Health IT deployments (across clients) associated with at least one FHIR resource returned, non-patient facing	2 and 4
Number of distinct Certified Health IT deployments (across clients) associated with at least one FHIR resource returned, both patient-facing and non-patient facing	4 only (optional)
Number of distinct Certified Health IT deployments (across clients) active at any time during the reporting period, overall	2 and 4
Number of distinct Certified Health IT deployments (across clients) active at any time during the reporting period, patient-facing	2 and 4
Number of distinct Certified Health IT deployments (across clients) active at any time during the reporting period, non-patient facing	2 and 4
Number of distinct Certified Health IT deployments (across clients) active at any time during the reporting period, both patient-facing and non-patient facing	4 only (optional)

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 associated with at least one FHIR resource returned (overall and by user type)

- **Definition:** Counts the number of certified health IT deployments (across clients) that successfully return at least one FHIR resource
- Reported as:
  - Overall (total across user types)
  - By user type
- User type breakout:
  - 1. Patient-facing (apps used by patients to access their EHI)
  - 2. Non patient-facing (apps used by providers, payers, researchers, etc.)
  - 3. *Optional*: Both patient-facing and non patient-facing (apps that serve both groups)

User type categories are mutually exclusive (each deployment is classified once as patient-facing, non–patient-facing, or both).

Metric: Number of distinct certified health IT deployments (across clients) **active** at any time during the reporting period, overall and by user type

Number of FHIR Resource Requests (by Type) Metric

- Definition: Counts the number of Certified Health IT deployments that were **active** (had a functioning § 170.315(g)(10) FHIR endpoint) at any point during the measurement year.

- Reported as:
  - Overall (total across user types)
  - By user type

- User type breakout:
  - 1. Patient-facing (apps used by patients to access their EHI)
  - 2. Non patient-facing (apps used by providers, payers, researchers, etc.)
  - 3. *Optional:* Both patient-facing and non patient-facing (apps that serve both groups)

User type categories are mutually exclusive (each deployment is classified once as patient-facing, non–patient-facing, or both).

Metric: Number of requests made to distinct certified health IT deployments (across clients) that returned at least one FHIR® resource by resource type

Number of FHIR Resource Requests (by Type) Metric

- **Definition:** Counts the total number of API requests to Certified Health IT deployments where at least one FHIR resource was returned, broken out by type of resource
- Each request must have returned at least one FHIR resource
- Data are reported by FHIR resource type
- Note:
  - Provides insights into how frequently different resource types are accessed across deployments

FHIR Resource Types	
•AllergyIntolerance •CarePlan •CareTeam •Condition •Coverage •Device •DiagnosticReport •DocumentReference •Encounter •Endpoint •Goal •Immunization •Medication •MedicationDispense •MedicationRequest •Observation	•Patient •Procedure •Provenance •QuestionnaireResponse •RelatedPerson •ServiceRequest •Specimen •Location (***optional***) •Organization (***optional***) •Practitioner (***optional***) •PractitionerRole (***optional***) •HealthcareService •Media •ValueSet •Questionnaire

This metric is reported by FHIR resource type only (e.g., AllergyIntolerance, CarePlan, Observation). User type breakout does not apply.

Updated CCG Guidance: Insights Condition and Maintenance of Certification

Percentage of Customers

Certification Companion Guide (CCG): Insights

Reporting Requirements for Certified Health IT Developers: September Updates

- CCG Version 1.3 was published to clarify “customer” definition and reporting percentage of customers represented in submitted data

- Developers must:
  - Report the percentage of total customers represented in the data
  - Developers must specify the definition of customer and how it is operationalized in the documentation

- Options for customer definition:
  - Provider-based: Hospitals (inpatient) or clinicians (outpatient)
  - Deployment-based: Unique FHIR based URLs or API functionality implementations
  - Encounter-based: Number of encounters during the reporting year

- Documentation must also explain reasons for excluded customers (e.g., functionality not enabled, systems not updated, customers declined to share data)

Insights Condition CCG: https://www.healthit.gov/condition-ccg/insights

Calculating % of Customers: Provider-based Example

Customer percentages should be reported for each metric

Denominator= Total number of "customers" with product certified to g(10) criteria

Numerator= Total number of "customers" with product certified to g(10) criteria who are included in the data

Operationalize

Denominator= Total number of hospitals with inpatient product certified to g(10) criteria

Numerator= Total number of hospitals with inpatient product certified to g(10) criteria who are included in the data

Denominator= Total number of clinicians with outpatient product certified to g(10) criteria

Numerator= Total number of clinicians with outpatient product certified to g(10) criteria who are included in the data

Reporting of percentage of customers using FHIR deployment-based definition

Customer percentages should be reported for each metric

Denominator= Total number of "customers" with product certified to g(10) criteria

Numerator= Total number of "customers" with product certified to g(10) criteria who are included in the data

Operationalize

Denominator= Total number of FHIR deployments associated with product certified to g(10) criteria

Numerator= Total number of FHIR deployments associated with product certified to g(10) criteria that are included in the data

Reporting of percentage of customers using encounter-based definition

Customer percentages should be reported for each metric

Denominator= Total number of "customers" with product certified to g(10) criteria

Numerator= Total number of "customers" with product certified to g(10) criteria who are included in the data

Operationalize

Denominator= Total number of encounters within past year across all customers with product certified to g(10) criteria

Numerator= Total number of encounters within past year across all customers with product certified to g(10) criteria who are included in the data

Calculating Percent of Customers for Each Metric

Steps to Calculate % of Customers

- For a given product during the reporting period, determine definition of customer (either provider-based, deployment-based, or encounter-based) that will most accurately reflect your customer base
- Denominator: All customers with product certified to g(10)
- Numerator: Customers with product certified to g(10) that are included in in each metric
- Calculate the % of Customers Represented using numerator and denominator as specified above

What to Report

- % of customers included in each metric
- Document:
  - Chosen customer definition and how it was operationalized
  - Reasons for excluded customers:
    - Functionality not enabled
    - Systems not updated
    - Customers declined to share data

Note: Percentages must be aggregated at the product level

More Information

- What should Certified Health IT Developers Do Next?
- FAQs
- Resources

What Should Certified Health IT Developers Do Next?

1. Determine whether you meet the reporting qualifications for Insights Condition “use of FHIR in apps through certified health IT” measure
   - Do you have at least 50 hospital sites or 500 clinician users across your certified health IT products?
   - Does your product have a certified API (45 CFR 170.315(g)(10))?
   - Does it have users?

2. Know your options for specifications
   - Report using either Version 2 or Version 4 of the measure specifications
   - Optional Version 4-only metrics are not required

3. Prepare for reporting
   - If applicable, begin collecting data as of **January 1, 2026**
   - Watch for updates on submission format and templates

4. Understand your response obligations
   - All Certified Health IT developers must submit a response annually, beginning **July 1, 2027**
     - Report data if applicable
     - Attest if not applicable

Certified Health IT Developer FAQs

Q: Do I still need to submit something if no measures apply to me?

A: Yes. You must submit an attestation that you do not meet the qualifications for reporting.

Q: Does enforcement discretion mean I still need to collect data but not report it?

A: No. For measures other than the “use of FHIR in apps through Certified Health IT” (45 CFR 170.407(a)(3)(iv)), you do not need to collect or report data while enforcement discretion is in effect.

Q: Can I use Version 4 of the measurement specifications?

A: Yes. You may use either Version 2 (finalized in HTI-1) or Version 4 for the “use of FHIR in apps” measure

Q: When do I need to start collecting data?

A: For required reporting as of July 1, 2027, Certified Health IT developers need to begin collecting applicable data starting January 1, 2026

Insights Condition Resources

- Insights Condition Resources

https://www.healthit.gov/topic/certification-health-it/insights-condition

- Insights Condition Certification Companion Guide (CCG)

https://www.healthit.gov/condition-ccg/insights

- Insights Measure Specifications Version 4 Clarifications Fact Sheet

https://www.healthit.gov/sites/default/files/2025-04/Insights_Measure_Spec_Sheet_4_Fact_Sheet.pdf

- Insights Condition and Maintenance of Certification Enforcement Discretion

https://www.healthit.gov/topic/insights-condition-and-maintenance-certification-enforcement-discretion

- Health IT Feedback and Inquiry Portal

https://www.healthit.gov/feedback to submit a ticket under “Insights Condition”

Please direct further questions to the Health IT Feedback and Inquiry Portal :
https://www.healthit.gov/feedback