## Welcome, Anti-trust Reminder, and Agenda

<table>
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<th>Topic</th>
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| Welcome, Anti-Trust Reminder, and New Members Admitted  
  Dave Lee, Leavitt Partners | 11:30am – 11:35am ET |
| Leadership Perspective  
  Aneesh Chopra, Care Journey | 11:35am – 11:45am ET |
| Patient and Caregiver Perspective  
  Liz Salmi, Open Notes and Patient Informatician | 11:45am – 11:55am ET |
| **Topic #1 – CMS Patient Access API**  
  *CARIN Blue Button IG standard and May HL7® connectathon update  
  Patient Access API = CARIN CPCDS (Claims Data) + USCDI Core R4 (Clinical Data)  
  Health plan and developer implementation feedback* | 11:55am – 12:45pm ET |
| **Topic #2 – COVID-19: Consumer Engagement with Public Health agencies**  
  *Apple / Google Exposure Notification API & contact tracing discussion (e.g., public health privacy standards, application marketplace)  
  Symptom Checkers (with public health notification)  
  Consumer-directed lab results sharing with public health agencies* | 12:45pm – 1:30pm ET |
| **BREAK** | 1:30pm – 1:40pm ET |
| **CARIN Alliance activities – Where we’ve been and where we’re going**  
  Ryan Howells  
  *General Announcements and Upcoming Events  
  Code of Conduct and [MyHealthApplication.com](http://MyHealthApplication.com)  
  CARIN Blue Button API and May HL7 connectathon  
  RTPBC API and September Connectathon  
  Digital Identity and the Federated Trust Agreement  
  Policy-focus areas (e.g., FTC Breach Notification NPRM, etc.)* | 1:40pm – 2:25pm ET |
| **Next Steps and Adjourn** | 2:25pm – 2:30pm ET |
My Health Application.com

Discover Health Apps

Affiliations
- 1upHealth
- CMS Medicare Blue Button 2.0
- Commonwell
- Carequality
- Veterans Health Administration
- Apple Health
- COVID-19 Support

Platforms
- IOS
- Android
- Web

1upHealth Patient App
1upHealth
CMS Medicare Blue Button 2.0
Veterans Health Administration
COVID-19 Support

At 1upHealth, we believe that you should be in control of your health information. You choose how much data to share and where you want to share it. Looking for a second opinion? No more calling and waiting for faxed records. Need help managing your conditions? Easily share information with family and friends. Let us help you on your way to better health. Get connected today!

b.well Connected Health
b.well Connected Health
CMS Medicare Blue Button 2.0
COVID-19 Support

b.well is a middleware for interoperability and aggregation that consolidates real-time data and point solutions to deliver value to consumers.

Citizen
Citizen
1upHealth
CMS Medicare Blue Button 2.0

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

Easy links to the privacy policy and affiliations
Patient and Caregiver Perspective

Liz Salmi
Topic #1 – CMS Patient Access API
CMS Patient Access API

• CMS Patient Access and Interoperability rule is final!
  • What is in the final rule
  • What are we doing to help members
  • Plans calling us to ask implementation related questions

• Progress on CPCDS / CARIN Blue Button IG
  • Current state of the implementation guide
  • More than 50 participants in the May HL7 Connectathon

• Group discussion on questions we have been hearing
CMS Patient Access API

Question #1 – Are health plans required to use the CARIN Blue Button IG to be compliant with the claims and encounter requirements and is it sufficient to meet the Patient Access API requirement?

Answer: No, but if health plans don’t use the CARIN Blue Button IG they need to publish all of their technical API documentation and find applications who are willing to customize their interfaces

Regulatory text: (c) Technical requirements. An MA organization implementing an API under paragraph (a) of this section: (1) Must implement, maintain, and use API technology conformant with 45 CFR 170.215; . . . .AND MORE. For the purposes of this section, “publicly accessible” means that any person using commonly available technology to browse the internet could access the information without any preconditions or additional steps, such as a fee for access to the documentation; a requirement to receive a copy of the material via email; a requirement to register or create an account to receive the documentation; or a requirement to read promotional material or agree to receive future communications from the organization making the documentation available; (1) API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns; (2) The software components and configurations an application must use in order to successfully interact with the API and process its response(s); and (3) All applicable technical requirements and attributes necessary for an application to be registered with any authorization server(s) deployed in conjunction with the API.
CMS Payer-to-Payer Data Exchange

Question #2 – Does payer-to-payer data exchange require government-sponsored health plans to exchange claims data with a date of service on or after January 1, 2016 ‘with the approval and at the direction of a current or former enrollee or enrollee’s personal representative’?

Answer: No, the payer only needs to send the clinical USCDI information they have in their systems.

Regulatory Text:

Coordination among payers.

(1) An MA organization must maintain a process for the electronic exchange of, at a minimum, the data classes and elements included in the content standard adopted at 45 CFR 170.213 <USCDI>. Such information received by an MA organization must be incorporated into the MA organization’s records about the current enrollee. With the approval and at the direction of a current or former enrollee or the enrollee’s personal representative, the MA organization must:

(i) Receive all such data for a current enrollee from any other payer that has provided coverage to the enrollee within the preceding 5 years;

(ii) At any time an enrollee is currently enrolled in the MA plan and up to 5 years after disenrollment, send all such data to any other payer that currently covers the enrollee or a payer the enrollee or the enrollee’s personal representative specifically requests receive the data; and

(iii) Send data received from another payer under this paragraph (f) in the electronic form and format it was received.
CMS Patient Access API = CARIN Blue Button (Claims) + US Core R4 (USCDI)

**Mutual Goal**
Develop the data elements associated with meeting the administrative/financial and clinical requirements of the CMS Patient Access API

**Providers**
(EHRs & Practice Management Systems)

**Payer A System of Record**
(Adjudication -> Claims -> EOB)

**Payer B System of Record**
(Adjudication -> Claims -> EOB)

Submit for payment

**Clinical Data**
(DaVinci PDEx or any other format)

SMART OAuth request

**CMS Patient Access API**

Mapping & translations

**CARIN Blue Button API**
ADMINISTRATIVE/FINANCIAL information
(FHIR resources: EOB, Patient, Item, Coverage, Observation)

**US Core R4 (USCDI)**
CLINICAL information
(the source could be the claims data directly)
(FHIR resources: Patient, Provider, Organization, Location, Conditions, Observation, Medication... )
CMS Patient Access API

Question #3 – So in summary, what is the total amount of information required under the Patient Access API?

Answer: Upon the member’s request and where available, the member’s current health plan must provide the claims / encounter information from the member’s current health plan and the clinical USCDI information that the current health plan maintains with a date of service on or after January 1, 2016 in a FHIR R4 API format. The plan must also make available current formulary or preferred drug list information, as applicable. MA organizations with MA-PD plans must also make available the current member’s pharmacy claims with a date of service on or after January 1, 2016.
Implementation Opportunities

Patient Access API = Claims data from a member’s current health plan + clinical USCDI data the health plan has for the member with a date of service on or after 2016

Option #1 – For claims information, Health Plan A (a member’s current health plan) can create and publish their own FHIR R4 API. For clinical information, Health Plan A can map the clinical data in their current system to US Core R4 (USCDI).

Option #2 – For claims information, Health Plan A can use the CARIN Blue Button IG. For the clinical information, Health Plan A, B, and C can map the clinical data in their current system to US Core R4 (USCDI) and supply US Core R4 (USCDI) to the member.

Option #3 – For claims information, Health Plan A can use the CARIN Blue Button IG. For clinical information, Health Plan A, B, and C can negotiate via their provider contracts the ability to receive FHIR resources on patients for whom they can access (currently accessible as Argonaut FHIR R2) and then supply the clinical data (including any clinical data not currently in R2) to the member via US Core R4 (USCDI).
Health Plan Implementation Forum

• What is working and what is not?
• What questions do you have?
• How can we help you succeed?
Topic #2 – COVID-19: Consumer Engagement with Public Health Agencies
Apple / Google Exposure Notification API

Speakers
Dr. Karen DeSalvo – Google
Dr. Ricky Bloomfield – Apple
Wendy-Kay Logan – Google
Apple/Google Exposure Notification

For Public Health Authorities
Exposure Notifications (ENs) are alerts that people can receive on their phones to let them know they’ve been exposed to someone diagnosed with COVID-19.

**Supporting role:** Meant to augment public health’s contact tracing efforts, not replace them

**Privacy preserving:** Built on non-identifiable Bluetooth signals that indicate proximity and protect people’s privacy (no GPS or location data)

**Configurable:** Public health authorities can control:
- what factors and criteria trigger an exposure notification
- what next steps to advise (self-quarantine, get tested, etc.)
- how to ask exposed individuals to contact them for further contact tracing and containment initiatives
Why are Apple and Google getting involved?

Traditional contact tracing techniques have challenges

**Resourcing:** need many contact tracers to control a pandemic
**Speed:** takes time to call cases, conduct interviews, identify contacts, and then call contacts
**Completeness:** people have imperfect memories and can’t identify strangers

As a result, public health authorities are turning to mobile phone apps to help with these challenges and augment their contact tracing programs

Without our assistance, exposure notification apps that rely on Bluetooth won’t work well

**Cross-platform compatibility:** Apple and Android phones won’t be able to detect each other
**Battery:** Battery will drain quickly because of the need to keep apps open all the time
Alice and Bob don’t know each other, but have a lengthy conversation sitting a few feet apart.

Their phones exchange non-identifiable bluetooth beacons, which change frequently.

Bob is positively diagnosed for COVID-19 and enters the test result in an app from his public health authority.

With Bob’s consent, his phone uploads the last 14 days of his bluetooth keys to the server.

Apps can only get more information via user consent.

~14 day temporary store
Alice continues her day unaware she had been near a potentially contagious person.

Alice’s phone periodically downloads the non-identifiable bluetooth keys of everyone who has tested positive for COVID-19 in her region. A match is found with Bob’s non-identifiable beacons.

Alice receives a notification on her phone.

**ALERT:** You have recently come in contact with someone who has tested positive for Covid-19
Tap for more information -->

The notification includes information about what to do next (e.g. to quarantine, monitor symptoms, get tested, call public health).

Additional information is provided by the public health authority app.
Exposure Notification (EN) System

**Exposure Notification API:** Exchanges non-identifiable bluetooth keys and proximity/duration info

- **Diagnosis Key Server:** Holds positive diagnosis bluetooth keys, which are used to help trigger exposure notifications
- **Test Verification System:** Allows for verification of positive tests by app, e.g., using PINs

Traditional Contact Tracing (CT)

- **Public Health Authority App:** Main conduit between EN API & CT system, and can link to websites
- **Contact Tracing CRM:** CRM for contact tracing

CT tools to manage cases
CT staff and admin
COVID-19: Consumer Engagement with Public Health Agencies

How are cities and states responding to the pandemic?

**Mike Wilkening** – Special Advisor on Innovation and Digital Services, Office of Governor Gavin Newsom, State of California

**Nick Lucius** – Chief Data Officer, City of Chicago, Office of the Mayor

**DISCUSSION:** How can the CARIN application community help?
CARIN Alliance Activities
Volunteer Trust Framework and Code of Conduct

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.
Trust Framework and Code of Conduct progress

I. Code of Conduct
   A. Published a draft process for how we will be updating and publishing the code of conduct on an annual basis including how we will be getting feedback from the broader community

II. Questionnaire / Nutrition Label
   A. Developed a draft detailed nutrition label that includes areas where CARIN is supportive of best practices
   B. Working to develop reconcile the nutrition label work with the CARIN code of conduct to ensure consistency and a summary of consumer choices
   C. CARIN/LP staff will be reaching out to patient groups to get additional feedback

III. Validation
   A. Started initial conversations with 2 independent validation organizations to begin to develop an application verification and validation program based on the CARIN code of conduct
Advancing person-centric digital ID credentials
More than 30 organizations attended the summit including digital ID experts outside of health care

Focused on 5 problems:

1. **Identity** – NIST 800-63-3 (IAL2)
2. **Authentication** – Multi-factor authentication / FIDO2 (AAL2)
3. **Trust & federation** – Open contractual principles with private sector certification bodies
4. **Consent** – Informed, proactive consent
5. **Matching** – Matching based on contractual trust principles and criteria

**Major Questions**

- How do we identify unique users across systems using person-centric mobile technologies?
- How do we securely authenticate individuals across systems using modern, open standards?
- Once a patient is identified at one organization, how do we cross-facility match a patient to their records?
- What does a consumer-directed, electronic federated consent approach look like?

**NEXT STEPS**

Investigate a proof of concept, develop identify pilot partners, and develop a federated digital trust agreement
Talking Points

- Contractual terms would be an open, consensus process
- Ideally, contractual terms would be built into the TEFCA / Carequality (e.g., common agreement) or other HIN for those who voluntarily want to participate
- Contractual terms would require an independent certifier to validate the credentialing service provider
- Health care actors would use the contractual terms, independent certifying requirements, or a mixture of both
Digital Identity Tiger Team

Working to develop a set of open contracting principles for digital identity federation.

Process:

• A small working group is collaborating on a draft set of open contractual terms and conditions.
• Once developed, the draft framework will be presented to the broader CARIN ID & Authentication workgroup for their input. (Target July/August timeframe)
• With approval from the group, we will socialize the framework with other groups which could eventually adopt the principles (e.g. Carequality).

Stakeholders involved in draft framework development:

• DIACC
• DirectTrust
• EMR Direct
• Google
• Kantara Initiative
• Microsoft
• SAFE Identity
• Secure Technology Alliance (Mobile Driver’s License standards)
• Videntity

CARIN is also participating in the World Economic Forum’s Digital ID Coalitions Network. Representatives include: Smart Africa, multiple global financial services firms, Canada, European Commission, Open ID Exchange, U.K., Singapore, Mastercard, Finland, Germany, Ireland, Norway, and others.

The goal is to advance global activities towards digital identities that are collaborative and put the user interest at the center: e.g. they are fit for purpose, inclusive, useful, secure, and offers choice to individuals.
Consumer-directed Real-time Pharmacy Benefit Check API

**Government**
- One of few policy agenda items with bipartisan support.
  - Presidential Executive Orders and Drug Pricing Blueprint
  - CMS Part D Drug Pricing Final Rule
    - B2B real-time pharmacy benefit tool required by January 2021
    - Proposed Part D Technical Changes for 2021/2022
    - B2C real-time pharmacy benefit tool required by January 2022
  - CMS RFI Reducing Administrative Burden To Put Patients Over Paperwork
  - Multiple committee hearings and introduction of bipartisan bills

**Consumers**
- Employers, patients and consumers of all types are demanding drug price transparency.

**Market Entrants and Innovators**
- Companies with strong consumer facing business models are entering healthcare with an eye on prescription drug services.

**Next Steps**
- 4 of the 5 largest PBMs now part of CARIN
- PBMs are working to build out their FHIR infrastructures
- Targeting Fall 2020 for additional testing by the PBMs and Apps
Problem: State Medicaid agencies are behind the commercial industry in adopting FHIR and modernizing their technology infrastructure. In addition, they may not be aware of the work CARIN, DaVinci, and others are doing to assist them in being compliant with the CMS rule.

Approach: CARIN will be holding state Medicaid listening sessions with CMS and HL7 where we can listen to questions states have and develop consensus-based solutions to help states with their implementations. We will start with a small, forward-leaning set of stakeholders and then look to expand over the next few months.

First Virtual Roadshow: June 24th from 3:30 – 5pm ET

Objectives: Begin to gather a list of Q&As related to specific state Medicaid nuances associated with implementing the Patient Access APIs and integrate those best practices into the IG and other documentation

Invitees: DXC and CNSI (approximately 75% of the state MMIS/claims vendor market), CMS, HL7, states of CO, WA, MN, and the CARIN Blue Button technical team

Other Events: CARIN presented virtually at Health IT Connect (5/1) and is looking to present at MESC (August) which are the two largest Medicaid technology conferences in the country