



Office of the National Coordinator
for Health Information Technology

Enabling the 21st Century Digital Infrastructure

12/1/2023



Key Areas of Focus

Build the digital foundation

- Data standards
- Health IT gaps

Make interoperability easy

- TEFCA
- 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

Key Policy Levers

HHS Health IT Alignment Policy (8/22)

HTI-1 (draft 3/23)

HTI-2 (draft 12/23)

TEFCA (go-live 2023)

TEFCA FHIR Exchange (go-live 2024)

IB Appropriate Disincentives (draft 10/23)

CMS Interoperability Rule (draft 12/22)

OIG IB Enforcement Rule (final 6/23)

ONC FHIR API Requirements: Access “without special effort”



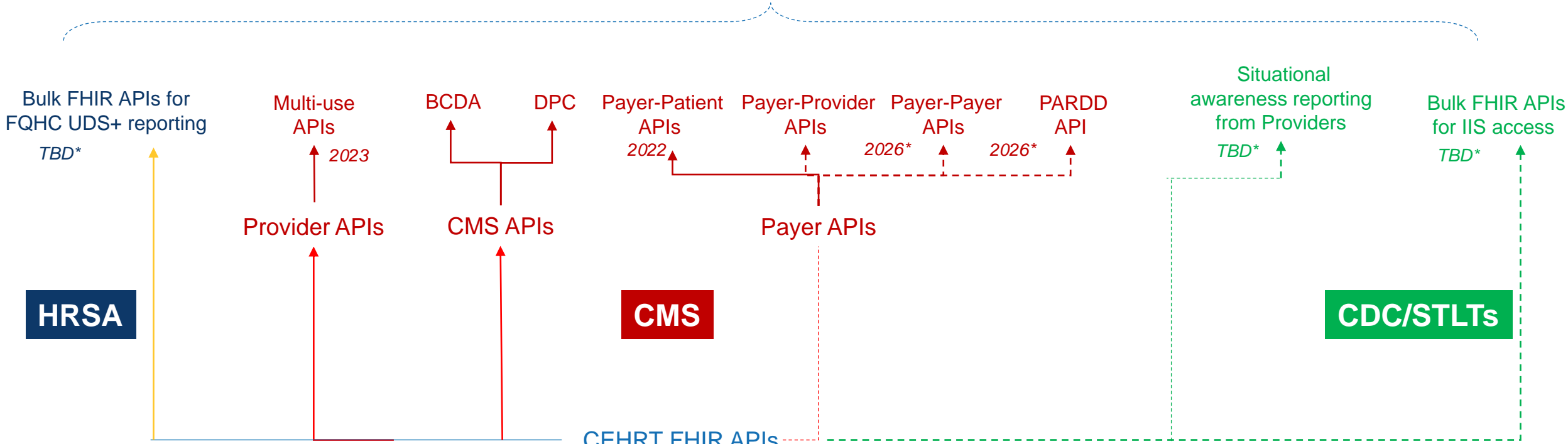
HL7[®] FHIR[®]

- 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
- 21st 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, subscriptions, FHIR hooks

HHS FHIR Initiatives



ONC TEFCA FHIR Support
2024



HRSA

CMS

CDC/STLTs

ONC

* HRSA-ONC currently building FHIR reporting infrastructure

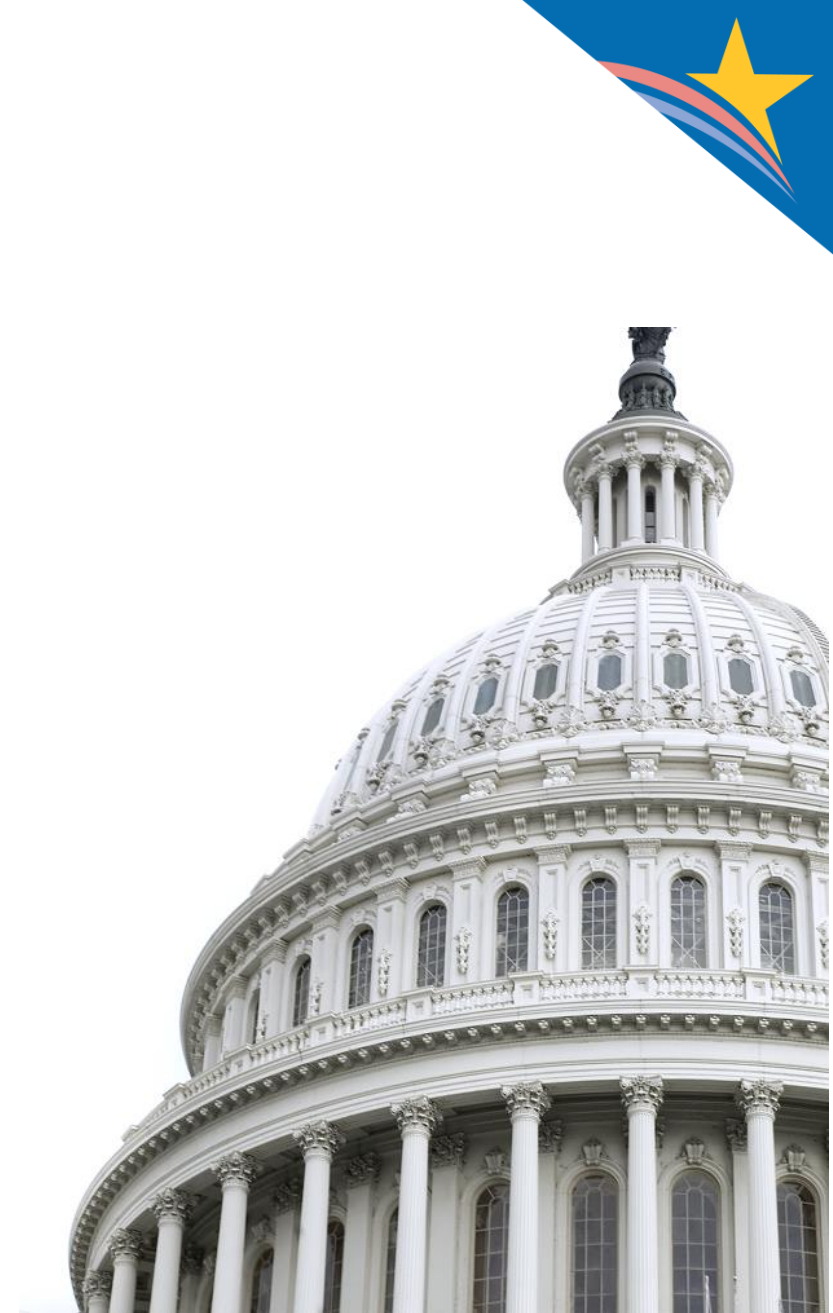
* Current CMS NPRM date

* Current Helios projects – no further plans specified yet

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]



Why TEFCA?

Nation-wide and state/local networks have made considerable progress, but there is much unfinished business:

- Individual access
- Less well-resourced providers, behavioral health, LTPAC
- Payers (government and commercial)
- Public health (Provider-PHA, CDC-STLT, STLT-STLT)
- Social services
- Research
- FHIR API scalability
- State/local HIE connectivity

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



Exchange Purposes

- The Exchange Purpose identifies the reason for which information could be requested or shared through QHIN-to-QHIN exchange
- Only these six Exchange Purposes are currently authorized under the Common Agreement.
- Additional Exchange Purposes may be added over time

Permitted Exchange Purposes



Treatment



Payment



Health Care Operations



Public Health



Government Benefits Determination



Individual Access Services

Timeline to Operationalize TEFCA

2021

- Public engagement
- Common Agreement Work Group sessions
- RCE and ONC use feedback to finalize TEFCA

Q3/Q4 2022

- Finalize initial SOPs
- QHIN application review
- Prepare for TEFCA FHIR-based exchange pilot

Q3/Q4 2023

- Additional QHIN applications processed
- Establish Governing Council
- Refine Common Agreement, SOPs, and QTF, including to support FHIR-based exchange
- Update Common Agreement and SOPs for FHIR-based exchange

2021

Q1/Q2 2022

Q3/Q4 2022

Q1/Q2 2023

Q3/Q4 2023

2024

Q1 of 2022

- **Publish Common Agreement Version 1**
- **Publish QHIN Technical Framework (QTF) Version 1 and FHIR Roadmap**
- Initiate work to enable FHIR-based exchange
- Public education and engagement

Q1/Q2 of 2023

- **First QHINs approved for implementation**
- Onboarding of initial QHINs
- Additional QHIN applications processed
- Establish Transitional Council
- Launch TEFCA FHIR-based exchange pilot
- Payment & Operations SOP
- Public Health SOP

First QHINs go-live with IHE document exchange

First QHINs go-live with FHIR exchange

TEFCA Launch Event: February 13, 2023



HHS Secretary Becerra



President's Science Advisor
Dr Prabhakar



CMS Deputy Administrator Blum



CDC Director
Dr Walensky

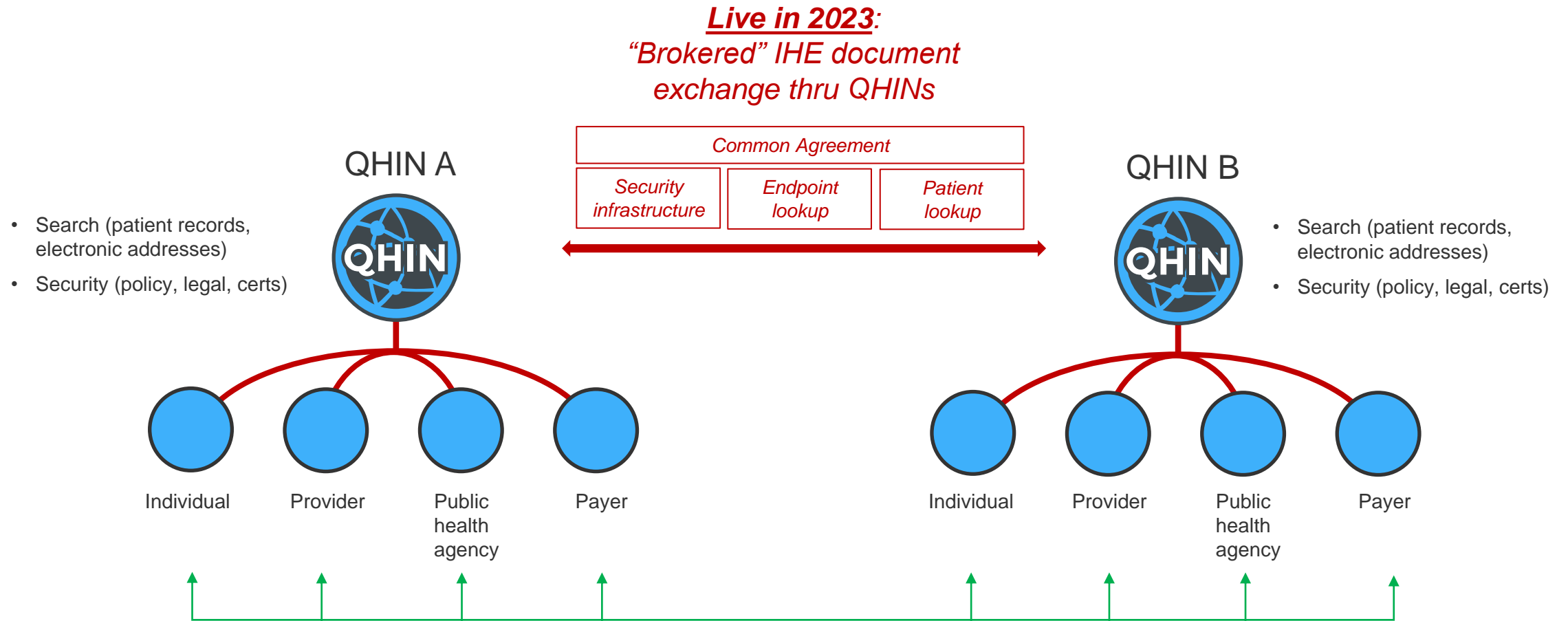


Under Secretary of Veterans Affairs for Health
Dr Elnahal

Approved QHINs (as of February 13, 2023)



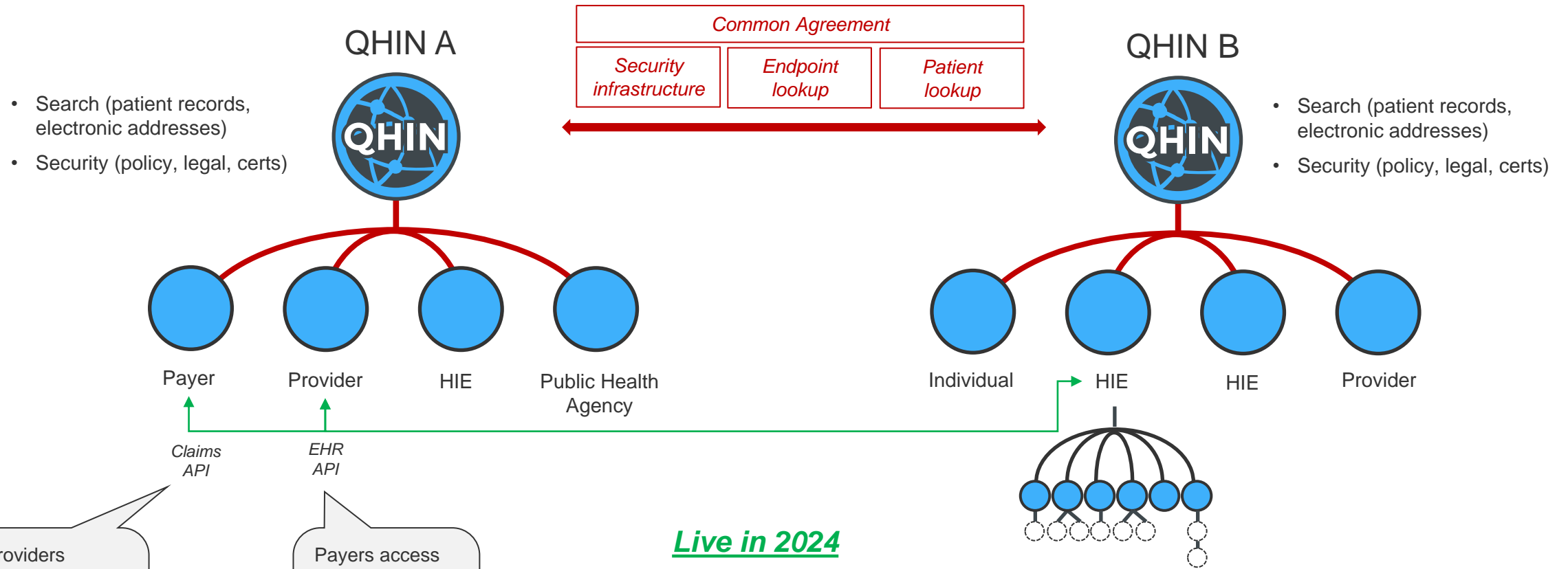
TEFCA will support both IHE and FHIR Exchange





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Live in 2023:



- Search (patient records, electronic addresses)
- Security (policy, legal, certs)

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- Security (policy, legal, certs)

Live in 2024

Providers access claims data via Provider Access API as per CMS Interop NPRM

Payers access EHR data via Certified EHR FHIR API as per CMS and ONC regs

Cures Act Definition of Interoperability

“(10) INTEROPERABILITY.—The term ‘interoperability’, with respect to health information technology, means such health information technology that—

“(A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology **without special effort on the part of the user;**

“(B) allows for complete **access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and**

“(C) **does not constitute information blocking as defined in section 3022(a).”.**

Summary: Information Blocking Regulations

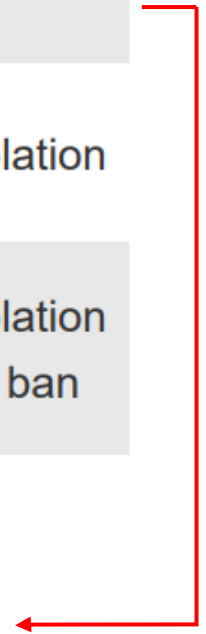
- **Required by 21st Century Cures Act of 2016, ONC Final Rule put into effect April 5, 2021**
- **Prohibits “interference” by providers, health information networks, and certified health IT developers, with access, exchange, and use of health information by other authorized parties**
- **Does not apply 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 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

Penalties for Non-Compliance

“Actor”	Consequence
Health care providers	<ul style="list-style-type: none"> • Appropriate disincentives
Health information networks and Health information exchanges	<ul style="list-style-type: none"> • Civil monetary penalties (CMPs) up to \$1 million per violation
Health IT developers of certified health IT	<ul style="list-style-type: none"> • Civil monetary penalties (CMPs) up to \$1 million per violation • Certification action which could include a termination or ban

Enforcement began September 1, 2023 for HINs/HIEs and Health IT Developers. Will begin with Providers upon finalization of Appropriate Disincentives penalties.

Appropriate Disincentives Proposed Rule released in October 2023.





Manner Exception – Proposed TEFCA Manner Condition

Proposal

ONC proposes to add a TEFCA condition to the proposed revised and renamed Manner exception. The TEFCA condition would offer Qualified Health Information Networks (QHINs), participants, and subparticipants in TEFCA the ability to fulfill EHI requests from any QHIN, participant, or subparticipant in TEFCA using TEFCA means, even if the requestor would have preferred to use another means.

Benefits

- Aligns with the Cures Act's goals for interoperability and the establishment of TEFCA by acknowledging the value of TEFCA in promoting access, exchange, and use of EHI in a secure and interoperable way.
- Facilitates a responding actor reaching agreeable terms with a requestor to fulfill an EHI request and acknowledges that certain agreements have been reached for the access, exchange, and use of EHI.
- Provides a clear, efficient process for actors participating in TEFCA to prioritize the use of TEFCA means for fulfilling requests for access, exchange, and use of EHI from other TEFCA entities.



Office of the National Coordinator
for Health Information Technology

Contact ONC



Phone: 202-690-7151



Health IT Feedback Form:

<https://www.healthit.gov/form/healthit-feedback-form>



Twitter: [@onc_healthIT](https://twitter.com/onc_healthIT)



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Youtube:

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