



# Enabling the 21<sup>st</sup> Century Digital Healthcare System

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National Coordinator for Health Information Technology (ONC)  
HHS Office of the Secretary



November 16, 2022

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The Office of the National Coordinator for  
Health Information Technology



PAPER  
BRICKS  
MORTAR

digital

**Digitally native health care processes**

**Open architecture ecosystem**

**Information-sharing as a standard of care and business**

**Safe, equitable uses of health care information**

# Office of the National Coordinator for Health IT

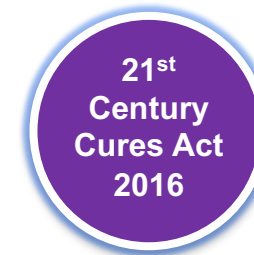
Founded in 2004 by executive order, established in statute in 2009

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**



## Laying the foundation of EHRs across the industry

- \$40B CMS investment to subsidize EHRs for hospitals and ambulatory providers
- ONC certification of EHR systems to support CMS and CDC programs



## 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

# New HHS Policy on Alignment of Health IT Activities

Interoperability

## E Pluribus Unum

Micky Tripathi and Steven Posnack | AUGUST 5, 2022



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As our nation transitions to a digital healthcare system, our stakeholders are discovering new opportunities for using health information technology to advance health care delivery, public health, and research to improve people's lives. The federal government is no exception in this regard; agencies across the Department of Health and Human Services (HHS) are beginning to leverage the data and capabilities available through electronic health records for a broad range of federal activities and programs, including product safety and surveillance, real world data and real world evidence for regulatory approvals, research, pandemic response, and social service integration, to name just a few.

While this is an exciting development for HHS overall, it does call for more proactive alignment and coordination of health IT activities across the department to ensure that we are operating as efficiently and cohesively as possible. To that end, Secretary Becerra has put into place a department-wide management policy directing ONC to engage with HHS agencies to align and coordinate health IT-related activities in support of HHS health IT and interoperability goals. Specifically, the secretary has directed ONC to establish and oversee a consistent HHS-wide approach for: 1) incorporating standard health IT requirements language in all applicable HHS funding programs, contracts, and policies; and 2) providing direct ONC assistance to HHS agencies to maximize the use of HHS-approved standards and authorities (such as [Section 3004 of the Public Health Service Act](#)) in their agency programs.

While it won't happen overnight, what we expect to see over time is greater consistency in health IT-based activities across HHS, which should result in lower cost and higher effectiveness agency programs, more sharing of data and health IT infrastructure across programs and agencies, and lower burden on health care providers, technology developers, and other stakeholders who engage with multiple HHS agencies. Maximizing federal use of open-industry, non-proprietary, scalable standards and approaches – such as the US Core Data for Interoperability (USCDI) and FHIR APIs as called for by the 21<sup>st</sup> Century Cures Act – will multiply the impact of the department's regulations and purchasing power to reinforce HHS health IT and interoperability goals. It will also directly support key Biden-Harris Administration priorities in [health equity](#), [federal customer experience and service delivery](#), and [promoting competition](#). ONC already works collaboratively with our federal agency partners, and we are excited to be able to better support our sister HHS agencies and ensure that HHS is more than the sum of its parts.

Specifically, the Secretary has directed ONC to establish and oversee a consistent HHS-wide approach for:

1. incorporating **standard health IT requirements language in all applicable HHS funding programs, contracts, and policies**; and
2. providing direct ONC assistance to HHS agencies to **maximize the use of HHS-approved standards and authorities**

# Advancing the health IT ecosystem

## “Retail” interoperability

(primarily lower volume, narrow band, focused exchange for B2B and B2C)



Providers

Payers

Consumers

Public Health

Researchers



*Information blocking  
regulations*



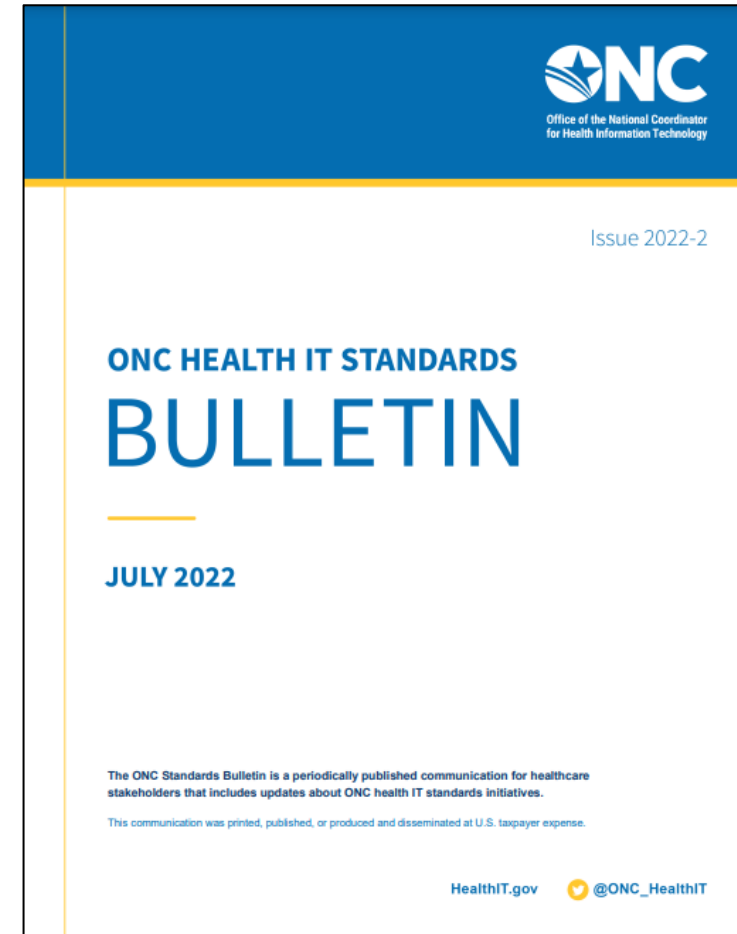
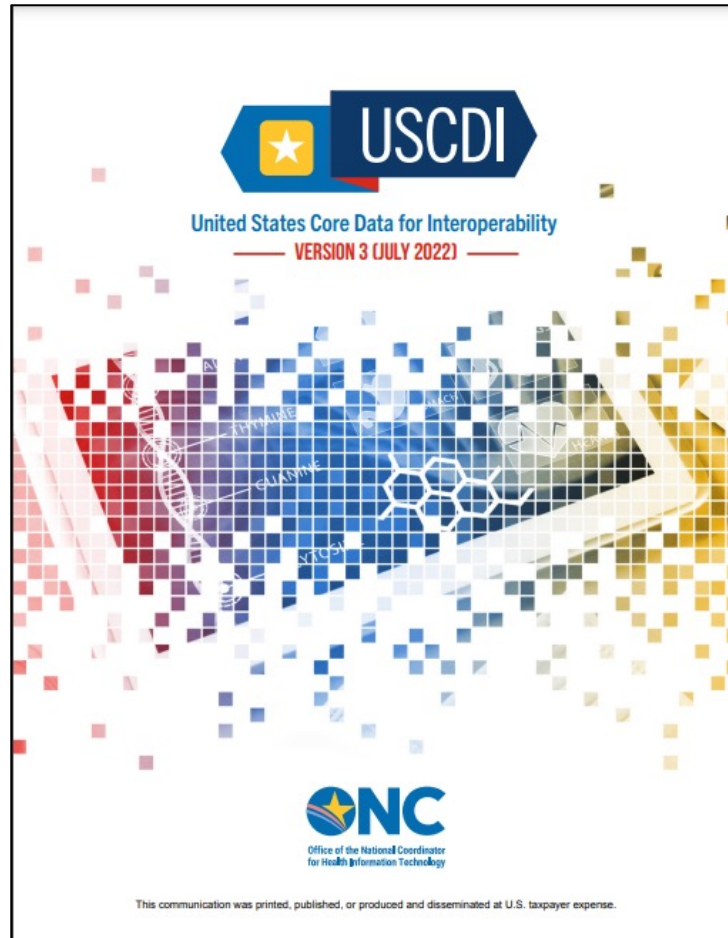
“Wholesale” interoperability (primarily  
high-volume, high-reliability B2B exchange  
of standard information)



# High-level interoperability roadmap

	2021	2022	2023	2023+
<b>Clinical data standards (USCDI)</b>	USCDI V2	USCDI V3	USCDI V4	USCDI V4+ USCDI+ (selected, TBD)
<b>Standard FHIR API</b>		CMS: Regulated payers • Patient API	CMS: Providers • Use CEHRT APIs  ONC: Certified EHRs • All access API	CMS: Regulated payers (NPRM): • Provider API • Payer-to-Payer API
<b>TEFCA</b>		Policy/technical framework released	First QHINs approved  FHIR pilots  First QHINs designated  Go-live (IHE)	Payment & Operations  Go-live (FHIR)  Public health
<b>Information Blocking deadlines</b>	In effect for USCDI	In effect for EHI	Enforcement begins (TBD)	

# US Core Data for Interoperability (USCDI) The Minimum Dataset of the Health Care Delivery System





# USCDI is the minimum data set for key EHR functions, interoperability, and patient access

## EHR functions requiring USCDI

USCDI is a required component for following 2015 Edition Cures Update Certification Criteria	
Standardized API for patient and population services (§170.315(g)(10))	Update to USCDI by December 31, 2022 (replacing Common Clinical Data Set)
Transitions of care (§170.315(b)(1))	
Clinical information reconciliation and incorporation (§170.315(b)(2))	
View, download, and transmit to 3rd party (§170.315(e)(1))	
Transmission to public health agencies –electronic case reporting (§170.315(f)(5))	
Consolidated CDA creation performance (§170.315(g)(6))	
Application access –all data request (§170.315(g)(9))	

## CMS patient access rule requires USCDI

**Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers**

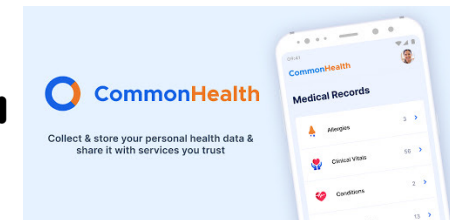
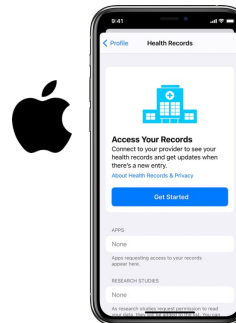
**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule.

## Interoperability networks requiring USCDI

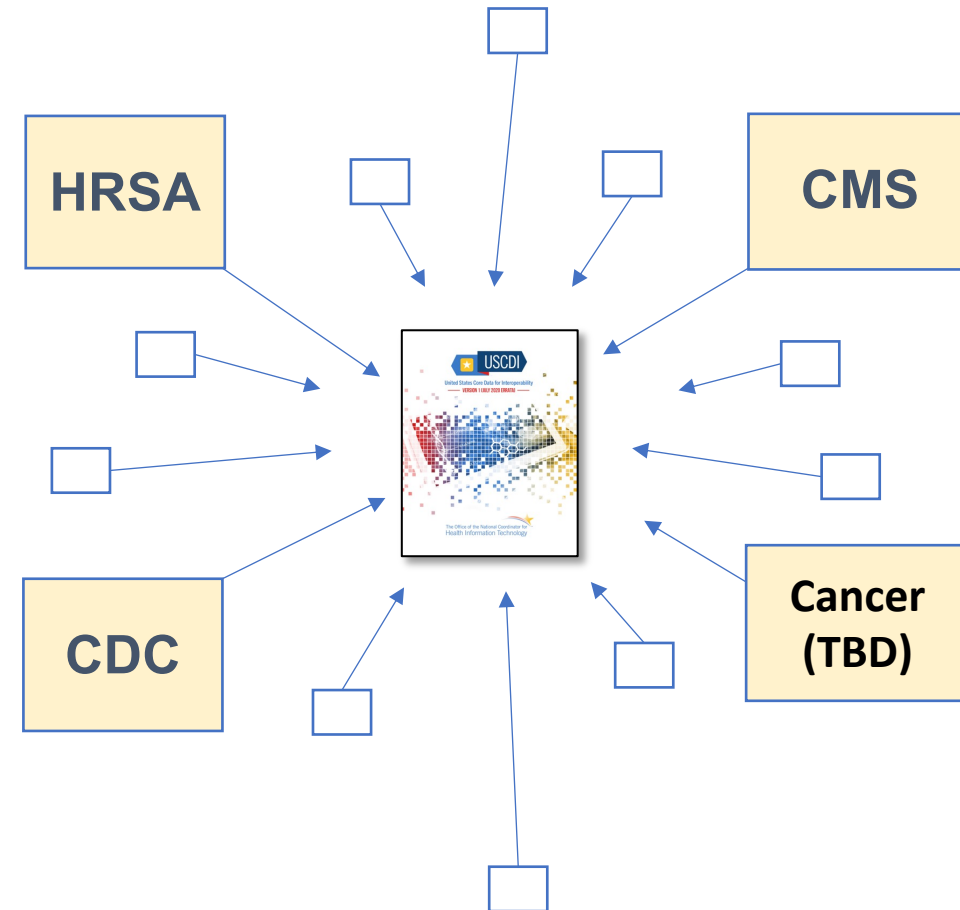


## Mobile apps based on USCDI



## USCDI+: Extending Beyond the USCDI

- Unique agency or program-specific data systems and requirements sometimes not fully met by USCDI
- **ONC USCDI+ initiative helps federal partners build on USCDI to support specific program needs**
- **Allows ONC to better serve federal partners, assures that extensions build from the same foundation, and creates the opportunity for aligning similar data needs across agency programs**



## HL7® Launches Helios FHIR® Accelerator for Public Health

Nov 16, 2021 3:55:58 PM / by HL7

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Alliance of government, private sector and philanthropic partners aims to use widely accepted healthcare standard to help advance public health

A new initiative launched by HL7 and jointly supported by the Centers for Disease Control and Prevention (CDC) and the Office of the National Coordinator for Health IT (ONC) seeks to use widely recognized data exchange standards to help advance public health. The effort, called Helios, intends to strengthen the capacity and streamline data sharing across all levels of public health using the HL7 Fast Healthcare Interoperability (FHIR®) standard.

## USCDI+ In Action! ONC and HRSA launch USCDI+ Initiative to support UDS Modernization

Ryan Argentieri; Matthew Rahn; Jasmine Agostino and Alek Sripipatana | AUGUST 29, 2022



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A few months ago, the Office of the National Coordinator for Health Information Technology (ONC) launched the **USCDI+ initiative** to support the identification and establishment of domain or program-specific datasets that will operate as extensions to the existing United States Core Data for Interoperability (USCDI). Recently, our colleagues at the Health Resources and Services Administration (HRSA) saw an opportunity to leverage USCDI+ and we have now launched a new USCDI+ collaboration to support HRSA's **Uniform Data System (UDS)** reporting through the **UDS Modernization Initiative**.

ONC and HRSA are working together to align the UDS with interoperability standards and transition to patient-level reporting requirements with USCDI and other quality reporting efforts. We are also establishing a strategic direction aligned with ONC's Cures Act Final Rule for HL7® Fast Healthcare Interoperability Resources (FHIR®)-based exchange to better support the needs of health centers across the country.

POLICY & VALUE-BASED CARE > VALUE-BASED CARE & QUALITY MEASUREMENT

## CMS Unveils Roadmap to Digital Quality Measurement

The federal agency has set an ambitious goal of transitioning to fully digital quality measures, leveraging FHIR APIs, which are already required for interoperability

[David Rath](#)

April 17, 2022

As part of the transition, CMS noted that it is considering how to use established standardized sets of data, such as ONC's USCDI, and how to support data standardization requirements while aligning with measurement needs and other use cases. Focusing on standardized data – FHIR, USCDI, and supplemental standards that allow for automated extraction – will allow for the interoperable exchange of data across the healthcare data ecosystem, serving many data needs and drive toward a learning health system that effectively measures quality and improves patient care, CMS said.

# Information Blocking Regulations

**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 ALL authorized parties**

**Favors standards-based approaches to interoperability**

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

**Went into affect April 5, 2021, with 18-month phase-in that completed on October 6, 2022**

# Information Blocking Rule Definitions of Providers and Health Information Networks



## Health Care Provider

A health care provider is a: hospital; skilled nursing facility; nursing facility; home health entity or other long term care facility; health care clinic; community mental health center; renal dialysis facility; blood center; ambulatory surgical center; emergency medical services provider; federally qualified health center; group practice; pharmacist; pharmacy; laboratory; physician; practitioner; provider operated by or under contract with the Indian Health Service or by an Indian tribe, tribal organization, or urban Indian organization; rural health clinic; covered entity under 42 U.S.C. 256b; ambulatory surgical center; therapist; and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the HHS Secretary.\*



## Health Information Network or Health Information Exchange

Health information network or health information exchange means an individual or entity that determines, controls, or has the discretion to administer any requirement, policy, or agreement that permits, enables, or requires the use of any technology or services for access, exchange, or use of electronic health information:

1. Among more than two unaffiliated individuals or entities (other than the individual or entity to which this definition might apply) that are enabled to exchange with each other; and
2. That is for a treatment, payment, or health care operations purpose, as such terms are defined in 45 CFR 164.501 regardless of whether such individuals or entities are subject to the requirements of 45 CFR parts 160 and 164.



## Expanding beyond the minimum dataset

### Protected Health Information (PHI)

### Electronic PHI (ePHI)

### EHI = all ePHI in the DRS

**On and after October 6, 2022**

The information blocking definition includes the entire scope of the Electronic Health Information (EHI) definition (i.e., ePHI that is or would be in a Designated Record Set (DRS))\*

### EHI = USCDI v1

**Prior to October 6, 2022**

The information blocking definition is limited to the EHI identified by the data elements represented in the United States Core Data for Interoperability (USCDI) v1\*



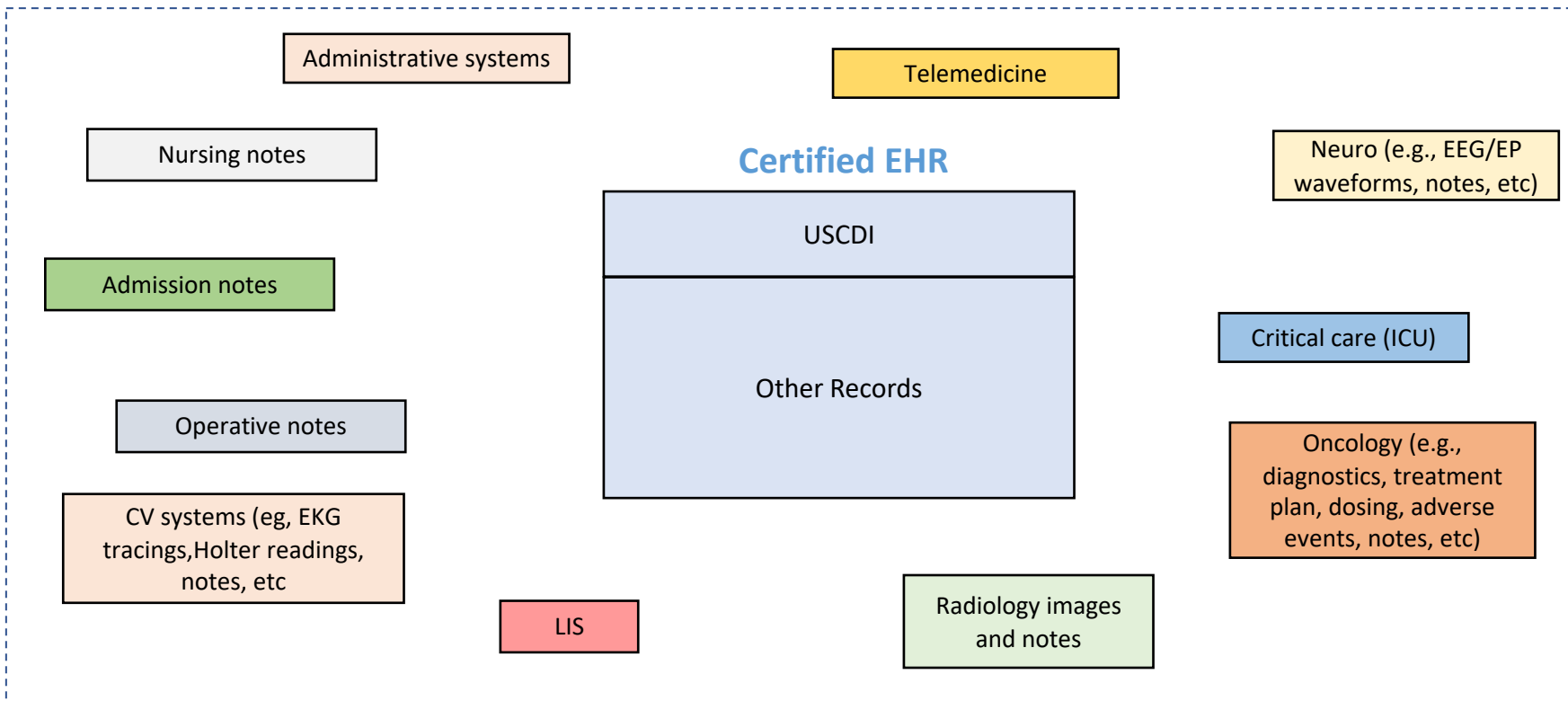
**Paper  
portion  
of DRS**

# EHI and Interoperability

*“...without special effort”*

*“...all electronically accessible information”*

EHI in hospital system (illustrative)



# ONC FHIR API Requirements: Access “without special effort”

**Open “application programming interfaces” (APIs) and apps are what make it easy to check your bank account or buy stocks or order meal delivery on your smartphone**

- We want providers and patients to have that same experience the health care system

**21<sup>st</sup> Century Cures Act requires availability of APIs that can be accessed “without special effort”**

- ONC rule takes steps to prevent business and technical barriers to information-sharing

**By December 31, 2022, all certified technology developers required to deploy a standard FHIR API (individual and bulk) across their entire customer base**

- Will create a climate for innovation as apps can now be developed that will work across all EHR systems

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





## 21<sup>st</sup> 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]*



# TEFCA Will Simplify Health Data Exchange

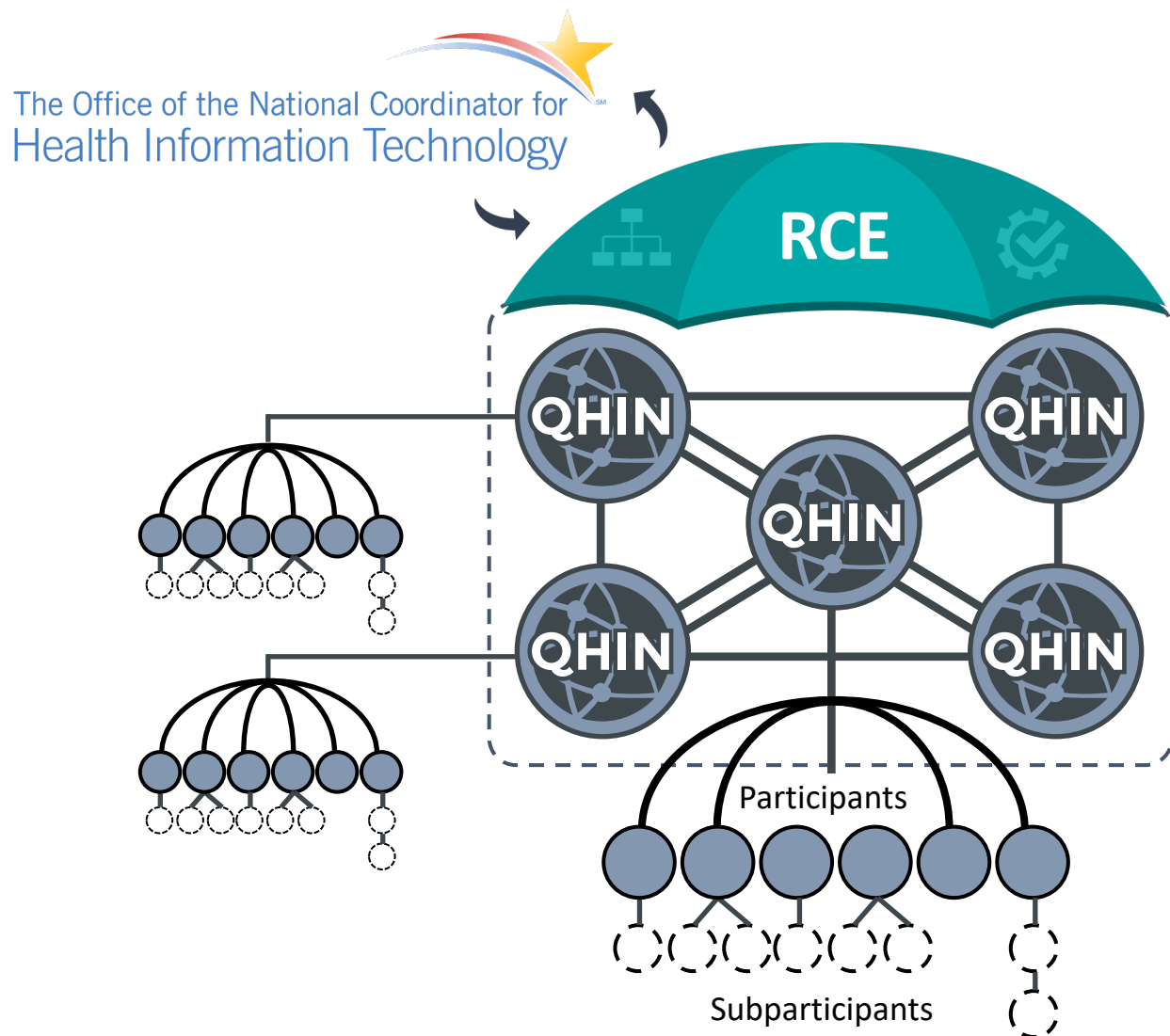
**While there has been growth in national networks, there is much unfinished business**

- Less well-resourced providers, behavioral health, LTPAC
- Payers (government and commercial)
- Public health
- Social services
- Research

**Federal government involvement required to spur the further evolution of nationwide network interoperability**



# How will exchange work under TEFCA?



← ONC defines overall policy and certain governance requirements.

← RCE provides oversight and governing approach for QHINs.

↘ Qualified Health Information Networks (QHINs) connect directly to each other to facilitate nationwide interoperability.

← Each QHIN connects Participants, which connect Subparticipants.

## eHealth Exchange™

### Is Your Organization Ready for TEFCA?

Organizations are preparing for the launch of the Office of the National Coordinator for Health IT's (ONC) Trusted Exchange Framework and Common Agreement, also known as TEFCA, in 2022.

#### NEWS FROM EPIC

June 20, 2022



**Epic Announces Plan to Join TEFCA,  
Champion Next Step in Evolution  
Toward Universal Interoperability**



## CommonWell newest to pledge TEFCA participation

The interoperability alliance, whose EHR vendor members include Oracle Cerner, athenahealth, Greenway, Meditech and others, says it will sign on as a Qualified Health Information Network.

By **Mike Miliard** | September 02, 2022 | 09:58 AM



ORACLE Cerner



News release

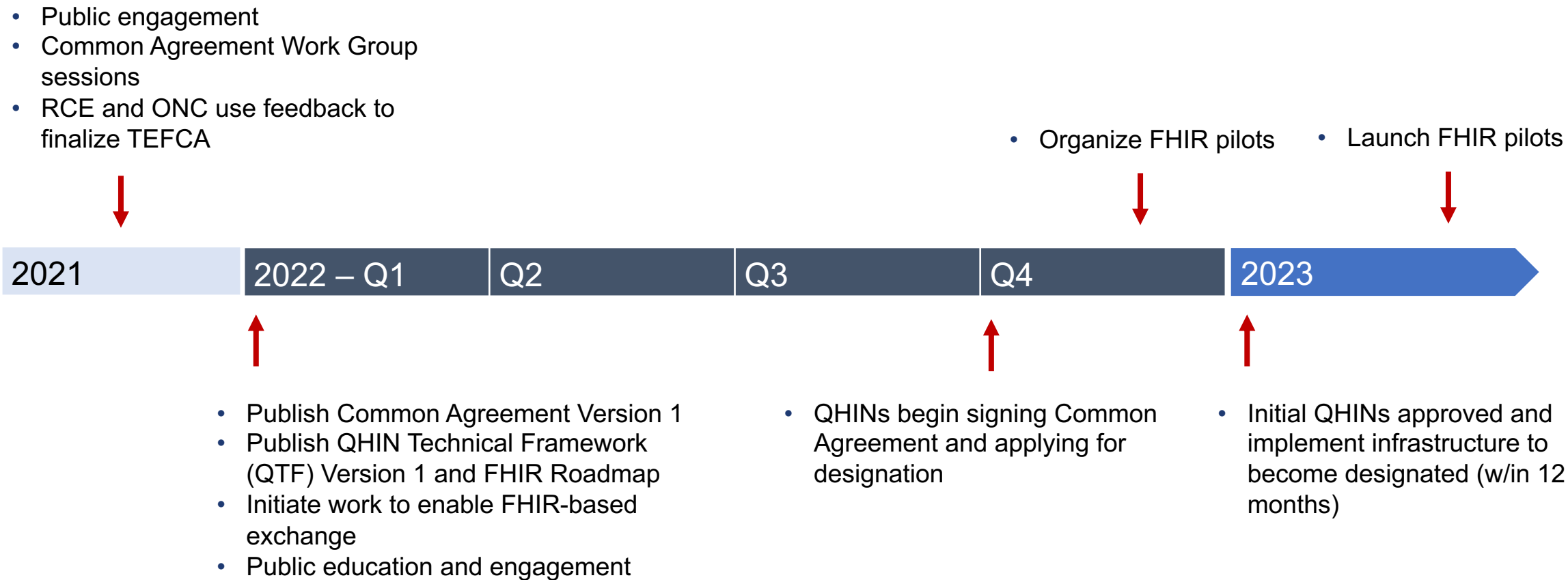
**TEFCA: A leap toward achieving  
nationwide interoperability**

by **Oracle Cerner**

Published on August 31, 2022



# Timeline to Operationalize TEFCA



# FHIR Roadmap for TEFCA

ONC and the RCE have published the “FHIR®  
Roadmap for TEFCA Exchange – Version 1.”

**Evolving health IT landscape requires TEFCA  
to rapidly include approaches that  
support FHIR.**

Approach leverages current state  
of FHIR today and allows TEFCA  
policy and technical infrastructure  
to accelerate FHIR adoption into  
the future.

## Planned Stages of FHIR Availability in TEFCA:

### Stage 1: FHIR Content Support

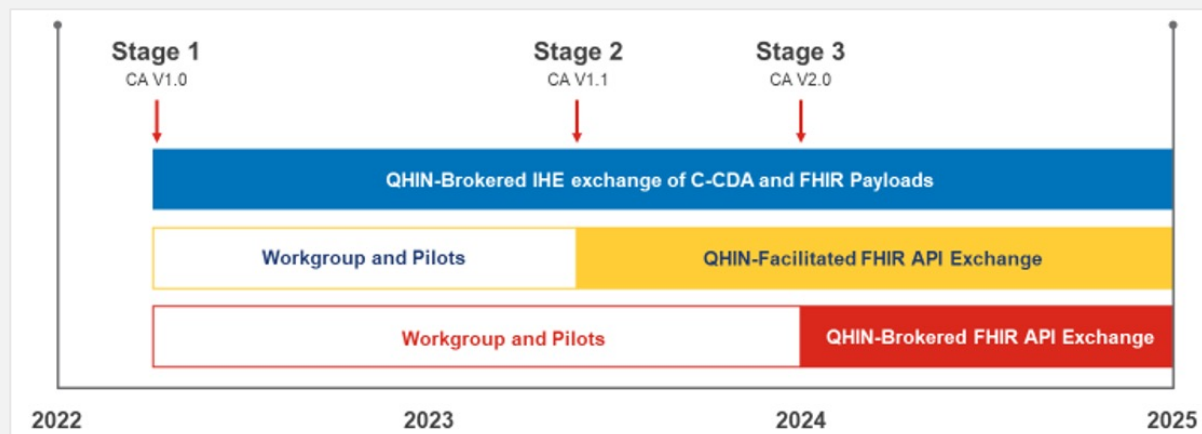
- FHIR exchange possible within QHINs’ own networks
- IHE exchange of FHIR payloads between QHINs *is possible with “out-of-band” coordination.*

### Stage 2: Network-Facilitated FHIR Exchange

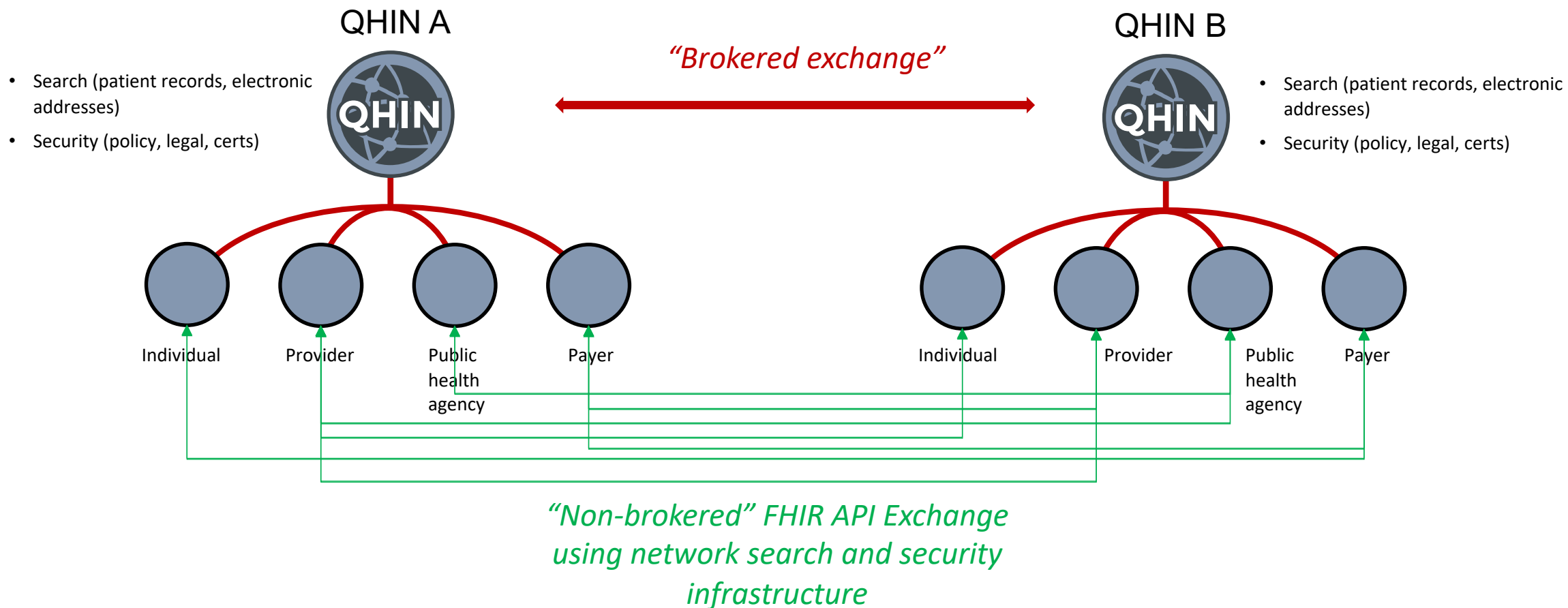
- QHIN-facilitated FHIR-based exchange available as an *option* under TEFCA.

### Stage 3: Network-Brokered FHIR Exchange

- QHIN-facilitated FHIR-based exchange *required* under TEFCA
- QHIN-brokered FHIR API exchange *optionally* available.



# FHIR APIs Won't Scale Without TEFCA



# Leveraging Interoperability for Public Health



Enable on-demand, uniform, nationwide interoperability for provider-STLT, STLT-STLT, STLT-CDC exchange



Catalyze the development of FHIR-based capabilities to address public health needs



Mechanisms for enhancing standardization of public health data systems

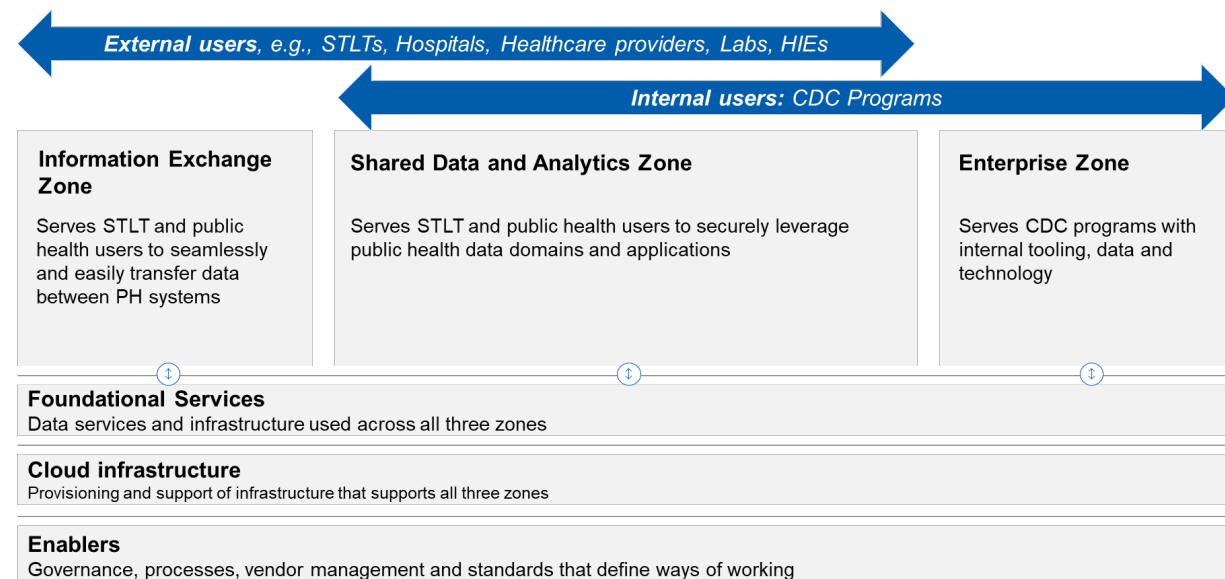
**USCDI+ for  
Public Health**

Establish a nationwide public health data model based on commonly adopted open-industry standards



## “North Star” Architecture

Open architecture public health cloud infrastructure to support STLT environments, shared applications and tooling, and data-sharing environments







The Office of the National Coordinator for  
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<https://inquiry.healthit.gov/>

# Thank you!



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