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

Who we are:
We are a group of more than 85 multi-sector stakeholders that includes: health plans, providers, hospitals, third-party-applications, consumer platform companies, EHR vendors, health plan technology systems, patient and caregiver advocates, and others committed to helping build a more interoperable health care ecosystem by ensuring consumers have more access to their health information.

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

Key Request:
Our request of OMB is to finalize and release the CMS and ONC proposed rules (Interoperability and Patient Access (CMS-9115-F; RIN: 0938-AT79) and the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (0955-HHS/ONC; RIN: 0955-AA01) without further delay with the understanding that CMS and ONC have incorporated the consensus recommendations made by the public during the comment period and with the assumption the public and private sectors can work together to improve and build upon the rules after they are released.

Although we may slightly differ in the specific details regarding how the proposed rules should be implemented, we are united regarding the consumer access sections of the two proposed rules and in our belief that both proposed rules should be finalized and released immediately. It will be to the benefit of all stakeholders to finalize the rules so the industry can work on implementation while continuing to work with the public sector to improve the rules over time.

We believe the two proposed rules should be finalized and released immediately for the following reasons.

1) These rules play an important role in empowering an individual with access to their own health care data using standard and secure HL7® FHIR® APIs and an application of their choice, while working on continuously increasing the privacy, security, and individual consent preferences associated with an individual's data by implementing public and private-sector safeguards.

Since the passage of HIPAA, the individual right of access under HIPAA (45 CFR § 164.524) allows every American to access their own health information. HHS, the Office for Civil Rights, and the Office of National Coordinator for Health IT have all made it clear an individual has the right to access their information in a 'readily producible form and format' which includes a paper copy, email, or digital access via an HL7® FHIR® API.

It's imperative to note how important and time sensitive aggregated health information across multiple provider and health plan systems can be for patients going through catastrophic events. This information is essential for patients as they consider options such as treatment planning, consenting to surgical procedures, exploring and enrolling in clinical trials, and matters of continuity of care, examples including expediting an urgent second opinion, appealing insurance denials for standard of care treatments prescribed by patient's board-certified physicians, as well as having all pertinent information when it comes to advance care planning, palliative care, and matters of end of life. Data access is a matter of patient safety, better outcomes, improved costs, and often life or death.

As an example of our how we are looking to continuously increase the use of health care data across systems, the CARIN Alliance has suggested since August of 2017 how the health care industry can voluntarily use the NIST 800-63-3 national identity standards to help individuals create and use their own person-centric digital identity credential across systems to better access their own health information. While we don't believe implementation of these standards are needed before the rules are released, we do believe these standards, which are required as part of the ONC's TEFCA, will help.

We believe the individual's ability to access their own health care information will allow them to make more informed health care decisions, including to find affordable, higher quality care that will help them achieve their goals and, ultimately, advance critical value principals in our health care system.

2) These rules present the opportunity to grow the economy by allowing individuals to create person-specific health care solutions to more securely and comprehensively access, store, and use an individual's complete health and health care information to help with their own personal health and health care needs and personalize their own privacy preferences.

Patients, their caregivers, and their care teams can now select from an array of tools and services to meet their needs versus relying solely on the health care system to share their data. HIPAA "locks" data with incumbents because the incumbents share only when it is in their interests to do so (except for sharing with the patient).

Both the public and private sectors are encouraging the use of the most advanced, modern-day technologies to secure and protect health information including the use of OAuth 2.0 which is a mechanism to grant individual-specific authorization using a patient's existing sign-in credentials without storing sensitive password information. We know that multiple other industries have adopted these modern-day technologies. ONC and CMS are planning to include it in their proposed regulations, and via Apple Health, the technology has been successfully working for over a year.

Standard and secure HL7® FHIR® APIs also enable employers to integrate and sponsor more patient-centered health apps, while protecting privacy. This keeps the 157M employer covered lives in the US more productive, globally competitive, and contributing to US economic output.

In addition, from a policy perspective the CARIN Alliance developed a comprehensive code of conduct with input from more than 60 stakeholders including health plans, hospitals, third-party apps, consumer advocacy organizations, and others that will help to bind a third-party application to a set of enforceable principles for protecting and securing a consumer's health information. The CARIN code of conduct can now be used by the Federal Trade Commission, State Attorneys General, and the private sector to enforce best practices for the data security and privacy of health information in the consumer space.

The code goes beyond HIPAA's privacy protections in several different areas. Some of those areas include: the need to capture informed, proactive consent for both identified and deidentified data (Section II(a)), the right for a consumer to be forgotten (Section IV(c)), and the requirement to bind downstream third-party vendors from using or disclosing user information beyond what the user had already agreed to without express consent from the user (Section III(a)).

Multiple patient advocates have recently discussed in leading publications the importance of accessing their own health data. Additional patient advocates have discussed their own story and emphasized how their health data needs to be available when they were ready to retrieve it. Recent studies[1] have shown people (especially women) use technology to support their own health goals. Forty-three percent of women use tablets or smartphones to help them track progress on a health-related goal such as quitting smoking, losing weight or increasing physical activity, compared to 36 percent of men. The data also indicates a 30+ percentage increase in the number of individuals who downloaded their medical record data in 2018. This number will further increase as the two proposed rules take effect.

3) These rules help expand the use of standard and secure HL7® FHIR® APIs for individuals, caregivers, providers, applications, health plans, and others, to help create a health care system that is more interoperable, value-based care driven, accessible, and person-centric.

Members in industry groups such as the CARIN Alliance and other HL7® FHIR® accelerator programs are making an individual's health care information more accessible and secure for individuals, caregivers, and providers. These two proposed rules will help advance these private-sector initiatives by requiring implementation of agreed upon industry standards.

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[1] ONC Data Brief, no.48 ONC for Health IT: Washington, D.C. Retrieved 24 May 2019, from https://www.healthit.gov/sites/default/files/page/2019-05/Trends-in-Individuals-Access-Viewing-and-Use-of-Online-Medical-Records-and-Other-Technology-for-Health-Needs-2017-2018.pdf