ASTP Assistant Secretary for Technology Policy

Advancing Interoperability Through Technology & Policy

August 2024

Office of the National Coordinator for Health IT

- **Founded in 2004 by executive order, established in statute in 2009**

- **ONC is charged with formulating the federal government's health IT strategy to advance national goals for better and safer health care through an interoperable nationwide health IT infrastructure**

HITECH Act 2009 ⟶ 21st Century Cures Act 2016

Laying the foundation for EHR adoption

- $40B CMS investment to subsidize EHRs for hospitals and ambulatory providers
- ONC certification of EHR systems to support CMS and CDC programs
- ONC certification now covers EHRs used by 97% of hospitals and 86% of ambulatory providers

Leveraging EHRs to drive value

- Information blocking: Prohibits providers, technology developers, and health information networks from interfering with access, exchange, and use of electronic health information
- Standards: Requires access to information through APIs "without special effort"
- TEFCA: Requires nationwide governance for health information exchange networks – Trusted Exchange Framework and Common Agreement

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Key Areas of Focus

Build the digital foundation

- Data standards
- Health IT gaps

Make interoperability easy

- Trusted Exchange Framework & Common Agreement (TEFCA)
- Application Programming Interfaces (APIs)

Promote information sharing

- Enforce information-blocking rules
- HHS Health IT Alignment policy

Ensure responsible use of digital information

- Health equity-by-design principles
- Transparency in areas such as AI use

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ONC Health IT Certification Program

ONC-certified health IT is the **foundation of the US digital health care infrastructure**, covering 400+ health IT products used by 96% of hospitals and nearly 80% of clinical offices and required by numerous federal programs.

ONC Health IT Certification:

- Establishes baseline technical and standards-based capabilities

- Enables interoperability and the exchange of electronic health information

- Sets privacy and security requirements

- Promotes competition and choice in health IT marketplace

- Increases transparency in the quality and performance of certified health IT

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Components of the Certification Program

Certification Criteria

Currently 54 certification criteria across 8 categories of functionality

Standards

Seven categories of adopted standards, including a "standard of standards" known as the US Core Data for Interoperability

Conditions and Maintenance of Certification

Seven ongoing business and behavioral requirements for developers of Certified Health IT

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FHIR API Requirements: Access "without special effort"

HL7 FHIR

Open APIs make it easy to use an app to check your bank account, order meal delivery, or purchase products on your smartphone
- We want providers and patients to have the same experience with the health care system

21st Century Cures Act requires availability of APIs that can be accessed "without special effort"
- ONC Cures Act Final Rule rule takes steps to prevent business and technical barriers to information-sharing

As of December 31, 2022, all certified technology developers required to deploy a standard FHIR API across their entire customer base
- Will create a climate for innovation as developers can create apps that will work across all EHR systems

Looking ahead to interactive functions: questionnaires, scheduling, FHIR links, subscriptions

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US Core Data for Interoperability (USCDI) –
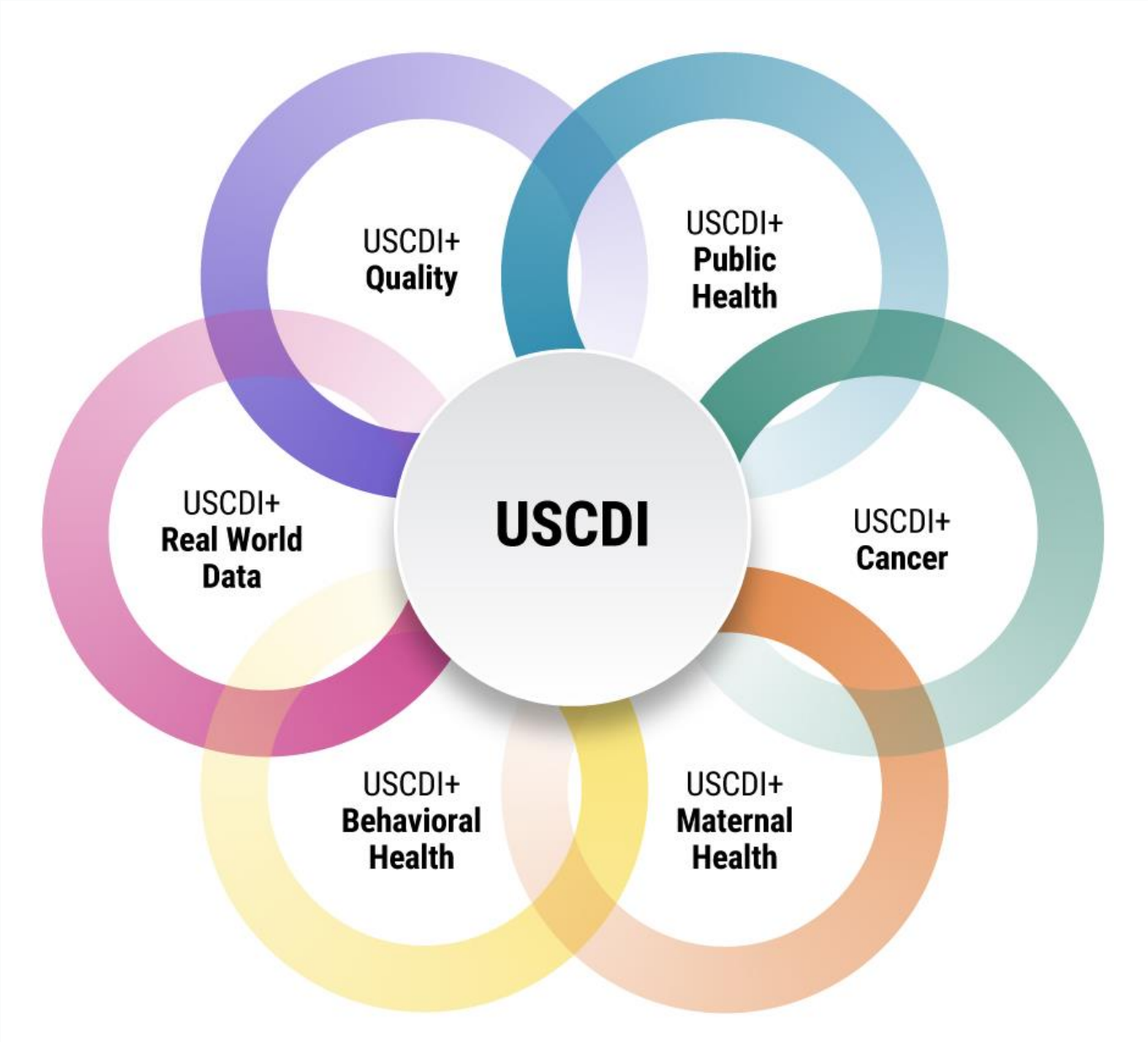# The minimum data set for the US health care delivery system
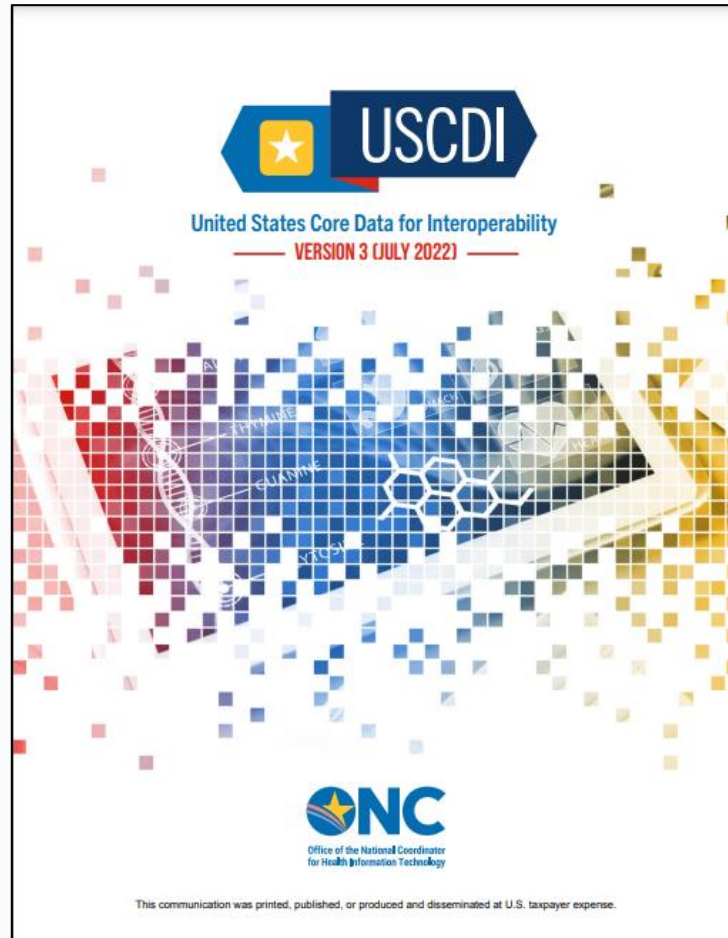
- **ONC standard for minimum dataset required for interoperability**
  - Defines required data elements and vocabulary standards
  - Agnostic to data format

- **Updated on annual cycle with federal agency and industry input**
  - Updates based on multiple criteria including standards maturity and public/industry priority

USCDI Version 3 – Required for Certified EHRs

Allergies and Intolerances
- Substance (Medication)
- Substance (Drug Class)
- Reaction

Assessment and Plan of Treatment
- Assessment and Plan of Treatment
- SDOH Assessment

Care Team Member(s)
- Care Team Member Name
- Care Team Member Identifier
- Care Team Member Role
- Care Team Member Location
- Care Team Member Telecom

Clinical Notes
- Consultation Note
- Discharge Summary Note
- History & Physical
- Procedure Note
- Progress Note

Clinical Tests
- Clinical Test
- Clinical Test Result/Report

Diagnostic Imaging
- Diagnostic Imaging Test
- Diagnostic Imaging Report

Encounter Information
- Encounter Type
- Encounter Diagnosis
- Encounter Time
- Encounter Location
- Encounter Disposition

Goals
- Patient Goals
- SDOH Goals

Health Insurance Information ⭐
- Coverage Status ⭐
- Coverage Type ⭐
- Relationship to Subscriber ⭐
- Member Identifier ⭐
- Subscriber Identifier ⭐
- Group Number ⭐
- Payer Identifier ⭐

Health Status/ Assessments
- Health Concerns ➡️
- Functional Status ⭐
- Disability Status ⭐
- Mental / Cognitive ⭐ Status
- Pregnancy Status ⭐
- Smoking Status ➡️

Immunizations
- Immunizations

Laboratory
- Test
- Values/Results
- Specimen Type ⭐
- Result Status ⭐

Medications
- Medications
- Dose ⭐
- Dose Unit of Measure ⭐
- Indication ⭐
- Fill Status ⭐

Patient Demographics/ Information
- First Name
- Last Name
- Middle Name (Including middle initial)
- Suffix
- Previous Name
- Date of Birth
- Date of Death ⭐
- Race
- Ethnicity
- Tribal Affiliation ⭐
- Sex
- Sexual Orientation
- Gender Identity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address
- Related Person's Name ⭐
- Related Person's Relationship ⭐
- Occupation ⭐
- Occupation Industry ⭐

Problems
- Problems
- SDOH Problems/Health Concerns
- Date of Diagnosis
- Date of Resolution

Procedures
- Procedures
- SDOH Interventions
- Reason for Referral ⭐

Provenance
- Author Organization
- Author Time Stamp

Unique Device Identifier(s) for a Patient's Implantable Device(s)
- Unique Device Identifier(s) for a patient's implantable device(s)

Vital Signs
- Systolic blood pressure
- Diastolic blood pressure
- Heart Rate
- Respiratory rate
- Body temperature
- Body height
- Body weight
- Pulse oximetry
- Inhaled oxygen concentration
- BMI Percentile (2 - 20 years)
- Weight-for-length Percentile (Birth - 24 Months)
- Head Occipital-frontal Circumference Percentile (Birth - 36 Months)

⭐ **New Data Classes and Elements** ➡️ **Data Element Reclassified**

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USCDI+

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Information Blocking

- **Defined by 21st Century Cures Act of 2016**

- **Prohibits "interference" by providers, health information networks, and certified health IT developers, with access, exchange, and use of health information by other authorized parties**

  - **Does not apply just to access, exchange, and use by patients – applies to <u>ALL</u> authorized parties**

- **Applies to purposes allowed by applicable law (federal, state, local) - does not supersede applicable law**

- **Complements HIPAA**

  - Covers a generally broader group of health care entities, including providers not regulated by HIPAA, certified health IT developers, and health information networks/exchanges

  - Directs (rather than just permits) health care entities to share electronic information with other authorized entities including patients

21st Century Cures Act – Section 4003(b)

*"[T]he National Coordinator shall convene appropriate public and private stakeholders to **develop or support** a **trusted exchange framework** for trust policies and practices and for a **common agreement** for exchange between health information networks."*

[emphasis added]

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TEFCA Will Simplify Health Data Exchange

**While there has been growth in national networks, there is much unfinished business**

- Public health

- Less well-resourced providers, rural, behavioral health, LTPAC

- Payers (government and commercial)

- Social services

- Research

Establish a universal policy and technical floor for nationwide interoperability

Simplify connectivity for organizations to securely exchange information
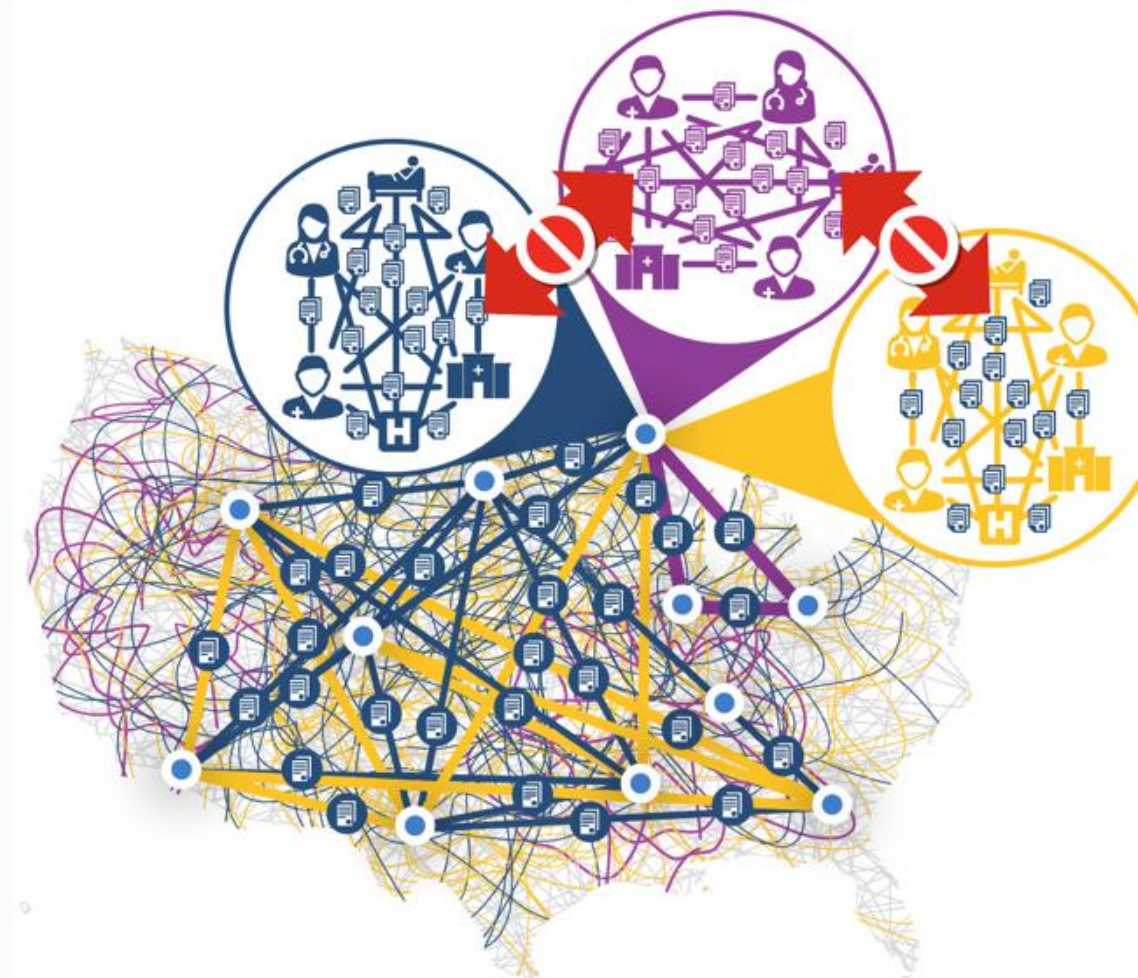
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How Does TEFCA Work?
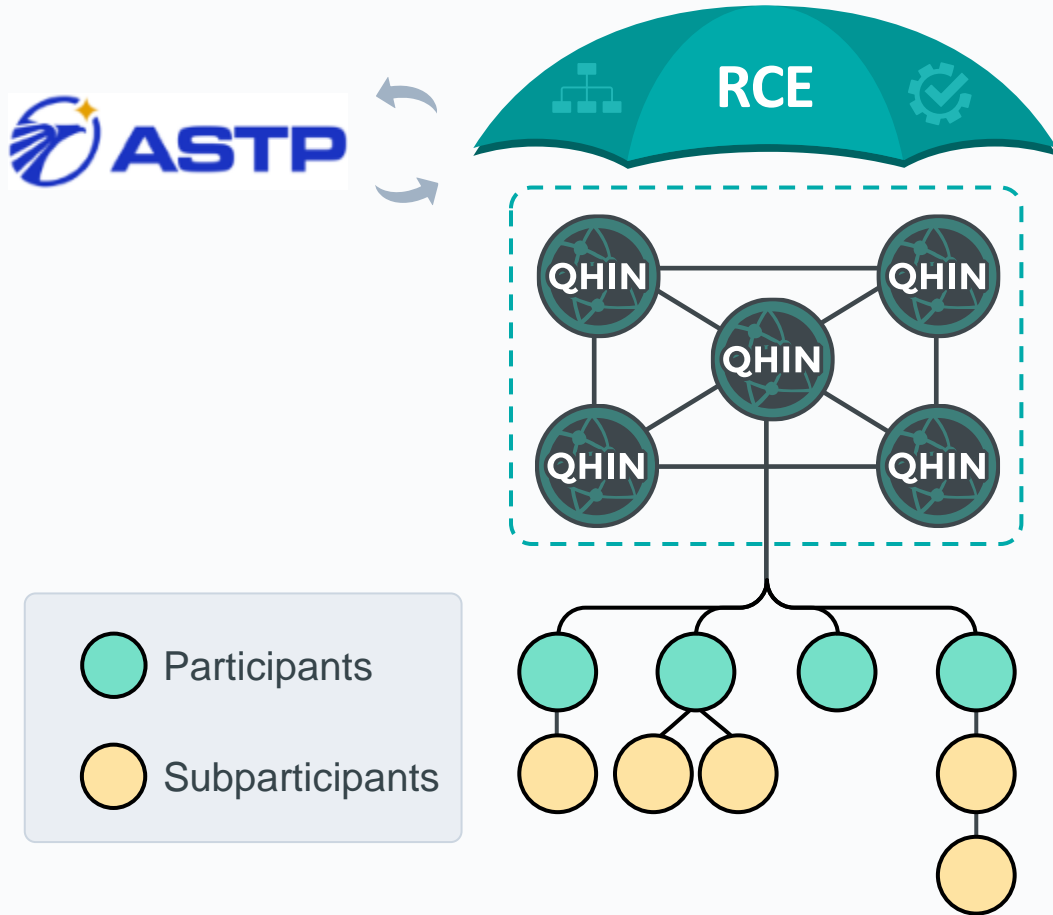
ASTP/ONC defines overall policy and certain governance requirements

RCE provides oversight and governing approach for QHINs

QHINs connect directly to each other to facilitate nationwide interoperability

Each QHIN connects Participants, which connect Subparticipants

Participants and Subparticipants connect to each other through TEFCA Exchange

- Participants contract directly with a QHIN and may choose to also provide connectivity to others (Subparticipants)
- Participants and Subparticipants sign the same Terms of Participation and can generally participate in TEFCA Exchange in the same manner

Support for HL7 Standards Development

- Collaboration w/HL7 beginning in 2015, goals include:

  - Facilitate ongoing development and publication of HL7 standards for the benefit of the general public

  - Enhance the underlying HL7 tools and infrastructure necessary to support effective implementation and use HL7 standards

  - Empower the HL7 standards development community

- Notable projects:

  - Annual USCDI updates for US Core FHIR IG and C-CDA standards

  - Gender Harmony Project

  - FHIR infrastructure support incl. IG publisher and FHIR validator

  - HL7 Unified Terminology Governance (UTG)

  - Web publication of C-CDA using FHIR structureDefinition format

  - FHIR IGs such as bulk data, International Patient Summary (IPS), PDMP

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Reach out via phone or web

📱 202-690-7151

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