

Leavitt Partners (LP) has deep experience bringing stakeholders together to develop consensus resolutions to policy, regulatory, legislative, and business challenges. We help diverse health care and life science organizations develop multi-disciplinary collaborations to resolve complex challenges and accomplish their objectives through policy reform, regulatory reform, legislative action, and development of industry best practices. We leverage our strong regulatory and policy expertise and decades of government and private-sector experience to serve as the conveners and leaders of alliances and to help clients develop, advocate for, and achieve innovative, consensus-based solutions. Our proven process of collaboration provides value through the enhanced influence of a broad unified voice; leverage of shared financial, multi-disciplinary, multi-sector and in-kind resources; and advocacy for shared policy positions without undesired attribution to any single organization.

The Creating Access to Real-time Information Now (CARIN) Alliance: The LP-led alliance, CARIN (carinalliance.com), is an example of a successful multi-sector, interdisciplinary collaboration resulting in significant legislative, regulatory, and operational achievements. Across several years, this diverse alliance has grown to include patient organizations, health care purchasers, data clearinghouses, payers, providers, application developers, health care technology and consumer technology organizations, identity service providers, and standards development groups.

CARIN's 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. Over more than 6 years of work, the group has helped advance legislation and regulation facilitating better consumer access to health information, developed multiple HL7-approved Implementation Guides that have been included in federal regulation,¹ established a proof of concept for federated digital identity sharing, and established an industry leading Code of Conduct for data transactions between HIPAA-regulated Covered Entities and FTC-regulated digital health actors.

The Issue. While patients and consumers have long had the right to access their information under the Health Insurance Portability and Accountability Act Individual Right of Access, there have been numerous barriers to such access. CARIN was convened by David Blumenthal, David Brailer, Aneesh Chopra, and Mike Leavitt in early 2016 to help break down the barriers related to increased consumer access to digital health information. These included:

1. **Trust barriers.** CARIN has developed, and continues to refine and implement, a trust framework for consumer-directed exchange.
2. **Technical barriers.** CARIN is developing ways to help providers and others share best practices on how they are implementing the Fast Healthcare Interoperability Resources (FHIR)-based application program interfaces (APIs) and using them to advance consumer-directed health information exchange.

¹ HL7 is a technology-focused Standards Development Organization. An implementation guide (IG) is a set of rules about how technical resources are used (or should be used) to solve a particular problem, with associated documentation to support and clarify the usage.

3. **Adoption barriers.** CARIN is developing ways to assist organizations who are implementing consumer-directed exchange with the goal of improving quality, outcomes, affordability, and patient satisfaction.
4. **Policy barriers.** CARIN is developing policy recommendations to help inform federal entities including the Department of Health and Human Services (HHS), the Office of the National Coordinator for Health IT (ONC), the Office of Civil Rights (OCR), the Federal Trade Commission (FTC), and other regulators about ways to support the private sector in implementing the above strategies.

Collaboration. CARIN has brought together over 70 national organizations from across the health care and consumer technology landscape. From traditional health care data holders, like providers and payers, to consumer advocate organizations like patients, caregivers, and health care service purchasers, and digital health innovators, CARIN members support the mission of helping all consumers of health care services better access their health information so that they can make better care decisions, facilitate patient engagement, and help with purchasing decisions. Not only does the group contain organizations that are traditionally rivals and competitors, but it also contains participants that have traditionally been concerned about data sharing outside of the traditional “treatment, payment, and operations” uses allowed by HIPAA. Through extensive collaboration under the guidance of Leavitt Partners’ leaders, the groups have come together to achieve consensus on legislative proposals, regulatory action, standards-based implementation guides, new paradigms for collaborating on digital identity, and a Code of Conduct for data sharing between entities in different regulatory regimes.

Process and Results. Leavitt Partners organized and coordinated the consensus development process across multiple domains aimed at addressing the trust, technical, adoption, and policy barriers that exist in consumer-directed health information exchange.

1. CARIN’s Trust Framework and Code of Conduct Workgroup convened to develop the CARIN Code of Conduct that outlines best practices for consumer-facing health application’s use of data outside of the HIPAA construct;
2. CARIN’s Health Plan Workgroup convened to develop multiple HL7-approved Implementation Guides that facilitate standard data exchange for consumer claims information and a digital insurance card;
3. CARIN’s Identity Workgroup convened to develop a model for a federated digital identity that can be used across platforms, facilitating better access for individuals and identity assurance for data holders;
4. CARIN’s Real-time Pharmacy Benefit Workgroup developed an HL7-approved Implementation Guide to help consumers better understand their options for purchasing therapies; and
5. CARIN’s Policy Workgroup convened to advance legislation and regulation at the federal level including the 21st Century Cures Act, the Patient Access and Interoperability Rule, and the Information Blocking Rule.

Continued Action. CARIN continues to work to advance numerous activities aimed at advancing consumer-directed health information exchange. Each workgroup is active in helping implement various aspects of the new data-sharing paradigm, working to establish trust, remove technical impediments to progress, advocate for broad adoption of consumer-facing tools, and making sure that federal policy continues to represent what is best for consumers.