

Kill the Clipboard!

A Federal Policy and Industry Roadmap to Accelerate Innovation and Cut Administrative Waste

Overview and Executive Summary

Since the passage of the HITECH Act, 21st Century Cures Act, and the promulgation of the CMS Interoperability Rules (CMS-9115-F and CMS-0057-F), significant work has been done to advance clinical and non-clinical data exchange in digital formats, but limited efforts have been done to advance non-EHR solutions and application programming interfaces required by Congress, which is critical to solving nationwide healthcare interoperability challenges and to eliminating billions of dollars in administrative waste that are passed on to the taxpayers.

The promise of these policy actions is limited because of inconsistencies in the implementation of the required standards, lack of coordinated early adopter projects, regulatory and administrative drift from HITECH and the 21st Century Cures Act legislation. As a result, the pace at which technology moves is significantly outpacing rule making for the use of modern internet-based standards. Consequently, there remains a lack of technical specification and a lack of enforcement of the required standards and information blocking provisions on both payers and providers. Compounding these issues is a private sector focus on prioritizing proprietary point solutions that add costs to health care over open standard-based approaches, which are more consistent with the original intent of the 21st Century Cures Act.

Trust cannot be mandated or regulated. Trust is extremely hard to develop, maintain, and grow. As such, it's very hard to begin at the national level especially with payer/provider data exchange. It must start at a regional or state level or between two strategic partners that need to build trust to support their patient populations. It also must be earned through transparency, data sharing, the elimination of fee-based data exchange, and effective multi-stakeholder governance.

- We need to improve both WHAT information we share and HOW we share the information to reduce billions of dollars in wasted private sector administrative spending; the burden on providers, people, and plans; and eliminate regulatory bloat. Most of the projects below could be accomplished in the first year of the administration.
- **Purpose of this paper: To reduce regulatory burden, cut the number of “trust” documents (e.g., data use agreements, contracts, business associate agreements [BAAs], etc.), make our fragmented health care system more interoperable, save billions of dollars in administrative overhead, expand national exchange networks, reduce provider and patient burden, make digital quality exchange more efficient, and expand digital identity services.**

The following recommendations will dramatically ease patient and provider burden, reduce redundant solutions, and eliminate wasteful spending. We hope these recommendations begin a conversation with both the public and private sectors on how to substantially move forward with effective federal policy to support interoperability and digital health across the country.

ELIMINATE ANTIQUATED INTEROPERABILITY POLICY AND BETTER ALIGN ACROSS THE FEDERAL GOVERNMENT

Problem

- Too much regulation has inhibited innovation, stifled competition, and produced vendor lock-in through regulatory capture.¹
- The DOJ has fined EHR companies for failing to include required functionality *within* their proprietary products,² which has increased the amount of regulatory capture, stifled innovation by the vendors, and limited competition.
- Regulatory deadlines between the ONC and CMS interoperability rules are out of sync and therefore have exasperated the problems with interoperability.
- Certified Electronic Health Record Technology (CEHRT) has been a valuable way to ensure provider systems are consistently developed across the country during HITECH, but it needs an upgrade to better meet the needs of supporting a modern computing architecture.

¹ <https://12mv2.com/2023/10/05/2851-miles-bill-gurley-transcript-slides/>

² <https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-155-million-settle-false-claims-act-allegations>

Proposal

Align federal interoperability efforts and redefine CEHRT to correspond with its original definition in the HITECH Act

1. Align federal interoperability, data privacy, and security efforts under a single division within CMS which includes Health Care standards (HIPAA standards, NCVHS), clinical standards (ONC), provider/payer standards (CMS), state Medicaid technology oversight and funding (Data and Systems Group within CMCS), and HIPAA privacy and security enforcement (from OCR).
2. ONC should change the definition of CEHRT (Certified Electronic Health Record technology) to “API CEHRT” (Application Programming Interface Certified Electronic Health Retrieval Technology).
3. The ONC is able to redefine API CEHRT based on the original definition in the HITECH Act,³ which includes the adoption of standards in Section 3004 and defines health information technology as inclusive all of the “hardware, software, . . . or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information.” This definition would include EHRs, payer systems, API vendors, and cloud-based solutions.
4. API CEHRT should focus exclusively on certifying the HL7 FHIR APIs that providers and payers send and receive and no longer certify the functionality within the EHRs or EDI X12 transactions.
5. CMS should then point to the new definition of API CEHRT in their regulations to ensure consistency between providers and payers

³ SEC. 3000. DEFINITIONS. “In this title: (1) CERTIFIED EHR TECHNOLOGY.—The term ‘certified EHR technology’ means a qualified electronic health record that is certified pursuant to section 3001(c)(5) as meeting standards adopted under section 3004 that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals).

(5) HEALTH INFORMATION TECHNOLOGY.—The term ‘health information technology’ means hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information.”

6. The APIs on ONC’s Inferno Test Kit website⁴ should be supported by payers and providers and implemented within the next two years. As of March 2025, they include:

API’s	Providers & EHRs	Payers
<u>Bulk Data Access Test Kit</u>	✓	
<u>CARIN Consumer Real-time Pharmacy Benefit Check (NEW)</u>		✓
<u>CARIN Digital Insurance Card and API (NEW)</u>		✓
<u>CARIN IG for Blue Button Test Kit</u>	✓	✓
<u>DaVinci Documentation Templates and Rules (DTR) Test Kit</u>		✓
<u>Da Vinci Coverage Requirements Discovery (CRD) Test Kit</u>		✓
<u>Da Vinci Payer Data Exchange (PDex) Test Kit</u>		✓
<u>Da Vinci Plan Net Test Kit</u>		✓
<u>Da Vinci Prior Authorization Support (PAS) Test Kit</u>		✓
<u>Da Vinci US Drug Formulary Test Kit</u>		✓
<u>International Patient Summary Test Kit</u>	✓	
<u>OAuth 2.0 Authorization Framework (NEW)</u>	✓	✓
<u>ONC Certification (g)(10) Standardized API Test Kit</u>	✓	
<u>OpenID Connect Core 1.0 (NEW)</u>	✓	✓
<u>PIQI open scorecard framework⁵; implement as part of the CEHRT process for each new EHR upgrade once it’s an HL7 open standard (NEW)</u>	✓	
<u>Service Base URL Test Kit</u>	✓	✓
<u>SMART App Launch Test Kit</u>		✓
<u>SMART Health Cards Test Kit</u>		✓

⁴ <https://inferno.healthit.gov/test-kits/>

⁵ <https://piqiframework.org/>

API's	Providers & EHRs	Payers
SMART Scheduling Links Test Kit	✓	
SMART UDAP Harmonization Test Kit	✓	✓
Subscriptions Test Kit	✓	✓
US Core Test Kit		✓
UDAP Security Test Kit	✓	✓
CDS Hooks (NEW)	✓	
Image Exchange using Argonaut work and SMART Sync for science designs (NEW)	✓	

- Employers who provide commercial insurance should also be obligated to support the same APIs as the CMS payers to ensure consumers with commercial insurance have a similar experience as those who have a CMS payer or provider. This would likely come under DOL's jurisdiction.

Outcomes

- Data exchange standards and ongoing API requirements will be implemented simultaneously by EHRs, providers, and health plans in the future.
- Provides innovative tech vendors, cloud platform providers, health plans, and provider organizations the ability to offer certified APIs would ease the way for non-EHR market entrants, spur innovation, and reduce costs.
- Bulk FHIR queries, which are critical to implementing value-based care will be able to be performed by cloud-based vendors and other innovators, extending beyond EHRs.
- EHRs will have more freedom to update the functionality within their systems without government intervention to improve provider workflows and patient safety.

IMPROVING PATIENT ACCESS TO HEALTH CARE DATA

Problem

- Patients today have a disjointed set of portals to access all their health care information, making it nearly impossible to proactively manage their health information across different providers and systems.

- Numerous trusted consumer-facing applications⁶ are on the rise, but many providers are having difficulty accessing health information on behalf of patients.
- Recent federal and state legislation makes it easier for consumers to access more health information than ever, but barriers still exist for consumers seeking to take full advantage of that information.
- Provider directories are costly to maintain, are designed to serve multiple purposes, and are often inaccurate because they do not solve the core problem of identity-proofing the individual provider and determining how to tie that information back to the provider digitally through a FHIR API endpoint.
- Open standards exist for patients to: digitally select a health plan based on their own unique health situation, select providers and schedule an appointment, estimate out-of-pocket costs for prescriptions and medical procedures before seeing a provider or dispensing a medication, register online before they see a physician and thus eliminate the need to complete paperwork on a clipboard, and access their health information from any provider in the country. The problem is they haven't been implemented at scale.

Solution

Selecting a plan

1. Require all providers and payers (including employers who provide commercial insurance) to implement the APIs in the CMS Interoperability and Patient Access Final Rule (CMS-9115).
2. Ensure all hospitals implement price transparency machine-readable files (MRFs) in accordance with the White House Executive Order on February 25th, 2025.⁷

Selecting a provider

1. CMS should develop a new provider directory that is based on an IAL2 digital identity-proofed credential created by the provider and the specific FHIR endpoint for digitally connecting with that provider. Additional meta data regarding the provider, the billing group, and other details can then be added over time.
2. Multiple consumer-facing applications should allow the consumer to book their own appointment. The Argonaut project has developed a framework that supports an open API approach for patient scheduling.⁸

⁶ <https://www.myhealthapplication.com/#apps>

⁷ <https://www.whitehouse.gov/presidential-actions/2025/02/making-america-healthy-again-by-empowering-patients-with-clear-accurate-and-actionable-healthcare-pricing-information/>

⁸ <https://www.fhir.org/guides/argonaut/scheduling/>

Determining a consumer's out-of-pocket costs

1. Implementation of the Patient Cost Transparency FHIR API Implementation Guide⁹ will support the ability of patients to determine their out-of-pocket costs
2. An industry consensus process called Project Clarity¹⁰ has developed open service packages to better enable consumers to shop for procedures and services across providers. We would encourage adoption of those open service packages so consumers can consistently compare costs across providers.
3. Pharmacy costs could be lowered by \$120–\$130 per prescription¹¹ by implementing the CARIN Consumer Real-Time Pharmacy Benefit Check API¹² across the country, which is already required in seven states.

Online check-in

1. A patient can use a consumer application and IAL2 digital identity provider (e.g., CLEAR, ID.me, etc.) to prove their identity and authenticate themselves thus saving on patient matching costs down the road if the provider updates their demographics with the patient's credential.
2. A patient can download and then share their digital insurance card using the CARIN IG for Digital Insurance card FHIR API IG¹³ with their provider thus saving time at check in and reduce revenue cycle management recovery costs for the provider.

Accessing a consumer's own health care data

1. A patient can aggregate and share their health information with their provider using the Patient Access API.
2. Data holders should accept an IAL2 digital identity credential from an identity provider certified by Kantara¹⁴ using the entire Open ID Connect standard.¹⁵
3. Data holders need to implement SMART User Access Brands¹⁶ and Endpoints to ensure the consumer knows which brand the provider or payer belongs to.

⁹ https://build.fhir.org/ig/HL7/davinci-pct/gfe_submission_and_aeob_overview.html

¹⁰ <https://servicepackages.health/project-clarity/>

¹¹ <https://drugstorenews.com/pharmacy/cvs-health-real-time-benefits-program-reduces-drug-costs/>

¹² <https://www.hl7.org/fhir/us/carin-rtpbcc/>

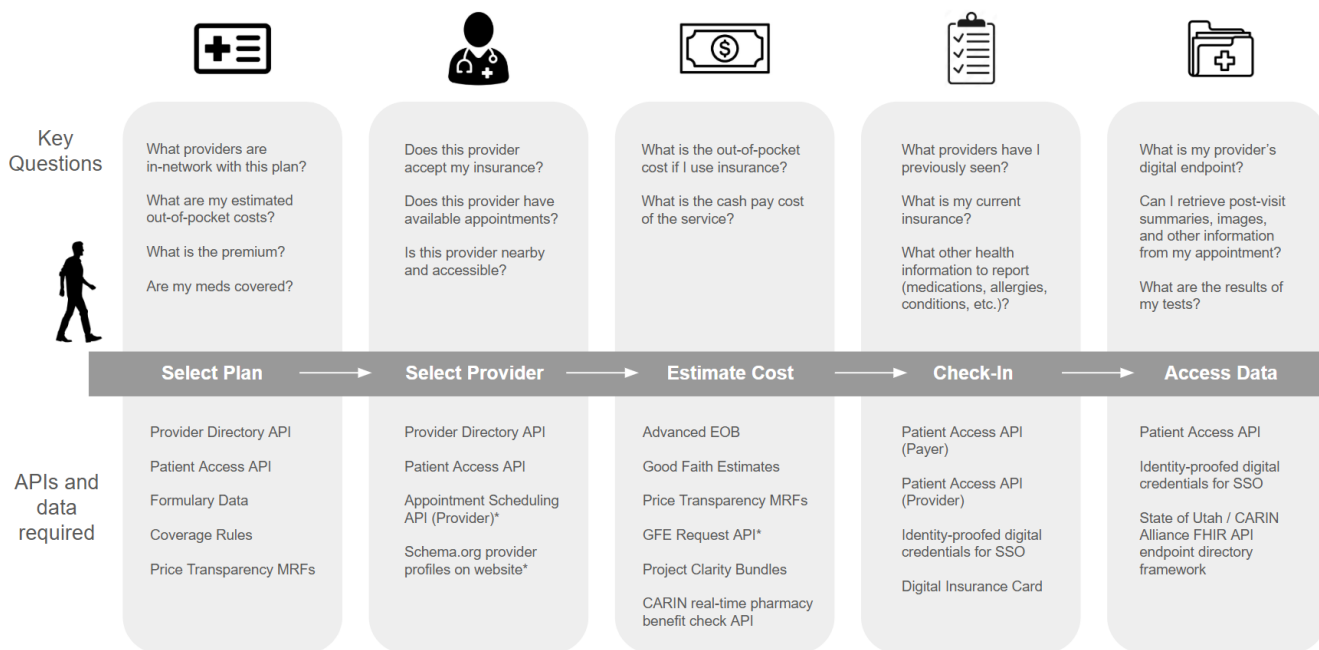
¹³ <https://www.hl7.org/fhir/us/insurance-card/>

¹⁴ <https://kantarainitiative.org/trust-status-list/>

¹⁵ https://openid.net/specs/openid-connect-core-1_0.html

¹⁶ <https://www.hl7.org/fhir/smart-app-launch/brands.html>

4. Data holders need a test sandbox, development environment, detailed technical documentation, and synthetic data for applications to test against like what was recommended by the CARIN Alliance.¹⁷
5. Data holders need to validate conformance to the regulations by testing their APIs against the ONC’s Inferno Test Kits.¹⁸
6. EHR version updates that include the required interoperability functionality need to be shipped to the client with all of the interoperability functionality turned on rather than defaulting off, which causes confusion and frustration.



Source: Many thanks to Defacto Health’s blog post which was the foundation for this graphic and other novel ideas.
<https://defacto.health/2025/01/28/empowering-patient-choice-with-payer-and-provider-data/>

¹⁷ <https://www.carinalliance.com/announcement/the-state-of-the-cms-patient-access-api-a-carin-alliance-webinar-november-2024>

¹⁸ <https://inferno-framework.github.io/docs/>

IMPROVE HEALTH CARE DATA EXCHANGE TO ENSURE FASTER IMPLEMENTATION OF FHIR APIS FOR B2B DATA EXCHANGE

Problem

Interpreting national data exchange exclusively as a single national approach ignores the progress we have made over the last few decades at a state and regional level.

Proposal

1. Harken back to the original wording in the 21st Century Cures Act¹⁹ which requires the health information technology developer or entity “has published application programming interfaces and allows health information from such technology to be accessed, exchanged, and used without special effort through the use of application programming interfaces . . . including providing access to all data elements of a patient’s electronic health record.”
2. Leverage the state-based HIE infrastructure and/or the QHINs to solve for problems like who could host FHIR endpoint directories and third-party confirmation of attributed lives between providers and health plans.
3. Identify ways to implement the key values of TEFCA, which include a single technical connection to the network, a single data use agreement, a FHIR endpoint directory, providing ways for patients to have greater control over their data, and a record location service using existing production interoperability assets to allow for additional use cases to be implemented and state specific requirements to be accommodated.

¹⁹ Section 4002, (a)(D)—‘CONDITIONS OF CERTIFICATION.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary, through notice and comment rulemaking, shall require, as a condition of certification and maintenance of certification for programs maintained or recognized under this paragraph, consistent with other conditions and requirements under this title, that the health information technology developer or entity— “(iv) has published application programming interfaces and allows health information from such technology to be accessed, exchanged, and used without special effort through the use of application programming interfaces or successor technology or standards, as provided for under applicable law, including providing access to all data elements of a patient’s electronic health record to the extent permissible under applicable privacy laws; (v) has successfully tested the real world use of the technology for interoperability (as defined in section 3000) in the type of setting in which such technology would be marketed; “(vi) provides to the Secretary an attestation that the developer or entity— “(I) has not engaged in any of the conduct described in clause (i); “(II) has provided assurances satisfactory to the Secretary in accordance with clause (ii); “(III) does not prohibit or restrict communication as described in clause (iii); “(IV) has published information in accordance with clause (iv); “(V) ensures that its technology allows for health information to be exchanged, accessed, and used, in the manner described in clause (iv); and “(VI) has undertaken real world testing as described in clause (v); and “(vii) submits reporting criteria in accordance with section 3009A(b).”

4. The original wording of the 21st Century Cures Act requires the administration to “take into account existing trusted exchange frameworks and agreements used by health information networks to avoid the disruption of existing exchanges between participants of health information networks.” It also states that “the Secretary shall ensure the consideration of activities carried out by public and private organizations related to exchange between health information exchanges to avoid duplication of efforts” by providing providers and health plans the ability to use existing national networks (e.g., eHealth Exchange) to meet the requirements within TEFCA.
5. Publish the TEFCA FHIR API endpoint directory publicly immediately, which includes the recommended data elements suggested on the HL7 website,²⁰ which lists the technical contact information (email and phone) and developer portal information to resolve any connectivity issues, thus streamlining registration and onboarding. This could be required under an accreditation program (such as NCQA Health Plan Accreditation).
6. The Office of the Inspector General (OIG) should investigate the more than 1,100 possible complaints of information blocking identified by the public and the ONC,²¹ publish the findings, and recommend fines to CMS to ensure data exchange is occurring.
7. OIG can define information blocking as not sharing the regulated FHIR APIs with payers, providers, or patients and recommend fines to CMS for those who do not comply.
8. ONC can provide a way for organizations to aggregate information blocking complaints and allow an independent third-party association or organization to act on behalf of a group of companies who believe information blocking is occurring. This would encourage additional payers and providers to submit more information blocking complaints since it wouldn’t be tied back to their individual organizations. The CARIN Alliance called this a “complaint clearinghouse” model.²²
9. Provide HHS statutory authority to offer Advisory Opinions for Information Blocking²³ claims, which allows the agencies to execute their full responsibilities under the 21st Century Cures Act.

²⁰ https://confluence.hl7.org/display/FHIR/Endpoint+directory+implementations+and+frameworks?preview=/113672758/218828161/API%20Endpoint%20Directory%20Inputs_Confluence%20Version.xlsx

²¹ <https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers>

²² CARIN public comments on a ‘complaint clearinghouse’ https://cdn.prod.website-files.com/66635361bd8176cd6413cb24/66688a5b53715a21676b2bf9_CARIN_Information-Blocking-Final-12.13.23.pdf

²³ HHS has requested in 2023 to, “Provide HHS the authority to create an advisory opinion process and issue advisory opinions for information blocking practices governed by section 3022 of the Public Health Service Act (PHSA), 42 USC 300jj-52. The opinion would advise the requester whether, in the Department’s view, a specific practice would violate the information blocking statutory and regulatory provisions; it would be binding on the Department, such that the Department would be barred from taking enforcement action against the practice. In addition, provide ONC with the authority to collect and retain fees charged for issuance of such opinions, and to use such fees to offset the costs of the opinion process.” (<https://www.healthit.gov/buzz-blog/information-blocking/information-blocking-and-the-presidents-fy23-budget-for-onc>)

10. Publish all regulated FHIR API endpoints in a publicly available location, regardless of whether those endpoints exchange data with a proprietary EHR or payer solution or not. Options must be made available to providers and health plans to make the APIs available in ways that are customized to that organization's unique business needs.

Outcomes

- Access to API endpoints will be openly available and allow innovators access to payer and provider data that is in accordance with the appropriate data use agreement they have agreed to (e.g., common agreement, point-to-point data agreement, DURSA, etc.).
- Organizations will begin to exchange FHIR APIs immediately using existing data use agreements they have with each other rather than wait for everyone to join a single national "network of networks" infrastructure.
- Binding opinions on information blocking claims across HHS that will provide guidance to the industry on what does and does not constitute information blocking.

IMPROVE THE TRUSTED EXCHANGE FRAMEWORK AND COMMON AGREEMENT (TEFCA)

Problem

- We support and want to expand participation in TEFCA but currently there are perverse incentives being proposed on the national networks that will prevent adoption of the treatment, payment, and operations use cases.
- TEFCA may exacerbate information asymmetry issues that favor payers because they receive the clinical data while only releasing a portion of the claims, operational and administrative data
- TEFCA cannot be the *only* option for health care data exchange across the country, but it could be *an* option.
- EHR vendors are making it difficult for their clients to switch QHINs by invoking financial penalties if they want to be "on their own". The EHR+QHIN organizations may not even agree to make these connections as a paid service, even though they have the technology to do so at scale. This behavior is contrary to the idea that Participants should be able to select the QHIN with the best services at the lowest cost.
- National early adopter programs (e.g., 10x10 or 10 1x1s) don't work because there is too little overlap to make it worthwhile for providers to change their prior authorization workflows.
 - In addition, states need to be compliant with the CMS-0057-F rule and can act as a natural convener.

- We need payer agnostic solutions that will work for any health plan and exposes the data as appropriate using secure, open APIs.
- We also need incentives for implementers to reduce costs such as eliminating the need to transfer data using X12.
- Charging for non-treatment-based use cases could incent entities to create fictional use cases, which may be treatment-adjacent but do not meet the HIPAA definition of treatment or the narrower definition currently proposed by ONC/RCE. We need to disincentivize this activity.
- We need multiple models to support provider-based data exchange to support the multiple use cases providers use the data for including with clinically integrated network partners, value-based care arrangements, and with other entities where data exchange happens outside the EHR.

Proposal

1. Eliminate fees for TEFCA-related data exchange for all participants including health plans, providers, consumers, public health, and disability benefits. Fees should reside solely at the QHIN-participant level where they can discuss the value of joining the specific QHIN.
2. Allow providers and health plans the ability to select more than one QHIN including potentially a different QHIN than their vendor is associated with.
3. Diversify the governance structure within TEFCA to ensure private and public sector participation from a cross section of stakeholders (payer, providers, patients, etc.) who are both participating and not participating in TEFCA²⁴ to reduce potential conflicts of interest. We need far more stakeholders representing consumer, public health, and health plan representation (even if they aren't participating in TEFCA) on the TEFCA governance structure to better define the use cases they are looking to implement. The current governance structure is far too provider and QHIN heavy. Organizations who participate in the governance structure should also be required to disclose their revenue models to indicate how they would benefit financially from decisions they would need to make.
4. Leverage industry working groups (e.g., HL7, FHIR accelerator programs, etc.) to inform the technology recommendations adopted by TEFCA not solely independent contractors or new invite-only workgroups.

²⁴ Carequality's Board, Steering Committee, and Advisory Council model provides a good starting point that incorporates a variety of stakeholder perspectives both within and outside of Carequality. <https://carequality.org/get-involved/steering-committee/>.

5. Formalize and publicize voting on specific technology and process recommendations using Robert’s Rules of Order within the TECCA Governance Process.
6. QHINs that offer other technical products - like EHR technology for example - should create a pathway for data from other QHINs to be incorporated into those products at little cost. This way, participants can confidently select the best QHIN for their needs, which would incentivize innovation.
7. Support and fund state-based FHIR early adopter projects that include multiple payers and multiple providers to facilitate the implementation of the CMS-0057-F rule (e.g., OneUtah Digital Health early adopter project²⁵ is the most advanced example) using a TECCA-based approach. This should not limit other early adopter pilots including point-to-point FHIR based transactions.

Outcomes

- Solves for more use cases that are value-based care focused and improving trust, transparency, and participation in TECCA.

AUTOMATE QUALITY MEASUREMENT REPORTING

Problem

- Physicians spend more than \$15 billion dollars a year on quality reporting.²⁶
- EHRs are important partners in data exchange, but not all provider data exchange happens through EHRs. Providers frequently have vendor products, Clinically Integrated Networks (CINs), Value Based Care populations, analytic warehouses, and other use cases that utilize EHR data but are not directly connected to a single EHR. For these reasons, it is crucial that we have a pathway to extract standards-based data at scale from EHRs.
- The Bulk FHIR functionality described in the 21st Century Cures Act was intended to allow permitted parties to extract standards-based data not for a single patient or for a single physician’s patient panel but for large populations. Most certified EHRs checked the box on implementing this Bulk FHIR functionality, but they did not invest to make Bulk FHIR usable in real-world situations, and it breaks down when querying information for more than a few patients.

²⁵ <https://www.uthealthcollaborative.org/accelerate-innovation/#featured-innovation>

²⁶ <https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.1258>

Proposal

1. CMS needs to implement receiving systems with FHIR APIs for providers and health plans for dQMs. HL7 Da Vinci's Data Exchange for Quality Measures (DEQM) standard can be adopted for part of this purpose.
2. Providers need to maintain US Core APIs to enable data exchange, through EHRs, in response to bulk FHIR queries from payers who use CQL engine, or certified CQL measure logic, to produce digital quality measurement reports to send to NCQA and CMS. We also need EHR vendors to support CQL. EHRs need to have reasonably priced US Core APIs for providers to exchange data.
3. Certified EHRs should deliver on the intent of the 21st Century Cures Act and offload the Bulk FHIR functionality to modern systems that are designed to be responsive and scale. Some large Health Information Exchanges and technology vendors created responsive Bulk FHIR systems in just a few months, and we should incentivize EHRs to do so as well.
4. Obviates the need for manual and bespoke quality measurement reporting and validation programs and accelerates the transition to digital quality measurement (dQM) reporting.

Outcomes

- An automated, standards-based digital measurement system that can be scaled for prospective and retrospective quality reporting to NCQA or CMS.
- Millions of dollars in administrative savings to help lower health care premiums and reduce provider and regulatory burden.

ADOPT DIGITAL IDENTITY SERVICES FOR INDIVIDUALS, PAYERS, AND PROVIDERS

Problem

- We have not adequately addressed the 21st Century Cures Act language, which requires “a common method for authenticating trusted health information network participants.”²⁷
- Cybersecurity threats in health care are at an all-time high with more than 100M people affected in 2023.²⁸

²⁷ Section 4003, (b)(9)(B)(i)(II): “(I) a common method for authenticating trusted health information network participants; (II) a common set of rules for trusted exchange; “(III) organizational and operational policies to enable the exchange of health information among networks, including minimum conditions for such exchange to occur; and “(IV) a process for filing and adjudicating noncompliance with the terms of the common agreement.

²⁸ <https://405d.hhs.gov/>

- Patients have not been involved in validating that they are who they say they are with their provider or health plan, which creates millions of dollars in downstream issues identifying individuals across systems.
- Technically, the \$Match solution will not work across the country and currently does not support a FHIR-only exchange pattern.

Proposal

1. Require that any system used for registration and login to access sensitive data on any health care network follow the NIST 800-63-3 digital identity guidelines for identity assurance level 2 (IAL2) and authenticator assurance level 2 (AAL2) for patient and provider identity and authentication.
 - A. This can be done by using a vendor on the Kantara certified vendor list²⁹ or by using vendors that provide those services today as part of an organization's user access management onboarding processes inside the organization.
2. Consumer identity for access to health care portals, personal health care applications, health care services (such as digital visits, condition management, and health devices) shall use open standards and support OpenID Connect. These services also shall support Identity Federation and shall accept a NIST 800-63-3 IAL2 or higher certified identity provider as valid for a consumer to access their data and to create a login session using OpenID Connect, with data provided via an openly provided API.
3. Access to identity federation and open data APIs shall not involve onerous approval or anticompetitive releases and shall not incur undue costs beyond the base costs of operating the system.
4. Adopt Open ID Federation or UDAP Tiered OAuth protocols to ensure all systems can accept an identity credential.
5. Encourage the use of the CARIN IG for Digital Insurance Card API and SMART Health Cards/Links.

²⁹ <https://kantarainitiative.org/trust-status-list/>

Outcomes

- Strengthen the identity and access management capabilities of each individual user on any network (providers, health plans, and individuals) by requiring the adoption of the NIST-800-63 identity and authentication standards recommended by HHS,³⁰ TEFCA,³¹ and supported by the industry.³²
- Promote online patient registration that allows patients to create their own single digital identity, aggregate their own health information with an application of their choice, and provide their insurance information digitally.
- Reduction in phishing and other cybersecurity attacks for health care organizations and individuals to prevent individual's health care data from being breached.
- Full transparency and trust that individuals are who they say they are and better identification of who each individual represents on any network.

CONCLUSION AND NEXT STEPS

What will be the impact of inaction (e.g., the status quo)?

Vendor lock-in, regulatory capture, lack of innovation, including more expensive and less effective solutions, treatment-only data exchange, and lack of trust in exchanging data with trading partners across the country.

What will be the combined impact of these changes?

- Billions of dollars of administrative waste eliminated from the system
- Igniting the innovation economy in health care
- Lower premiums, expanded access, better patient outcomes, empowered individuals with access to their own health information
- More secure and interoperable systems
- Less administrative burden on consumers and providers

³⁰ <https://405d.hhs.gov/Documents/tech-vol2-508.pdf>

³¹ <https://www.healthit.gov/sites/default/files/page/2019-04/FINALTEFCAQTF41719508version.pdf>

³² <https://info.hl7.org/hubfs/HIMSS23/The%20CARIN%20Alliance-Advancing%20Consumer-Directed%20Exchange.pdf>

We want to thank the group of multi-stakeholder partners who helped us put this paper together. They included consumers, payers, providers, national networks, HIEs, public sector colleagues, HIT vendors, digital health companies, and many others.

If you would like to further discuss these ideas or have some thoughts on how we might expand this list, please reach out to Ryan Howells, Principal at Leavitt Partners (ryan.howells@leavittpartners.com) or David Lee, Principal at Leavitt Partners (david.lee@leavittpartners.com) who help lead the Leavitt Partners Digital Health and Interoperability practice.