Overview of ONC’s Recently Released Notice of Proposed Rule Making (NPRM)

VISIT www.healthIT.gov/TEFCA TO VIEW the TEFCA Draft 2.

Disclaimer

- ONC must protect the rulemaking process and comply with the Administrative Procedure Act. During the rulemaking process, ONC can only present the information that is in the NPRM as it is contained in the NPRM. ONC cannot interpret that information, nor clarify or provide any further guidance.
- ONC cannot address any comment suggestion or statement made by anyone attending the presentation or consider any such comment or suggestion in the rule writing process.
- Please submit comments through the formal process outlined in the Federal Register.

Purpose

Increase Innovation and Competition
by giving patients and their health care providers safe and secure access to health information and to new tools, allowing for more choice in care and treatment.

Reduce Burden and Advance Interoperability
through the use of United States Core Data for Interoperability (USCDI) standard, new API requirements, and EHI export capabilities for the purposes of switching health IT or to provide patients their electronic health information.

Promote Patient Access
through a provision requiring that patients can electronically access ***all*** of their electronic health information (structured and/or unstructured) at no cost.

Implementation of Executive Orders

EXECUTIVE ORDERS	ONC'S WORK IN SUPPORT OF EXECUTIVE ORDERS
Executive Order 13813 Promoting Healthcare Choice and Competition Across the United States	• ONC's proposed rule would contribute to fulfilling Executive Order 13813 by furthering patient (and health care provider) access to EHI and supporting competition in health care markets through new tools to access EHI and policies to address the hoarding of EHI. • ONC's proposed rule calls on the health care industry to adopt standardized APIs, which would allow individuals to securely and easily access structured EHI using new and innovative applications for smartphones and other mobile devices. • The proposed rule would establish information blocking provisions, focusing on improving patient and health care provider access, exchange, and use of EHI.
Executive Orders 13771 & 13777 Reducing Regulation and Controlling Regulatory Costs, and Enforcing the Regulatory Reform Agenda	• ONC reviewed and evaluated existing regulations to identify ways to reduce burden and implement deregulatory actions. • ONC proposes potential deregulatory actions that will reduce burden for health IT developers, providers, and other stakeholders. These six deregulatory actions are: (1) removal of a threshold requirement related to randomized surveillance; (2) removal of the 2014 Edition from the Code of Federal Regulations (CFR); (3) removal of the ONC-Approved Accreditor (ONC-AA) from the Certification Program; (4) removal of certain 2015 Edition certification criteria; (5) removal of certain Certification Program requirements; and (6) recognition of relevant Food and Drug Administration (FDA) certification processes with a request for information on the potential development of new processes for the ONC Health IT Certification Program.

Implementation of the 21st Century Cures Act

KEY PROVISIONS IN TITLE IV OF THE CURES ACT	ONC'S WORK IN SUPPORT OF THE CURES ACT
Sec. 4004 Information Blocking	• ONC proposes seven categories of practices that would be considered reasonable and necessary that, provided certain conditions are met, would not constitute information blocking. These categories were developed based on feedback from stakeholders and consultation with appropriate federal agencies. • If the actions of a regulated actor (health care provider, health IT developer, or health information exchange or network) satisfy an exception, the actions would not be treated as information blocking and the actor would not be, as applicable, subject to civil penalties or other disincentives under the law.
Sec. 4005 Exchange with Registries	• ONC's proposed rule includes a Request for Information (RFI) on how a standards-based API might support improved information exchange between a health care provider and a registry in support of public health reporting, quality reporting, and care quality improvement. • Public input on this RFI may be considered for future HHS rulemaking to support the bidirectional exchange of clinical data between health care providers and registries for a wide range of use cases.
Sec. 4006 Patient Access	• ONC proposes to promote policies that would ensure a patient's EHI is accessible to that patient and the patient's designees, in a manner that facilitates communication with the patient's health care providers and other individuals, including researchers, consistent with such patient's consent through the following proposals: United States Core Data for Interoperability (USCDI) standard; "EHI export" criterion; "standardized API for patient and population services" criterion, "data segmentation for privacy (DS4P)" criteria, "consent management for APIs" criterion; API Condition of Certification; and information blocking requirements, which include providing patients access to their EHI at no cost to them. • Patient access to their EHI would be improved through the adoption of the following proposed 2015 Edition standard and certification criteria: USCDI standard; standardized APIs for patient and population services; and EHI export.

The Office of the National Coordinator for
Health Information Technology

User’s Guide to the Trusted Exchange Framework and Common Agreement Draft 2

April 2019 | Release

VISIT www.healthIT.gov/TEFCA TO VIEW the TEFCA Draft 2.

Cures Act Language

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. The common agreement may include—

> *"(I) a common method for authenticating trusted health information network participants;*
>
> *"(II) a common set of rules for trusted exchange;*
>
> *"(III) organizational and operational policies to enable the exchange of health information among networks, including minimum conditions for such exchange to occur; and*
>
> *"(IV) a process for filing and adjudicating noncompliance with the terms of the common agreement."*

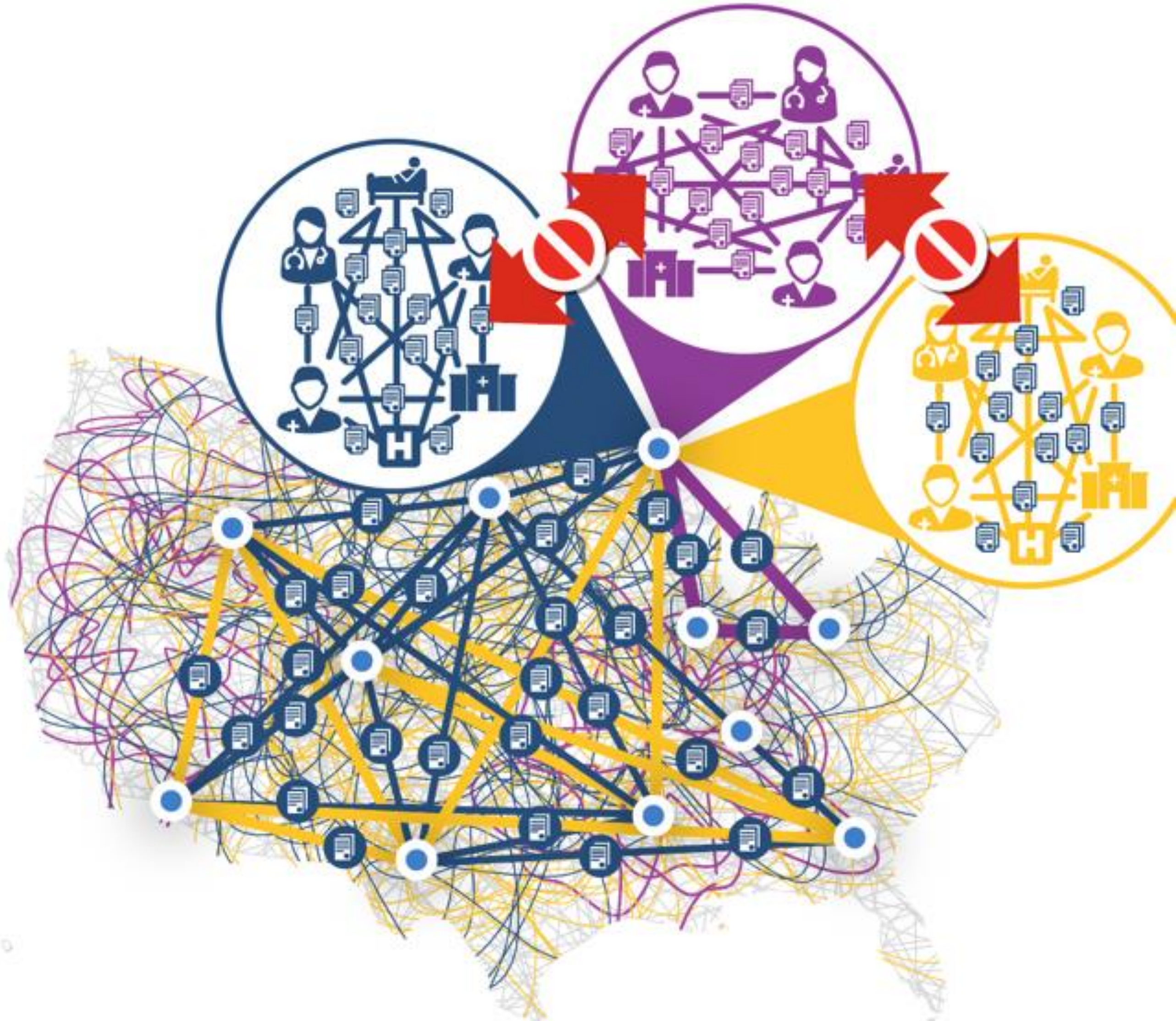
"[T]he National Coordinator shall publish on its public Internet website, and in the Federal register, the trusted exchange framework and common agreement developed or supported under paragraph B…"

Current Complexity

CURRENT PROLIFERATION OF AGREEMENTS

Many organizations
have to join multiple Health
Information Networks (HINs),
and most HINs do not share
data with each other.

Trusted exchange must be simplified in order to scale.



Current Costs

Healthcare organizations are currently burdened with creating many costly, point-to-point interfaces between organizations.

The Trusted Exchange Framework and the Common Agreement **would reduce the need for duplicative network connectivity interfaces**, which are costly, complex to create and maintain, and an inefficient use of provider and health IT developer resources.

Proliferation of Interoperability Methods

A nationally representative survey by the American Hospital Association found[1] that:

Few hospitals used only one interoperability method.

- 78% of hospitals use more than one electronic method to send records
- 61% of hospitals use more than one electronic method to receive records
- About 40% used five or more methods to send records

https://www.healthit.gov/sites/default/files/page/2018-12/Methods-Used-to-Enable-Interoperability-among-U.S.-NonFederal-Acute-Care-Hospitals-in-2017_0.pdf

Goals

GOAL 1

Provide a single "on-ramp" to nationwide connectivity

GOAL 2

Electronic Health Information (EHI) securely follows you when and where it is needed

GOAL 3

Support nationwide scalability

What is the Trusted Exchange Framework?

The Trusted Exchange Framework is a set of common principles that are designed to facilitate trust among Health Information Networks (HINs).

The Trusted Exchange Framework (TEF)

Principle 1 – Standardization: Adhere to industry and federally recognized standards, policies, best practices, and procedures.

Principle 2 – Transparency: Conduct all exchange and operations openly and transparently.

Principle 3 – Cooperation and Non-Discrimination: Collaborate with stakeholders across the continuum of care to exchange EHI, even when a stakeholder may be a business competitor.

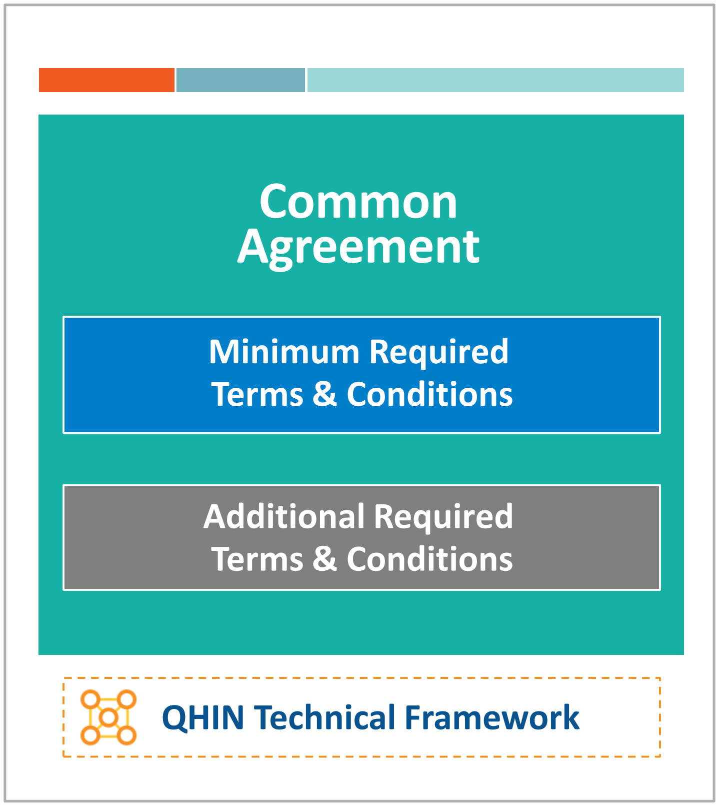
Principle 4 – Privacy, Security, and Safety: Exchange EHI securely and in a manner that promotes patient safety, ensures data integrity, and adheres to privacy policies.

Principle 5 – Access: Ensure that individuals and their authorized caregivers have easy access to their EHI.

Principle 6 – Population-Level Data: Exchange multiple records for a cohort of individuals at one time in accordance with applicable law to enable identification and trending of data to lower the cost of care and improve the health of the population.

What is the Common Agreement?

The Common Agreement will provide the governance necessary to scale a functioning system of connected HINs that will grow over time to meet the demands of patients, clinicians, and payers.



Common Agreement

Minimum Required Terms & Conditions

Additional Required Terms & Conditions

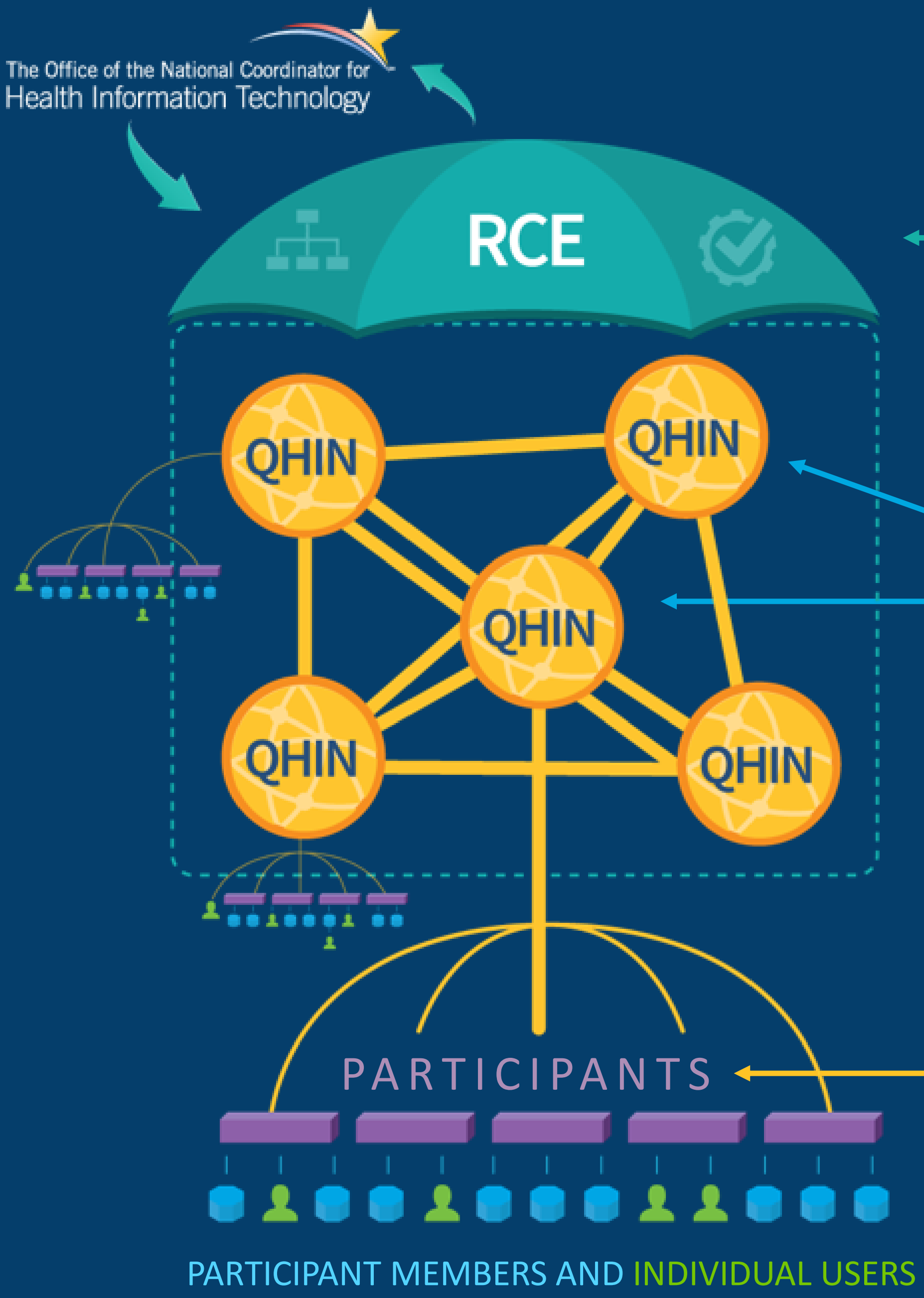
QHIN Technical Framework

Minimum Required Terms & Conditions (MRTCs): ONC will develop mandatory minimum required terms and conditions that Qualified Health Information Networks (QHINs) who agree to the Common Agreement would abide by.

Additional Required Terms & Conditions (ARTCs): In addition to the MRTCs, the Common Agreement will include additional required terms and conditions that are necessary for the day-to-day operation of an effective data sharing agreement. The Recognized Coordinating Entity (RCE) will develop the ARTCs and ONC will have final approval.

QHIN Technical Framework (QTF): Signatories to the Common Agreement must abide by the QHIN Technical Framework, which specifies functional and technical requirements for exchange among QHINS. The RCE will work with ONC and stakeholders to modify and update the QTF.

How Will the Common Agreement Work?



RCE provides oversight and governance for QHINs.

QHINs connect directly to each other to facilitate nationwide interoperability.

Each QHIN represents a variety of Participants that they connect together, serving a wide range of Participant Members and Individual Users.