ONC

**Office of the National Coordinator
for Health Information Technology**

HTI-1 Final Rule Overview with Question & Answer

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

**Information Session
February 1, 2024**

2/9/2024

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 21st Century Cures Act

- EHR Reporting Program

- APIs that allow EHI to be accessed, exchanged, and used without special effort

- Reasonable and necessary activities that do <u>not</u> constitute information blocking

Achieving the Goals of the Biden-Harris Administration Executive Orders

- 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

- HITECH Act

- Interoperability Advancement

- ONC Health IT Certification Program
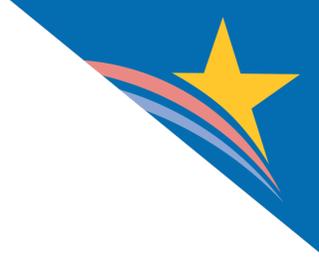
What's In the Final Rule?

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

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"

- 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

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.**

# 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)

How Can AI Be Used in Healthcare?
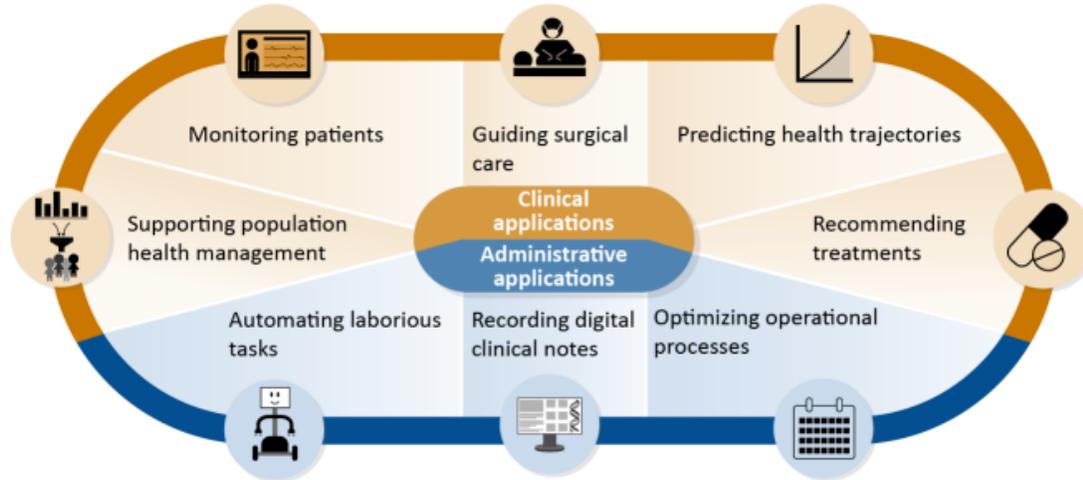
: GAO. | GAO-21-7SP

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

Source: "Getting the Best out of Algorithms in Health Care." Health IT Buzz blog. June 15, 2022

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"

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

Requirements for risk management practices to be applied for Predictive DSIs

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

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

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 <u>across</u> 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.
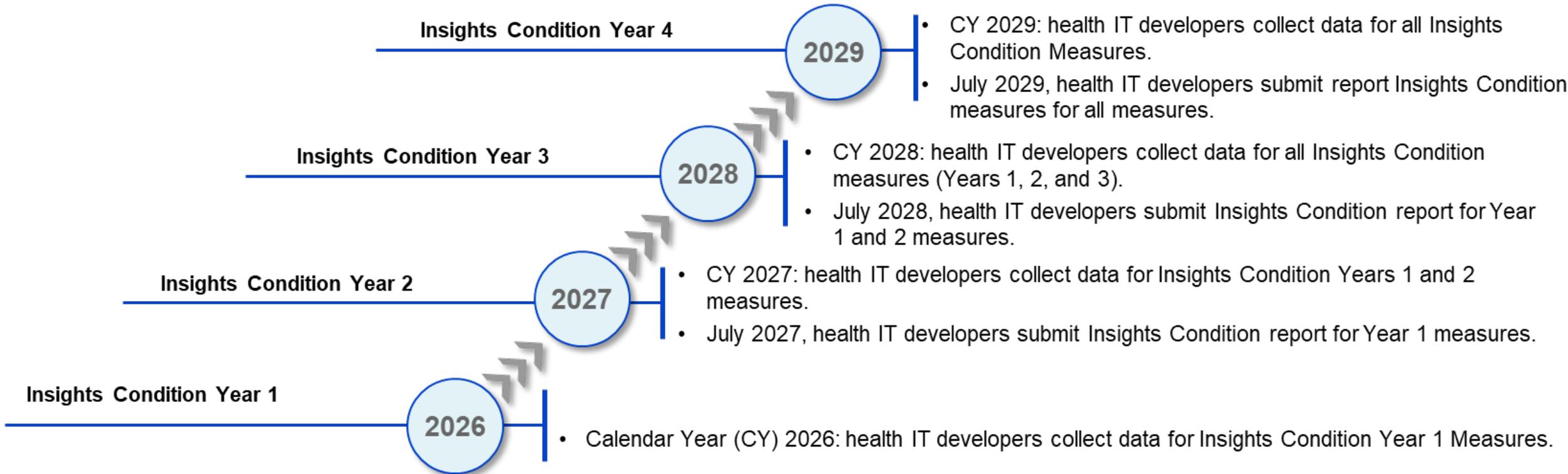
What Is the Reporting Timeline?

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?

Insights Condition Year 4

2029
- CY 2029: health IT developers collect data for all Insights Condition Measures.
- July 2029, health IT developers submit report Insights Condition measures for all measures.

Insights Condition Year 3

2028
- CY 2028: health IT developers collect data for all Insights Condition measures (Years 1, 2, and 3).
- July 2028, health IT developers submit Insights Condition report for Year 1 and 2 measures.

Insights Condition Year 2

2027
- CY 2027: health IT developers collect data for Insights Condition Years 1 and 2 measures.
- July 2027, health IT developers submit Insights Condition report for Year 1 measures.

Insights Condition Year 1

2026
- Calendar Year (CY) 2026: health IT developers collect data for Insights Condition Year 1 Measures.

- **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.**

Overview of Information Blocking Enhancements

Definitions

- Information Blocking

- Business Associate

- Health IT Developer of Certified Health IT
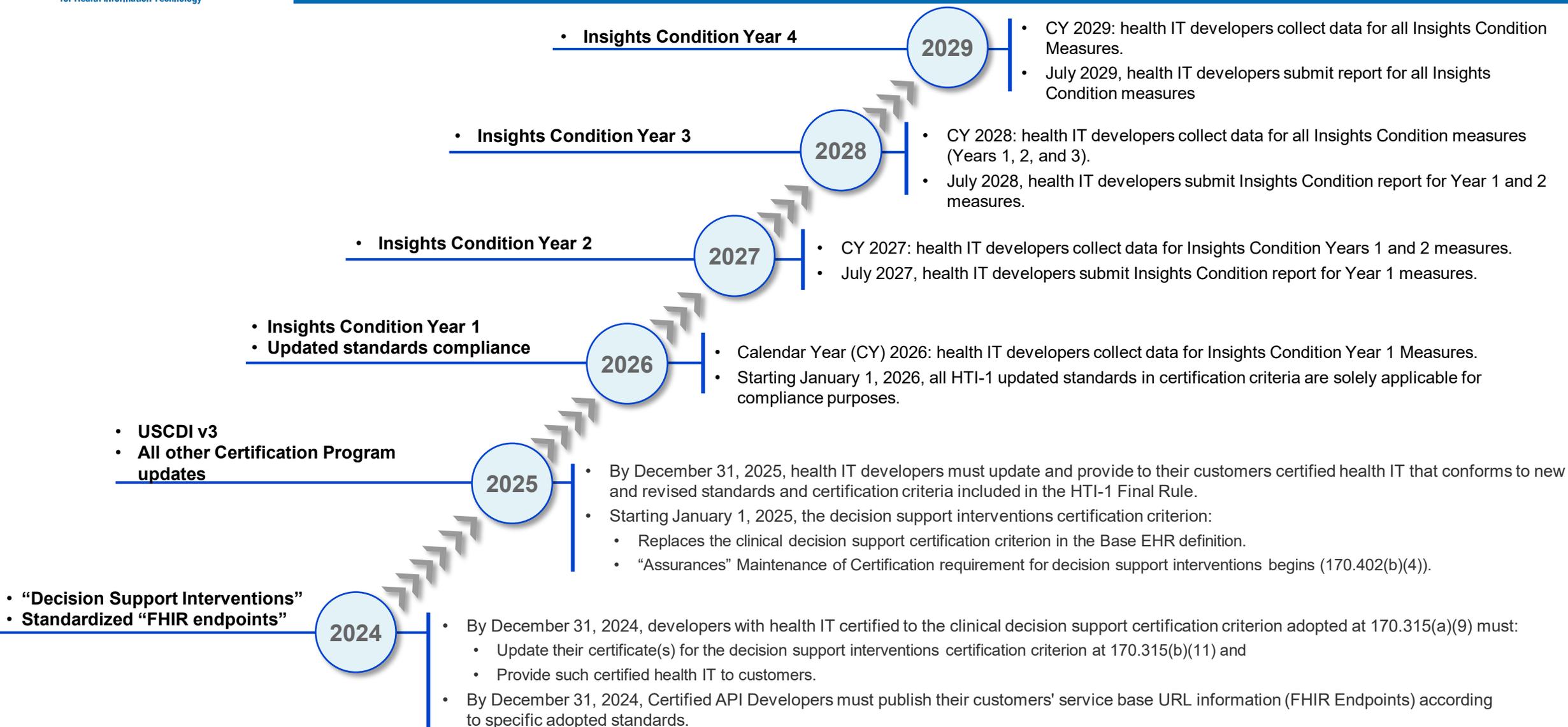
- Offer Health IT

Exceptions

- Infeasibility Exception – 1 revised and 2 new conditions

- Manner Exception – renamed, removed obsolete "content" condition

- TEFCA Manner Exception – new

Information Blocking Exception – 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).

- **Insights Condition Year 4** — **2029**
  - CY 2029: health IT developers collect data for all Insights Condition Measures.
  - July 2029, health IT developers submit report for all Insights Condition measures

- **Insights Condition Year 3** — **2028**
  - CY 2028: health IT developers collect data for all Insights Condition measures (Years 1, 2, and 3).
  - July 2028, health IT developers submit Insights Condition report for Year 1 and 2 measures.

- **Insights Condition Year 2** — **2027**
  - CY 2027: health IT developers collect data for Insights Condition Years 1 and 2 measures.
  - July 2027, health IT developers submit Insights Condition report for Year 1 measures.

- **Insights Condition Year 1**
- **Updated standards compliance** — **2026**
  - Calendar Year (CY) 2026: health IT developers collect data for Insights Condition Year 1 Measures.
  - Starting January 1, 2026, all HTI-1 updated standards in certification criteria are solely applicable for compliance purposes.

- **USCDI v3**
- **All other Certification Program updates** — **2025**
  - By December 31, 2025, health IT developers must update and provide to their customers certified health IT that conforms to new and revised standards and certification criteria included in the HTI-1 Final Rule.
  - Starting January 1, 2025, the decision support interventions certification criterion:
    - Replaces the clinical decision support certification criterion in the Base EHR definition.
    - "Assurances" Maintenance of Certification requirement for decision support interventions begins (170.402(b)(4)).

- **"Decision Support Interventions"**
- **Standardized "FHIR endpoints"** — **2024**
  - By December 31, 2024, developers with health IT certified to the clinical decision support certification criterion adopted at 170.315(a)(9) must:
    - Update their certificate(s) for the decision support interventions certification criterion at 170.315(b)(11) and
    - Provide such certified health IT to customers.
  - By December 31, 2024, Certified API Developers must publish their customers' service base URL information (FHIR Endpoints) according to specific adopted standards.

Resources Available on HealthIT.gov!

Visit https://healthIT.gov/HTI-1 for additional information.
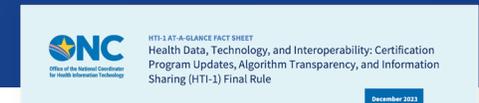
Fact Sheets

- General Overview

- Final Rule At-a-Glance

- Decision Support Interventions and Predictive Models

- Insights Condition

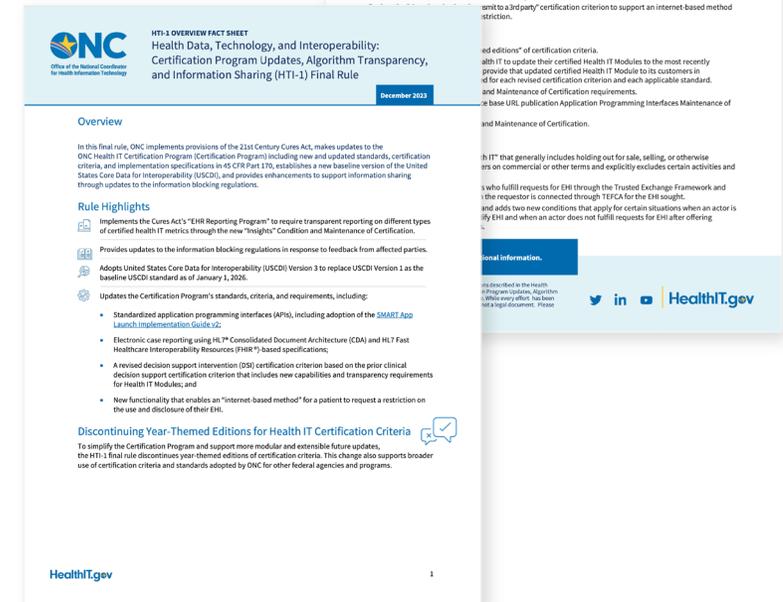- HTI-1 Information Blocking

- HTI-1 Key Dates

Measurement Spec Sheets

- For each of the Insights Condition measures

Upcoming Webinars

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

Upcoming Webinar

Insights Condition

February 8, 3:00 PM ET

Contact ONC

📞 **Phone:** 202-690-7151

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