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Digital Health & Interoperability Policy:

New Ideas to Drive Federal Government Efficiency

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AGENDA

- Eliminate Antiquated Interoperability Policy
- Inferno APIs
- Additional Consumer Use Cases
- Improving B2B Data Exchange
- Improving TEFCA
- Automate Digital Quality Measurement
- Digital Identity Federation

Eliminate Antiquated Interoperability Policy

THE PROBLEMS

01

Too much regulation has inhibited innovation, stifled competition, and produced vendor lock-in through regulatory capture.

02

Regulatory deadlines between the ONC and CMS interoperability rules are out of sync and therefore have exasperated the problems with interoperability.

03

Certified Electronic Health Record Technology (CEHRT) policy needs an upgrade to better meet the needs of supporting a **modern computing architecture**.

Eliminate Antiquated Interoperability Policy

THE PROPOSALS

- **ONC should change the definition of CEHRT** (certified electronic health record technology) to "API CEHRT" (application programming interface certified electronic health retrieval technology).
- **The ONC is able to redefine API CEHRT based on the original definition in the HITECH Act**, which includes the adoption of standards in Section 3004 and defines health information technology as inclusive of all 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, APIs, and cloud-based solutions.
- **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.
- **CMS should then point to the new definition of API CEHRT in their regulations** to ensure consistency between providers and payers.
- **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.

Support the Inferno APIs

INFERNO.HEALTHIT.GOV

Providers and EHRs

ONC Certification (g)(10) Standardized API Test Kit	UDAP Security Test Kit
International Patient Summary Test Kit	SMART UDAP Harmonization Test Kit
Bulk Data Access Test Kit	Service Base URL Test Kit
CARIN IG for Blue Button Test Kit	OpenID Connect Core 1.0 (NEW)
SMART Scheduling Links Test Kit	OAuth 2.0 Authorization Framework (NEW)
Subscriptions Test Kit	Implement the PIQI open scorecard framework5 as part of the CEHRT process for each new EHR upgrade once it's an HL7 open standard (NEW)

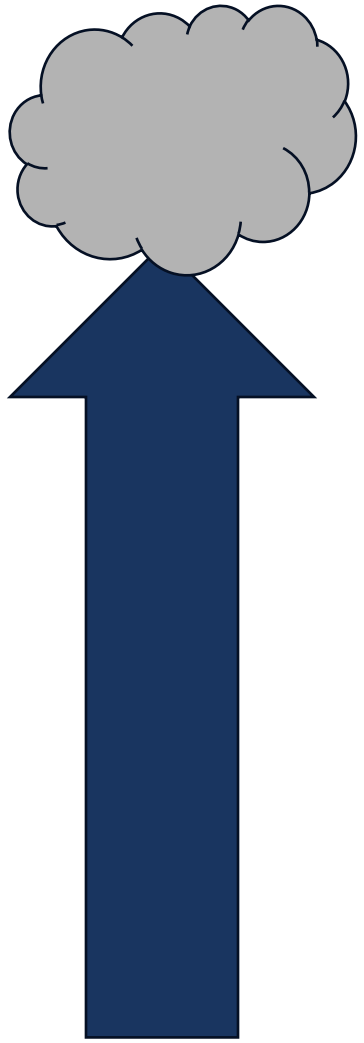
Payers

Da Vinci Plan Net Test Kit	Subscriptions Test Kit
Da Vinci US Drug Formulary Test Kit	UDAP Security Test Kit
CARIN IG for Blue Button Test Kit	SMART Health Cards Test Kit
DaVinci Documentation Templates and Rules (DTR) Test Kit	Service Base URL Test Kit
Da Vinci Prior Authorization Support (PAS) Test Kit	SMART App Launch Test Kit
Da Vinci Coverage Requirements Discovery (CRD) Test Kit	CARIN Consumer Real-time Pharmacy Benefit Check (NEW)
US Core Test Kit	CARIN Digital Insurance Card and API (NEW)
SMART UDAP Harmonization Test Kit	OpenID Connect Core 1.0 (NEW)
Da Vinci Payer Data Exchange (PDex) Test Kit	OAuth 2.0 Authorization Framework (NEW)

Five Pillars of a Modern, Open, Health Data Ecosystem

Pillar	Why is it a pillar?	What administrative burdens would this address?	How could it be implemented?
1) Standardized Open APIs with a publicly available FHIR endpoint directory	Open APIs provide more scalable, secure, and modern ways to send data to other stakeholders and innovators.	Prior authorization, patient information collection, quality measurement data collection and submission.	ONC's Inferno Test Kit (Inferno.HealthIT.gov)
2) Improved Data Quality through Measuring the Data Outputs	Data being exchanged today is not of high-quality and must be improved to be usable across systems.	Prior authorization, patient information collection, quality measurement data collection and submission.	PIQI Framework (PIQIFramework.org)
3) An Open, Cloud-Based, Semantically Interoperable, Clinical Data Model	An open cloud-based data model is more secure, flexible, standardized, and scalable to use—especially for Bulk FHIR use cases.	Prior authorization, patient information collection, quality measurement data collection and submission.	S2 Health / Graphite Health
4) Digital Identity Federation	Identity helps to answer these questions: • Are you who you say you are? • Who do you represent? • What data are you authorized to receive?	Patient information collection, provider directories	IAL2 / AAL2 Digital Identity Credentials for all stakeholders
5) Robust Information Blocking Enforcement	To ensure compliance with data exchange regulations, we need government enforcement.	Prior authorization, patient information collection, quality measurement data collection and submission.	An administration that prioritizes the OIG or other appropriate federal agency

Public and private sector steps to innovation and interoperability



Functionality	Details	Which Agency would be involved?
Cloud-Based Architecture	Apps, UI/UX, CDS, remote patient monitoring, consumer experience, and AI.	TBD
S2 Health Data Model	Semantically Interoperable, cloud-based data model	CMS
PIQI Framework	Objectively measuring the quality of the data	ONC/CMS (NEW Policy)
Inferno Certification	Open test harness to standardize the data being sent from the EHR	ONC (NEW Policy)
APIs	Structured Data required to be sent from the EHR	ONC (NEW Policy)
API Gateway	Access control, performance optimization, security, scalability	ONC (NEW Policy)
Core legacy EHR System	Clinician workflow and billing software	ONC

FHIR® APIs Enable Multiple Consumer Use Cases





	Select Plan →	Select Provider →	Estimate Cost →	Check-In →	Access Data →
Key Questions	• What providers are in-network with this plan? • What are my estimated out-of-pocket costs? • What is the premium? • Are my meds covered?	• Does this provider accept my insurance? • Does this provider have available appointments? • Is this provider nearby and accessible?	• What is the out-of-pocket cost if I use insurance? • What is the cash pay cost of the service?	• What providers have I previously seen? • What is my current insurance? • What other health information to report (medications, allergies, conditions, etc.)?	• What is my provider's digital endpoint? • Can I retrieve post-visit summaries, images, and other information from my appointment? • What are the results of my tests?
APIs & Data Required	• Provider Directory API • Patient Access API • Formulary Data • Coverage Rules • Price Transparency MRFs	• Provider Directory API • Patient Access API • Appointment Scheduling API (Provider)* • Schema.org Provider Profiles on Website*	• Advanced EOB • Good Faith Estimates • Price Transparency MRFs • GFE Request API* • Project Clarity Bundles • CARIN Real-Time Pharmacy Benefit Check API	• Patient Access API (Payer) • Patient Access API (Provider) • Identity-Proofed Digital Credentials for SSO • Digital Insurance Card	• Patient Access API • Identity-Proofed Digital Credentials for SSO • State of Utah / CARIN Alliance FHIR API Endpoint Directory Framework

Original Source: https://defacto.health/2025/01/28/empowering-patient-choice-with-payer-and-provider-data

Improve Health Care Data Exchange and Immediate Implementation of FHIR APIs for B2B Data Exchange

THE PROPOSALS

- Harken back to the original wording in the 21st Century Cures Act 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."

- 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**.

- 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.

Improve Health Care Data Exchange and Immediate Implementation of FHIR APIs for B2B Data Exchange

THE PROPOSALS

- **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.

- **Publish the TEFCA FHIR API endpoint directory publicly immediately**, which includes the recommended data elements suggested on the HL7 website, 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).

- **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, publish the findings, and recommend fines to CMS to ensure data exchange is occurring.

Improve Health Care Data Exchange and Immediate Implementation of FHIR APIs for B2B Data Exchange

THE PROPOSALS

- 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**.

- **Provide HHS statutory authority to offer Advisory Opinions for Information Blocking claims**, which allows the agencies to execute their full responsibilities under the 21st Century Cures Act.

- **Publish all regulated FHIR API endpoints in a publicly available location**, regardless of whether those endpoints exchange data with a proprietary 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.

Improve the Trusted Exchange Framework & Common Agreement (TEFCA)

THE PROBLEMS

01

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.

02

TEFCA may exacerbate information asymmetry issues that favor payers because they receive the clinical data while only releasing a portion of the claims, and operational and administrative data.

03

TEFCA cannot be the only option for health care data exchange across the country, but it could be an option.

04

EHR vendors are strongarming their EHR clients into potentially low performing QHINs. EHR clients may receive financial penalties and be “on their own” if they select another QHIN, meaning that their annual EHR costs may be higher and that they would have to do the work to connect their QHIN’s data into the EHR.

Improve the Trusted Exchange Framework & Common Agreement (TEFCA)

THE PROBLEMS

05

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, provide a single user interface for providers, 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.

06

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.

07

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.

Improve the Trusted Exchange Framework & Common Agreement (TEFCA)

THE PROPOSALS

- **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.
- **Allow providers and health plans the ability to select more than one QHIN** including potentially a different QHIN than is associate with their vendor.
- **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 TEFCA** 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.

Improve the Trusted Exchange Framework & Common Agreement (TEFCA)

THE PROPOSALS

- **Leverage industry working groups (e.g., HL7, FHIR accelerator programs, etc.)** to inform the technology recommendations adopted by TEFCA.
- **Formalize and publicize voting on specific technology and process recommendations** using Robert's Rules of Order within the TEFCA Governance Process.
- **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 FHIR pilot)** using a TEFCA-based approach. This should not limit other early adopter pilots including point-to-point FHIR based transactions.

Automate Quality Measurement Reporting

THE PROBLEMS

01

Physicians spend more than $15 billion a year on quality reporting.

02

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.

03

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.

Automate Quality Measurement Reporting

THE PROPOSALS

- **CMS needs to implement receiving systems with FHIR APIs for providers and health plans for eCQMs.**
- **Providers need to maintain US Core APIs to enable data exchange in response to Bulk FHIR queries from payers** who use CQL engine providers to produce digital quality measurement reports to send to NCQA and CMS.
- 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.

Adopt Digital Identity Services for Individuals, Payers, and Providers

THE PROBLEMS

01

We have not adequately addressed the 21st Century Cures Act language, which requires “a common method for authenticating trusted health information network participants.”

02

Cybersecurity threats in health care are at an all-time high with more than 100 million people affected in 2023.

03

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.

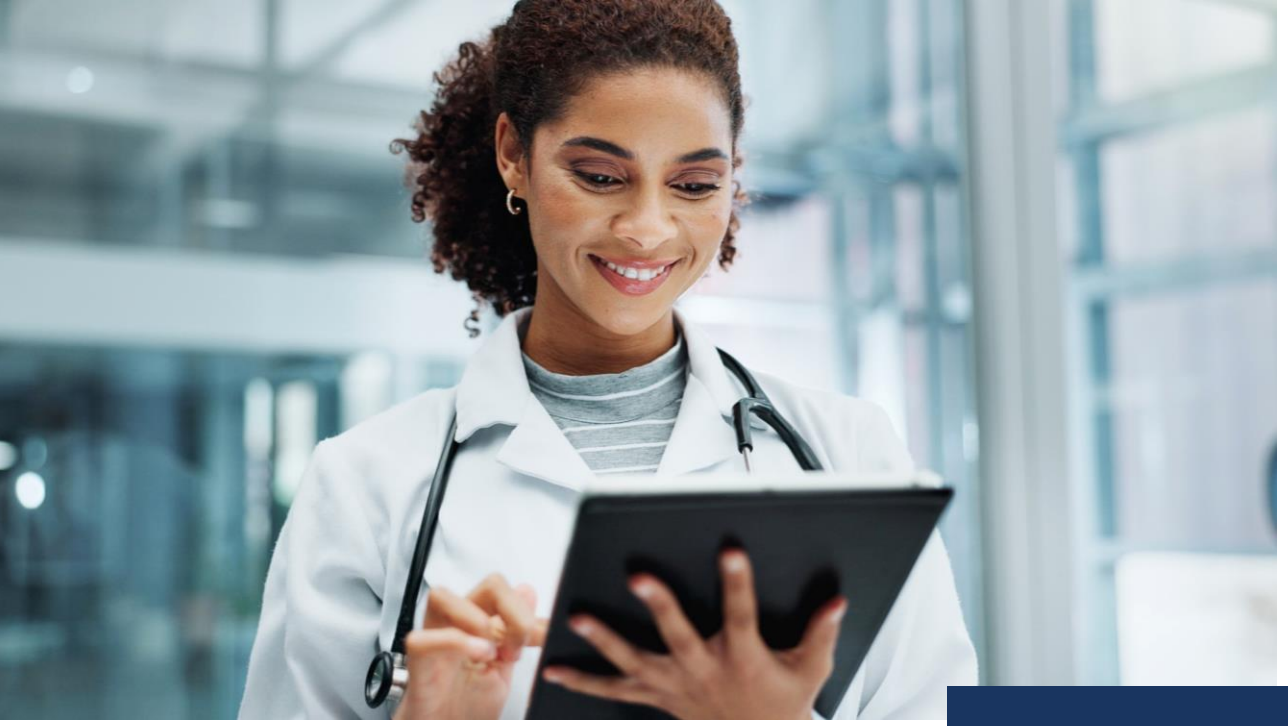
04

Technically, the $match solution will not work across the country and currently does not support a FHIR-only exchange pattern.

Adopt Digital Identity Services for Individuals, Payers, and Providers

THE PROPOSALS

- Require that any system used for registration and login for anyone accessing 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**.
- This can be done by **using a vendor on the Kantara certified vendor list** or by using vendors that provide those services today as part of an organization's user access management onboarding processes inside the organization.
- 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**.
- 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.
- **Adopt Open ID Federation or UDAP Tiered OAuth protocols** to ensure all systems can accept an identity credential.
- **Encourage the use of the CARIN IG for Digital Insurance Card API and SMART Health Cards / Links.**



What could be the impact of action?

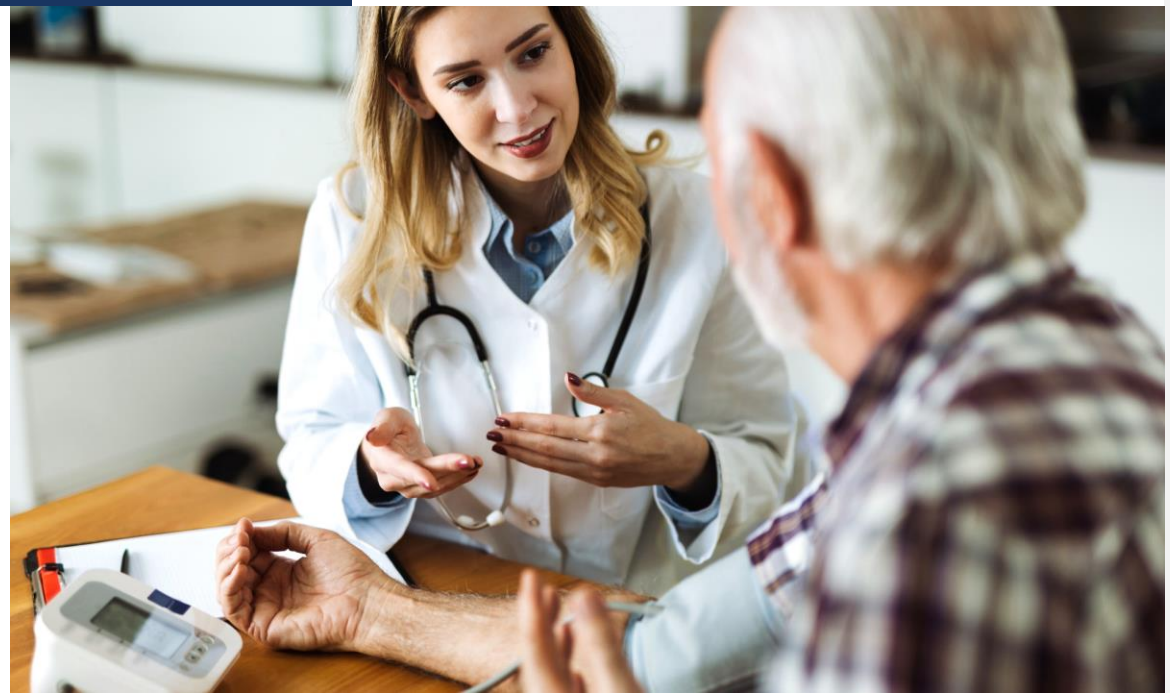
What will be the combined impact of these changes?

- Billions of dollars of administrative waste eliminated from the system.
- 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.

Conclusion & Next Steps

What could 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, and treatment-only data exchange.



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Acronyms for Use

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Common Acronyms (1 of 2)

Acronym	Meaning	Description
APIs	Application Programming Interfaces	Standardized communication for disparate software systems to communicate
ASTP/ONC	Assistant Secretary for Technology Policy/Office of the National Coordinator	Principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information. Set up by Congress as ONC, the name was changed in 2024.
CARIN Alliance	Consumer Access to Real-time Information Now	Multi-sector health care alliance committed to enabling consumers and their authorized caregivers to easily get, use, and share their digital health information when, where, and how they want to achieve their goal
CMS	Centers for Medicare and Medicaid Services	Federal agency within the U.S. Department of Health and Human Services that administers the nation's major healthcare programs including Medicare, Medicaid, and the Children's Health Insurance Program.
CQL	Clinical Quality Language	Standardized, domain-specific programming language designed to enable clinical informaticists and IT staff to build and execute queries to support clinical quality measurement and clinical decision support
DQIC	Digital Quality Implementers Community	Collaborative consensus-based effort to develop, advance and standardize tools and platforms that optimize digital quality measurement, initially focusing on Clinical Quality Language engines
dQMs	Digital Quality Measures	Measures that use standardized, digital data from one or more sources of health information that are captured and exchanged via interoperable systems, using standards-based code packages that are computable without additional effort
FFEs	Federally Facilitated Exchanges	Health insurance marketplaces operated by the federal government in states that did not establish their own exchanges, where individuals and small businesses can shop for qualified health plans and access federal subsidies

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Common Acronyms (2 of 2)

Acronym	Meaning	Description
FHIR	Fast Healthcare Interoperability Resources	Modern data exchange standard that makes it easier for systems to share healthcare information, enabling seamless data sharing and robust measure logic for digital quality measures.
HIE	Health Information Exchanges	Organizations established that enable the secure electronic sharing of patient health information across different healthcare entities, improving care coordination, reducing medical errors, and supporting better patient outcomes through directed, query-based, and consumer-mediated exchange methods.
NCQA	National Committee for Quality Assurance	Nonprofit organization dedicated to improving healthcare quality through accreditation, measurement, and quality improvement programs for health plans and healthcare providers
PSV	Primary Source Verification	Long-standing process in health care credentialing, mandated by accrediting bodies like NCQA, where an organization directly confirms the authenticity of a healthcare provider's qualifications from the original issuing sources.
QHP	Qualified Health Plan	Health insurance plan that is certified by a Health Insurance Exchange, provides essential health benefits, follows established limits on cost-sharing, and meets other requirements under the Affordable Care Act
TEFCA	Trusted Exchange Framework and Common Agreement	A comprehensive framework that establishes a standardized, nationwide approach for secure health information exchange across disparate networks through Qualified Health Information Networks (QHINs), enabling authorized access for treatment, payment, public health, and other specified purposes, while adhering to privacy and security principles. Established by the 21st Century Cures Act.
USCDI	United States Core Data for Interoperability	A standardized set of health data classes and constituent data elements for nationwide exchange.

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