



Office of the National Coordinator  
for Health Information Technology

# HTI-1 Final Rule Overview

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

**HITAC Meeting  
January 18, 2024**

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1/16/2024



## 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.



# Purpose of HTI-1 Final Rule



## Implementing the 21<sup>st</sup> Century Cures Act

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- EHR Reporting Program
- APIs that allow EHI to be accessed, exchanged, and used without special effort
- Reasonable and necessary activities that do not constitute information blocking



## Achieving the Goals of the Biden-Harris Administration Executive Orders

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- E.O. 13994 “Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats”
- E.O. 13985 “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government” and E.O. 14091 “Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government”
- E.O. 14110 “Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence”



## Leveraging Health IT and Advancing Interoperability

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- HITECH Act
- Interoperability Advancement
- ONC Health IT Certification Program



# What's In the Final Rule?

1. New Regulatory Approach for Certification Criteria (“edition-less”)
2. Certification Standards and Functionality Updates
3. Decision Support Interventions (DSI) and Algorithmic Transparency
4. Insights Condition and Maintenance of Certification Requirements (EHR Reporting Program)
5. Information Blocking



## **New Regulatory Approach for Certification Criteria (“Edition-less”)**

# Discontinuing Year-Themed “Editions”

## HTI-1 Final Rule

Discontinues the year-themed editions and establish a single set of certification criteria, “ONC Certification Criteria for Health IT”

## Benefits

- Allows the Certification Program and health IT developers to more effectively utilize new and updated standards and functionality in a timely manner
- Allows users of health IT to work in partnership with health IT developers to update their systems for new standards or functionality in the manner that works best for their unique needs
- Assists health care industry participants in other HHS programs that reference Certification Program standards and criteria, such as CMS’s Promoting Interoperability Program, by ensuring developers provide timely updates for any new or updated certification criteria
- Supports users of health IT by reducing potential confusion of tracking use of different editions of certified health IT



# Establishing Applicability and Expiration Dates for Certification Criteria and Standards

## HTI-1 Final Rule



- Establishes the dates by which a prior version of a criterion is no longer applicable when a revised version (including new and revised standards) of that criterion is adopted
- Establishes applicable timelines, including expiration dates, for the adoption of standards when a new, revised, or updated version of the standard is adopted for the same purpose

## Benefits



- Supports establishment of clear timelines associated with the specific criterion or standard
- Facilitates ease of reference for federal, state, local or tribal programs seeking to align their program requirements to the standards and implementation specifications available in certified health IT
- Ensures that customers are provided with timely technology updates

# Two Forms of Compliance

## Certification Criteria

Health IT developers with a Health IT Module certified to any revised certification criterion must update their Health IT Modules and provide such update to their customers in accordance with the dates identified for each revised criterion and/or standard included in § 170.315.

## Assurances Condition and Maintenance of Certification Requirements

Condition: A health IT developer must provide an assurance that it will not interfere with a customer's timely access to interoperable health IT certified under the Program.

### Maintenance of Certification:

- *Update*: A health IT developer must update a Health IT Module, once certified to a certification criterion adopted in § 170.315, to all applicable revised certification criteria, including the most recently adopted capabilities and standards included in the revised certification criterion;
- *Provide*: A health IT developer must provide all Health IT Modules certified to a revised certification criterion to its customers
- *Timeliness*: **A health IT developer must follow the timeliness requirements identified in the rule.**





# **Certification Standards and Functionality Updates**

# Select New and Revised Standards and Certification Criteria

## Standards

- United States Core Data for Interoperability Standard Version 3
- C-CDA Companion Guide Release 4.1
- US Core Implementation Guide 6.1.0
- “Minimum Standards” Code Sets Updates
  - SNOMED, RxNorm, LOINC, NDC, etc.

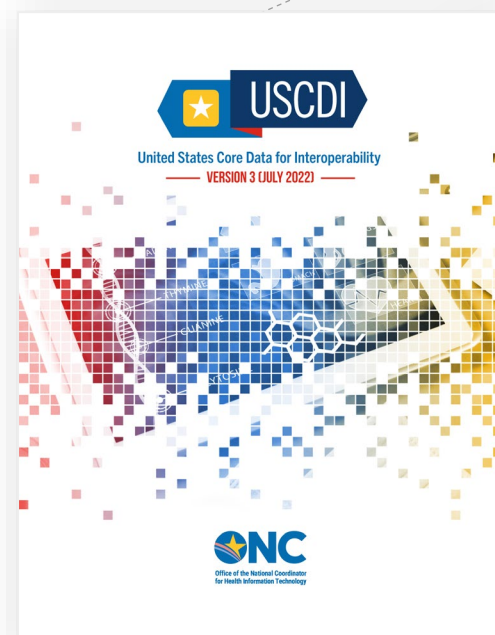
## Revised Certification Criteria

- Electronic Case Reporting § 170.315(f)(5)
- Clinical Decision Support § 170.315(a)(9) ((as Decision Support Intervention § 170.315(b)(11))
- Standardized API for Patient and Population Services in § 170.315(g)(10)
- View, Download, and Transmit to 3rd Party § 170.315(e)(1)
- Patient Demographics and Observations Certification Criterion in § 170.315(a)(5)
- Transitions of Care Criterion in § 170.315(b)(1)



# USCDI Background

- Standard established by ONC in the 2020 21<sup>st</sup> Century Cures Act Final Rule
- Minimum dataset required for interoperability
  - Defines required data elements and vocabulary standards
  - Focuses on patient access/care coordination use cases
- Updated on an annual cycle with federal agency and industry input
  - Updates based on multiple criteria including standards maturity and public/industry priority



USCDI v3 Summary of Data Classes and Data Elements

<b>Allergies and Intolerances</b> <ul style="list-style-type: none"> <li>• Substance (Medication)</li> <li>• Substance (Drug Class)</li> <li>• Reaction</li> </ul>	<b>Health Status/Assessments</b> <ul style="list-style-type: none"> <li>• Health Concerns</li> <li>• Functional Status</li> <li>• Disability Status</li> <li>• Mental/Cognitive Status</li> <li>• Pregnancy Status</li> <li>• Smoking Status</li> </ul>	<b>Problems</b> <ul style="list-style-type: none"> <li>• Problems</li> <li>• SDOH Problems/Health Concerns</li> <li>• Date of Diagnosis</li> <li>• Date of Resolution</li> </ul>
<b>Assessment and Plan of Treatment</b> <ul style="list-style-type: none"> <li>• Assessment and Plan of Treatment</li> <li>• SDOH Assessment</li> </ul>	<b>Immunizations</b> <ul style="list-style-type: none"> <li>• Immunizations</li> </ul>	<b>Procedures</b> <ul style="list-style-type: none"> <li>• Procedures</li> <li>• SDOH Interventions</li> <li>• Reason for Referral</li> </ul>
<b>Care Team Member(s)</b> <ul style="list-style-type: none"> <li>• Care Team Member Name</li> <li>• Care Team Member Identifier</li> <li>• Care Team Member Role</li> <li>• Care Team Member Location</li> <li>• Care Team Member Telecom</li> </ul>	<b>Laboratory</b> <ul style="list-style-type: none"> <li>• Tests</li> <li>• Values/Results</li> <li>• Specimen Type</li> <li>• Result Status</li> </ul>	<b>Provenance</b> <ul style="list-style-type: none"> <li>• Author Organization</li> <li>• Author Time Stamp</li> </ul>
<b>Clinical Notes</b> <ul style="list-style-type: none"> <li>• Consultation Note</li> <li>• Discharge Summary Note</li> <li>• History &amp; Physical</li> <li>• Procedure Note</li> <li>• Progress Note</li> </ul>	<b>Medications</b> <ul style="list-style-type: none"> <li>• Medications</li> <li>• Dose</li> <li>• Dose Unit of Measure</li> <li>• Indication</li> <li>• Fill Status</li> </ul>	<b>Unique Device Identifier(s) for a Patient's Implantable Device(s)</b> <ul style="list-style-type: none"> <li>• Unique Device Identifier(s) for a patient's implantable device(s)</li> </ul>
<b>Clinical Tests</b> <ul style="list-style-type: none"> <li>• Clinical Test</li> <li>• Clinical Test Result/Report</li> </ul>	<b>Patient Demographics/Information</b> <ul style="list-style-type: none"> <li>• First Name</li> <li>• Last Name</li> <li>• Middle Name (including middle initial)</li> <li>• Name Suffix</li> <li>• Previous Name</li> <li>• Date of Birth</li> <li>• Date of Death</li> <li>• Race</li> <li>• Ethnicity</li> <li>• Tribal Affiliation</li> <li>• Sex</li> <li>• Sexual Orientation</li> <li>• Gender Identity</li> <li>• Preferred Language</li> <li>• Current Address</li> <li>• Previous Address</li> <li>• Phone Number</li> <li>• Phone Number Type</li> <li>• Email Address</li> <li>• Related Person's Name</li> <li>• Related Person's Relationship</li> <li>• Occupation</li> <li>• Occupation Industry</li> </ul>	<b>Vital Signs</b> <ul style="list-style-type: none"> <li>• Systolic Blood Pressure</li> <li>• Diastolic Blood Pressure</li> <li>• Heart Rate</li> <li>• Respiratory Rate</li> <li>• Body Temperature</li> <li>• Body Height</li> <li>• Body Weight</li> <li>• Pulse Oximetry</li> <li>• Inhaled Oxygen Concentration</li> <li>• BMI Percentile (2 - 20 years)</li> <li>• Weight-for-length Percentile (Birth - 24 Months)</li> <li>• Head Occipital-frontal Circumference Percentile (Birth - 36 Months)</li> </ul>
<b>Diagnostic Imaging</b> <ul style="list-style-type: none"> <li>• Diagnostic Imaging Test</li> <li>• Diagnostic Imaging Report</li> </ul>		
<b>Encounter Information</b> <ul style="list-style-type: none"> <li>• Encounter Type</li> <li>• Encounter Diagnosis</li> <li>• Encounter Time</li> <li>• Encounter Location</li> <li>• Encounter Disposition</li> </ul>		
<b>Goals</b> <ul style="list-style-type: none"> <li>• Patient Goals</li> <li>• SDOH Goals</li> </ul>		
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USCDI United States Core Data for Interoperability  
Version 3 (July 2022)

ONC  
Office of the National Coordinator  
for Health Information Technology

# USCDI v3



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# United States Core Data for Interoperability (USCDI) v3

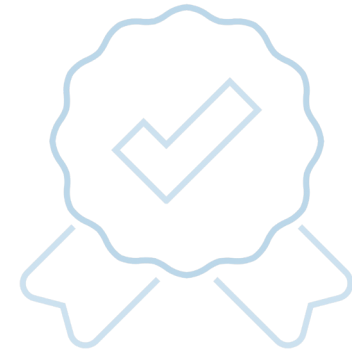
- Adopted USCDI v3 as the new baseline for certification.
- Expanding the data elements and data classes included in USCDI increases the amount of data available to be used and exchanged for patient care.
  - ONC is expanding the USCDI by moving from USCDI v1 to the adoption of USCDI v3 in 45 CFR 170.213(b) by **January 1, 2026**. Until that time, both versions will be accepted as in compliance with the USCDI standard in § 170.213.
- Health IT Modules certified to criteria that reference USCDI would need to update to USCDI v3 by the January 1, 2026, using the applicable US Core IG and C-CDA Companion Guide:

- § 170.315(b)(1): Transitions of Care
- § 170.315(b)(2): Clinical Information Reconciliation and Incorporation
- § 170.315(b)(9): Care Plan\*
- § 170.315(e)(1): View, Download, and Transmit 3rd Party
- § 170.315(g)(6): Consolidated CDA Creation Performance
- § 170.315(g)(9): Application Access-All Data Request
- § 170.315(g)(10): Standardized API for Patient and Population Service

\* § 170.315(b)(9) is only updated to the C-CDA Companion Guide

# “Minimum Standards” Code Sets Updates

- ONC updated minimum code set versions for vocabulary standards used in several certification criteria
- Code sets with updated versions in the final rule:
  - SNOMED CT US Edition March 2022
  - LOINC Database version 2.72, February 16, 2022
  - NDC – Vaccine NDC Linker, updates through July 19, 2022
  - CDC Race and Ethnicity Code Set Version 1.2 (July 2021)
  - RxNorm July 5, 2022, Full Monthly Release
- ONC policy enables developers of certified health IT to use newer versions of these adopted standards on a voluntary basis as these vocabulary code sets update, which may be several times per year



# Standardized API Revisions and Related API Conditions Updates

ONC requires several revisions to § 170.315(g)(10) including:

- Adoption of new standard baselines for USCDI v3, US Core, and SMART App Launch IG
- Adoption of HL7® FHIR® US Core IG STU version 6.1.0 – Provides the latest consensus-based capabilities aligned with USCDI v3 data elements for FHIR APIs
- Adoption of standards-based requirements for authentication, authorization, and token introspection, leveraging SMART App Launch IG v2
- Clarification for patient authorization revocation to occur within 1 hour of a request
- Revise and standardize the service base URL publication API Maintenance of Certification requirement





# Electronic Case Reporting

- ONC requires that Health IT Modules support eCR using consensus-based, industry-developed HL7® CDA and FHIR® standards
- Developers of certified health IT have until January 1, 2026, to adopt HL7 CDA or HL7 FHIR implementation guides to provide functionality
  - Health IT Modules may support either the CDA -based IG or the FHIR suite of profiles identified in the IG
  - This supports the current mix of system capabilities across the country and encourages a transition to FHIR -based reporting
  - Health IT Modules must support a baseline version of the RCTC value set, but are able to certify using a newer version
  - Health IT Modules may certify to the standards –based requirements beginning on the effective date of the final rule



# Patient Requested Restrictions

## Background

- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule provides individuals with several legal, enforceable rights intended to empower them to be more active participants in managing their health information.
- In the HTI-1 Proposed Rule, we made several proposals in support of the HIPAA Privacy Rule's individuals' "right to request a restriction" on certain uses and disclosures of their PHI (see *also* 45 CFR 154.522(a)).

## HTI-1 Final Rule

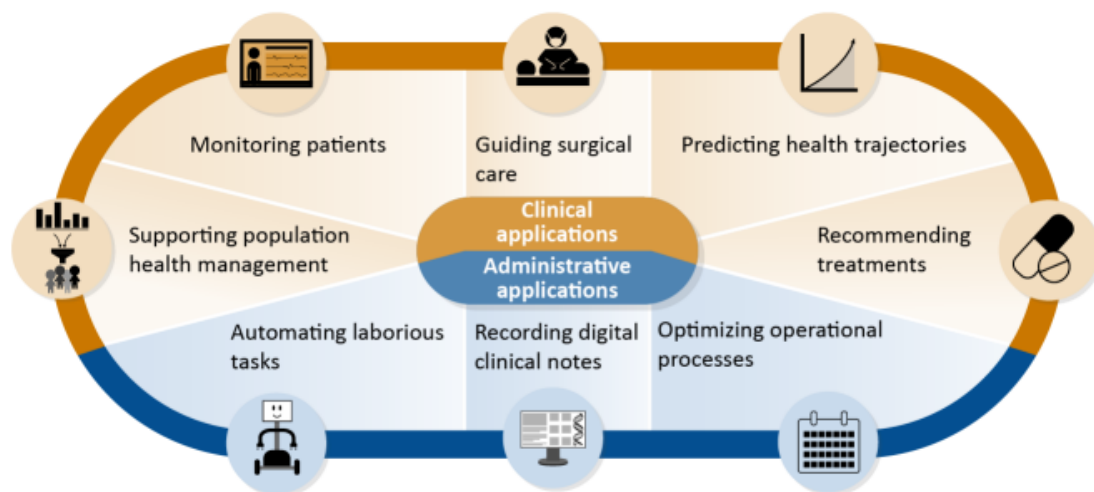
- In the HTI-1 Final Rule, we require support for an "internet-based method" for patients to request a restriction on the use or disclosure of their data in § 170.315(e)(1).
- Based on feedback received and readiness of the technology, we have decided not to finalize the remainder of the proposals for new criteria.
- We will continue to monitor efforts in the industry related to technological advancement to support patient-requested restrictions.





**DSI and Algorithmic Transparency**

## How Can AI Be Used in Healthcare?



: GAO. | GAO-21-7SP

## What Are the Challenges?

- Amplify implicit and structural biases
- Magnify ethical, legal, and social concerns related to data collection and use
- Reinforce common, non-evidence-based practices
- Baking-in existing inexplicable differences in health outcomes
- Perpetuate information asymmetries regarding a model's quality
- Lead to recommendations that are ineffective or unsafe

# DSI Certification Criterion At-a-Glance

## HTI-1 Final Rule:

- Revises existing CDS certification criterion by building on existing capabilities
- Streamlines and simplifies requirements for all Health IT Modules, while maintaining conditional requirements for Predictive DSIs
- Narrows the scope of impacted Predictive DSIs from what was proposed by constraining requirements to only those Predictive DSIs that are *supplied by a developer of certified health IT as part of its Health IT Module*

## The DSI certification criterion includes:

A definition for “predictive decision support intervention”

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Requirements for Health IT Modules to enable users to:

- Provide electronic feedback data for evidence-based DSIs and export such feedback data
  - Select both evidence-based and Predictive DSIs
  - Access complete and up-to-date source attribute information for evidence-based and Predictive DSIs
  - Record, change, and access source attributes for evidence-based and Predictive DSIs
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Requirements for risk management practices to be applied for Predictive DSIs

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Establishes new Assurances Maintenance of Certification requirement to review and update information on an ongoing basis

# Policy Impact of DSI Certification Criterion

## Improve Transparency



Regarding how a Predictive DSI is designed, developed, trained, evaluated, and should be used

## Enhance Trustworthiness



Through transparency on how certified health IT developers manage potential risks and govern predictive DSIs that are supplied by the health IT developer as part of its Health IT Module

## Foster an information ecosystem



Necessary to help healthcare organizations and users of these tools better determine whether their Predictive DSIs are fair, appropriate, valid, effective, and safe (FAVES)

## Advance Health Equity by Design



By addressing bias and health disparities, potentially propagated by predictive DSIs, to expand the use of these technologies in safer, more appropriate, and more equitable ways for patients and individuals

# How ONC Fits Into the Larger HHS Health AI Picture



## Health AI Areas of Activity



### Applicable Federal Policies

**Nondiscrimination in Health Programs and Activities Proposed Rule (Section 1557 of the Affordable Care Act)**

**CDS and Device Software Function-related Guidance Documents**

**ONC Health IT Certification Program (HTI-1 rulemaking)**

### Who Must Comply?

*Health care provider and health plan using AI to support decision-making in covered health programs and activities*

*Manufacturer of device software functions (e.g., AI-enabled software that meets the definition of medical device)*

*Developers of certified health IT that supply a predictive DSI as part of a Health IT Module*

### What Must Be Done?

Not use clinical algorithms in discriminatory ways

Receive FDA-approval for demonstrating the device software function's safety and effectiveness

Provide transparency information about predictive DSI's to clinical customers and engage in risk management practices



# **Insights Condition and Maintenance of Certification Requirements (EHR Reporting Program)**

# 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

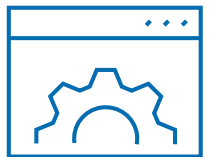


AREA	MEASURE	RELATED CRITERION/CRITERIA
Individual Access to EHI	Individuals' Access to Electronic Health Information Through Certified Health IT	§§ 170.315(e)(1) and (g)(10)
Clinical Care Information Exchange	C-CDA Problems, Medications, and Allergies Reconciliation and Incorporation Through Certified 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)

**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.
- 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												

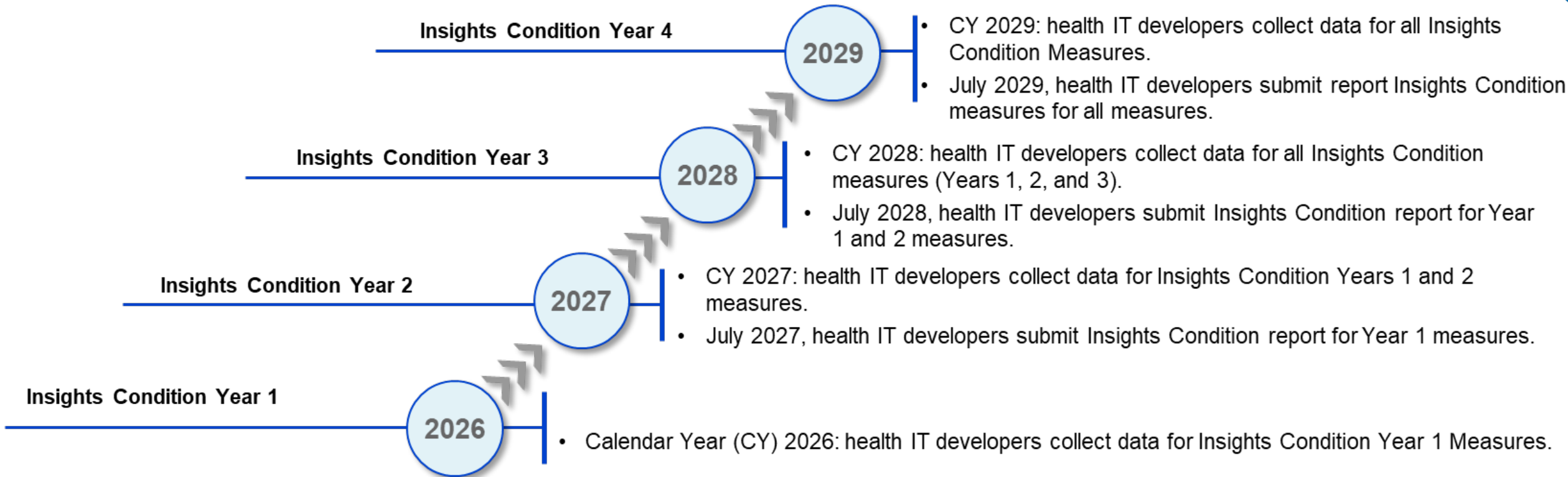
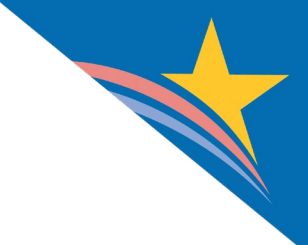
# What Is the Reporting Timeline?



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

MEASURE	Program Year Data Collection Begins
Individuals' Access to Electronic Health Information 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

# What Is the Reporting Timeline?



- **CY 2026: Data collection for Year 1 measures.**
- **CY 2027: Data collection for Year 1 and 2 measures. Year 1 measures reported in July.**
- **CY 2028: Data collection for Year 1, 2 and 3 measures. Year 1 and 2 measures reported in July.**
- **CY 2029: Data collection for all measures (Years 1-3) and all measures reported in July.**



# Information Blocking



# Overview of Information Blocking Enhancements



## Definitions

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- Information Blocking
- Business Associate
- Health IT Developer of Certified Health IT
- Offer Health IT



## Exceptions

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- Infeasibility Exception – 1 revised and 2 new conditions
- Manner Exception – renamed, removed obsolete “content” condition
- TEFCA Manner Exception – new



# Information Blocking Definitions

- “Offer Health IT”
  - The HTI-1 final rule defines what it means to “offer health IT” for purposes of the information blocking regulations. This definition confirms that proffering or supplying any certified health IT to be deployed by others will generally be considered an offer of health IT, while confirming that certain implementation and use activities are not considered an offer. The finalized definition also narrows the potential applicability of the “health IT developer of certified health IT” definition by explicitly excluding certain activities from what it means to “offer” health IT.
- “Health IT Developer of Certified Health IT”
  - The HTI-1 final rule changes the wording in the “health IT developer of certified health IT” definition so that it remains clear that a health care provider that self-develops certified health IT will not be considered a health IT developer of certified health IT if the provider does not “offer” any certified health IT.
- “Information Blocking”
  - The HTI-1 final rule revises the definition of “information blocking” to remove language that was no longer applicable. Specifically, ONC removed language that applied before October 6, 2022, that limited the definition to the subset of electronic health information (EHI) represented by data elements identified in the USCDI v1).



# Information Blocking Exceptions – Infeasibility Exception

- The HTI-1 final rule revises one condition and creates two new conditions for the Infeasibility Exception.
- The Uncontrollable Events Condition
  - A revision to the “uncontrollable events” condition further clarifies when an actor’s practice meets the “uncontrollable events” condition. Where this condition is met and the overall exception is met, it will not be considered information blocking when an actor does not fulfill a request to access, exchange, or use EHI that the actor cannot fulfill because of an uncontrollable event.
- Third Party Seeking Modification Use Condition
  - ONC added a new “third party seeking modification use” condition. Where this condition is met and the overall exception is met, an actor’s practice of not fulfilling a request for use of EHI will not be considered information blocking when:
    - the actor is asked to enable a third party to:
    - modify EHI within the records or systems maintained by the actor; and
    - the request is not from a health care provider (including a business associate acting on the health care provider’s behalf) requesting such use from an actor that is its business associate.

# Information Blocking Exceptions – Infeasibility Exception

- Manner Exception Exhausted
  - The new “manner exception exhausted” condition applies where an actor does not fulfill a request for access, exchange, or use of EHI after offering alternative, interoperable manners. This condition only applies under certain circumstances where the actor does not currently provide the requested manner of access, exchange, or use of the requested EHI to a substantial number of individuals or entities that are similarly situated to the requestor.



# Information Blocking Exceptions – Manner Exception

- Manner Exception
  - Because the date before which the “content” condition was relevant (October 6, 2022) has now passed, the HTI-1 final rule revises the exception. The final rule:
    - removes the “content” condition as no longer necessary changes the name from “Content and Manner Exception” to “Manner Exception,” and
    - finalizes redesignation of paragraphs within the “Manner Exception” consistent with removal of the “content” condition.



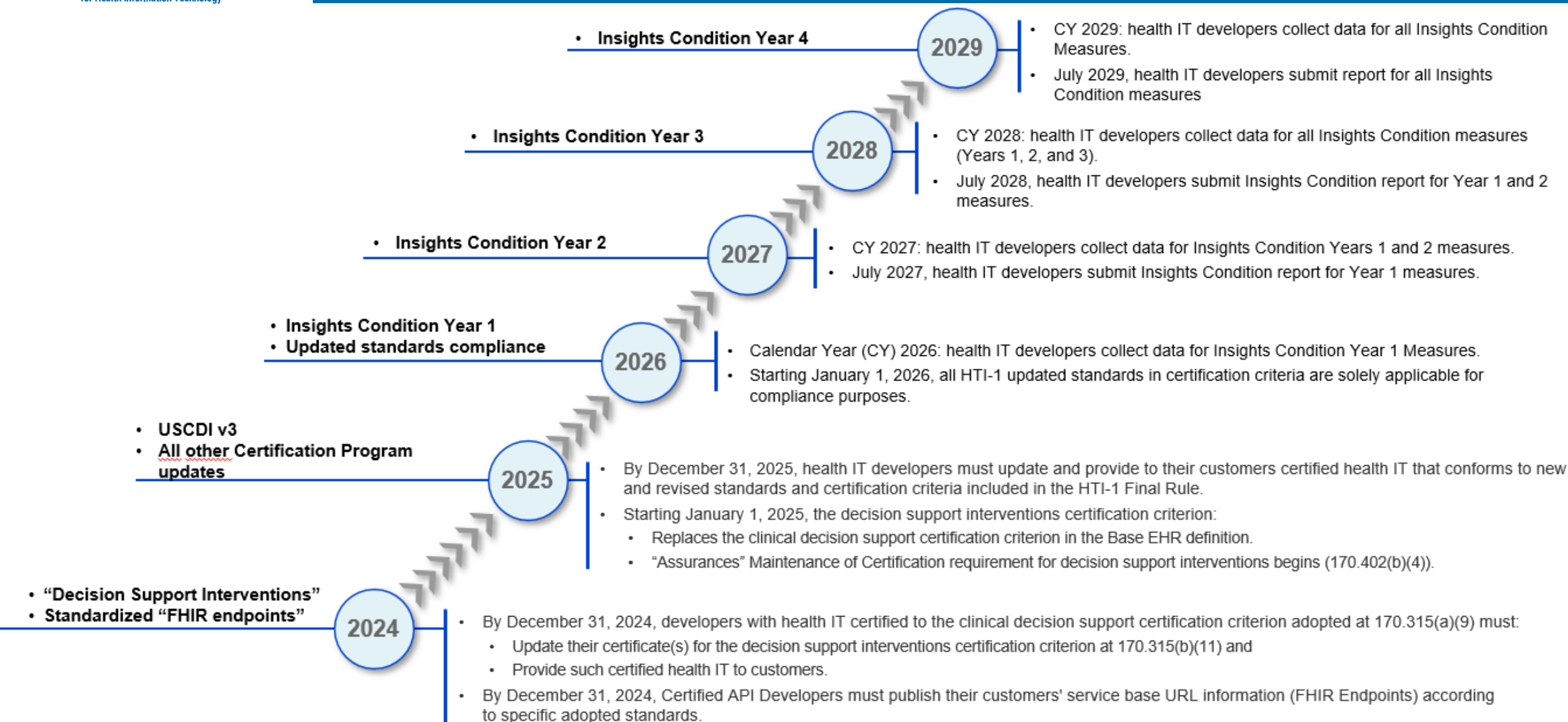
# Information Blocking Exceptions – TEFCA Manner Exception

- New Exception for Actors and Requestors Capable of Exchange via TEFCA
  - The HTI-1 final rule establishes a “TEFCA Manner” Exception that applies where an actor and requestor are both part of TEFCA. Where the exception is met, an actor’s practice of fulfilling certain requests for access, exchange, or use of EHI only via TEFCA will not be considered information blocking. The finalized exception applies only where:
    - the actor and requestor are both part of TEFCA;
    - access, exchange, or use of the requested EHI can be supported via TEFCA for both the actor and requestor;
    - the request for access, exchange or use is not via API standards adopted under the ONC Health IT Certification Program;
    - any fees charged and any licensing of interoperability elements by the actor in relation to fulfilling the request via TEFCA satisfy, respectively, the Fees Exception (§ 171.302) and Licensing Exception (§ 171.303).





# Key Dates





# 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

**HTI-1 AT-A-GLANCE FACT SHEET**  
Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule  
December 2023

**Standards and Certification Criteria**

- Adopts United States Core Data for Interoperability Version 3 (USCDI v3) as the new dataset 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 renames the demographics certification criterion.
- Adds a new "internet-based method" certification criterion to support an internet-based method restriction.

**HTI-1 OVERVIEW FACT SHEET**  
Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule  
December 2023

**Overview**

In this final rule, ONC implements provisions of the 21st Century Cures Act, makes updates to the ONC Health IT Certification Program (Certification Program) including new and updated standards, certification criteria, and implementation specifications in 45 CFR Part 170, establishes a new baseline version of the United States Core Data for Interoperability (USCDI), and provides enhancements to support information sharing through updates to the information blocking regulations.

**Rule Highlights**

- Implements the Cures Act's "EHR Reporting Program" to require transparent reporting on different types of certified health IT metrics through the new "Insights" Condition and Maintenance of Certification.
- Provides updates to the information blocking regulations in response to feedback from affected parties.
- Adopts United States Core Data for Interoperability (USCDI) Version 3 to replace USCDI Version 1 as the baseline USCDI standard as of January 1, 2026.
- Updates the Certification Program's standards, criteria, and requirements, including:
  - Standardized application programming interfaces (APIs), including adoption of the [SMART App Launch Implementation Guide v2](#);
  - Electronic case reporting using HL7® Consolidated Document Architecture (CDA) and HL7 Fast Healthcare Interoperability Resources (FHIR™) based specifications;
  - A revised decision support intervention (DSI) certification criterion based on the prior clinical decision support certification criterion that includes new capabilities and transparency requirements for Health IT Modules; and
  - New functionality that enables an "internet-based method" for a patient to request a restriction on the use and disclosure of their EHI.

**Discontinuing Year-Themed Editions for Health IT Certification Criteria**

To simplify the Certification Program and support more modular and extensible future updates, the HTI-1 final rule discontinues year-themed editions of certification criteria. This change also supports broader use of certification criteria and standards adopted by ONC for other federal agencies and programs.

HealthIT.gov

# Don't Miss Our Upcoming Webinars!

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

## Upcoming Webinars



### Information Blocking

January 25, 1:00 PM ET



### Overview of HTI-1 Final Rule with Q&A

February 1, 1:00 PM ET



### Insights Condition

February 8, 3:00 PM ET



# Discussion



Office of the National Coordinator  
for Health Information Technology

# Contact ONC



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