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

CARIN Community Meeting
September 28, 2020 **|** Virtual

Objectives

The CARIN community, made up of the CARIN Board, Affiliate Members, and Special Guests, met virtually to discuss CARIN Alliance Workgroup progress and how each of the CARIN efforts are advancing consumer directed exchange. The primary meeting focus was on implementation; CARIN Alliance members shared observations from the field and discussed pilot and partnering ideas that could address implementation challenges and opportunities.

Key Discussion

General Announcement – Ryan Howells, Leavitt Partners
- Ryan welcomed the group to the meeting and thanked them for their engagement. He provided context for the meeting discussion stating that the CARIN community is involved in implementation efforts to be compliant with ONC information blocking rule, which begins to take effect in November 2020 and the CMS patient access rule, which begins to take effect in 2021.
- Ryan noted that the group convening was an opportunity to discuss progress and implementation challenges and opportunities related to both rules.

Leadership Perspectives – Aneesh Chopra, Care Journey
- Aneesh welcomed the CARIN Community to the meeting and congratulated them on the progress the CARIN Alliance has made. He outlined three key points for the day:
  - The alliance has transitioned to an interoperability phase and it is critical to understand the reality on the ground. He called on the group to share their experiences on what is working well and where there are challenges to be addressed collaboratively.
  - The group must keep our long-term goal in mind during the discussion today: advancing consumer directed exchange so that patients get meaningful access to their health data. He noted that we should continue robust discussion on *how* we facilitate consumer directed exchange (e.g. technical components, liability, etc.) but that we should not lose site of our driving objective.
  - There remains an importance of identifying and advancing new but related projects and pilots. He noted there would be opportunity later in the day for the group to brainstorm about pilot and partnering ideas which could help advance interoperability implementation and address critical challenges.

Consumer Advocate Story – Dr. Grace Cordovano
- Grace spoke about the imperative to provide patient and their caregivers their data immediately when it is generated.
  - She described a recent experience working with a cancer patient to gather their data and the difficulty of aggregating and sharing that data. The challenges delayed critical patient care for more than 10 weeks.
  - She reminded the group that both structured and unstructured data must be shared with patients. While digital solutions will facilitate the sharing of both structure and unstructured data in the future, now, it is the simplest for patients to be asking for *all* records to be provided before they are discharged.
  - Grace noted that patients want to be involved in their care, but they do not have the information they need to fully participate. There is no "model patient" handbook.
  - She suggested that provisions mandating the data elements to be made available to patients should align with the follow up plan post-discharge, and that there was an opportunity to define mandatory

elements for common specialties a patient may need to follow up with. This could help patients receive the records they need but do not know to ask for.

- o She noted that on discharge, most patients need comprehensive records on their medications, lab tests and diagnostic tests and reports.
- The CARIN Alliance members thanked Grace for speaking to the group. Several members discussed the need for the USCDI to align with the HIPAA designated record set. Until then, there will not be digital access to the full set of records which a patient might need. Others noted the potential need for an e-consent framework that could reduce the friction for sharing patient records.

CARIN Workgroup Update – Ryan Howells
- Ryan Howells provided an update on the progress of the CARIN Workgroups and described how the efforts align.
- He reminded the group that the CARIN voluntary code of conduct fits in the broader framework to establish trust among the entities. Ryan noted the industry is adopting the code of conduct and applications which attest to the code are made public on MyHealthApplication.com. The CARIN Alliance and Leavitt Partners are not endorsing applications by listing them, our focus is to provide consumers and caregivers with transparent information about apps that self-attest to the code so they can make informed decisions about which apps to use based on the terms, conditions, and privacy policies which align with their preferences.
    - o The number of applications listed on the site increased by 50% in the last 90 days.
    - o CMS, 7 of the 10 largest health plans, state Medicaid agencies, large Medicaid claims system vendors, additional EHR companies, and others have all adopted part or all of the CARIN code of conduct as part of their application registration process.
- Ryan described the FHIR Implementation Guide (IG) options included in the CMS Patient Access rule. The CARIN Alliance IG for Blue Button® for Payer and Pharmacy Claims is one of the three FHIR IGs indicated in the CMS Rule which are tied to the Patient Access API (the other two include the Da Vinci Formulary and the Da Vinci Payer Data Exchange PDEX for Clinical Data for US Core). While there is no specific CMS requirements to use any HL7 IG, using one of the FHIR IGs options indicated in the rule simplifies compliance with the CMS Patient Access API for 2021 and is listed on the CMS website as guidance for the industry.
    - o There is also a FHIR API for Provider Directory which needs to be made available without the need for a member to login.
    - o The CARIN Real Time Pharmacy Benefit Check (RTPBC) FHIR IG is an opportunity to expand the CMS Patient Access API for 2022. The CARIN RTPBC FHIR IG provides members information on drug cost and therapeutic alternatives of medicines in real-time based on their specific enrolled formulary. The Da Vinci Formulary FHIR API allows patient to identify which plans cover their medicines and is most useful during open enrollment when members are selecting a plan.
- Ryan discussed what the CARIN Alliance is calling health care's new "digital front door," which describes the new ecosystem and infrastructure needed for sharing data between patients and data holders through applications.
    - o In the ecosystem, there are data holders; the "family", or the related patients, members, caregivers and others who will seek access to data using an application; and the "community of problem solvers," or the business-to-business and business- to-consumer health care applications which are providing data holders services to address a variety of health care uses, including "family" data access.
    - o To facilitate data sharing in the ecosystem, data holders must use:
        - ▪ A "key," which controls who can access data; this requires establishing digital identity for the organization, application and individual who will hold, request and use data. Activities which establish they key include publication of FHIR end points, application registration, and IAL2 identity proofed digital credential. There was feedback that we should also point to the need for AAL2 to support authorization in addition to identification.

- - A "door," or the API Gateway, which controls the clinical, financial, and other data that is shared (both in and out). There are many players creating API gateways. Currently, we observe only read capacity but would like to move to create, read update and delete (CRUD) functionality.
  - The CARIN Alliance ID and Authentication Workgroup is working on advancing a voluntary standardized agreement to federate trusted identity across the ecosystem. CARIN is focusing on developing an industry-level framework and set of open contractual terms and conditions which establish trusted policies to support federated digital identity. We believe this which will advance the ability to exchange personal health information across systems electronically.
    - Identity providers or issuers 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 identity providers.
    - CARIN seeks to develop contractual language that links each of the trust framework organizations together and outlines the standards, policies, and contractual terms for how identity providers can be trusted across trust frameworks.
    - The benefit of this approach is that a relying party, which needs a verified identity to share data, can trust and use an identity credential provided by any identity provider who has been certified by a trust framework organization.
    - Related, the CARIN Alliance has announced a relationship with Carequality to work closely to integrate this work into their agreement and hopefully, include in the TEFCA.

TOPIC #1: Learning from the Field: Implementers of CMS and ONC Requirements
- Members of CARIN Alliance shared updates and challenges from their experience implementing the CMS and ONC final rule requirements.
- Implementers View – Payers:
  - The group shared an update on the CARIN IG for Blue Button®. We are in the final phase of getting the CARIN IG through the HL7 ballot process and are on track to be published by November. The team has taken steps to socialize information about the IG and have observed the payer community becoming more involved in the technical aspects and use of the common framework (SMART App Launch).
  - A large national payer provided his organization's approach to the new "digital front door." He noted they have recognized the need to support identity and authentication process to ensure that they are sharing the right data with the right member across all of their member companies. They are planning to identity proof members. This will increase the probability the individual is who they say they are and verify that one of their members is the actual person requesting their own data be shared.
  - Another large national payer called for volume testing, pharmacy benefit manager (PBM) integration and mechanisms to access structured clinical data. He noted that in the process to accelerate progress on the IGs, they are finding there are discrepancies in the data payers have access to (data is sometimes contracted to vendors) and the data requested from payers. Volume testing can ensure the IG fits CMS expectations and maps to the data payers actually have whereas testing data is often generated for the IG and does not reveal the discrepancies which exist in real world data. He stated that CMS had eased its earlier requirements for which would require payers to generate meta data for unstructured data. Citing the burden to payers, CMS is evaluating its previous requirements but it is still unknown what CMS will decide. Finally, he noted they are considering whether additional data is needed for PBM integration.
  - A large national Medicaid technology vendor discussed state Medicaid approaches to implementing the CMS rule. He stated that state Medicaid has traditionally been oriented toward EDI not FHIR,

and many are just now becoming aware of open API and FHIR. Based on their experience, most state Medicaid agencies will pursue a July 1 implementation. It was also noted that states are considering an API gateway for sharing across their health and human service enterprise, not just the Medicaid program. This is an opportunity for an API gateway to facilitate a consumer- rather than provider-centric ecosystem and enhance referrals to and between health and social service providers and programs.

- Implementers View – Providers:
  - o A major EHR vendor discussed how EHRs want to engage the consumer. While they have traditionally focused on a busines-to-business data exchange, consumer solutions have become even more important during COVID-19 and accelerated the need for patient tools not just tools for their provider clients. They are continuing to consider opportunities and challenges related to the following areas: managing FTC versus HIPAA covered apps, and how to write data back into the electronic medical record. There is guidance from OCR for determining if the app is or isn't covered by HIPAA ([here](#)), noting that HIPAA rules are agnostic to the data source (e.g. if a patient write it in) — once it comes into possession, you treat it in accordance to the rules that apply to you.
- Implementers View – Applications:
  - o A consumer facing application discussed the need to scale digital identity. Application adoption will be inhibited without a digital identity solution.
  - o The application community also discussed the upcoming implementation timelines for the information blocking and patient access API rules and the benefit of being an early implementer. Given the mapping requirements which must be completed to be compliant with the information blocking rule this November, being an early implementer of the patient access API will be less burdensome because many EHRs vendors have noted already they will support FHIR R4. It was noted that implementing early aligns with the CARIN Alliance mission to advance consumer directed exchange and to achieve our objective of securing consumer data access as soon as possible.

TOPIC #2: Ongoing Opportunities for Community Collaboration and Pilots – Aneesh Chopra

- Aneesh facilitated discussion with CARIN Alliance members to identify pilot and partnering opportunities to address the implementation challenges discussed earlier in the meeting. Several action items where identified:
  - o CARIN members noted that there will be greater demand for and utility from patient access when comprehensive and complete data are made available to patients.
    - ▪ Patients do not seek their data for the sake of having it; patient seeking their data need it to put it to use. However, there is a discrepancy between the data that patients expect to receive and the data available. This impacts the overall demand for consumer directed exchange and consumer use of health data. Members noted this is true among healthier patients, who want basic data, and patients or caregiver who need robust health data. However, for some, it is critical:
      - Individuals seeking data will fall across a spectrum: healthier individuals who proactively seek wellness, individuals who have an acute interaction with healthcare, individuals who have chronic illness and multiple com-morbidities, individuals with a life-altering diagnosis, and individuals receiving end of life care. Once you cross the divide into chronic illness and beyond, you need your health information to live your best life.
      - Individuals and their caregivers need data to schedule appointments, for post-discharge follow-up, filing and appealing social security disability applications, filing appeals for insurance denials and participating in peer-to-peer discussions, preparing for or coordinating multi-specialty care, and end of life care planning.

- The group discussed demand for health data. Individuals need to be educated about the value and potential use of their health data (e.g. address patient safety, improve care coordination); this will also drive demand for health data.
- The group noted that 80-90% of valuable health information is captured in the clinical notes. There will be greater utility when notes are made available and it is up to health systems to make notes available.
- Some members noted the importance of also making health data available to payers. Payer care management may provide supportive service to facilitate accurate, appropriate health data, particularly when a patient has the stress and emotion of a difficult diagnosis and has little medical understanding but urgent need.
- Other members noted the importance of advancing bidirectional information flow so patient can share their data back when they want to a structured way.

o Model agreement to handle the re-use of business-to-business data: CARIN members noted that in order to be compliant with the information blocking and patient access rules, some data must be made available to payers by their third party vendors. There is an opportunity to draft contract language or a model diagram defining how business associates that maintain data on a plan's behalf should release data back to payers.
- The purpose of this effort would be to accelerate backend interoperability.
- Some members noted that this should focus on policies and programs but should be technology agnostic; FHIR can be a layer added on top which specifies how business associates should release FHIR data back to payers using the appropriate FHIR Resources.
- The group discussed the need for a model contract between plan and provider referencing lab and clinical data. Lab data was highlighted as an area which could benefit from agreements although standards exist already.
- Others wondered why we would not just use US Core for lab data noting they did not see value in something different or need for a different IG. Almost all labs can deliver results to EHRs as HL7 V2 ORU messages, which should map to FHIR observations.

o The group also noted the need to continue discussing identity solutions but the conversations was cut short because of time.

o Others suggested that CARIN should begin to consider and discuss more real-world use cases now that more data are and will be available.

Next Steps

- CARIN Alliance Members interested in participating in either of the pilot opportunities discussed – the notes accelerator project, or in participating in development of a model BAA agreement – should follow up with Leavitt Partners staff.
- The Q4 Community meeting will be virtual. Dates will be communicated shortly.