COMMUNITY HEALTH CARE ASSOCIATION of New York State

CHCANYS NYS- HCCN presents

The Next Frontier of Interoperability: Innovations in Policy, Technology, & Workflows

Day 1 – Policy and Technology Focus
December 7, 2021 – 2:00 pm

For more information, please email us at HCCN@chcanys.org

Zoom Guidelines

- You have been muted upon entry. Please respect our presenters and stay on mute if you are not speaking.
- Please share your questions in the chat. CHCANYS staff will raise your questions to our speakers and follow up as needed if there are unanswered questions.
- The workshop is being recorded.
- Slides and presentations will be sent following the event

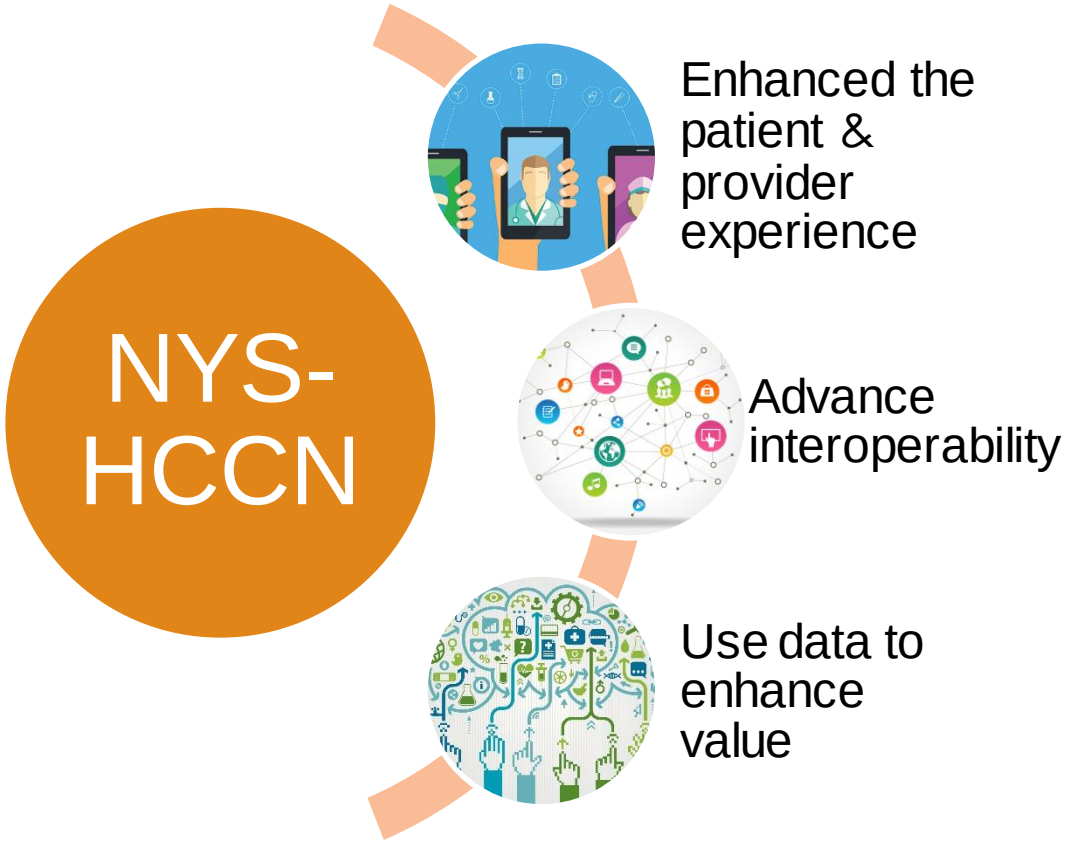
Reminder: Secure a spot in the NYS-HCCN Community for 2022-2025 by December 15th

The NYS-HCCN is a collaborative network of New York State FQHCs working together to leverage health information technology in a value-based care environment. Core focus areas include:

- ✓ 21st Century Cures Act and Information Blocking Rule
- ✓ Patient Privacy and cybersecurity
- ✓ Data strategies for SDOH, REaL data, predictive analytics, data visualization, etc.
- ✓ EHR experience and optimization
- ✓ Interoperability and data exchange
- ✓ Staff training on digital health tools

Please contact Jen Pincus, HCCN Director, for questions or more information
jpincus@chcanys.org/518-434-0767 ext. 231

The New York Statewide Health Center Controlled Network



Agenda

- Update on Operationalizing TEFCA by the Sequoia Project
- Expanded Immunization Sharing: Bronx RHIO and HealtheLink
- Consumer Directed Data Exchange by CARIN Alliance

An Update on Operationalizing TEFCA

Mariann Yeager, MBA

Chief Executive Officer, The Sequoia Project

Trusted Exchange Framework and Common Agreement (TEFCA): An Overview

December , 2021

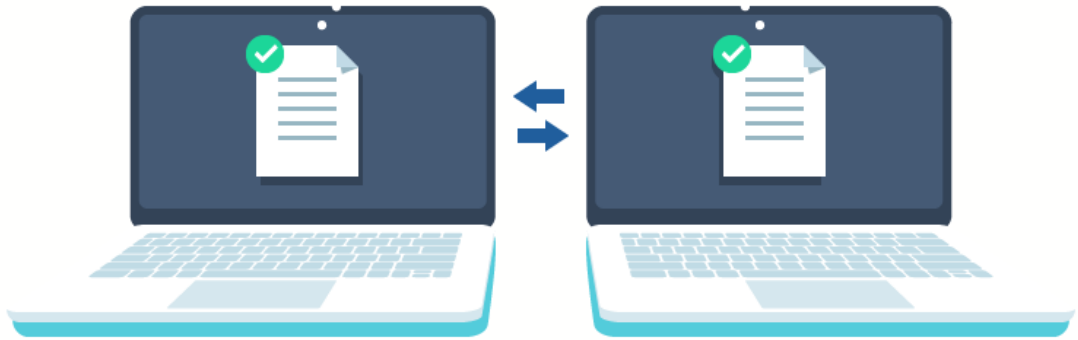
ONC
TEFCA
RECOGNIZED
COORDINATING
ENTITY

This project is supported by the Office of the National Coordinator for Health Information Technology (ONC) of the U.S. Department of Health and Human Services (HHS) under 90AX0026/01-00 Trusted Exchange Framework and Common Agreement (TEFCA) Recognized Coordinating Entity (RCE) Cooperative Agreement. This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by ONC, HHS or the U.S. Government.

ONC TEFCA RECOGNIZED COORDINATING ENTITY

Agenda

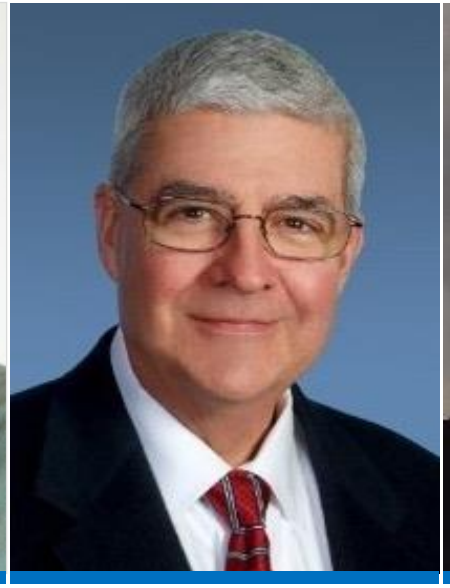
- Welcome
- CURES Act and TEFCA: A Brief History
- Components of a Trusted Exchange Framework and Common Agreement
- Elements of the Common Agreement
- Timeline for Implementation and Opportunities for Stakeholder Feedback
- Questions and Answers



Meet the RCE Team

Mariann Yeager
CEO
The Sequoia Project

Alan Swenson
Executive Director
Carequality



Steve Gravely
Founder & CEO
Gravely Group

Cait Riccobono
Attorney
Gravely Group

Chantal Worzala
Principal
Alazro Consulting

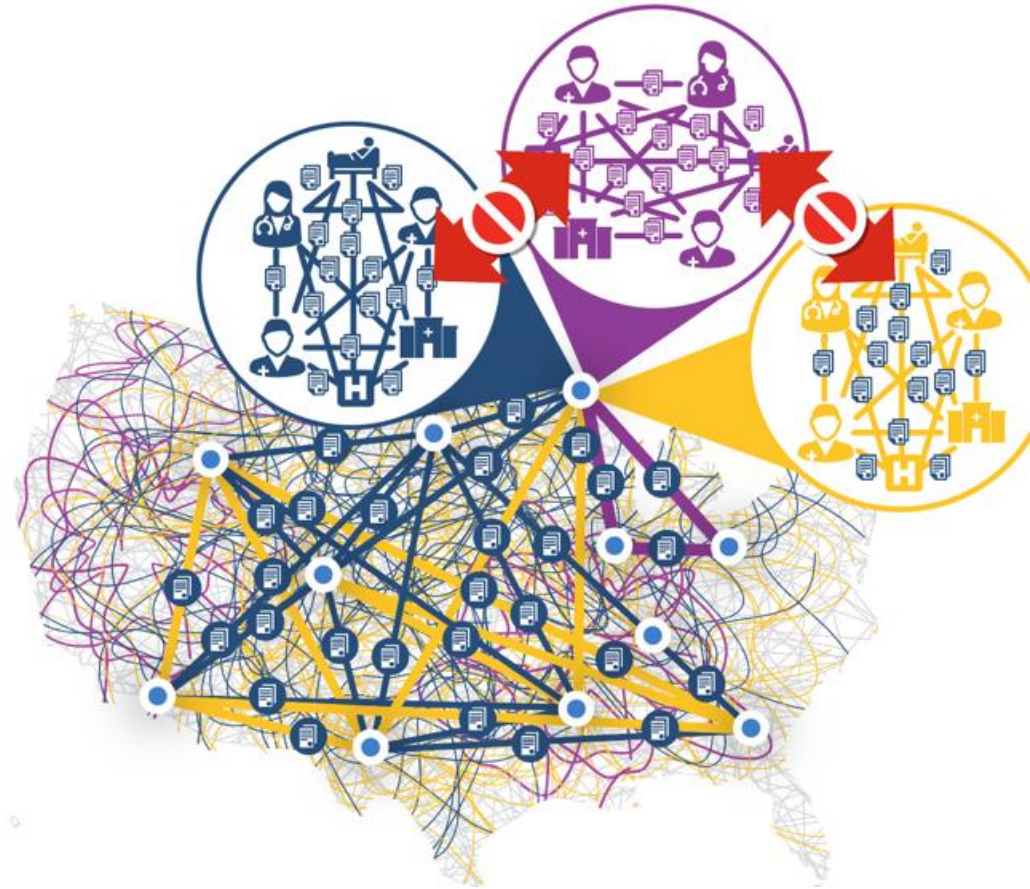
CURES Act and TEFCA: A Brief History

Why do we need the Trusted Exchange Framework and Common Agreement (TEFCA)?

COMPLEXITY OF 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.



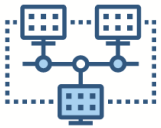
ONC TEFCA RECOGNIZED COORDINATING ENTITY

21st Century Cures 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 Goals

GOAL 1
Establish a floor of universal interoperability across the country



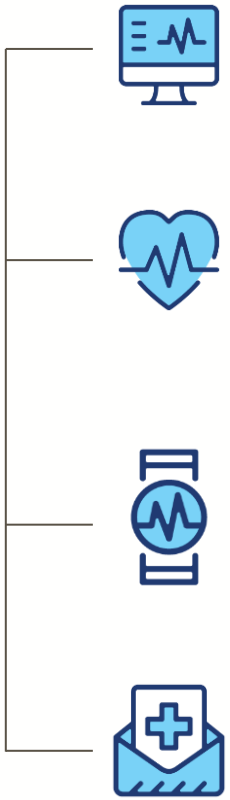
GOAL 2
Create simplified nationwide connectivity

GOAL 3
Provide the infrastructure to allow individuals to gather data

Simplified connectivity for individuals, health care providers, health plans, public health agencies, and other stakeholders.

Benefits of TEFCA

Relevant, trusted information from nationwide sources



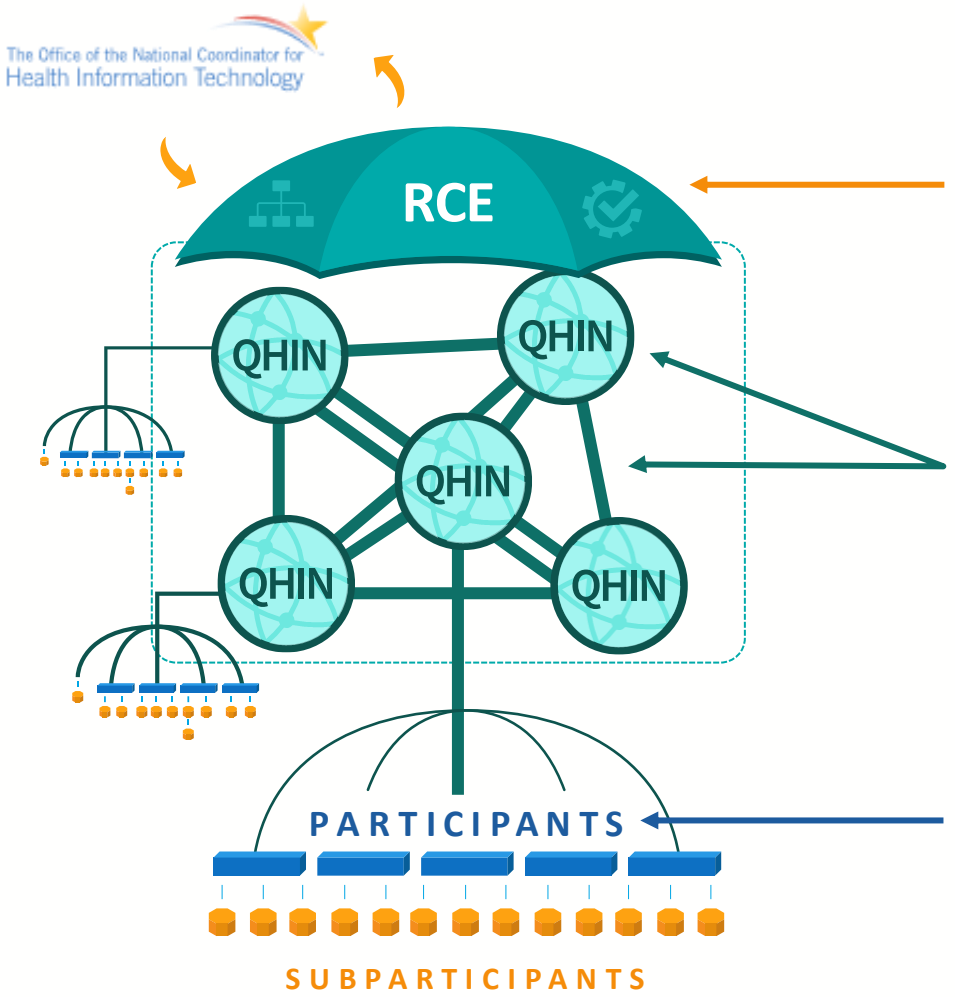
Consumers
Access their own records from sources located across the nation.

Providers and health systems
Obtain complete picture of care across settings to improve care and coordination with fewer connection points.

State programs and public health
Enhance understanding of health metrics, reduce cost of public health reporting and program management.

Payers
Get and share data needed for care management, value-based care, etc.

How Will TEFCA Work?



RCE provides oversight and governance for QHINs.

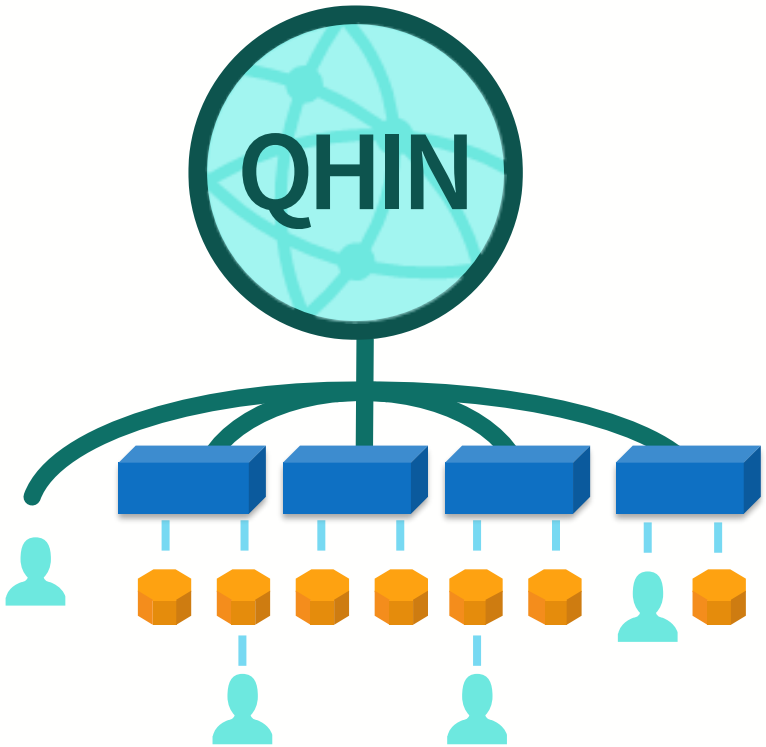
QHINs connect directly to each other to facilitate nationwide interoperability.

Each QHIN represents a variety of Participants that they connect, serving a wide range of Subparticipants.

Recognized Coordinating Entity (RCE)

- Develop, update, implement, and maintain the Common Agreement.
- Modify and update the QHIN Technical Framework.
- Virtually convene public stakeholder feedback sessions.
- Identify, designate, and monitor Qualified Health Information Networks (QHINs).
- Develop and maintain a process for adjudicating QHIN noncompliance.
- Propose strategies to sustain the Common Agreement at a national level.

Structure of a Qualified Health Information Network (QHIN)



Participant

a U.S. Entity, or a non-U.S. Entity if and to the extent permitted by an SOP, regardless of whether the entity is a Covered Entity or a Business Associate, that has entered into a Participant-QHIN Agreement whereby the QHIN agrees to transmit and receive TEFCA Information (TI) via QHIN-to-QHIN exchange on behalf of the party to the Participant-QHIN Agreement for the Exchange Purposes. Without limitation of the foregoing, a health information exchange, health IT developer, health care system, payer, or federal agency could each be a Participant.

Subparticipant

a U.S. Entity, or a non-U.S. Entity if and to the extent permitted by an SOP, regardless of whether the entity is a Covered Entity or Business Associate, that has entered into either: (i) a Participant-Subparticipant Agreement to use the services of a Participant to send and/or receive TI or (ii) a Downstream Subparticipant Agreement pursuant to which the services of a Subparticipant are used to send and/or receive TI.

Individual

one or more of the following:

1. An individual as defined by 45 CFR 160.103;
2. Any other natural person who is the subject of the TEFCA Information being requested, Used, or Disclosed;
3. A person who legally acts on behalf of a person described in paragraphs (1) or (2) of this definition in making decisions related to healthcare as a personal representative, in accordance with 45 CFR 164.502(g);
4. A person who is a legal representative of and can make healthcare decisions on behalf of any person described in paragraphs (1) or (2) of this definition; or
5. An executor, administrator, or other person having authority to act on behalf of a deceased person described in paragraphs (1) or (2) of this section or the individual's estate under Applicable Law.

Certain Provisions of the Common Agreement will flow down to Participants and Subparticipants

What Kinds of Exchange Will be Supported?

Initial Exchange Modalities:

- QHIN query
- QHIN message delivery

Primary Data Exchanged:

- Available electronic health information in C-CDA 2.1, including the US Core Data for Interoperability (USCDI)

Potential Future Additions:

- Population-level data exchange
- FHIR-based exchange
- Additional exchange purposes, use cases, and exchange modalities based on industry need and input

Exchange Purposes:

- Treatment
- Payment
- Health Care Operations
- Public Health
- Benefits Determination
- Individual Access Services

Elements of the Common Agreement

TEFCA Elements

Common Agreement

Standard Operating Procedures

QHIN Technical Framework

QHIN Onboarding

Metrics

Governing Approach

The Common Agreement

- The **Common Agreement** would establish the infrastructure model and governing approach for users in different information exchange networks to securely share clinical information with each other—all under commonly agreed-to expectations and rules, regardless of which network they happen to be in.
- The Common Agreement will be a legal document that each QHIN signs with the RCE.
- Some provisions of the Common Agreement will flow down to other entities (Participants and Subparticipants) via other agreements.
- The Common Agreement will incorporate the QHIN Technical Framework and the Standard Operating Procedures (SOPs).

The RCE welcomes stakeholder feedback.

Standard Operating Procedures

To provide more specificity on particular issues, the RCE will also develop SOPs on topics such as:

Dispute Resolution Process

Governing Approach (Governing Council, Transitional Council, Advisory Groups)

Conflicts of Interest

QHIN Eligibility Criteria, Onboarding, and Designation

QHIN Security Requirements for the Protection of TEFCA Information

Standard Operating Procedure(s) or **SOP(s):** a written procedure or other provision that is adopted pursuant to the Common Agreement and incorporated by reference into the Common Agreement to provide detailed information or requirements related to the exchange activities under the Common Agreement, including all amendments thereto and any new SOPs that are adopted pursuant to the Common Agreement. SOPs will be adopted to address the application process, the Onboarding process, and other operational processes.

Elements of the Common Agreement

1. Definitions
2. Exchange Purposes
   - Requests
   - Uses and Disclosures
   - Responses
3. Participants and Subparticipants
4. Required Flow-Down Provisions
5. TEFCA Information and Required Information
6. Governing Approach to Exchange Activities Under the Common Agreement
7. QHIN Designation and Eligibility Criteria
8. Cooperation and Nondiscrimination
9. RCE Directory Service
10. Individual Access Services
11. Privacy and Security
12. Special Requirements (including Consent)
13. Fees

Timeline for Implementation

Timeline to Operationalize TEFCA

Summer/Fall/Winter 2021

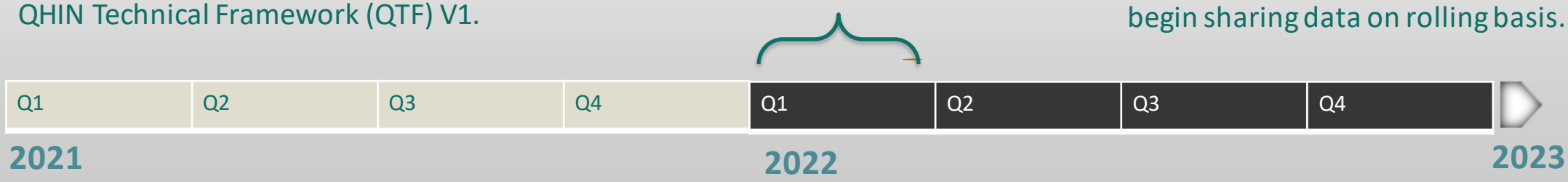
- Public engagement webinars.
- Common Agreement (CA) Work Group sessions.
- RCE and ONC use feedback to finalize CA V1 and QHIN Technical Framework (QTF) V1.

Calendar Q1 of 2022

- Release Final Trusted Exchange Framework, CA V1 Final, and QTF V1 Final.

During 2022

- QHINs begin signing Common Agreement.
- QHINs selected, onboarded, and begin sharing data on rolling basis.



What Does All This Mean For You?

Prepare for Participation Under TEFCA

- Follow the RCE work and consider your place in this new ecosystem
  - Join monthly informational calls
  - Visit RCE.sequoiaproject.org for FAQs, previous drafts, and other resources
- Become familiar with the contemplated Exchange Purposes and consider how nationwide exchange could support your operations
- Be engaged with stakeholder feedback opportunities

Benefits of TEFCA

- Supports a healthier population through easier access to relevant information
- Establishes a floor for universal interoperability nationwide
- Expands the set of Exchange Purposes beyond a foundation of Treatment
- Simplified information exchange will also support:
  - Medicaid and other state health programs
  - Public health reporting and bidirectional exchange
  - Emergency preparedness and response

ONC TEFCA RECOGNIZED COORDINATING ENTITY

Questions & Answers

Expanded Immunization Sharing: Star HIE - Bronx RHIO

Kathryn Miller, MS

Chief Operating Office

Bronx RHIO

Alison Connelly- Flores

CMIO/PA-C

Urban Health Plan

BronxRHIO
Connecting for Better Health

Bronx RHIO: NYC Regional Health Information Exchange-enabled Response and Recovery (HIERR)

About US

- The NYC Regional Health Information Exchange-enabled Response and Recovery (HIERR) was created as a result of being one of the earliest communities to be disproportionately impacted by COVID-19.
- Bronx RHIO began working collaboratively with the NYC Department of Health & Mental Hygiene (DOHMH) and NYS Department of Health (DOH) to expand our infrastructure and services to address ongoing COVID-19 related needs and prepare for other public health emergencies in the future.
- By expanding our HIE infrastructure to include new tools will enable better surveillance and contact tracing to contain spread of the virus and track vaccination activity, support ongoing knowledge enhancement for policy making and intervention, and provide public health and provider staff with actionable information about the COVID-19-related status of their populations.

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Strengthening the Technical Advancement and Readiness of Public Health Agencies via Health Information Exchange (STAR HIE) Program

The STAR HIE Program

- Bronx RHIO was awarded federal funding through the Strengthening the Technical Advancement and Readiness of Public Health via Health Information Exchange (The STAR HIE Program): Improving COVID-19 Vaccination Data: Connecting Immunization Information Systems (IIS) to Health Information Exchanges from the Office of the National Coordinator for Health Information Technology (ONC).
- The STAR HIE Program will support innovative health information exchange services that benefit public health agencies and improve the health information exchange services available to support communities disproportionately impacted by the COVID-19 pandemic. As part of the program, Bronx RHIO project focuses on increase data sharing between Health Information Exchanges (HIEs) and Immunization Information Systems (ISSs).

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The STAR HIE Program

- Program is designed to strengthen uses of health information via HIEs to support public health agencies, including for COVID-19 response.
- The program has the following objectives:
  - Build innovative health information exchange services that benefit public health agencies.
  - Improve the health information exchange services available to support communities disproportionately impacted by the COVID-19 pandemic.

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Program Goals

The STAR HIE Program allows Bronx RHIO to support public health agencies and its member organizations in tracking and identifying patients who need COVID-19 vaccinations, especially in communities disproportionately affected by COVID-19.

Program goals include:

- Identifying high-risk patients for vaccination
- Improving vaccination tracking and administration
- Monitoring long-term vaccination effects, adverse reactions, and breakthrough infections
- Measuring the effect of social determinants of health on vaccination patterns

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Program Activities to Date

- Established Connection to both New York Immunization Information Systems
  - New York State Immunization Information System (NYSIIS) for vaccinations to people living outside NYC
    - NYSIIS sends daily flat file
  - NYC DOHMH Immunization Registry (CIR) for residents of NYC
    - QUERY MODEL allowing 300,000 queries/day
  - Two different file/data formats needed to be reconciled and mapped to support reporting

- Query model required creation of hierarchy for which patients to query in what order
  1. 8 HIE member organizations who were requesting data
  2. Queried all remaining patients
  3. Created sets of patients fully vaccinated, partially vaccinated, not vaccinated
  4. Re-querying on all partially vaccinated and not vaccinated patients
  5. Creating sets of patients eligible for Boosters based on current guidance and will re-query on those

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Vaccination Activity

	Age 12 and Up	Children 0-11
Master Patient Index Size	6,900,000	700,000
Fully Vaccinated (as of 11/1/2021)	1,900,000	28
Partially Vaccinated (as of 11/1/2021)	170,000	32

Note: The Bronx population is ~80 black and brown individuals. We are currently working to cross reference census data on race and ethnicity with our vaccination data as the HIE race and ethnicity data shows ~50% as Unknown for those fields.

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Population Breakdown of Vaccination Status of Bronx Residents by Age

Age Bracket	Partially Vaccinated	Fully Vaccinated	TOTAL	Bronx MPIDs
5 - 11	32	28	60	240,582
12 - 17	8,624	54,318	62,942	234,937
18 - 24	13,614	66,673	80,287	285,018
25 - 34	18,445	103,206	121,651	482,126
35 - 44	11,338	105,903	117,241	403,028
45 - 54	7,785	109,640	117,425	346,222
55 - 64	6,461	119,717	126,178	363,984
65 - 79	4,559	100,257	104,816	342,408
80+	1,422	28,333	29,755	165,949
Grand Total	**72,280**	**688,075**	**760,355**	**2,864,254**

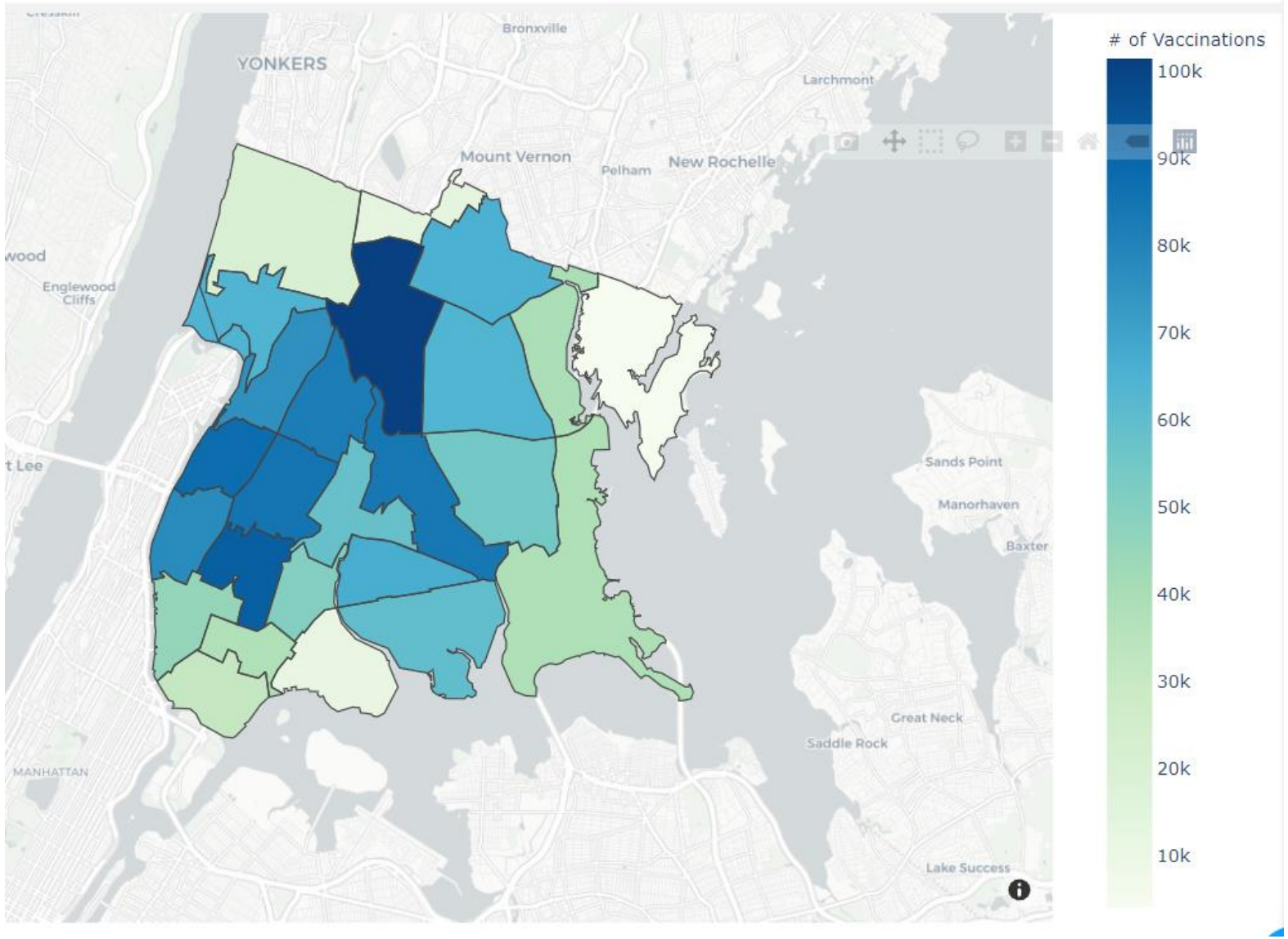
PCR COVID Test Statistics in 2021

119,023	Positive PCR COVID-19 Tests	94,174	# of Pts with Positive PCR COVID-19 Tests
2,407,020	PCR COVID-19 Tests Total	1,108,908	# of Pts with PCR COVID-19 Tests Overall
4.94%	Positivity Rate	8.49%	Positivity Rate

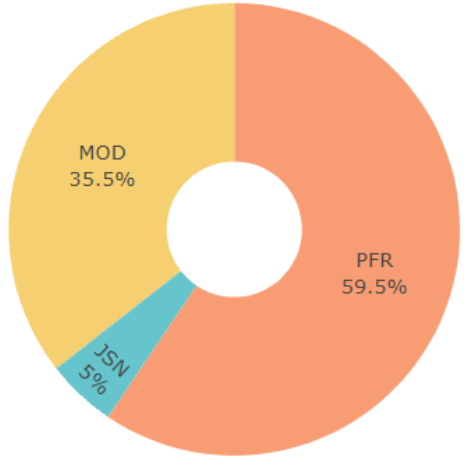
Percentage Breakdown of Vaccination Status of Bronx Residents by Age

Age Bracket	% Partially Vaccinated	% Fully Vaccinated	% of Total Bronx MPIDS
5 - 11	0.01%	0.01%	0.02%
12 - 17	3.67%	23.12%	26.79%
18 - 24	4.78%	23.39%	28.17%
25 - 34	3.83%	21.41%	25.23%
35 - 44	2.81%	26.28%	29.09%
45 - 54	2.25%	31.67%	33.92%
55 - 64	1.78%	32.89%	34.67%
65 - 79	1.33%	29.28%	30.61%
80+	0.86%	17.07%	17.93%
Grand Total	**2.52%**	**24.02%**	**26.55%**

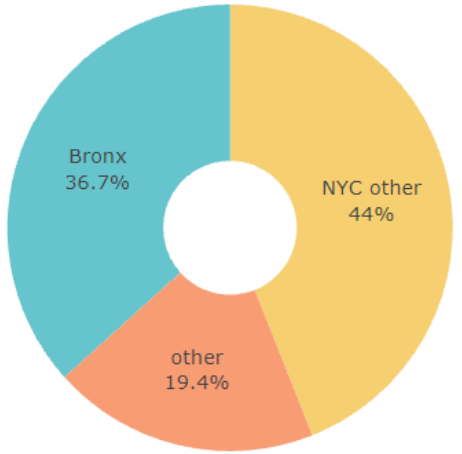
Map of Vaccinations by Zip Code in 2021



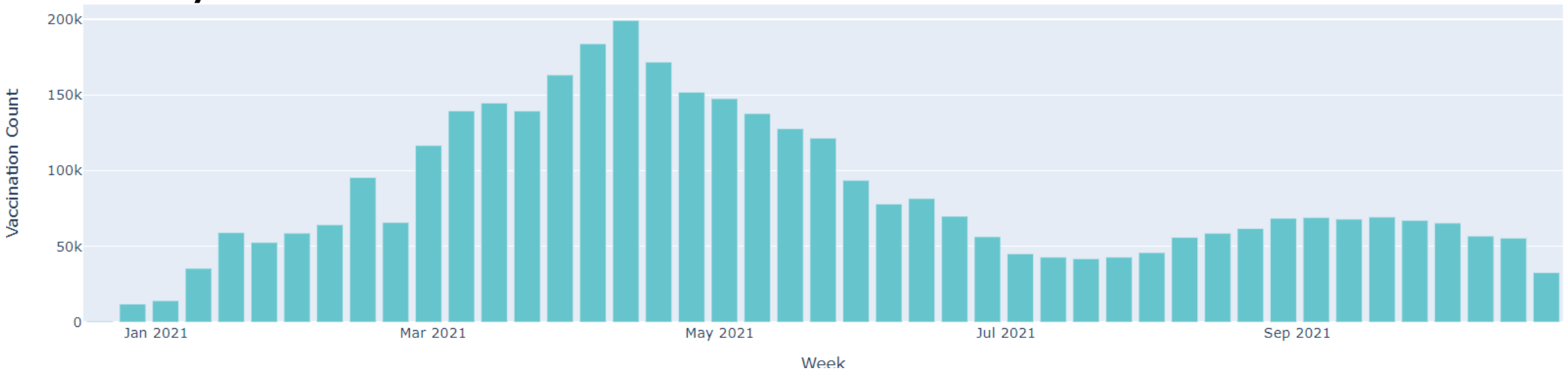
Vaccinations by Manufacturer - Bronx Only



Vaccinations by Region



Weekly Vaccinations for Entire MPI



Weekly Vaccinations - Bronx Only

Challenges

Challenge	Mitigation Strategy
No administration location in CIR data	Requested CIR to add this to query response
Patients with 6 or 8 doses reported	Probable matching issues; requested correction process to be created with CIR without success; we exclude these patients from reports
No visibility into CIR patient matching algorithm	When no match, we re-query with other demographics if they are on file
Immunization data had no "home" in our data storage and retrieval structures as it is a new data type for us	Worked with vendor to set up data storage logic and modify provider portal display to include vaccinations

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Case Study: Urban Health Plan

- Before receiving Bronx RHIO COVID-19 vaccination reports, UHP was only aware of vaccinations done at UHP
- The original process of UHP querying the CIR was onerous because vaccination records had to be queried manually in each patient's chart
- Bronx RHIO began conducting batch queries to the CIR on UHP's behalf, delivering a digest report of vaccinations that took place outside UHP
  - Reports incorporate State vaccination data as well
- The simplicity of a report format allowed for a smoother data entry process in patient charts
- With complete vaccination records in eCW, UHP was able to determine which patients were still unvaccinated or had yet to complete their vaccination series and prioritized them for vaccine education outreach

Program Activities in Progress

- Adding logic around booster shots to reports and alerts as guidelines are clarified by CDC/FDA
- Creating interactive data dashboards that will be available on our website to visualize vaccination progress with filters for race/ethnicity, age, co-morbidities, social determinants of health, etc.
- Enhanced vaccination reporting and alerting incorporating risk factors such as being immunocompromised, having certain co-morbidities, age, social determinants of health, etc.
- Monitoring of breakthrough infections and adverse reactions

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Post-Program Plans

- Use COVID-19 vaccination data, reporting, and alerting infrastructure as framework for future immunization data projects, including flu and childhood vaccination reporting
- Support current and future COVID-19 research and quality improvement projects using available vaccination, infection, and recovery data, especially projects focused on areas and populations disproportionately affected

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Thank You

QUESTIONS?

Expanded Immunization Sharing: Star HIE – HealtheLink

Stephen Gates, Sr.

Manager – Business Development

HEALTHeLINK

Amy Pease, RN, MA

The Chautauqua Center and

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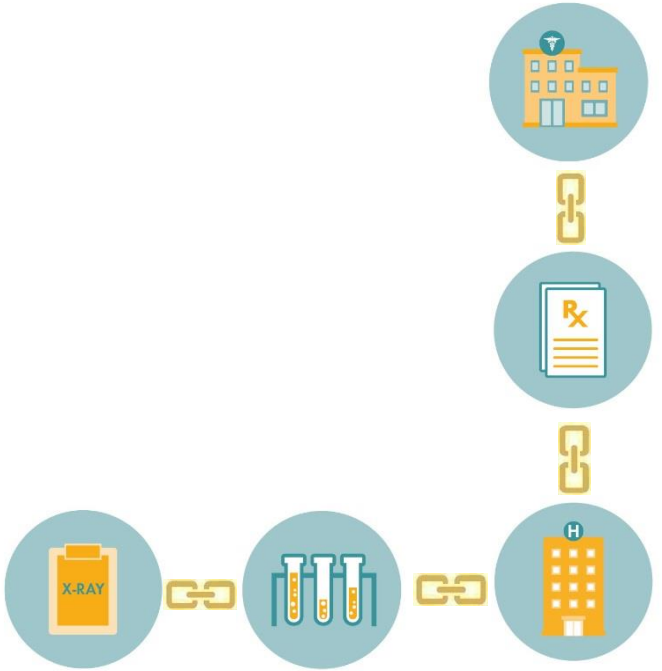


About HEALTHeLINK

- Support 8 western counties of New York
- Collaborative partnership since 2001
- Part of the SHIN-NY
- Stats:
  - 1.5M patient population
  - Over 900 participants
  - Over 300M results available
  - Over 1M results delivered monthly
  - Over 1M alert notifications sent monthly
  - Over 625K patient queries monthly
    - A query happens every 5 seconds

Program Activities

Activity 1: Evaluation of COVID-19 Immunization Status for Western New York Patients

- Identify patients with immunization
- Identify patients without second dose of immunization
- Identify high risk patients who had not received vaccine

Activity 2: Ongoing Monitoring of Patients with COVID-19 Immunization

- Work sessions with public health and community physicians to identify reporting needs

Activity 3: Notifications

- Notify our participants of patient's immunization status identified in activity 1

Accomplishments

- Sent more than 4.4M vaccine alerts YTD
- Worked with NYS DOH to pilot NYSIIS file in February and in March began sending alerts
- Assisted regional vaccine HUB by providing weekly reports with vaccine breakdown by age, race, and ethnicity by zip code to assist with distribution of vaccine to areas in need
- Responded to community request for herd immunity metrics
- Enabled vaccine alerts for participants that previously didn't have vaccine alerts (VA, FQHCs)

Challenges

- Data quality issues with NYSIIS file
  - Patient matching
  - Vaccine status/source/brand
  - Human error
- Wasn't an EHR priority to send vaccine alerts via FHIR

Post Program Plans

- Continue to send vaccine alerts to participants
- Continue to respond to local and state requests for vaccine information
- Continue to evolve and update processes as vaccine guidance progresses
- Continue to work towards more efficient methods of delivering alerts (interface to EHR)

Value of the data-TCC perspective

- Inbound file received
  - Historical
  - Daily
- High-risk patients registry generated from Azara
- Cross-referenced lists for outreach/assistance with scheduling
- Ongoing use with 3rd shots and boosters

Q&A

A moderator will now bring questions forward from the chat

Take a Quick Break

Please return in 5 minutes

Consumer Directed Data Exchange: Building an Ecosystem of Digital Trust for Consumers and Applications

Ryan Howells, MHA, PMP

CARIN Alliance

The CARIN Alliance:
Building an Ecosystem of Digital Trust for Consumers and Applications

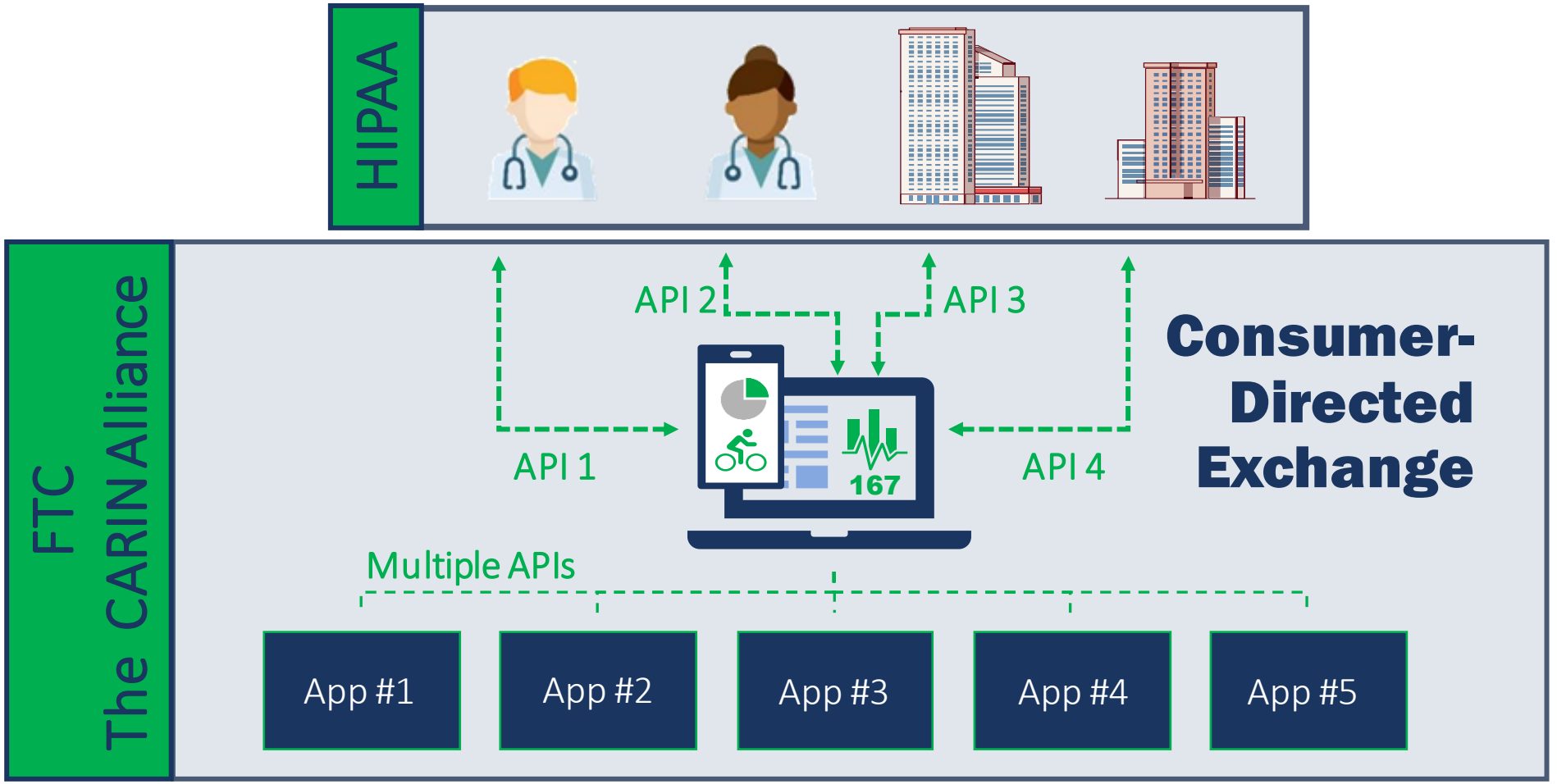
DirectTrust™

HL7® FHIR® ACCELERATOR

carin
Creating Access to Real-time Information Now through Consumer-Directed Exchange

LEAVITT PARTNERS

How will consumers aggregate and share data in the future?



The CARIN Alliance

Our Vision

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.

*Sample list of CARIN members. For a full list of the CARIN board and members go to: https://www.carinalliance.com/our-membership/carin-board-participants/

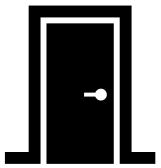
Consumer's new "digital front door" to health care

"The Key"

Digital Identity and Authentication for the Individual

What: Acceptance or creation of an IAL2 identity proofed digital credential

Solution: Identity and access management (IAM) solution

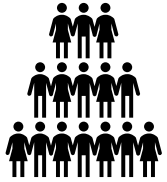


"The Door"

Standardized FHIR-based API data exchange

What: Standardized clinical, financial, administrative, and SDOH APIs

Solution: Development of an API Gateway



"Community of Problem Solvers"

B2C health and health care applications

What: Innovative applications solving a myriad of health care use cases

Solution: A development portal that includes an automated application registration process

"Your Family"

Individual consent-based data sharing framework for patients, members, and caregivers

What: Consumers consenting to when, where, and how they want to share their data to achieve their goals

Solution: An individual proactive, informed, and (ideally) federated consumer-directed, consent-based data sharing framework (As a start: CARIN's Code of Conduct and Trust Framework)

The Key:

Digital Identity and Authentication for the Individual

CMS / ONC / CARIN Digital Identity Summit – June 4th, 2019

Representative Attendee Organizations (30)

All Clear ID, AARP, American Association of Motor Vehicle Administrators (AAMVA), b.Well Connected Health, BCBSA, Boston Children's Hospital, Cambia Health Solutions, Capital One, CMS, Cerner, Coral Health, Direct Trust, Dr. First, EMR Direct, Epic, Humana, ID.me, IPRD/Gates Foundation, Kaiser Permanente, Kantara Initiative, Lush Group, My PatientLinks, New Jersey Health Information Exchange, Northwestern University, The Office of National Coordinator (ONC), The Pew Foundation, Regenstrief, Sage BioNetworks, Sequoia Project, Singular Key, Inc., United States Digital Service, Venable, VISA

Focused on 5 issues and developed the following solutions:

(1)**Identity** – NIST 800-63-3 (IAL2) for individual and GLEIF for organizational

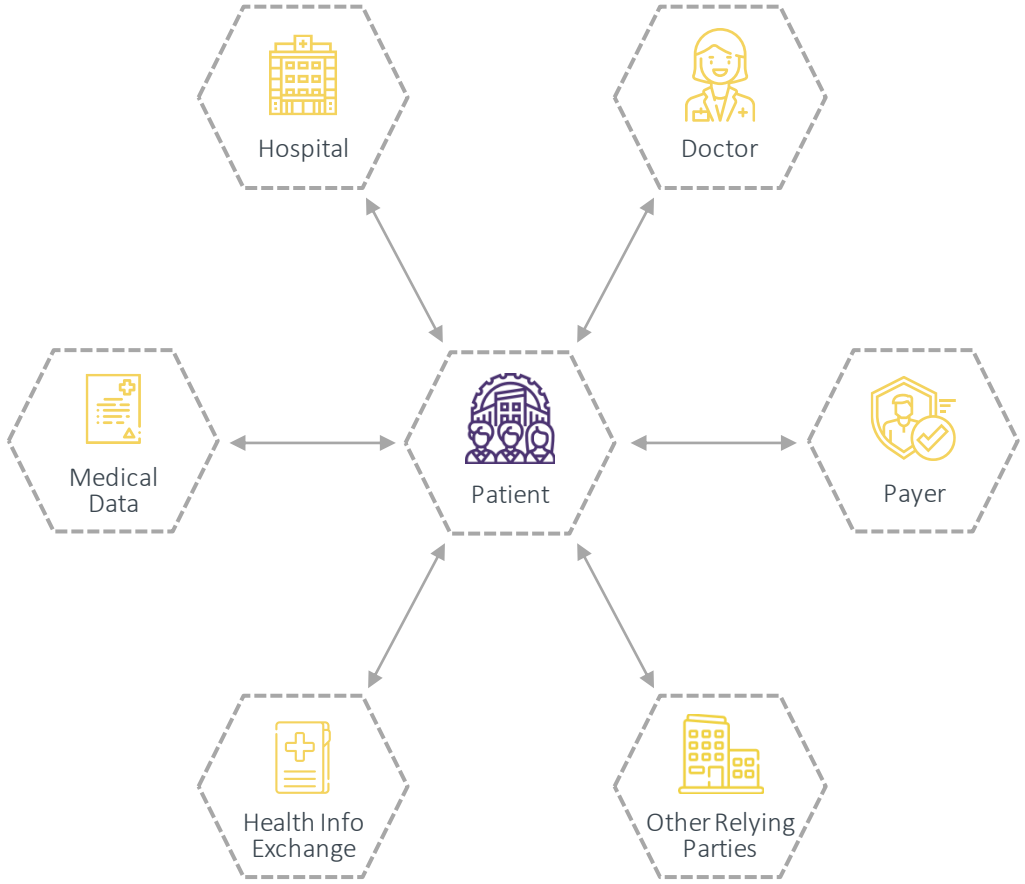
(2)**Authentication** – Multi-factor authentication / SMART / FIDO2 (AAL2)

(3)**Trust & federation** – Open contractual principles with private sector certification bodies tied together with UDAP.org

(4)**Consent** – Informed, proactive user consent

(5)**Matching** – Matching based on contractual trust principles and criteria

Federation and Trust
A Person-Centric Approach to Health Data

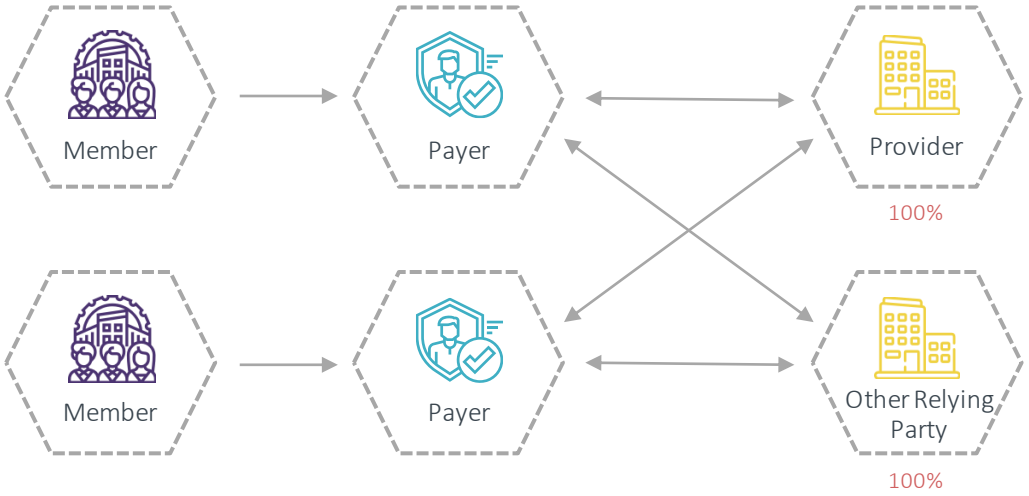


Federation and Trust
Have We Seen This Problem Before?

Federation and Trust
The Current State of Identity

Creating Access to Real-time Information Now through Consumer-Directed Exchange

Current State

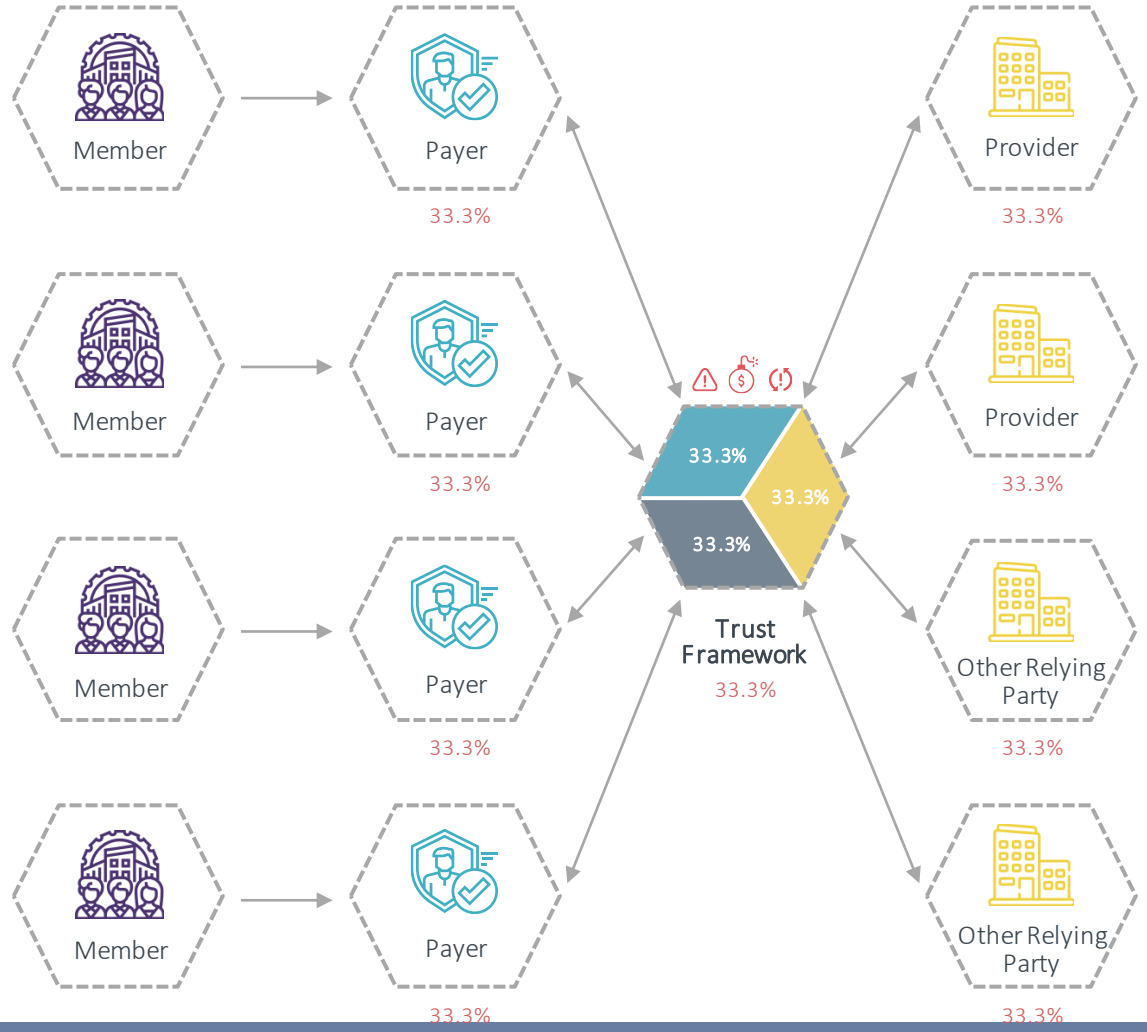


Risk
Unmanaged or unknown risk that fluctuates between each identity provider

Liability
Unmanaged or unknown legal liability unless defined in bi-lateral agreements with each identity provider

Technical Interoperability
Technical interoperability achieved by working with each external entity independently

Future State



Federation and Trust
Federating Trust is What a Trust Framework Does

Current Approach

- Number of federations increases quadratically for vendors and buyers
- Most security auditors don't know how to audit identity systems
- Establishing legal and liability agreements with all entities is very expensive for both parties
- Lack of global governance leads to inconsistent identity assurance between companies
- Evaluating annual audits of 10s or 100s of identity providers is not viable with limited resources

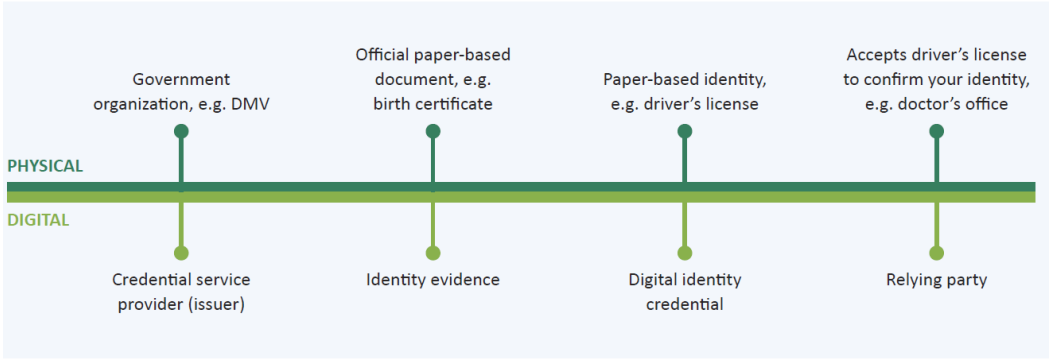
Trust Framework Approach

- Federate Trust rather than identities
- Enables participants to buy products that support standards in identity and cryptography
- One industry-led governance body to aggregate and manage federations between organizations
- Require vendors to procure or issue their own credentials when engaging in business with you that you can rely on
- Support all identity use cases to include authentication, digital signatures, encryption and IoT for your entire supply chain
- Consolidate liability, warranties indemnification and other legal matters across all vendor identity credentials

Federation and Trust
Digital Identity and Federation in Health Care

IDENTITY CREDENTIALS IN PHYSICAL WORLD VS. DIGITAL WORLD

To illustrate the principle of a "person-centric" identity in the digital world, we can describe it in terms of the process in the physical world now. In today's physical world, an individual who wants to establish a digital identity credential for a specific authorized purpose will go to a "trusted source" – a credentialing service provider (issuer), which is likely a state or federal government agency – to prove they are who they say they are. In the case of a driver's license, the individual will go to their state department of motor vehicles who has the authority to issue a driver's license (paper-based identifier). The state requests that the individual prove they are who they say they are using paper-based document from other third parties who have validated identifying information about the individual; for example, birth certificates, passports, mortgage papers, utility bills, etc. (identity evidence). After those documents have been validated, the individual receives a physical driver's license (digital identity credential) that can be used as a single, trusted identity credential anywhere in the physical world when someone is required to prove their identity (relying party). The challenge is that sharing everything on your driver's license for every use case when you are sharing your identity with a relying party often results in oversharing of information. Creating a digital identity credential can help in avoiding oversharing by allowing individuals to only share the specific identity evidence needed to fulfill a specific use case.



It is possible to replicate this process in the digital world to create a digital identity credential, but there are challenges. Digital identity is a relatively new concept, especially in health care. Organizations (relying parties) are hesitant to trust a digital identity credential issued by a credentialing service provider they do not have intimate experience or knowledge of in the same way that they trust a driver's license issued by a DMV in the physical world.[5] There are trust framework organizations which will certify that the digital identity credential was issued by a credentialing service provider that follows reliable, trusted, and agreed-upon processes; this creates the conditions for digital trust across organizations. In an ideal world, we could use that single digital credential, no matter which trust framework certified the credentialing service provider, to access our health information from different health care organizations, including health plans, providers, and applications. Currently, there are several different trust frameworks that do not have equivalency in the market today, and this restricts the portability of a digital identity credential.

OpenID® + carin

Creating Access to Real-time Information Now through Consumer-Directed Exchange

FEDERATED TRUST AGREEMENT: AN OVERVIEW

PURPOSE

Within a trusted federated digital identity ecosystem, there are identity providers or issuers which provide organizational or individual identity products and services. Trust framework organizations are third-party organizations who certify the legal, policy, and technical aspects of the products being provided by the identity providers. A relying party is any stakeholder which needs a trusted identity to exchange data. The CARIN Alliance seeks to develop a digital federated trust agreement which outlines the technical, policy, legal and certification guidelines necessary for equivalency to link each of the trust framework organizations together. The benefit of this approach is that a relying party, which needs a verified identity to authorize access to health data, can trust and rely on an identity credential provided by any identity provider who has been certified by a trust framework organization who participates in the federated trust agreement.

The Federated Trust Agreement will address standardization and best practices related to security, data protection, authentication, identity proofing, privacy, user experience, interoperability and the conformance regime to ensure these specifications and policy obligations are certified and enforced by the trust framework organization. While our paper addresses a specific approach for US health care, there could be multiple schemes and technologies associated with a specific trust framework.

TRUSTED FEDERATED IDENTITY ECOSYSTEM

Digital Federated Trust Agreement: Content Oversight Board	Contractual language that links each of the trust framework organizations together and outlines the standards, policies, and contractual terms for how relying parties can trust ID providers across trust framework; the content board will oversee the content for the federated trust agreement.
Trust Framework Organizations (Certifiers)	Third-party organizations who certify the legal, policy, and technical aspects of the products being provided by identity providers. Organizations such as DirectTrust, DIACC, FIDO, Kantara, SAFE Identity and others.
Identity Providers (Issuers)	Identity providers or issuers who provide organizational or individual identity products and services. Organizations such as ID.me, Okta, ForgeRock, AllClearID, or anyone else issuing an IAL2 identity-proofed credential. These identity providers may use technologies and standards, such as Open ID Connect/APIs, PKI, DIDs, Verifiable Credentials, etc.
RELYING PARTIES	Anyone who wants to accept an IAL2 certified credential from an identity provider who has been certified by a trust framework organization

carin FOCUS

https://www.carinalliance.com/our-work/digitalidentity/

Federation and Trust
Our approach to create a volunteer Trusted Federated Identity Ecosystem

Creating Access to Real-time Information Now through Consumer-Directed Exchange

Digital Federated Trust Agreement : Content Oversight Board

Contractual language that links each of the trust framework organizations together and outlines the standards, policies, conformance, and contractual terms for how relying parties can trust ID providers across trust frameworks; the content board will oversee the content for the federated trust agreement

Trust Framework organizations (Certifiers)

Third-party organizations who certify the legal, policy, and technical aspects of the products being provided by identity and authentication providers. Organizations such as: DirectTrust, Kantara, SAFE Identity, and others

Identity Providers (Issuers)

Identity & authentication providers or issuers who provide organizational or individual identity products, services, & credentials at an NIST 800-63-3 IAL2 / AAL2 level or higher. These identity providers (e.g., Login.gov, ID.me, etc.) may use technologies such as Open ID Connect/APIs or PKI.

Creating Access to Real-time Information Now through Consumer-Directed Exchange

Focus is on policy equivalency across trust frameworks

Relying Parties

Anyone who wants to accept an IAL2 certified credential from an identity provider who has been certified by a trust framework organization

To access the Digital ID and Federation whitepaper, go to:
CARINAlliance.com and select Our Work → Digital Identity → Download our Digital Identity and Federation White Paper

NextGen XMS – Capabilities

U.S. Department of Health and Human Services

NextGen XMS is a scalable, cloud-based solution that allows OpDivs to focus on their mission; and takes into consideration:

- Alignment with Digital Identity guidelines, ICAM and Cloud modernization efforts
- Security and compliance with federal standards (NIST, OMB, HHS EPLC requirements, etc.)
- Identity and Access Governance and delegated administration model
- Enterprise service that can secure access to external HHS applications
- Centralized platform that is flexible to integrate with third-party providers and services

Capabilities & Benefits

Secure Access:	*Allows external users to access protected applications using credentials issued by the General Services Administration's (GSA's) Login.gov or via other agency's PIV/CAC*
NIST 800-63-3 Compliance:	*IAL1, IAL2, and IAL3, and AAL2 and AAL3*
Identity Proofing/Delegated Proofing:	*Remote ID proofing using Login.gov; and delegated proofing for users that affiliate with an organization that's managed within NextGen XMS.*
Organization Affiliation:	*Ability to create organizations and manage affiliations to those organizations within NextGen XMS*
Access Requests/Approvals:	*Configurable access request framework for an application*
Organization Relationship Management:	*Ability to create organizations and manage affiliations to those organizations*
Accredited Platform and Helpdesk:	*NextGen ATO in place which includes Login.gov; no impact to integrated application's ATO, only ISA/MOU required*

Q4 2021 / Q1 2022 Digital Identity Federation Pilot

How to prepare:

Applications: Ensure you are partnered with an IdP/CSP that issues IAL2 digital credentials (e.g., ID.me, Login.gov, Mastercard, Lexis Nexis, ZenKey, Experian, etc.)

Health Plans: Will you be an IdP or relying party?

Providers: Do you have a stand-alone IdP that is separate from your core EHR system? If not, can you get one?

IdPs/CSPs: Get certified with Kantara (API/OIDC) or DirectTrust/SAFE Identity (PKI)

Relying Parties: What questions do you need to get answered internally before you can participate in the pilot?

Trust Framework: Participate on our tiger team

**HHS XMS is an identity federation broker tool that allows for individuals to choose to log in by choosing from multiple CSPs that have been certified by a trust framework organization. It will feature prominently in the pilot.

How can we pull the digital identity components together?

July 1st – Patient Access APIs

Requirement: Member needs to be provisioned by the primary data holder

- Member portal-based: Member is provisioned by the data holder's *portal* and the app uses the UN/PW via SMART
- **PREFERRED**: Member IdP-based: Member is provisioned by the data holder's *NIST 800-63 IAL2 IdP that's been certified by an approved trust framework organization* and the app uses the UN/PW via SMART

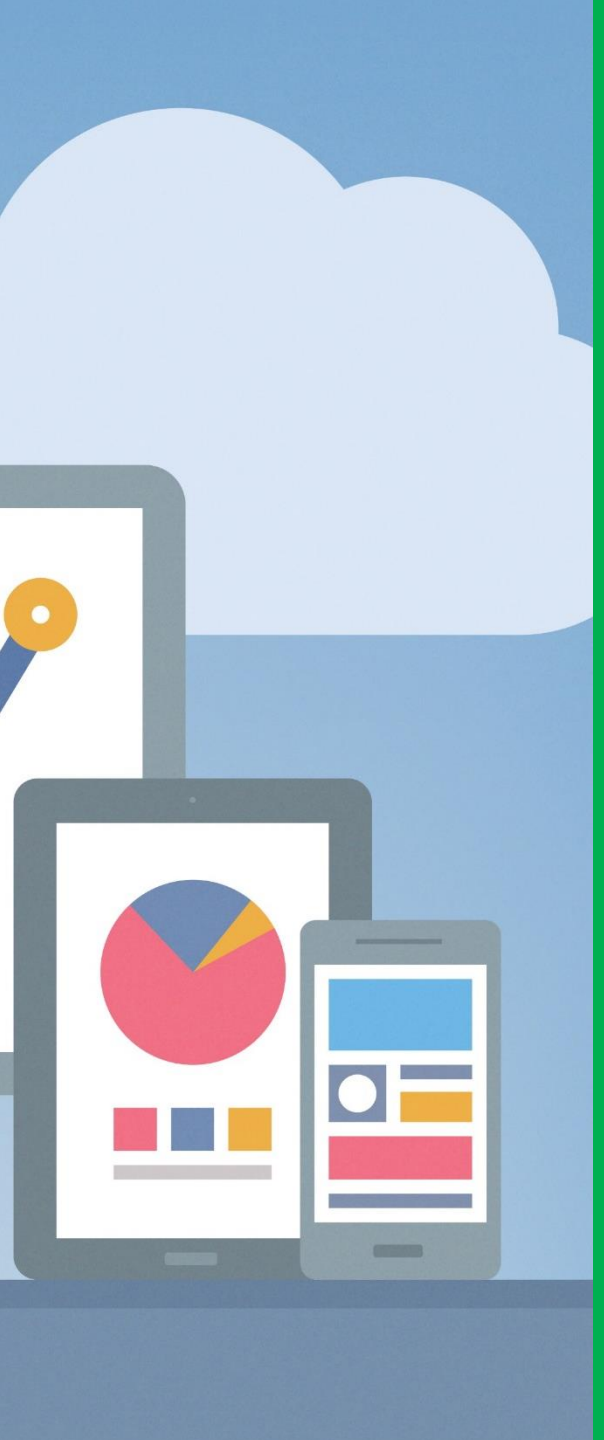
January 1st – Payer to Payer APIs

Requirement: Member needs to be provisioned by the primary data holder *and* the secondary data holder needs to accept the primary data holder's user provisioning event including an indication of the member's consent *and* the primary data holder's *organizational identity* provisioning event

- Member Portal-based: Member is provisioned by the data holder's *portal* and the app uses the UN/PW via SMART
- **PREFERRED:** Member IdP-based: Member is provisioned by the data holder's *NIST 800-63 IAL2 IdP that's been certified by an approved trust framework organization* and the app uses the UN/PW via SMART
- Organizational Identity: Organization gets a Legal Entity Identifier (LEI) from a Legal Operating Unit (LOU) that is part of GLEIF or use Open Corporates.
- Digital Federation Agreement: CARIN's tiger team work to contractually provide equivalency across trust framework organizations so IdPs and relying parties can establish trust across the ecosystem

Community of Problem Solvers:

B2C health and health care applications



Key Principles in the Code of Conduct

https://www.carinalliance.com/our-work/trust-framework-and-code-of-conduct/

I. Informed Choice
   - **Well informed** consumers who make an **intentional decision** is the best way for consumers to direct their health information

II. Application Attestation
   - Applications should attest to and be held accountable for a set of **structured, consistent, and reportable** responses regarding how they plan on using consumer's data

III. Purpose Specification
   - Consumers should have the ability to **specify the purposes** in which their data can be used by an application

New CARIN Alliance Application Registration Guide

https://tinyurl.com/24c9rcs9 or the www.carinalliance.com home page

Creating Access to Real-time Information Now through Consumer-Directed Exchange

Provides a series of best practice recommendation for how applications register with data holders that are centered around 5 specific use cases:

(1) Easily search for and find CMS-regulated payers' respective developer portals, which provide publicly accessible links to all resources needed for them to understand and develop software to interact with the Rule's required API endpoints (Section 5.1).

(2) Testing the required APIs in a sandbox environment (Section 5.2).

(3) Registering with a payer to establish connections with the required APIs in a manner that complies with the Rule (Section 5.3).

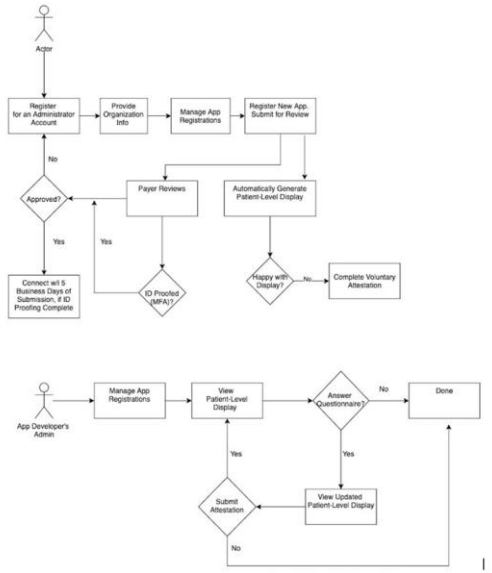
(4) Knowing in advance the information a payer will share with members about the developer's application privacy and security practices including template questions related to the CARIN code of conduct (Section 5.4).

(5) Understanding in advance the payers' policies regarding session and refresh tokens, and other service level expectations (Section 5.5).

Table 5.3.1 - App Registration Workflow - Information Requested, and Verification Methods

Information Requested	Verification Methods
About the Developer	
What's the legal name for the developer requesting an API connection?	1. Check corporate information against public records. o Most jurisdictions support business entity search features through their respective corporation departments. 2. Use public or subscription-based business look-up services to validate legal existence. 3. Validate the developer's provided email address and phone number. 4. Use a recognized third-party legal entity verification service. The CARIN Alliance recommends using the Global Legal Entity Identifier Foundation (GLEIF) which is used and accepted globally across multiple countries, regulators, and industries. (https://www.gleif.org/en/about-lei/introducing-the-legal-entity-identifier-lei).
What type of legal entity is the requestor (e.g. corporation, partnership, LLC, sole proprietor)?	
Under the laws of what jurisdiction is the entity organized?	
What is the name, job title, phone number and email address for the registrant's primary business point of contact?	
What is the name, job title, phone number and email address for the registrant's primary technical/developer point of contact?	
What is a physical address for the entity (not a P.O. box)? (home address for a sole proprietor)	
What is the URL for the entity's corporate website?	
About the Application	
What is the name of the application?	1. Validate information against provid 2. Check domains and IP addresses f URL against blacklists of malicious with undesirable and/or illegal acti o There are both commercia services available, o An example of one com Anomali, https://www.anc intelligence-feeds.
If different from the developer, what's the legal name for the owner of the application, according to its terms of service and privacy policy?	
Redirect URLs	
As applicable, what is the application's: • Homepage URL? • iOS store link? • Android link? • Legal Terms of Service URL? • Privacy Policy URL?	

Figure 5.3 - Process Diagram - Registration for Production Environment



4. Transparency –

   a. The Organization includes a publicly accessible link to the Application's Privacy Policy on its website and through the Application.

      ☐ Yes

      ☐ No

   b. The Privacy Policy covers collection, use, and disclosure of Personal Data.

      ☐ Yes

      ☐ No

   c. The Privacy Policy covers collection, use, and disclosure of De-identified Information.

      ☐ Yes

      ☐ No

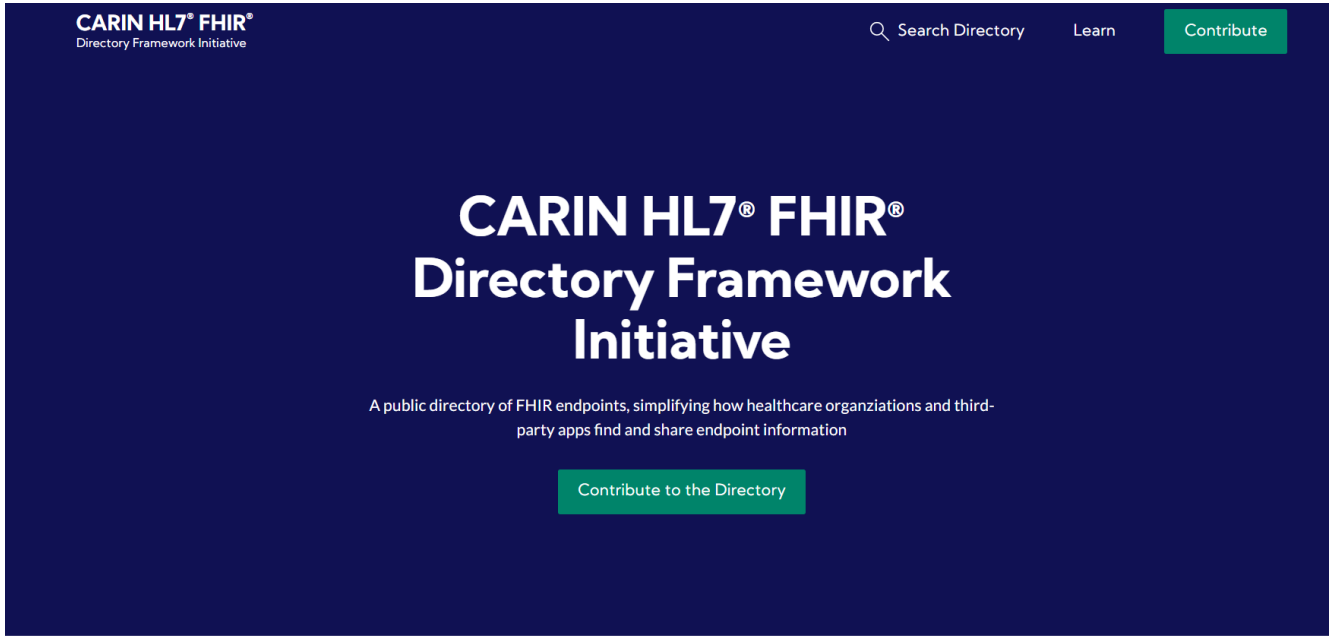
   d. The Organization provides updates when Privacy Policies have changed, and provides individuals with the option to re-affirm consent or to withdraw consent.

      ☐ Yes

New CARIN Alliance HL7® FHIR® Directory Framework Initiative

https://carinfhirdirectory.com/

- There will be no single, public sector, national payer/provider endpoint directory any time soon
- Multiple private sector options (e.g., CAQH, Change Healthcare, CARIN, etc.)
- CARIN applications requested to provide their feedback on best practices and lessons learned
- CARIN payers requested a crowdsourced list of endpoints that could be published in GitHub for anyone to freely access for P2P



Why Contribute?

Be Transparent

Payers must make their API endpoints "publicly accessible" by posting them directly on the payer's website or via publicly accessible hyperlink(s). The community asked for help and the CARIN Alliance answered with CARIN HL7® FHIR® Directory Framework Initiative.

Don't be a Blocker

For Payer to Payer Data Exchange, the payer community needs to know how to engage with with one another. A public directory with each payer's conformance statement helps to alleviate the costs and burdens of compliance on payers subject to CMS Interoperability and Patient Access Final Rule.

Make it Easy

Providing information in a public directory that is accessible by payers and third-party application developers reduces the cost and burn on payer organizations to provide the information to each payer or third-party application individually. We also hope that other private-sector partners who are developing endpoint directories can use these best practices in their solution offerings.

New CARIN Alliance Code of Conduct UX Guide https://carinuxguide.arcwebtech.com

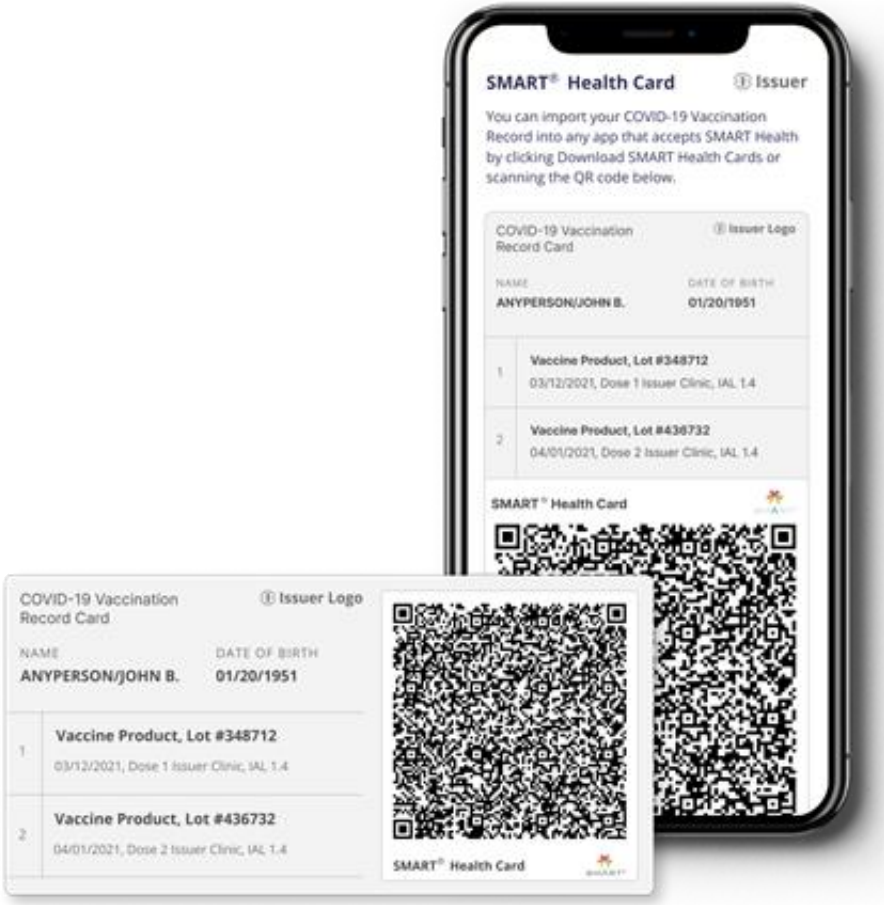
- Multiple consumer-facing applications listed on MyHealthApplication.com are integrating and following the CARIN Code of Conduct
- We need a user-friendly way to display the privacy terms and conditions and application terms of use related to the CARIN Code of Conduct to the consumer.
- Arcweb Technologies, a leader in user experience and design, has co-developed with us the CARIN Alliance Code of Conduct UX guide

About SMART Health Cards

What is a SMART Health Card?

A SMART Health Card is a paper or digital version of an individual's clinical information, such as vaccination history or test results. They allow individuals to keep a copy of their records on hand and easily share this information with others if they choose.

When scanned, a verifier can easily authenticate the information on the card, making SMART Health Cards **a safe and reliable way to demonstrate health status.**



Sample SMART Health Card (paper and digital)

The lifecycle of a SMART Health Card

There are several parties involved in the transfer of the information contained in a SMART Health Card, from its origin to its use in realworld situations where trustworthy, secure, verifiable clinical information is needed.

Issuers

The **Issuer** is the party that generates the SMART Health Card

SMART Health Card (Digital or Paper)

The issuer provides a digital or paper copy of vaccination information to an **Individual**

Any Digital Wallet (e.g. Apple Health / CommonHealth)

The **Individual** keeps their SMART Health Card where they wish, and shares when they choose to

Verifiers

The **Verifier** receives and verifies information was generated by a trusted issuer

A **Trust Framework** is a registry of known Issuers a Verifier may check to ensure information is trustworthy.

What is the global trust framework we are building?

Creating Access to Real-time Information Now through Consumer-Directed Exchange

What is it?

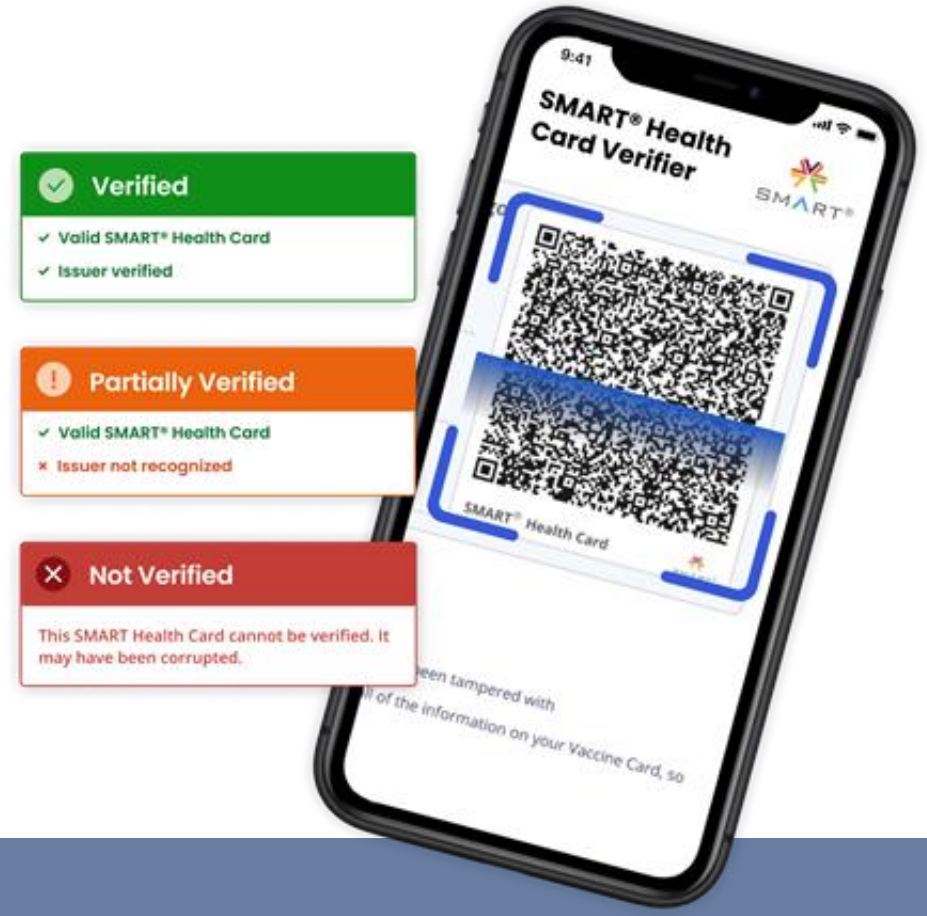
The independent criteria being used to provide the red, green, orange/yellow check marks for verifiers.

An example of those rules of the road:

- Need to define both primary and secondary issuers in a global trust registry
- Outlines the process for how we will identity proof individuals and organizations
- How organizations can manually and electronically verify SMART Health Cards (there is a verifier app)
- How verifiers will match individuals across systems
- What are the public health validation rules required by country

Next Steps

- Review the draft trust framework with targeted countries to gather feedback (U.K., Iceland, E.U., Caribbean)



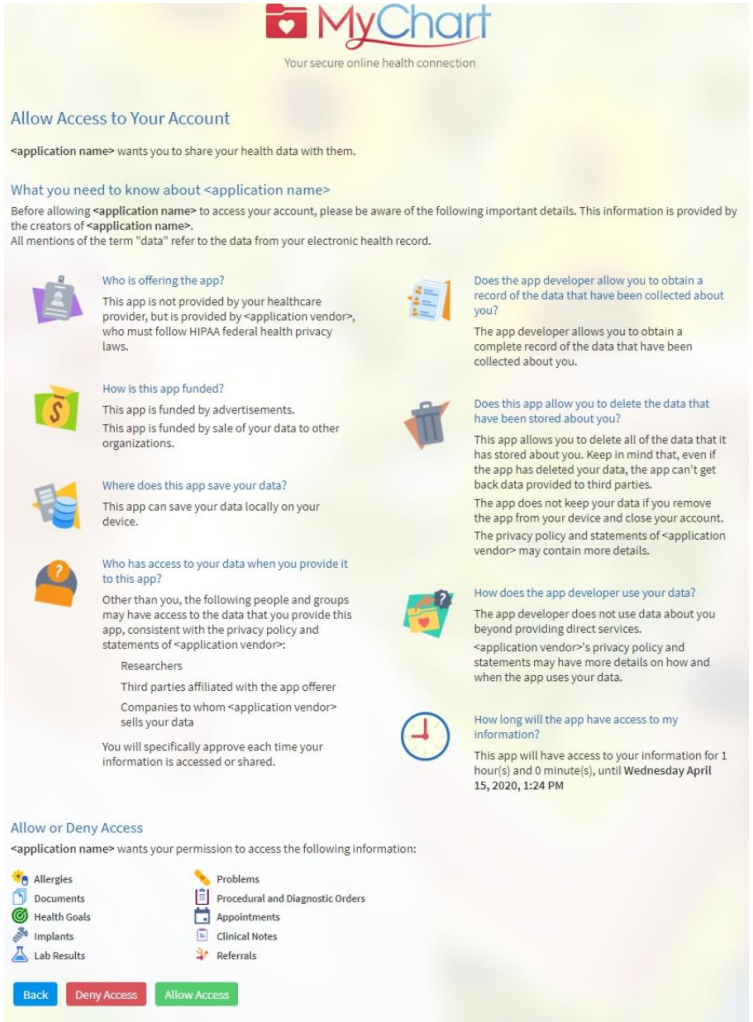
SMART Health Card Verifier App

Your Family:

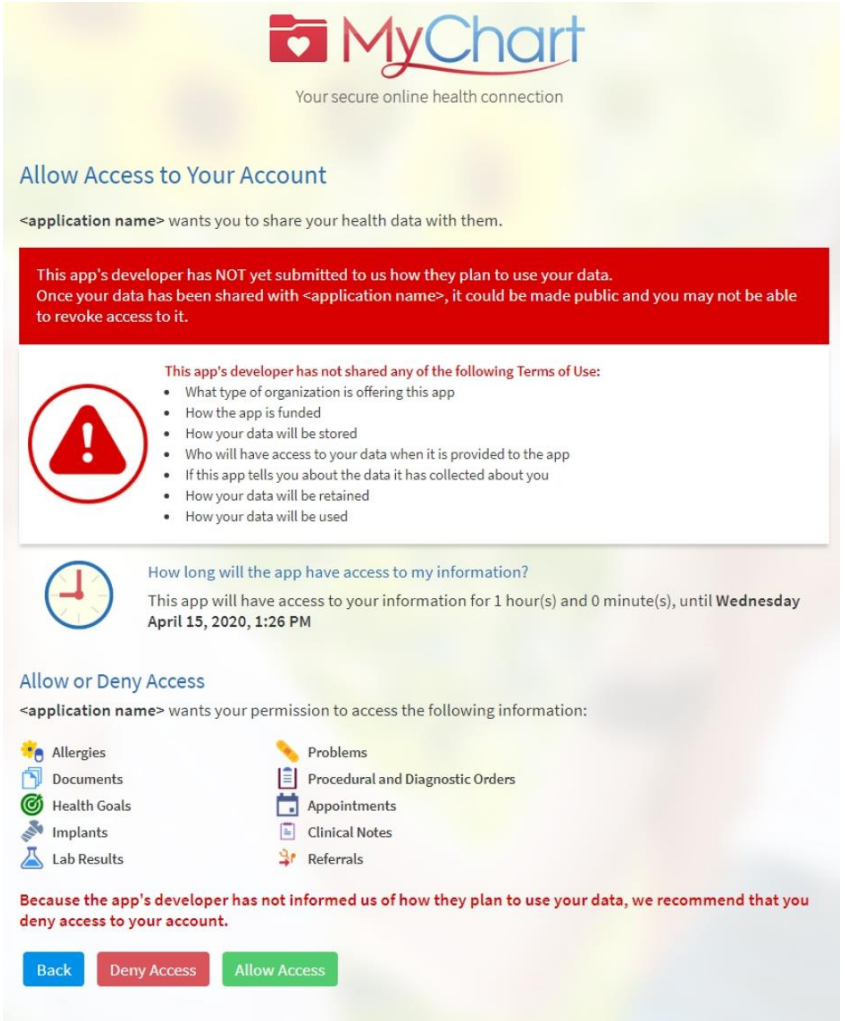
Individual consent-based data sharing framework

Today's Consent-based Data Sharing Framework

"Known" applications who have followed the CARIN Code of Conduct Framework



"Unknown" applications who have not followed the CARIN Code of Conduct



Industry, CMS, & VHA Adoption of the CARIN Code of Conduct

CAMBIA HEALTH SOLUTIONS

UPMC HEALTH PLAN

CVS Health

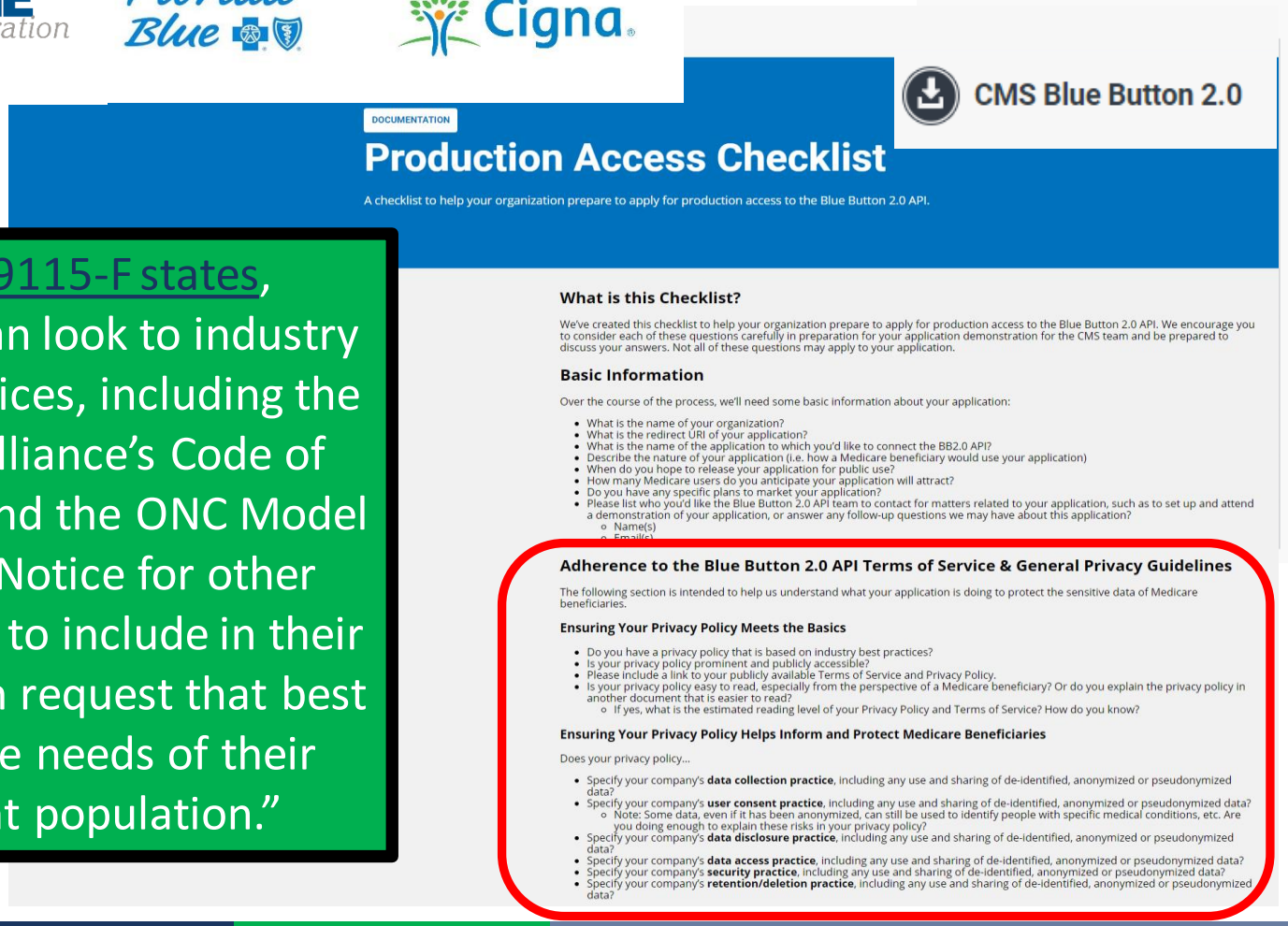
CENTENE Corporation

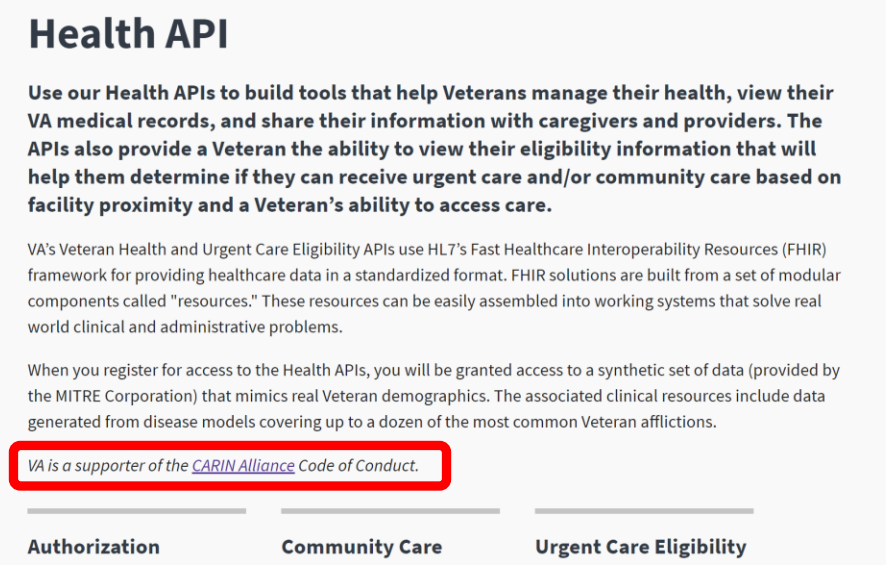
Florida Blue

Cigna

HL7 FHIR ACCELERATOR

carin — Creating Access to Real-time Information Now through Consumer-Directed Exchange





CMS 9115-F states,

"Payers can look to industry best practices, including the CARIN Alliance's Code of Conduct and the ONC Model Privacy Notice for other provisions to include in their attestation request that best meet the needs of their patient population."

carequality

https://carequality.org/consumer-directed-exchange/

- MyHealthApplication.com
- Code of Conduct adoption
- Federated Trust Agreement

MyHealthApplication.com and Third-party certification

Application Gallery

1upHealth Patient App
1upHealth

CARIN Code of Conduct

At 1upHealth, we believe that you should be in control
choose how much data to share and where you want to

b.well Connected Health
b.well Connected Health

CARIN Code of Conduct

b.well enables the digital transformation in healthcare t
We work with healthcare organizations as the middlewa
aggregation, consolidating disparate data and point sol
one seamless experience to consumers.

Buzz Secure Medical Messenger
Skyscape

CARIN Code of Conduct

Buzz is a HIPAA-secure communications platform for healthcare providers &
It Supports live video, texts, calls, audio, images reports.

Ciitizen
Ciitizen

CARIN Code of Conduct

Ciitizen is an online platform for patients - beginning with cancer patients - to collect and share their records digitally, free of charge.

CommonHealth
The Commons Project Foundation

CARIN Code of Conduct

CommonHealth helps people collect and manage their personal health data and share it with the health services, organizations and apps they trust.

My Health Application — Select an App

Humetrix

iBlueButton

Go to App

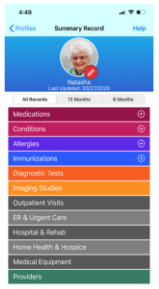
iBlueButton securely aggregates Medicare claim, VA and EHRs with AI powered analytics for individualized care guidelines.

Affiliations
CARIN Code of Conduct

Platforms
iOS
Android

Contact
Website
Contact Email

Developer Links
Privacy Policy
Terms of Service
Signed Code of Conduct



DocuSign Envelope ID: 197C38A9-8EA6-4424-9892-14ACC2C28580

We will:

a) Inform users about their personal data disclosure choices and the consequences of those choices including the risks, benefits, and limitations of data disclosure by providing educational materials ourselves or pointing to appropriate third-party resources.

ATTESTED BY:

Company	HUMETRIX
Chief Executive Officer (Print)	Bettina Experton
Chief Executive Officer (Signature)	DocuSigned by: Bettina Experton 9535DDA6CC0C4E2...
Date	November 10, 2020

Attestation to the CARIN Code of Conduct now includes **signed versions of the code of conduct** by the application's senior executive

Certification Progress

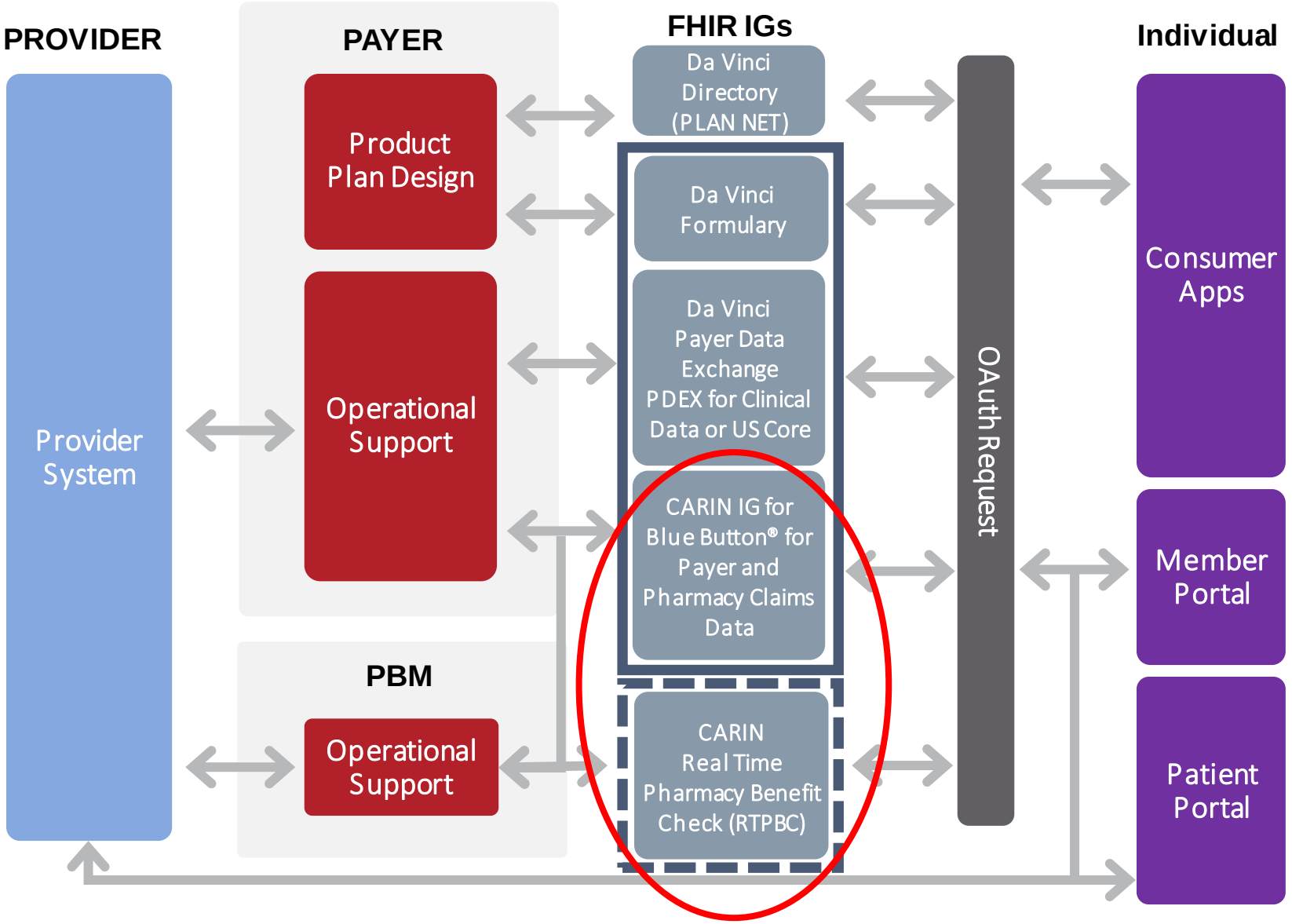
EHNAC CERTIFIED TDRAAP-BASIC

EHNAC ACCREDITED TDRAAP-COMPREHENSIVE

Application **certification programs** have launched which includes attestation and independent certification options

The Door:
Standardized FHIR-based API data exchange

CMS final rule: FHIR Implementation Guide (IG) Options



FHIR Accelerator Commentary

1. Goal is to reduce burden on payers, providers, vendors and patients to meet 1/1/21 req, excludes 1/1/22 requirements
2. There is no specific CMS requirement to use any HL7 Implementation Guide
3. FHIR Community is working collaboratively to ensure the specific guide meets CMS final rule
4. All guides are Draft Standards for Trial Use (DSTU) or moving towards a published version of STU1

Legend

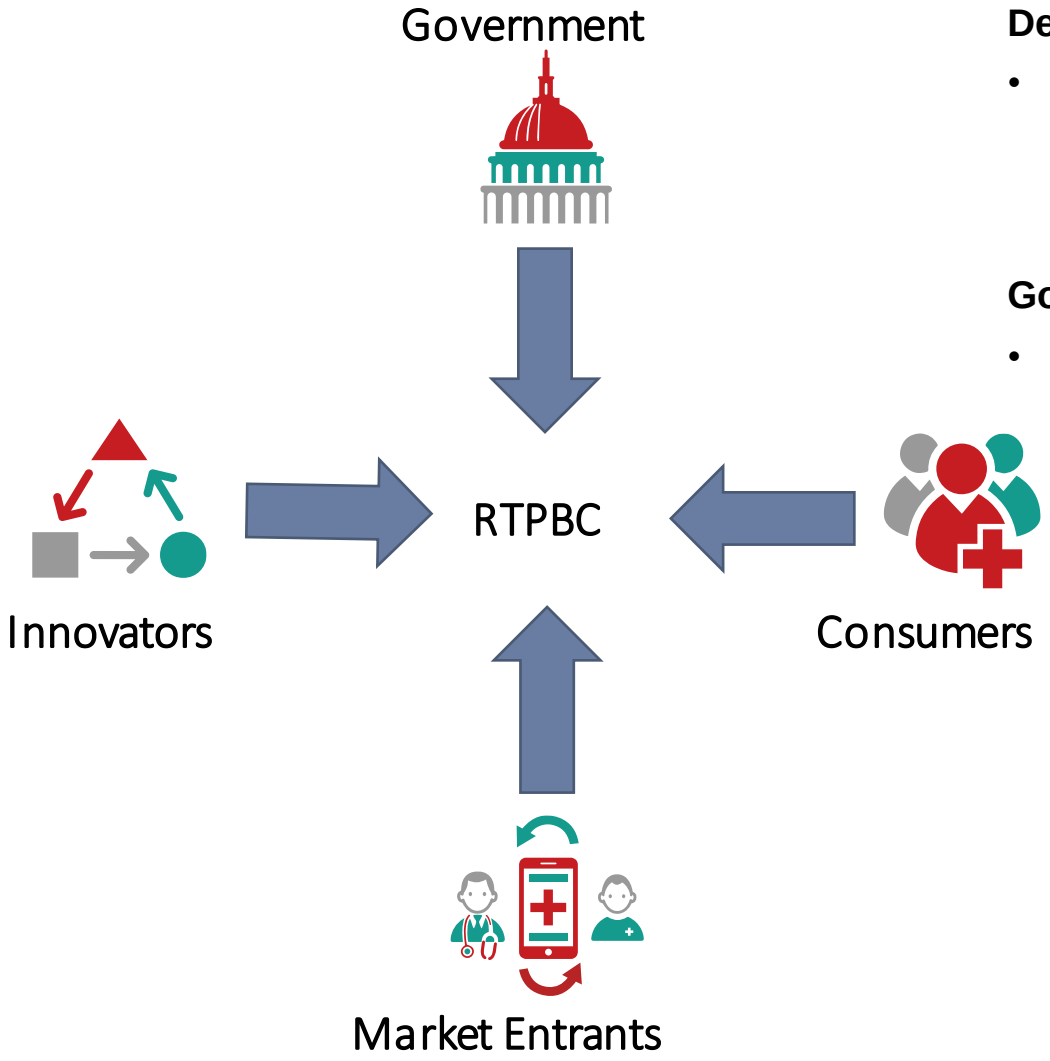
CMS Patient Access API for 2021

Opportunity to expand CMS Patient Access API for 2022

CARIN HL7® FHIR® Implementation Guides

Implementation Guide	Purpose	Latest Updates	IG Page
CARIN IG for Blue Button® STU1 and STU2 (Health Plan WG)	This implementation guide describes the CARIN for Blue Button® Framework and Common Payer Consumer Data Set (CPCDS), providing a set of resources that payers can display to consumers via a FHIR API to meet part of the CMS requirements related to the Patient Access API.	STU1 published in November 2020. Minor technical corrections were published in early July 2021 as STU1.1.0. We will ballot STU2 in January 2022. Publication in Q1/Q2 2022. At the September HL7 Connectathon and November CARIN testing event a number of clients and servers successfully connected and exchanged the oral and vision types for the first time. We will also test at the January HL7 Connectathon.	http://hl7.org/fhir/us/carin-bb/
CARIN IG for Digital Insurance Card STU1 (Health Plan WG)	This guide will develop artifacts (FHIR implementation guides, code mappings, reference implementations, etc) to enable the digital exchange and digital rendering of the elements found on a person's physical insurance card. The primary use case is to support insurance members who wish to retrieve their proof of insurance coverage digitally via a consumer-facing application. Images, barcodes, and QR codes from the physical card will be considered as optional fields for representation within FHIR, but these elements will be optional and up to the implementer to decide whether they want to provide them. The scope of this IG does NOT address eligibility checks between health providers and the insurance company.	The draft IG is now live. Ballot scheduled for January 2022. Publication in Q1/Q2 2022. Implementers also successfully tested at the November CARIN testing event. We will also test at the January HL7 Connectathon.	https://build.fhir.org/ig/HL7/carin-digital-insurance-card/
CARIN IG for Consumer-facing Real-time Pharmacy Benefit Check STU1 (RTPBC WG)	Provide a patient with real-time pharmacy information associated with their benefit and formulary information, out of pocket costs, therapeutic alternatives, and cash price options.	Published the IG in August 2020. Will be testing with the 5 major PBMs in Q1 2022 after they've built out their support for FHIR by 7/1.	http://hl7.org/fhir/us/carin-rtpbc/

Consumer-facing Real-time Pharmacy Benefit Check



Definition

- Provide consumers with access to their formulary and benefit information, estimated out of pocket costs, therapeutic alternatives, and cash price in real-time after a provider has prescribed a medication

Government

- One of few policy agenda items with bipartisan support.
  - Presidential Executive Orders and Drug Pricing Blueprint
  - **Electronic B2B Real-time Benefit Tool or "RTBT"**
    - Addressed in CMS Part D Drug Pricing Final Rule in May 2019 (CMS-4180-F)
    - Required for Part D plans by January 2023
  - **Transparency in Coverage Final Rule (CMS-9915-F) October 29, 2020**
    - "To that end, the final rules require plans and issuers to disclose in element (i), an individual's out-of-pocket cost liability for prescription drugs, and in element (iii), the negotiated rate of the drug."
    - Effective January 1, 2022
    - You can use the Consumer-facing real-time pharmacy benefit check API to be in compliance with this rule

Published HL7® FHIR® STU1 version: https://build.fhir.org/ig/HL7/carin-rtpbc/index.html

Questions

Presenter and Contact Information

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Continue the Conversation

The second part of this virtual workshop is taking place tomorrow **Wednesday, December 8th from 2:00 – 4:00 pm**

We hope to see you then!

Please share your feedback using the survey link in the chat, the QR code below, or the link in the follow up email!

Thank you for joining us today!