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WEBINAR Q & A

Kill the Clipboard

What Does the CMS-Aligned Network Strategy Mean for the Future of Interoperability?

Watch the Replay →

This webinar was held on August 8, 2025.

These questions were unable to be addressed during the webinar, or we wanted to expand our answers. For more information, or to discuss ways that Leavitt Partners can help your organization adjust to these changes, please contact any of the webinar speakers.

LEARNING OBJECTIVES

- Identify how the CMS-aligned network strategy reflects the policy priorities outlined in the Kill the Clipboard roadmap
- Describe the structural and policy changes needed to improve the way health care data is shared and governed and why the EHR is no longer sufficient
- Analyze how TEFCA and other national networks are positioned to evolve in response to this federal strategy
- Assess the opportunities and risks for public and private sector collaboration in advancing interoperable, standards-based data exchange

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Q: Amen to the CD-ROM interoperability limited to CCDAs continues to promote "books without pictures." Without the images being shared, most referral or patient transfers will be partially uninformed and many will end up re-imaged with high cost imaging and radiation exposure. What are your thoughts pushing the industry (EHRs and Imaging MedTech) to be incorporated into the HIE landscape?

A: We are 100% on board with sharing images with patients. The last work we have seen on how to do that is the work the Argonaut project did a few years ago. Our hope is the CMS-aligned network participants will desire to advance this effort once the work begins.

Q: How is Project Clarity working with Da Vinci's Patient Cost Transparency efforts for Good Faith Estimate and Advanced Explanation of Benefits?

A: The CARIN Alliance, DaVinci Project, and Argonaut project were all named as the first three HL7® FHIR accelerator programs in 2019. As such, we have been actively working with DaVinci for many years.

Q: Will the Provider Directory CMS speaks of leverage the National Directory of Healthcare Providers & Services (NDH) Implementation Guide?

A: It's our understanding that the HL7 FAST FHIR directory work is where the industry and CMS are gathering to discuss a technical approach for nationwide provider and API endpoint directory.

Q: How will this impact CMS audits of health plans/systems—will site visits and request for info end?

A: We do not speak on behalf of CMS or speculate on what they may or may not do.

Q: How will the CMS Aligned network leverage TEFCA? Are they separate networks?

A: The CMS Aligned Network and TEFCA are intended to be complementary, not duplicative. From our understanding in reading the announcement and understanding what TEFCA is attempting to do, TEFCA will continue to operate with its own legal agreements, governance structure, and designated QHINs to connect networks across the country, while the CMS Aligned Network is a principles-based, voluntary framework that any type of entity can join not just QHINs.

If a QHIN becomes a CMS Aligned Network, it would continue meeting TEFCA's binding requirements while also committing to CMS's voluntary principles and use cases creating the potential for both to meet the requirements of the formal TEFCA framework and the broader, inclusive CMS-led effort.

Q: Will organizations and individuals that don't pledge via sending CMS an email still have the opportunity to engage, provide feedback, and contribute to the standards development?

A: You will need to reach out to CMS to get an answer to that question.

Q: ONC seems to be moving more and more towards not enforcing Info Blocking. What do they speakers on this webinar feel are the areas where we do need enforcement? It can't be all carrot and good will....

A: Based on comments from Dr. Tom Keane, the National Coordinator for Health IT, it appears information blocking is one of ASTP/ONC's priorities.

Q: CMS requires and recommends FHIR APIs that are currently lacking a certification program. Do we envision certification and conformance testing across all FHIR APIs?

A: The recently released HTI-4 Final Rule from ASTP/ONC does include certification criterion for the three recommended IGs listed in CMS 0057-F (e.g., CRD, DTR, PAS). We do not know of any certification plans for the CMS required APIs but Inferno can be used by implementers to ensure their APIs are conformant with the regulation on a voluntary basis.

Q: Is there a specific date that early adopters need to commit by?

A: Please refer to the CMS announcement.

Q: Without updating HIPAA or creating a new national privacy framework, how will the initiative ensure that entities not covered under HIPAA (e.g., apps) have comparable privacy standards to ensure the privacy of patient records?

A: Please review the CARIN Alliance Code of Conduct and MyHealthApplication.com for how we have tackled that question. The Code has been named in multiple CMS regulations, the FTC Health Breach Notification rule, TEFCA, and is required by dozens of organizations including the VHA. It also has a certification program through Direct Trust. As such, it's become the industry standard for how personally identifiable health data can be reliably protected when sent to a consumer who is covered by FTC regulations. In fact, at least in our view, CARIN apps who have signed the code are protecting health data and honoring a consumer's data sharing preferences better than HIPAA covered entities or their business associates are today.

Q: Data movement occurs at the speed of trust. There is no trust between health care as a system of care and individuals seeking care. Can the movement and call to action get a commitment from all participants that the data being collected is for care delivery, care coordination and will not be profited on…in other words…all involved will not sell my data. If we can move the mark on this the enthusiasm can and should be real.

A: There is a strong emphasis on trust, consent, and transparency in the CMS Aligned Network, but no blanket prohibition was made against selling or profiting from data. That kind of commitment would require either voluntary agreement from all participants (similar to CARIN's Code of Conduct) or future CMS policy action.

Q: Could PIQI be used as part of Real World Testing and Certification under ONC rules?

A: We won't speculate on what ONC will or will not do but PIQI can help the private sector objectively score patient health data for specific use cases before they send that data to others thus improving the data quality over time.

Q: Beyond pledging, as this movement advances, how can innovators contribute to the standards work or pilot efforts that ensure this ecosystem helps engage and educate patients and their families, especially when they're coordinating care for pediatrics and older adults?

A: The private sector has organized within HL7®, the CARIN Alliance, and other private sector led efforts to develop open standards and be early adopters for many of these topics. We would welcome participation from others.

Q: Would emphasize the HIPAA issue: provider organizations are held accountable to maintain patient privacy; currently others are not. The playing field must be leveled so that everyone exchanging information is held to the same standards', and penalties.

A: Thanks for the feedback. Our hope is that the Code of Conduct, coupled with action from the FTC and states against bad actors, will help with the consumer-facing application portion of the market.

Q: Given recent trust issues in health info exchange (e.g., between Epic and Particle Health), how can organizations and individuals trust that queries for treatment are really for treatment?

A: The CMS Aligned Network framework tries to build trust in treatment queries through identity assurance, required audit logs, patient-accessible receipts, and transparency about consent preferences. However, it does not add a new real-time policing mechanism for "is this really for treatment?" that still depends on each network's trust framework and compliance processes.

Q: The presentation slide cites US Core 3.1.1 compliance by Jan 2026. Should that be US Core 6.1.0 by 2026?

A: Correct. It references USCDI v3, which maps to US Core 6.1.

Q: In terms of data quality, while APIs may be certified, will there be data quality metrics that ensure things like reasonable fill rates and appropriate content in required fields? This is a broad issue across claims data.

A: There is activity happening in the PIQI Alliance with the PIQI framework that we hope helps with the data quality issues.

Q: What about 42CFR part 2 that governs Substance Use Data; is there a plan to integrate, but protect this data?

A: We're anticipating this will be a discussion once the CMS workgroups begin.

Q: Will there be any overlap in the new national provider directory with the existing NPPES directory? Specifically, will there be linkages between a physician's NPI to a provider's FHIR server? E.g., I want to get my records from Dr. Smith, but I don't remember the portal.

A: We would encourage you to join the HL7® FAST National Health Care Directory calls that relate to the standard.

Q: Also, what is the plan for consumers who, by virtue of their condition (serious and persistent mental illness, substance use, homelessness, lack of access to technology, etc.) to participate, get credentials, etc.?

A: The CARIN Alliance has been working in parallel on delegated access patterns and consent frameworks that could be applied here, enabling proxies, caregivers, or authorized representatives to manage data access on behalf of someone else. However, we are not aware of a public plan for how CMS will support vulnerable populations in obtaining credentials and participating. Addressing these gaps will likely require coordination among CMS, states, provider organizations, community-based intermediaries, and standards bodies like CARIN to operationalize inclusive access.

Q: Under what law(s) can violations of a code of conduct be enforced? Has that ever happened?

A: The FTC Act can enforce codes of conduct and yes, there is case law precedent on enforceable codes of conduct.

Q: One of the largest concerns in health care is cost. There is a substantial body of economic analysis demonstrating that regulatory burdens, particularly those related to technology and quality reporting, add significant administrative costs to the health care system. While the stated goal of these regulations is to improve quality and safety, their impact on overall health care spending is a complex and often debated topic, with many studies pointing to technology as a major driver of cost growth. Work needs to be done to really assess whether these are helping or hurting health care and how to move forward in a way that can provide benefit without continuing to increase costs.

A: It is estimated that Digital Quality Measurement reporting, Digital Identities for consumers, electronic prior authorization, and Digital Insurance Cards alone will likely save hundreds of billions of dollars in manual quality measurement reporting, patient matching costs, and revenue cycle management workflows respectively across the entire health care system.

Q: What do transaction logs cover? Provider-internal transactions or data access/change logs as well?

A: It has not been defined yet to our knowledge.

Q: Given that ANSI X12 remains the mandated standard for backend claims transactions under HIPAA, would you agree that FHIR isn't replacing X12 per se, but instead serves as a translation and abstraction layer which allows claims data to be exposed via modern APIs for application development, consumer access, and payer-provider interoperability? And if so, what architectural patterns or best practices are emerging to manage the X12-to-FHIR mapping and synchronization at scale?

A: Under HIPAA, ANSI X12 remains the required standard for the back-end exchange of claims and related transactions between payers and providers. FHIR is not replacing X12; rather, it serves as a modern "translation" layer that takes the information from those X12 transactions and makes it easier to use for consumer access so patients can view their claims data in apps as well as for application development by innovators building new tools, and for payer–provider collaboration on activities like quality measurement and care coordination. In other words, X12 will continue to carry the "official" transaction behind the scenes, while FHIR will present that same information in a faster, more flexible, and more user-friendly way.

Q: If everyone is a network, will they all be subject to information blocking penalties as a covered information blocking actor?

A: When the phrase "everyone can be a network" was used on the webinar, it was meant to imply that everyone (payers, providers, patients) can get seamless access to the health care data they are authorized to receive using a digital identity credential and a FHIR API with the CMS-aligned network principles. Interpretations of what an actor is under information blocking is left up to the regulatory agencies.

Q: What could this look like? Where is public health in this eco-system/network?

A: We hope that advancing FHIR and some of this standardization process will help with a number of PH use cases. We'd encourage engagement with Project Helios for those interested. We also believe that if public health simply requested the deidentified US Core/USCDI API from all of their health system partners, it would dramatically improve their ability to do syndromic surveillance and case reporting. The implementation of Bulk FHIR would help even more.

Q: "FHIR adoption" is very uneven from "FHIR-adjacent" or "FHIR-like" to "FHIR US Core Conformant." Certification programs are necessary for interoperability.

A: The CMS Aligned Network announcement does not appear to require FHIR certification. The ONC's Inferno test suite is a voluntary way to ensure the ONC and CMS required APIs are conformant to the regulations.

Q: The concept of a CMS-Aligned Network seems to be basically TEFCA without an actual agreement or governance (at least not yet). How do you see TEFCA coexisting with CMS Aligned Networks if QHINs become CMS Aligned Networks?

A: The CMS Aligned Network and TEFCA are intended to be complementary, not duplicative. From our understanding in reading the announcement and understanding what TEFCA is attempting to do, TEFCA will continue to operate with its own legal agreements, governance structure, and designated QHINs to connect networks across the country, while the CMS Aligned Network is a principles-based, voluntary framework that any type of network can join not just QHINs.

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Q: Will the Leavitt team be participating in the ASTP/ONC Un-Blocking Health Information Bootcamp on Thursday September 4, 2025?

A: We will not be participating in the event.

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