Interoperability
Methods, Progress & Opportunities

AMDIS

June 20, 2019

Perspective

- Primary care family physician x 30 years
- Clinical informaticist x 25 years
  - Care Everywhere Governing Council
  - The Sequoia Project Board
  - Carequality Board, Steering Committee
  - DirectTrust Clinicians Steering Workgroup
  - HL7 Da Vinci Steering Committee
  - California Payer-Provider HIE Collaborative Workgroup
  - ONC Health Information Technology Advisory Committee
    - Interoperability Standards Priorities Task Force
    - US Core Data for Interoperability Task Force

Outline

- Interoperability Background
    - 21st Century Cures Act
    - Definitions
- Interoperability Successes
    - Regional HIEs
    - Direct Interoperability
    - National Networks
    - Carequality Framework
    - FHIR and Consumer Directed Exchange
- ONC / CMS Cures Act Implementation Activities

21st Century Cures Act

One Hundred Fourteenth Congress
of the
United States of America

AT THE SECOND SESSION

An Act

To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes.

- Signed 12/13/2016
- $6.3B in funding
  - NIH, FDA drug approval process, opioids, human subjects protections,…
- Health information interoperability
  - Patient access to data
  - Exchange standards
    - Open APIs without special effort
  - Information Blocking
  - Trusted Exchange Framework & Common Agreement (TEFCA)

Interoperability Definition

Health information technology that:

- 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**
- Allows for **complete access, exchange, and use** of **all electronically accessible health information** for **authorized use** under applicable State or Federal law
- Does not constitute **information blocking**

Information Blocking Definition

A practice that is **likely to interfere with, prevent, or materially discourage** access, exchange, or use of electronic health information

- If conducted by a **health IT developer, exchange, or network**, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information
- If conducted by a **health care provider**, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information

Degrees of Interoperability

- Foundational - Connectivity
- Structural - Message and field level formatting > Syntax
- Semantic - Codification / standard vocabularies > Meaning
- Organizational - Functional – policy, social, organizational > Integration into workflows, usability

Interoperability Successes

- Regional HIE/HIOs
  - Disaster access via Patient Unified Lookup System for Emergencies
  - Patient Centered Data Home
  - EMS-hospital exchange for pre-hospital care coordination
- Direct Interoperability
- National Networks
  - eHealth Exchange
  - Vendor-based Networks: CommonWell, Epic Care Everywhere, etc.
- Car*e*quality Framework
- Consumer-directed exchange
  - Blue Button 2.0
  - CARIN Initiative
  - Apple Health
  - Da Vinci Project

Patient Unified Lookup System for Emergencies

- Live continuously since the Carr Fires near Redding CA in July, 2018

- Deployed for the November, 2018 Camp Fire for relief in eight evacuation centers providing medical services near Paradise CA

- Used by disaster healthcare volunteers to search for health information, primarily problem lists, allergies, and medications on victims and evacuees of the fire

- Current connectivity via the California Trusted Exchange Network (CTEN) governed under the CalDURSA

- Six CA health systems and HIEs on-boared with four in testing

- Planned expansion via eHealth Exchange

PULSE Architecture

http://www.ca-hie.org/initiatives/pulse/
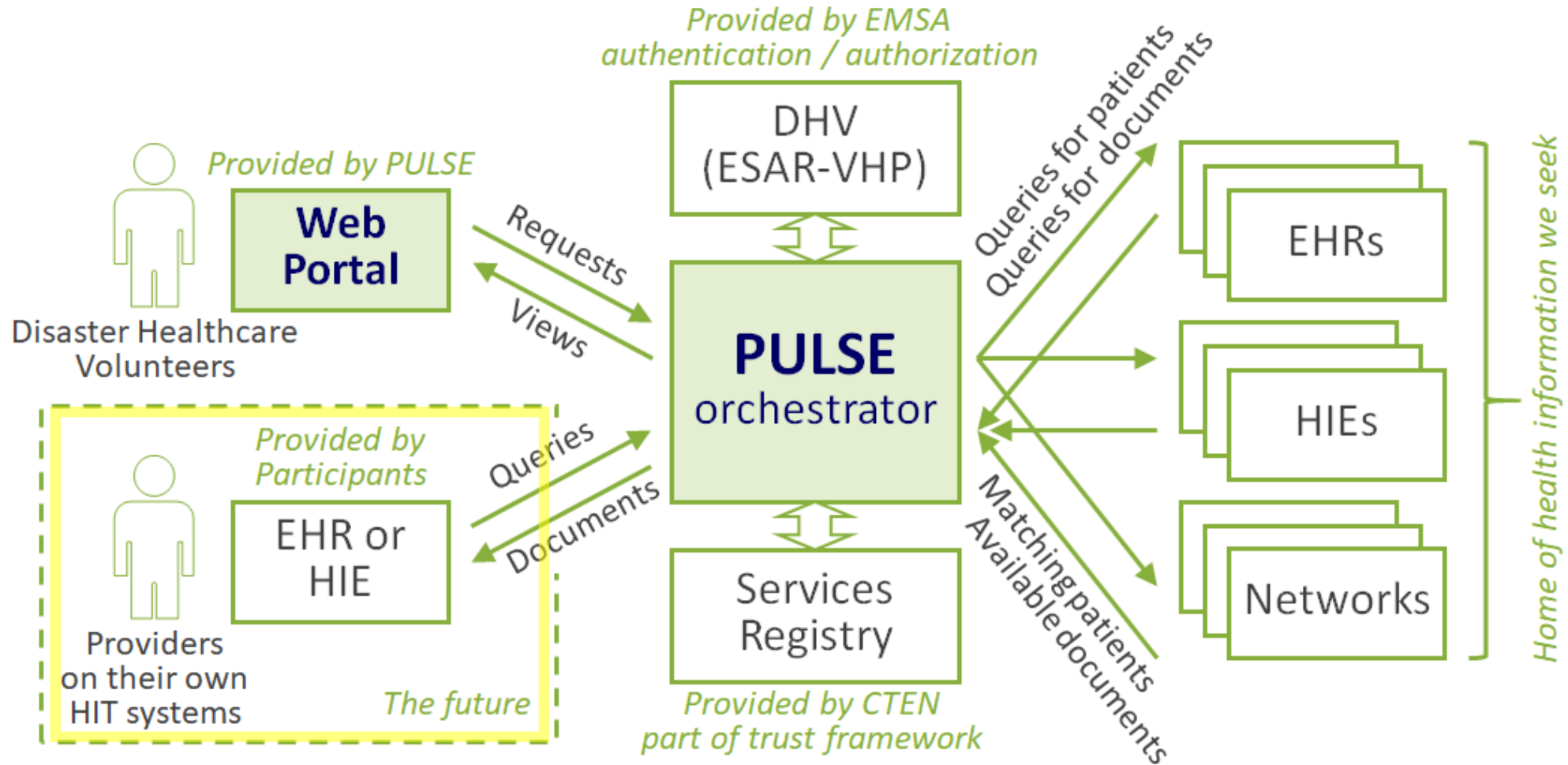
Patient Centered Data Home

- Strategic Health Information Exchange Collaborative (SHIEC)
- HIE to HIE communication and interoperability based on the notion that each patient has a "data home" within their local regional HIE. 42 participating HIEs covering 1M patients
- https://strategichie.com/initiatives/pcdh/

- **3M** event notifications to date

PCDH Workflow

Patient receives care at facility outside their data "home"

1. Away Care Team facility sends Alert to Away HIE of a patient encounter (ADT).

2. Away HIE sends Alert to Home HIE based on ZIP code look up tables.

3. Home HIE notifies Away HIE if there are patient records. At the same time, the Home HIE sends the Alert to the patient's usual home doctors.

4. Home HIE and Away HIE exchange clinical data on the patient to improve short and long-term care coordination.

5. Away HIE delivers records to Away Care Team and Home HIE shares post-encounter summary with Home Care Team.

EMS-Hospital Interoperability

- Real-time connection Ambulance to ED
  - Connectivity via regional HIEs

- "SAFR" data exchange model
  - SEARCH – paramedics search for patient in HIE and query for clinical data
  - ALERT – EMS system sends real-time data to ED > track board
  - FILE – Submission of medic's report into hospital EHR
  - RECONCILE – Hospital to EMS system to close the loop: billing, eOutcomes

- Clinical data
  - EMS receives Problems, Meds, Allergy, encounters, POLST
  - EMS sends Narrative, EKGs, vital signs, GPS/arrival data

Direct Interoperability

- All ONC certified EHRs have the ability to send and receive Direct messages, though many have not implemented this functionality
  - 1.9M Direct Addresses, 167K organizations, 265K patients/consumers

- Use cases:
  - Transitions of care
  - Closed loop referrals
  - Care Coordination
  - Push notifications
  - #KillTheFax

- **50M** transactions / month
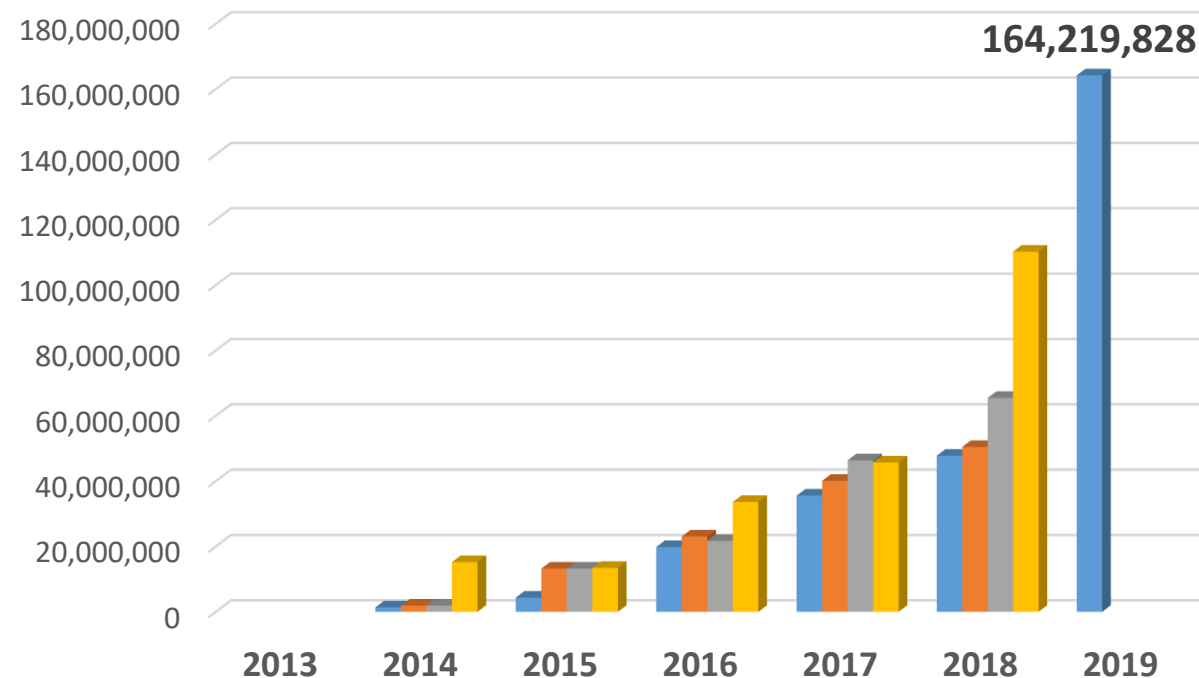
Direct Resources

- Consensus Statement: Feature and Function Recommendations to Optimize Clinician Usability of Direct Interoperability to Enhance Patient Care – Appl Clin Inform 2018;9:205–220.
    - https://www.thieme-connect.de/products/ejournals/pdf/10.1055/s-0038-1637007.pdf

- Success Stories:
    - https://www.directtrust.org/wp-content/uploads/2018/11/Master-List-of-Direct-Interoperability-Success-Stories.pdf

eHealth Exchange

- The largest and oldest national health information network
  - Four Federal Agencies
    - Veterans Affairs – 1.8M+ CA Veterans
    - Department of Defense
    - CMS – ESRD quality reporting
    - Social Security Administration – Benefits determination
  - 70,000 medical groups, 3,400 dialysis centers, 8,300 pharmacies
  - 59 regional and state HIEs

- **17M** documents exchanged / month

CommonWell

- Services:
  - Patient ID and linking
  - Record locator
  - Data Broker – Document exchange
- Participants:
  - https://www.commonwellalliance.org/who-is-connected/

- **5M** documents exchanged / month

Epic Care Everywhere

- Launched 2007
- Australia • Canada • England • Lebanon • The Netherlands • UAE • USA
  - Epic Hospitals: 1,912; Clinics: 44,913
  - Non-Epic connections: 1,642 connections to 110 unique vendors

- **110M** documents exchanged / month
  - Since go-live: 5 BILLION

Carequality Framework

- A network of networks – Policy framework and technical methodology for networks and other implementers to exchange with each other
  - CommonWell
  - Epic Care Everywhere
  - eHealth Exchange (soon)
- 1,400 hospitals, 40,000 Clinics, 600,000 Physicians

- **19M** documents exchanged / month

Fast Healthcare Interoperability Resources (FHIR®)

- Supports exchange of granular data (Resources) via Application Programming Interfaces (APIs)
  - Allows you to ask for specifically for the data you care about
- Consumer-mediated / directed exchange
  - CMS - Blue Button 2.0
  - Argonaut Project - Apple Health Records
  - CARIN Alliance
- Payer-Provider Exchange for value-based care
  - Da Vinci Project
- Social Determinants of Health
  - Gravity Project

Consumer-directed Exchange

- Consumer-directed exchange occurs when a consumer or an authorized caregiver invokes their HIPAA Individual Right of Access and requests their digital health information from a HIPAA covered entity via an application or other third-party data steward.

- Rather than simply viewing or saying where the data should go, patients get the data to use, manage and share it as they see fit.

- ONC Data Brief: *Trends in Individuals' Access… 2017-18*
  - Half of patients have online access to their medical records. Of these:
    - 60% viewed their record
    - 25% downloaded their data
    - 17% transmitted their data to others

Blue Button 2.0

- Individual access to their historic CMS claims data via FHIR
- NewWave Telecom & Technologies – MyCareAI app
  - Standards-based, consumer-controlled health data convergence hub
    - Providers enroll Medicare beneficiaries
    - App requests claims history via Blue Button
    - Query for clinical data from providers based on claims data
    - Aggregate data and assemble longitudinal patient record
    - Evaluate quality metrics, identify risks – patient / population
    - Feedback to patient and providers (via regional health information network)
    - Offer services

Apple Health Records

- Launched January, 2018

- Healthcare organizations offer FHIR® API-based access to data from 3 EHR vendors:
  - AthenaHealth, Cerner, Epic
  - Patient authentication using EHR portal credentials

- LabCorp and Quest lab data

- 297 organizations/practices live as of 06/07/2019

- User survey: 90% of users endorsed:

  "The smartphone solution improved their understanding of their own health, facilitated conversations with their clinicians, or improved sharing of personal health information with friends and family."

Christian Dameff, MD; Brian Clay, MD; Christopher Longhurst, MD. *JAMA.* 2019;321(4):339-340.

Patient-facing Apps Using Apple Health Data

- App Store > Apps > Top Categories > See All > Medical > Apps That Work With Health Records
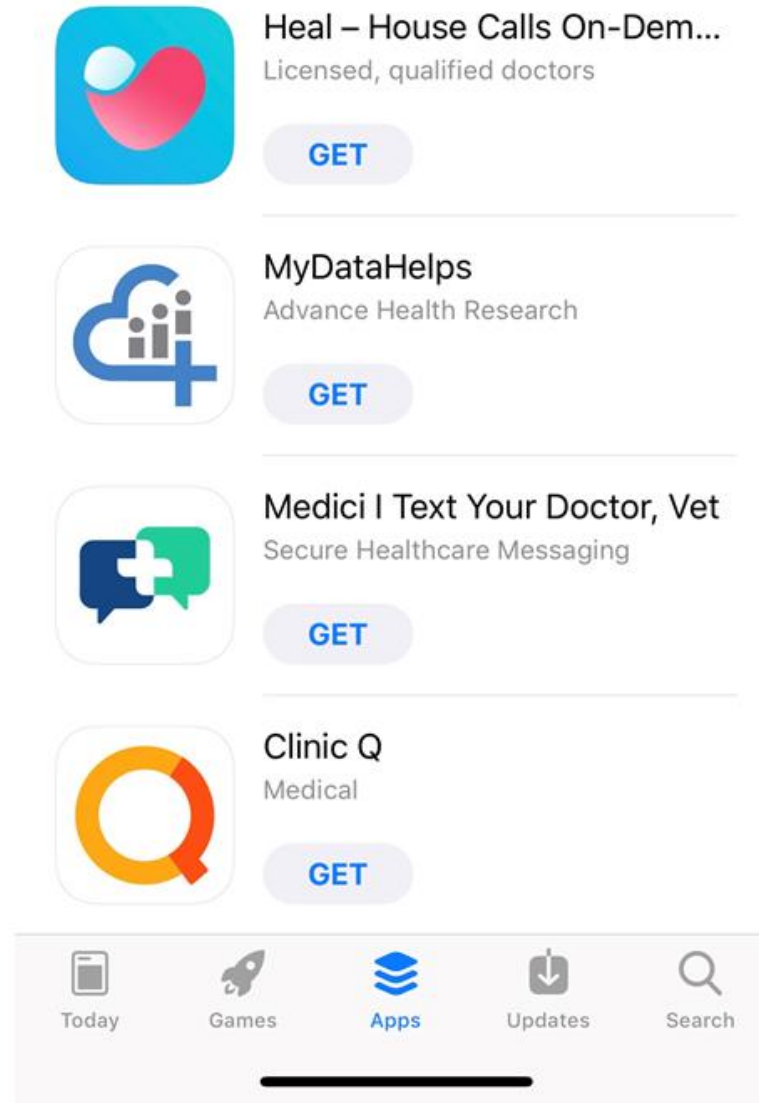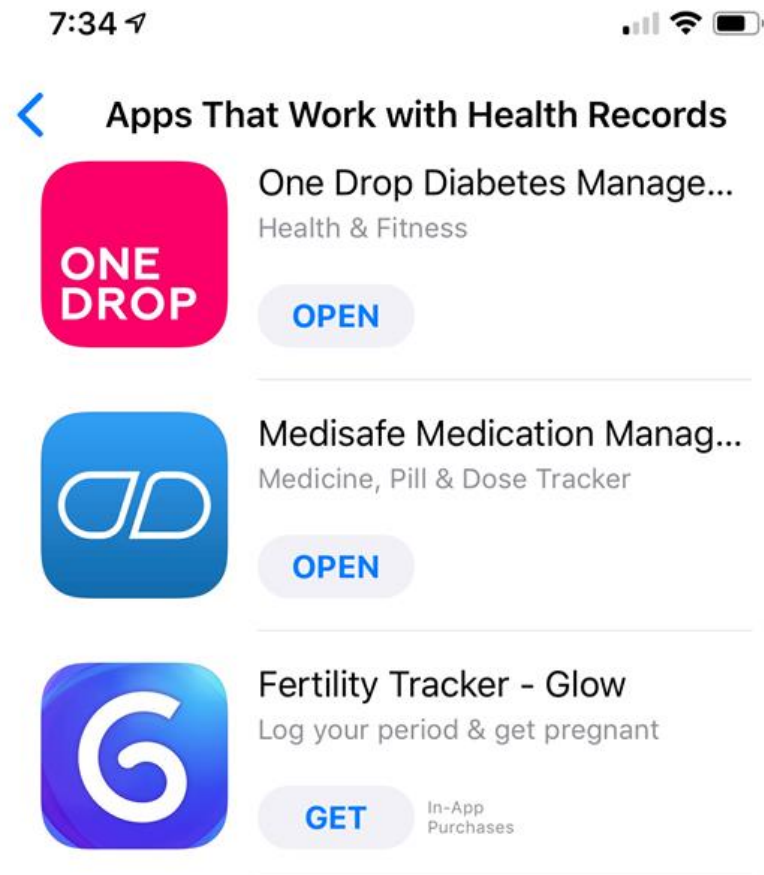
Service Providers Using Apple Health Data

- Care plans, patient monitoring

- Telehealth

- Sexual health, STD testing, treatment
- Integrate with social media, dating apps to incentivize testing and sharing
  - FHIR: lab, EHR data
  - HL7 V2: pharmacies for e-prescribing & delivery
  - Carequality: bidirectional C-CDA exchange with EHRs

CARIN Alliance

- Our vision is to rapidly advance the ability for consumers and their authorized caregivers to easily get, use, and share their digital health information when, where, and how they want to achieve their goals.

- Specifically, we are promoting the ability for consumers and their authorized caregivers to gain digital access to their health information via non-proprietary application programming interfaces or APIs.

- We envision a future where any consumer can choose any application to retrieve both their complete health record and their complete coverage information from any provider or plan in the country.

https://www.carinalliance.com/

CARIN Trust Framework

- Three phases

PHASE I – FOUNDATIONAL
Application developers self-attest to the principles in the CARIN Code of Conduct

PHASE II – QUESTIONNAIRE
Application developers fill out a questionnaire and self-attest to how they will use, manage, and secure the consumer's health information

(Optional) PHASE III – VALIDATION
Multiple, independent certifiers validate the self-attested questions & the application's systems, processes, clinical guidelines, clinical decision support, etc.

CARIN Code of Conduct

As an organization that handles personally identifiable health care information outside of HIPAA, we commit to the following regarding how we will handle personally identifiable consumer health care data.

I. Consent
II. Use & Disclosure
III. Individual Access
IV. Security
V. Transparency
VI. Provenance
VII. Accountability
VIII. Education
IX. Availability
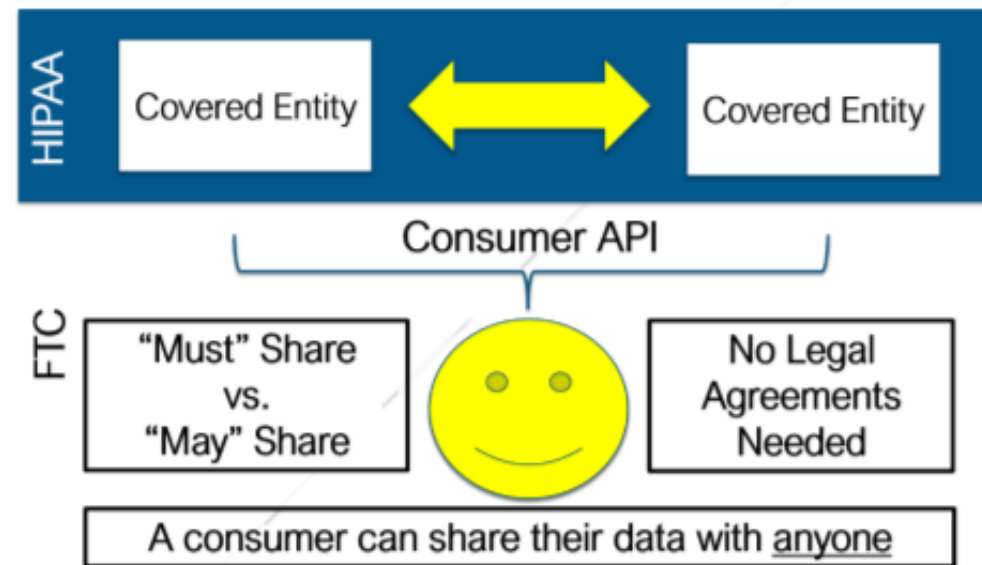
https://www.carinalliance.com/wp-content/uploads/2018/11/2018_CARIN_Code_of_Conduct_11262018.pdf
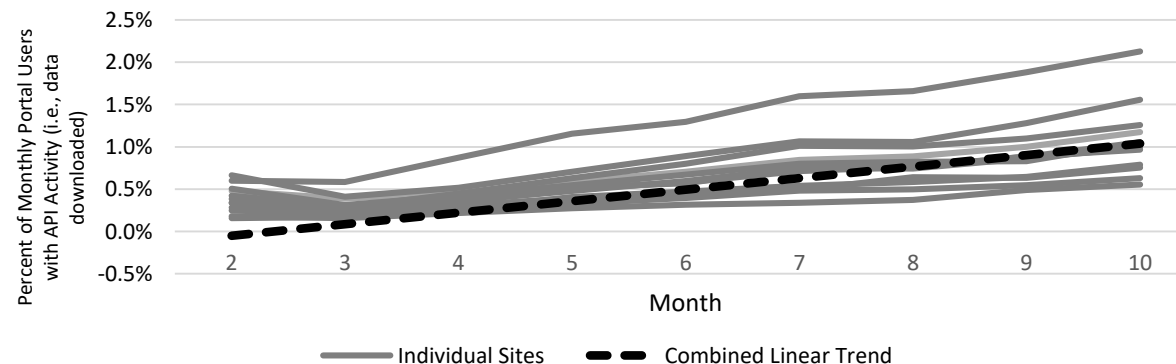
Patient-facing API Access Metrics

- 12 health systems' go-live experience (Adler-Milstein J, Longhurst C, submitted)
  - Cumulative New Users
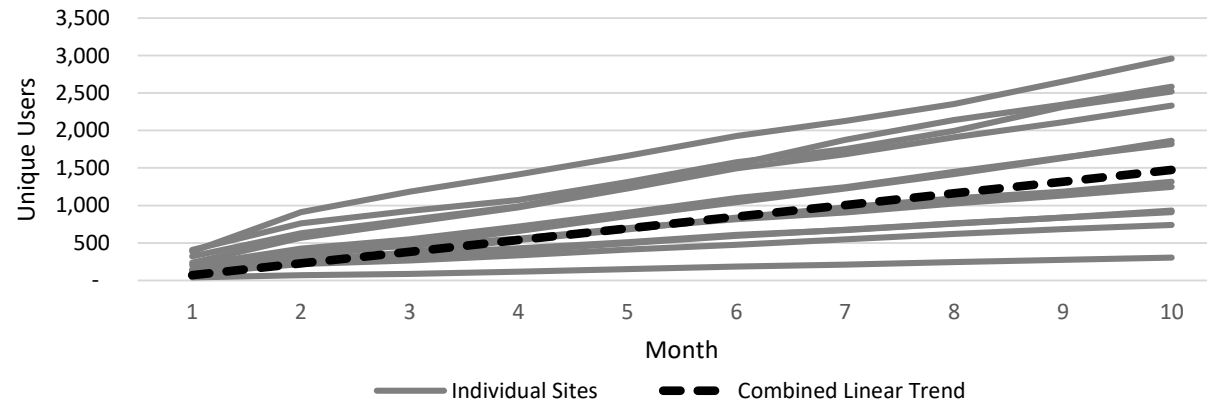
Average 1,500 users after 10 months

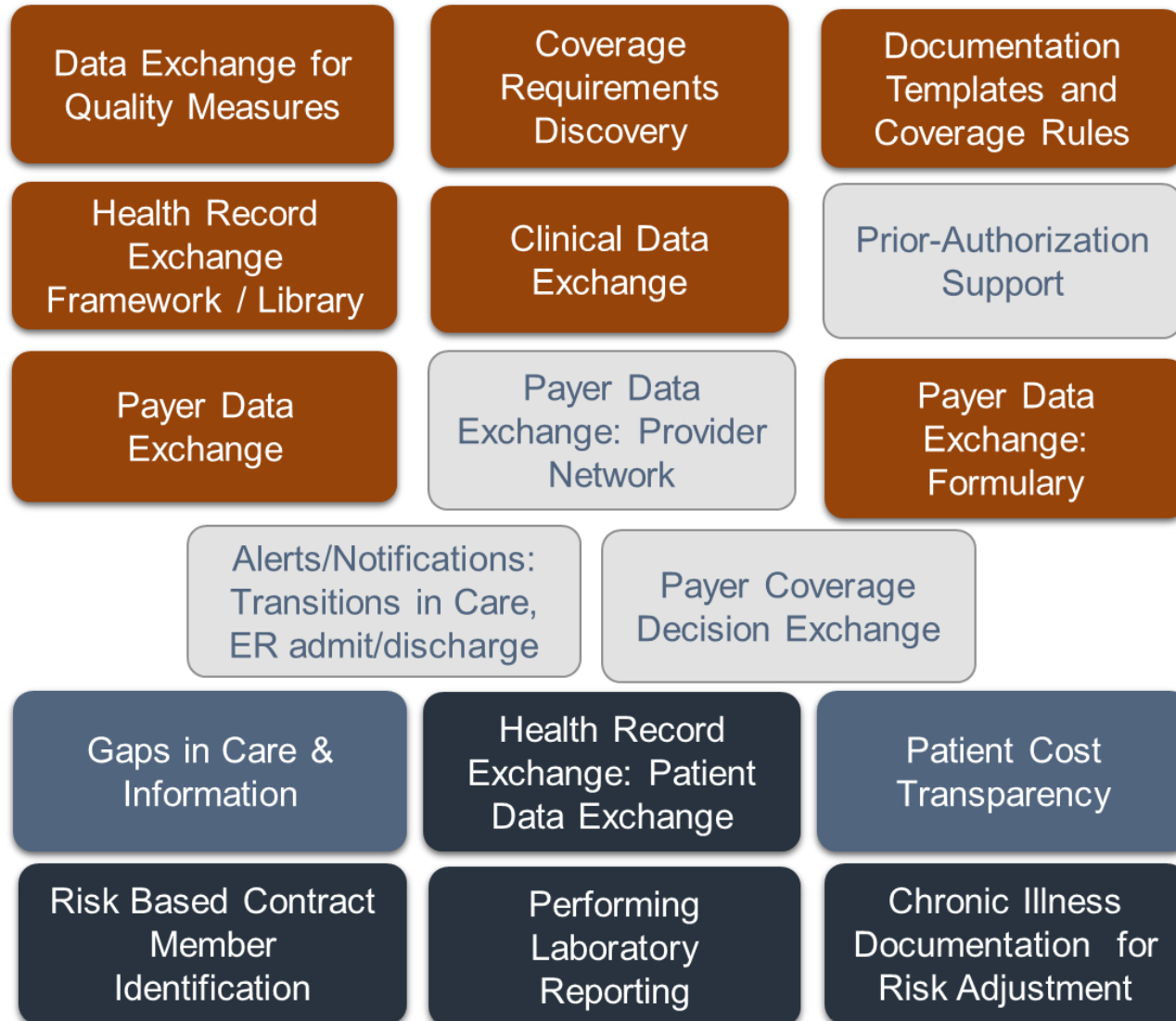 - Monthly Users as a Proportion of Patient Portal Users per Month

Average 1% of portal users after 10 months

Da Vinci Project

- Payer-Provider Exchange via FHIR®

- Support the industry's shift to Value Based Care

- Rapid multi-stakeholder process

- Identify, prioritize, and implement use cases

- Minimize the development and deployment of unique solutions

- Reference architectures to promote industry wide standards and adoption

- http://www.hl7.org/about/davinci/

- https://confluence.hl7.org/display/DVP/Da+Vinci

Da Vinci Use Cases

Data Exchange for Quality Measures	Coverage Requirements Discovery	Documentation Templates and Coverage Rules
Health Record Exchange Framework / Library	Clinical Data Exchange	Prior-Authorization Support
Payer Data Exchange	Payer Data Exchange: Provider Network	Payer Data Exchange: Formulary
Alerts/Notifications: Transitions in Care, ER admit/discharge	Payer Coverage Decision Exchange	
Gaps in Care & Information	Health Record Exchange: Patient Data Exchange	Patient Cost Transparency
Risk Based Contract Member Identification	Performing Laboratory Reporting	Chronic Illness Documentation for Risk Adjustment

Project Process

- ❑ Define requirements (clinical, business, technical and testing
- ❑ Create Implementation Guide (IG)
- ❑ Create and test Reference Implementation (RI) - Prove the IG works
- ❑ Pilot the solution
- ❑ Deploy the Solution

Use Case Status

- ▇ In Ballot Process through HL7
- ▢ Targeted for September Ballot
- ▇ In Discovery targeted for HL7 January Ballot
- ▇ Use cases in discovery (some may be balloted in January 2020)

Recent Efforts to Implement Provisions of the 21st Century Cures Act

- 02/11/2019 – ONC Notice of Proposed Rule Making (NPRM)
- 02/11/2019 – CMS NPRM
- 04/18/2019 – New HIPAA FAQs
- 04/19/2019 – Draft 2 Trusted Exchange Framework and Common Agreement
- 04/19/2019 – Notice of Funding Opportunity (NOFO) for the Recognized Coordinating Entity (RCE) to develop Common Agreement and implement TEFCA

ONC NPRM

- Highlights:
  - APIs without special effort
  - US Core Data for Interoperability (USCDI)
  - Information Blocking Exceptions
  - EHI Export for Patients and Providers
  - HIT for Pediatric Care and Practice Settings
  - Transparency requirements
  - Limitations on pricing, contracts
  - Free patient electronic access to EHI

US Core Data for Interoperability

Assessment and Plan of Treatment

Care Team Members

Clinical Notes *NEW
- Consultation Note
- Discharge Summary Note
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

Goals
- Patient Goals

Health Concerns

Immunizations

Laboratory
- Tests
- Values/Results

Medications
- Medications
- Medication Allergies

Patient Demographics
- First Name
- Last Name
- Previous Name
- Middle Name (including middle initial)
- Suffix
- Birth Sex
- Date of Birth
- Race
- Ethnicity
- Preferred Language
- Address *NEW
- Phone Number *NEW

Problems

Procedures

Provenance *NEW
- Author
- Author Time Stamp
- Author Organization

Smoking Status

Unique Device Identifier(s) for a Patient's Implantable Device(s)

Vital Signs
- Diastolic Blood Pressure
- Systolic Blood Pressure
- Body Height
- Body Weight
- Heart Rate
- Respiratory rate
- Body Temperature
- Pulse oximetry
- Inhaled oxygen concentration
- Pediatric Vital Signs *NEW
  - BMI percentile per age and sex for youth 2-20
  - Weight for age per length and sex
  - Occipital-frontal circumference for children < 3 years old

USCDI Advancement Process

Level 3 "USCDI" | Vetted for entry by HITAC, Public, & ONC | **Nationwide Adoption** | N<=10s

Level 2 | Updated by Stakeholders Classified by ONC | **Evidence of Impact/Use** | N=10s

Level 1 | Updated by Stakeholders Classified by ONC | **Specified and Pilot Tested/Prototype Use** | N<100

Comments | Open Submission | **Novel Usage/Prepared for Testing** | N=100s
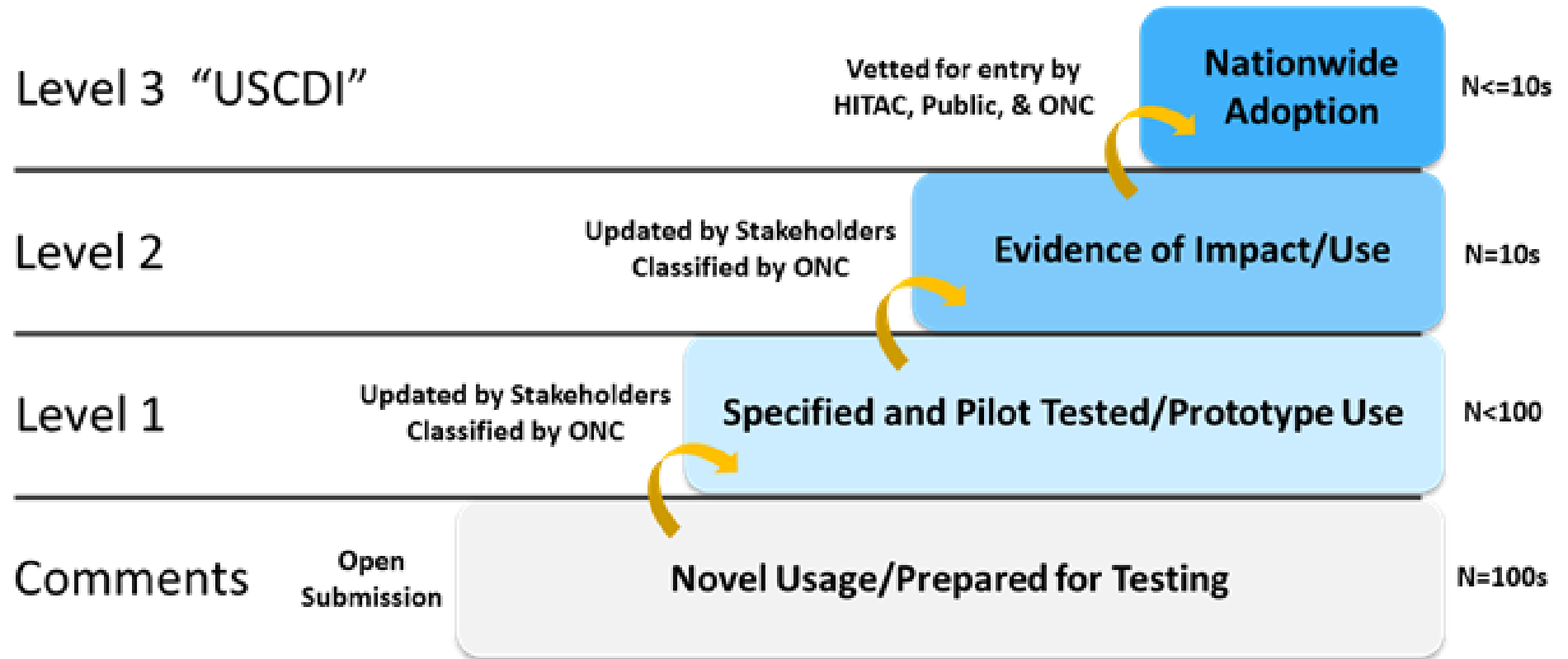
Information Blocking

- The Cures Act establishes stringent requirements around the prohibition of information blocking

- Penalties of $1M per incident.

- The statutory language requires ONC to identify reasonable and necessary activities that interfere with the access, exchange, or use of EHI and that do not constitute information blocking.

Information Blocking Exceptions

1. Preventing Harm

2. Promoting the Privacy of Electronic Health Information

3. Promoting the Security of Electronic Health Information

4. Recovering Costs Reasonably Incurred

5. Responding to Requests that are Infeasible

6. Licensing of Interoperability Elements on Reasonable and Non-discriminatory Terms

7. Maintaining and Improving Health IT Performance

EHI Export

- Require health information technology developers to provide the capability to export <u>all</u> Electronic Health Information (EHI) they produce and manage in a computable format – for a single patient or a population

CMS NPRM

- Impacts all providers/hospitals and payers participating in CMS-funded programs
  - Medicare Advantage, Medicaid, Children's Health Insurance Program (CHIP) participants, Qualified Health Plans in the federal exchanges

- Interoperability requirements to improve **patient access** to their health information
  - Hospitals must enable notifications for inpatients who are admitted, transferred, or discharged
  - Payers must adopt open APIs and share health information with patients as well as with other payers when requested by the patient
  - Payers must join a Trusted Exchange Network that supports secure messaging or electronic querying by and between patients, providers and payers

NPRM Feedback: > 2,000 submissions

- Increased complexity, costs
- Duplicative and disruptive of existing interoperability methods
- Patient privacy
  - When data leaves HIPAA covered entities
  - Secondary impacts, e.g., on family members
- Data Segmentation for Privacy (DS4P)
  - Safety risks of incomplete data sharing
- Unrealistic timelines
  - Some CMS provisions proposed to go into effect in early 2020
  - Only 2 years from finalization of rules for full implementation

OCR HIPAA FAQs – 04/18/2019

- An individual's right to access her/his protected health information under HIPAA generally obligates a covered entity to send PHI to a patient-designated app, *even if* the covered entity is concerned about the app's security or how the app will subsequently use or disclose the PHI.

- A covered entity would not be liable under HIPAA for an app's subsequent use or disclosure of PHI sent to the app at the direction of an individual, **unless** the app was "developed for, or provided by or on behalf of the covered entity – and, thus, creates, receives, maintains, or transmits ePHI *on behalf of* the covered entity".

- A covered entity that transmits ePHI to an app via an unsecure manner or channel – at an individual's direction – would not be responsible for unauthorized access during such transmission, but such an entity may want to *counsel the individual* regarding the security risks involved in such a transmission.

https://www.hhs.gov/hipaa/for-professionals/faq/health-information-technology/index.html

Consumer Privacy Concerns

- **Protecting Personal Health Data Act** introduced in the Senate 06/14/2019 would direct the Secretary of HHS to enhance privacy controls over health technology including apps, wearables and direct-to-consumer genetic tests.
  - Intended to cover data not explicitly covered by HIPAA, which was established before many of these technologies existed
  - Would require that the new regulations take into account varying levels of sensitivity for consumer data, including genetic, biometric and general personal health information
  - Would create a National Task Force on Health Data Protection to evaluate health data cybersecurity and privacy, and to study the efficacy of de-identification methods

Trusted Exchange Framework and Common Agreement (TEFCA)

- Draft 1 – 1/5/2018
- Draft 2 – 4/19/2019

https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement
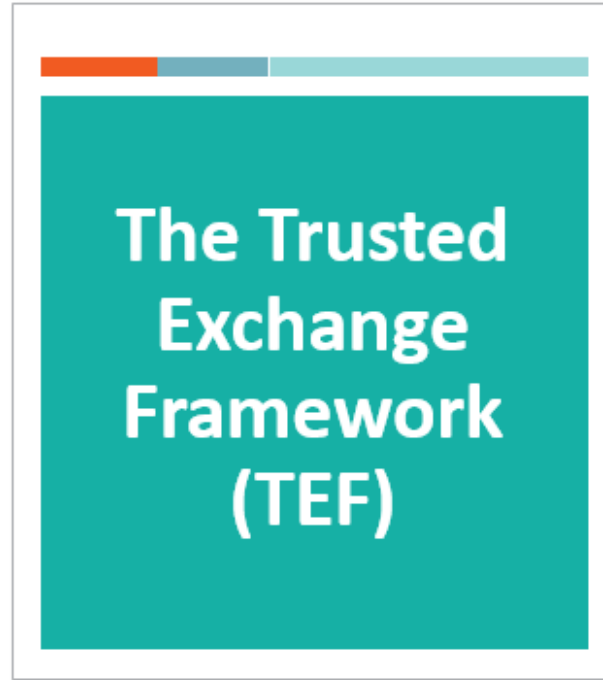
Trusted Exchange Framework - Goals

GOAL 1

GOAL 2

GOAL 3

Provide a single "on-ramp" to nationwide connectivity

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

Support nationwide scalability

TEFCA Stakeholders

HEALTH INFORMATION NETWORKS

GOVERNMENT AGENCIES
Federal, state, tribal, and local governments

PUBLIC HEALTH
Public and private organizations and agencies working collectively to prevent, promote and protect the health of communities by supporting efforts around essential public health services

INDIVIDUALS
Consumers, patients, caregivers, family members serving in a non-professional role and professional organizations that represent these stakeholders' best interest

PAYERS
Private payers, employers, and public payers that pay for programs like Medicare, Medicaid, and TRICARE

Stakeholders

PROVIDERS
Professional care providers who deliver care across the continuum, not limited to but including ambulatory, inpatient, long-term and post-acute care (LTPAC), emergency medical services (EMS), behavioral health, and home and community based services

TECHNOLOGY DEVELOPERS
People and organizations that provide health IT capabilities, including but not limited to health information exchange (HIE) technology, laboratory information systems, personal health records, pharmacy systems, mobile technology, medical device manufacturers, telecommunications and technologies to enable telehealth, and other technology that provides health IT capabilities and services

TEFCA Exchange Purposes

Operations, payment, formulary

Business Planning and Development*

Prior auth, coverage/ premium/ reimbursement determination

Utilization Review*

Safety, guidelines, outcomes

Quality Assessment & Improvement*

Exchange Purposes

Public, non-healthcare

Benefits Determination

Public Health*

Obtain or direct the sending of a copy of EHI

Individual Access Services

Treatment*

Only applies to HIPAA covered entities and business associates

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TEFCA Exchange Modalities

QHIN Broadcast Query
A QHIN's electronic request for a patient's EHI from all QHINs.
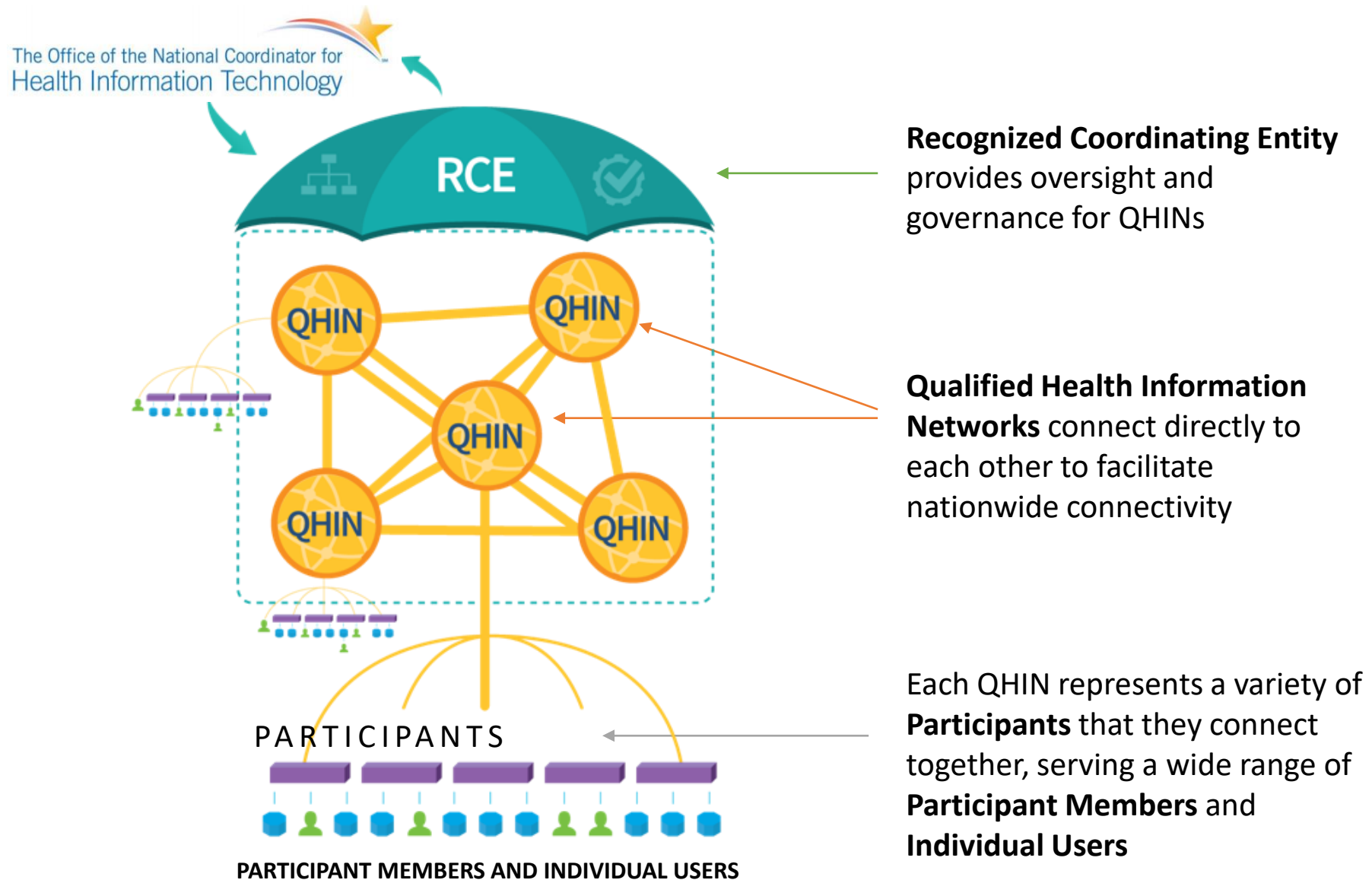
QHIN Targeted Query
A QHIN's electronic request for a patient's EHI from specific QHINs.

QHIN Message Delivery (Push)
The electronic action of a QHIN to deliver a patient's EHI to one or more specific QHINs.

TEFCA Architecture

Recognized Coordinating Entity provides oversight and governance for QHINs

Qualified Health Information Networks connect directly to each other to facilitate nationwide connectivity

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

PARTICIPANTS

PARTICIPANT MEMBERS AND INDIVIDUAL USERS

TEFCA Version 2

- Narrowed permitted purposes for exchange
- Added QHIN Message Delivery – Push messaging
- Clarified QHIN Requirements
  - QHIN definition now includes HIEs, vendor networks
  - Minimum and Additional Required Terms and Conditions
  - QHIN Technical Framework
- Recognized Coordinating Entity (RCE) requirements
  - Develop and maintain the Common Agreement
  - Oversee implementation of TEFCA, approve and monitor QHINs

TEFCA Version 2 Feedback

- Duplicative and disruptive of current efforts, e.g., Carequality and Direct
- Timelines do not allow for full stakeholder engagement
- Should align with other regulations – HIPAA, Interoperability Rule
- TEFCA should outline functional requirements and avoid identifying specific technical solutions
- Should allow "specialized" health information networks to address only a subset of exchange purposes and/or modalities
- Need for greater clarity regarding the implementation of the Meaningful Choice requirements

Opportunities for Participation

- HHS / ONC Federal Advisory Committees – *Work Groups and Task Forces*
  - https://www.healthit.gov/topic/federal-advisory-committees/membership-application

- ONC FHIR at Scale Taskforce (FAST) – *Tiger Teams*
  - https://oncprojectracking.healthit.gov/wiki/display/TechLabSC/Tiger+Teams

- The Sequoia Project – *Interoperability Matters Workgroups*
  - https://sequoiaproject.org/interoperability-matters/

- Carequality – *Advisory Committee, Workgroups*
  - https://carequality.org/get-involved/

- DirectTrust – *Task forces*
  - https://www.directtrust.org/

Questions?

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