

ONC Health IT Certification Program Developer Roundtable

ONC Health IT Certification Program

May 28, 2025

1. Certification Program Updates and Reminders
2. Electronic Prescribing Testing Tool
3. Insights Condition and Maintenance of Certification

Certification Program Updates and Reminders

USCDI v3 Data Elements Enforcement Discretion

On January 20, 2025 Executive Order (EO) 14168, “Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government” was issued. The United States Office of Personnel Management (OPM) issued a memorandum, dated January 29, 2025, that provided initial guidance for EO 14168. Section 1(f) of the guidance directs agencies to withdraw any final or pending documents, directives, orders, regulations, materials, forms, communications, statements, and plans that inculcate or promote gender ideology.

Consistent with EO 14168 and OPM guidance, the Assistant Secretary for Technology Policy (ASTP) and the Office of the National Coordinator for Health Information Technology (ONC) (collectively, ASTP/ONC) is exercising enforcement discretion and issuing certification guidance for the ONC Health IT Certification Program. Section 170.550 of Title 45 of the Code of Federal Regulations requires an ONC-Authorized Certification Body (ONC-ACB), when certifying Health IT Modules, to certify in accordance with the applicable certification criteria adopted in regulation.

<https://www.healthit.gov/topic/certification-ehrs/enforcement-discretion>

End of Year Program Requirements: USCDI

- By December 31, 2025, any Health IT Modules seeking certification for criteria referencing § 170.213 would need to be capable of exchanging the data classes and data elements that comprise the [United States Core Data for Interoperability, version 3 \(USCDI v3\)](#).

End of Year Program Requirements: C-CDA Updates

- Certified Health IT developers with modules certified to criteria that reference HL7 C-CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 must update those Health IT Modules to C-CDA R2 IG Companion Guide, Release 4.1 and provide capabilities to customers by December 31, 2025.

End of Year Program Requirements: Minimum Code Sets

The following minimum standard code sets and accompanying certification criterion must be updated by December 31, 2025:

Certification Criterion	Previous Code Set	Revised Code Set
§ 170.315(a)(5) Demographics	§ 170.207(f)(2) CDC Race and Ethnicity Code Set Version 1.0 (March 2000)	§ 170.207(f)(3) CDC Race and Ethnicity Code Set Version 1.2 (July 15, 2021)
	§ 170.207(n)(1) Birth sex must be coded in accordance with HL7® Version 3 Standard, Value Sets for Administrative Gender and NullFlavor	§ 170.207(n)(2) Sex must be coded in accordance with SNOMED CT® U.S. Edition codes 248152002 Female (finding) ; and 248153007 Male (finding) .
§ 170.315 (a)(12) Family health history	§ 170.207(a)(4) SNOMED CT®, U.S. Edition, September 2015 Release	§ 170.207(a)(1) SNOMED CT®, U.S. Edition, March 2022 Release
§ 170.315 (a)(15) Social, psychological, and behavioral data	§ 170.207(c)(3) LOINC® Database version 2.52	§ 170.207(c)(1) LOINC®, Database Version 2.72, February 16, 2022
	§ 170.207(m)(1) The Unified Code for Units of Measure, Revision 1.9	§ 170.207(m)(2) The Unified Code for Units of Measure, Revision 2.1, November 21, 2017
§ 170.315 (b)(1) Transitions of care	§ 170.207(a)(4) SNOMED CT®, U.S. Edition, September 2015 Release	§ 170.207(a)(1) SNOMED CT®, U.S. Edition, March 2022 Release
	§ 170.207(n)(1) Birth sex must be coded in accordance with HL7® Version 3 Standard, Value Sets for Administrative Gender and NullFlavor	§ 170.207(n)(2) Sex must be coded in accordance with SNOMED CT® U.S. Edition codes 248152002 Female (finding) ; and 248153007 Male (finding) .
§ 170.315 (b)(3) Electronic prescribing	§ 170.207(d)(3) RxNorm, September 8, 2015 Full Release Update	§ 170.207(d)(1) RxNorm, July 5, 2022 Full Monthly Release

Certification Criterion	Previous Code Set	Revised Code Set
§ 170.315 (c)(4) CQM – filter	§ 170.207(f)(2) CDC Race and Ethnicity Code Set Version 1.0 (March 2000)	§ 170.207(f)(3) CDC Race and Ethnicity Code Set Version 1.2 (July 15, 2021)
	§ 170.207(a)(4) SNOMED CT®, U.S. Edition, September 2015 Release	§ 170.207(a)(1) SNOMED CT®, U.S. Edition, March 2022 Release
	§ 170.207(r)(1) Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy, April 2, 2015	§ 170.207(r)(2) Medicare Provider and Supplier Taxonomy Crosswalk, October 29, 2021
	§ 170.207(s)(1) Public Health Data Standards Consortium Source of Payment Typology Code Set Version 5.0 (October 2011)	§ 170.207(s)(2) Public Health Data Standards Consortium Source of Payment Typology Code Set, December 2020, Version 9.2
§ 170.315 (f)(1) Transmission to immunization registries	§ 170.207(e)(3) HL7® Standard Code Set CVX—Vaccines Administered, updates through August 17, 2015	§ 170.207(e)(1) HL7® Standard Code Set CVX - Vaccines Administered, updates through June 15, 2022
	§ 170.207(e)(4) National Drug Code Directory (NDC)—Vaccine NDC Linker, updates through August 17, 2015	§ 170.207(e)(2) National Drug Code Directory (NDC) - Vaccine NDC Linker, updates through July 19, 2022
§ 170.315 (f)(3) Transmission to public health agencies – reportable laboratory tests and value/results	§ 170.207(a)(3) HTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release	§ 170.207(a)(1) SNOMED CT®, U.S. Edition, March 2022 Release
	§ 170.207(c)(2) LOINC® Database version 2.40	§ 170.207(c)(1) LOINC®, Database Version 2.72, February 16, 2022
§ 170.315 (f)(4) Transmission to cancer agencies	§ 170.207(a)(4) SNOMED CT®, U.S. Edition, September 2015 Release	§ 170.207(a)(1) SNOMED CT®, U.S. Edition, March 2022 Release
	§ 170.207(c)(3) LOINC® Database version 2.52	§ 170.207(c)(1) LOINC®, Database Version 2.72, February 16, 2022
§ 170.315 (f)(5) Transmission to public health agencies – electronic case reporting	§ 170.207(a)(4) SNOMED CT®, U.S. Edition, September 2015 Release	§ 170.207(a)(1) SNOMED CT®, U.S. Edition, March 2022 Release

End of Year Program Requirements: § 170.315(e)(1)

- In addition to the C-CDA and USCDI standards updates required for [§ 170.315\(e\)\(1\) View, download, and transmit to 3rd party](#), Certified Health IT Modules must also update functionality for this criterion by December 31, 2025.
 - ▶ Patients (and their authorized representatives) must be able to use an internet-based method to request a restriction to be applied for any data expressed in USCDI.

End of Year Program Requirements: § 170.315(g)(10)

- Health IT Modules certified to [§ 170.315\(g\)\(10\) Standardized API for patient and population services](#) must update to the following standards as of December 31, 2025:
 - HL7 FHIR US Core Implementation Guide STU 6.1.0 in support of USCDI v3
 - HL7 SMART Application Launch Framework Implementation Guide Release 2.0.0

SITE Tooling Update

- Deployed Fixes for the following Tests:
 - SMTP MT Tests 39, 40, 41: A fix has been implemented to address issues with the “Check MDN for Delivery Notification” button.
 - XDR Receive Tests: A fix has been deployed to resolve the root cause of a PKIX error that was affecting XDR receive test cases (3, 4a, 4b, 5, 8, and 9).
 - XDR Test 1: A fix has been deployed to address an error with the XDR send test.
- Please be advised that we are actively working on resolving an ongoing issue with the Direct Certificate Discovery Tool (DCDT).

Electronic Prescribing Testing Tool

Electronic Prescribing Testing Tool

Attention all developers for products certifying to § 170.315(b)(3) Electronic Prescribing criteria!

- Beta testing for NCPDP SCRIPT Standard Version 2023011 updates will be available from June 2- December 31, 2025.
 - ▶ Interested developers can create a Stage Environment login at <https://erx-stg.healthit.gov> and beta test on weekdays between 7 AM and 8 PM EST.
- We encourage engagement and welcome your feedback in a dedicated beta testing Google Group (<https://groups.google.com/g/erxrtpb-2023011-beta-testing>). Additionally, you can directly email feedback and inquiries to erxrtpb-2023011-beta-testing@googlegroups.com.

Thank you for your continued partnership!

Insights Condition and Maintenance of Certification

Agenda

- Overview of Insights Condition and Maintenance of Certification
- Enforcement Discretion and Guidance
- Flexibility related to Measurement Specifications
- Guidance related to Percentage of Customers Included in Data—Coming Soon!

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 Certified Health IT developers

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.

Year 1 (2026)												Year 2 (2027)																		
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 or Attest												
												Collect Data for Year 1 and 2 measures/metrics																		

How Will These Measures Be Reported? (Part 1)

- Responses will be **aggregated and reported at the product level** (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 will submit responses and documentation for the Insights Condition using a **web-based form and method**.
 - ▶ ASTP/ONC will provide **templates** that enable submitting the data in a **structured, electronic format**

How Will These Measures Be Reported? (Part 2)

- 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** plans and results

Measures and Related Criteria Finalized in HTI-1








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 [ASTP/ONC's website](#).

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.

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

New 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

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 <u>by user type</u>	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 <u>by user type</u>	

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

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)

Further 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>



Thank you!

Please submit questions, concerns, or feedback to
<https://inquiry.healthit.gov/>