Office of Science and Technology Policy; Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, D.C. 20504

Re: CARIN Alliance Response to Connected Health RFI

The CARIN Alliance is a multi-sector group of stakeholders representing consumers, patients, health systems, insurers, technology organizations, personal health record developers, and others. We are universally committed to enabling consumers and their authorized caregivers easy access to their personal health information.

Over the past few years, administrations across parties have made great strides in advancing digital access to health information. Through the HITECH Act, MyHealthEData campaign, Blue Button 2.0, and other initiatives, the federal government has significantly advanced industry efforts to empower consumers and their authorized caregivers. However, additional work is needed to make sure the promise of these initiatives progress.

1. Successful models within the U.S.

A number of successful models have been advanced over the last several years. Specifically, the HL7 FHIR Accelerator program has allowed for accelerated development of implementation guides and industry adoption of new standards. The CARIN Alliance has built the CARIN IG for Blue Button to advance consumer access to claims information and the CARIN Real-time Pharmacy Benefit Check IG to allow consumers to get real-time pricing information about their therapies at the point of prescribing and dispensing.

CARIN has also had success in developing the CARIN Code of Conduct, a consensus, voluntary framework by which applications used by the consumer agree to treat the individual's health care information. Numerous applications have attested to the best practices in the Code of Conduct and the Centers for Medicare and Medicaid Services (CMS) has named the CARIN Code of Conduct as 'an industry best practice' in their Interoperability and Patient Access final rule.

2. Barriers

Notwithstanding the great strides that have been made in helping consumers, patients, and caregivers access their health information, barriers remain. These include:
a. Misunderstanding about patient rights (HIPAA, Interoperability and Patient Access Rule, App access, fees)
b. Inconsistent regulatory regimes
c. Identity verification and ongoing challenges to patient matching
d. Adoption of industry standards
e. Implementation of numerous regulations at Covered Entities

As outlined in our response to question 6, there are a number of areas where the federal government, in collaboration with the private sector, can reduce barriers to patient, consumer, and caregiver access.

3. Trends from the Pandemic

One of the criticisms of previous regulations or efforts advancing consumer-directed health information exchange is that consumers did not want their digital health information. During the pandemic, we have seen the public use technology at record levels. From the use of telemedicine to exposure notification apps to SMART Health Cards as a vaccine credential, patients, consumers, and caregivers have shown that they can and will engage with technology when available. Making more data available to the public, and increasing the use-cases, is critical to the ongoing utility of digital health tools and the utilization of such tools.

4. User Experience

The Office of the National Coordinator of Health IT developed a guide for consumers on how to access their health record. This resource, among other work done by the GetMyHealthData campaign, the National Partnership for Women and Families, the CARIN Alliance, and many others has helped millions of consumers gain access to some of their health information and use it across care and social need use cases.

However, numerous examples continue where health data holders, including HIPAA covered entities, do not easily facilitate consumer access. From covered entities restricting electronic and paper access to some records or information or requiring applications to go to great lengths to gain access to FHIR endpoints to incomplete data feeds and reliance on old paper records, too many consumers do not have access to information that is necessary for care delivery and care decision-making, social need coordination, or personal use. The government can and must do more to enforce current regulations to make more information available to consumers, patients, and caregivers without extra or special effort.

6. Proposed Government Action

a. Support digital identity in the health care ecosystem:

As mentioned above, one of the challenges to advancing consumer directed exchange is digital identity management and "portal fatigue" where consumers have to repeatedly enter their credentials to create connection between their providers or health plans and their chosen consumer application. We envision an ecosystem where an individual voluntarily creates a digital identity credential in an application of their choice, which they own, manage, and use to access their health information from any health care payer or provider in the country. We are currently engaged with the Department of Health and Human Services (HHS) and the General Services Administration (GSA) to develop a [federated digital identity proof of concept](#) to test a method for using a single digital identity across multiple systems. **We encourage the federal government to fund this digital identity federation proof of concept to fulfill the White House's recent [Executive Order on Transforming Federal Government Experience](#) which says the GSA a roadmap for, "the development of prioritized common services and standards (such as the United States Web Design System or systems for login and identity management) (to) increase efficiency, integration, and improved service delivery of designated customer life experiences."** We firmly believe this project will help to inform the GSA's roadmap to fulfill the White House EO.

b. Endorsement of CARIN Code of Conduct by FTC:

The CARIN Alliance Code of Conduct represents the consensus view of a group of multi-sector stakeholders that include leading providers, payers, health IT companies, EHR companies, consumer platform companies, consumers, caregivers and others focused on advancing consumer-directed exchange across the U.S. The Code is based on internationally recognized standards and numerous consumer information sharing accepted principles and practices. Various consumer applications have attested to the Code of Conduct via the website [MyHealthApplication.com](#), CMS has identified it as a best practice in the [Interoperability and Patient Access Rule](#), and the VHA has said they are a '[supporter of the CARIN Alliance Code of Conduct](#)' and require the application who connect with them to attest to the code. **We encourage the FTC to similarly point to the CARIN Alliance Code of Conduct as an industry best practice which will ensure all consumer-facing applications are using a similar code for how they handle, use, and share health information.**

c. CARIN IG for RTPBC as a standard:

The CARIN Alliance developed an implementation guide for the development of an API for real-time pharmacy benefit check for consumers that enables them to access their out-of-pocket costs, therapeutic alternatives, benefit and formulary information, and what their price would be if they paid cash. This API would allow Medicare Part D Plan Sponsors to comply with the [CMS requirement for plan-year 2023 to provide consumers with a real-time benefit tool](#). **CMS should specifically reference the [CARIN IG for Real-time Pharmacy Benefit Check](#) as one way to comply with the rule as it did with the CARIN IG for Blue Button as part of the [supplementary guidance](#) they provided for their Interoperability and Patient Access Rule.**