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<u>Introduction</u>

Redox appreciates the opportunity to respond to CMS's Request for Information on the Health Technology Ecosystem. As a company solely focused on healthcare interoperability, Redox provides a secure, scalable platform that enables real-time, API-based data exchange across the healthcare landscape. Today, we support nearly 10,000 healthcare organizations and over 12,000 active integrations, connecting systems across 100+ EHR vendors and a broad range of digital health applications. Our infrastructure is designed to reduce integration burden, normalize data across disparate sources, and accelerate access to clinical and administrative data—core priorities highlighted in this RFI. With HITRUST and SOC 2 Type II certifications, Redox meets the highest security and compliance standards. We welcome the opportunity to share recommendations for advancing a more open, interoperable, and patient-centered ecosystem that can support emerging use cases, improve care coordination, and drive better outcomes system-wide.

Public Comments

B. Patients and Caregivers, 2. Data Access and Integration, PC-10

How is the Trusted Exchange Framework and Common Agreement[™] (TEFCA[™]) currently helping to advance patient access to health information in the real world?

a. Please provide specific examples.

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TEFCA is a very nascent effort, but is working to build upon the best practices learned from networks such as eHealthExchange, CareQuality and Commonwell. By bringing in new use cases and stakeholders, TEFCA is pushing industry to have the ability to share data, in a trustworthy, yet controlled way in one place, ensure data silos do not exist, and by providing a network to all stakeholders involved in the patient journey, including most importantly the patient themselves. Having one method to share and exchange this common data is a cost effective way to ensure that the patient data flows to where it needs to go and ensures that the patient receives the right care at the right time. Although the existing networks have been very successful, they have stalled at exchanging data via documents between clinicians.

Important data exchanges happen for a variety of purposes, with a number of stakeholders, that require the exact same patient data to be exchanged, as defined in USCDI and US Core. Until recently, in these networks, there has been little forward momentum to move into improving exchanges and expand to new stakeholders including Patients, Payers, Researchers and Public Health. Many of these areas of new exchange, such as IAS, Operations Purpose of Use, and FHIR exchanges, need further trials to determine the best approach.

<u>Data quality is an issue:</u> The data shared today via existing networks is inconsistent and often incomplete. There needs to be a way to evaluate the data quality, and data completeness that is being produced by holders of clinical data. And this data quality and completeness needs transparency, so consumers of the data can compare and choose the right network solution to meet their needs.

<u>Document exchange is cumbersome:</u> The majority of data exchanges today happen via documents, making the most relevant and important data hard to determine. Moving to a FHIR based exchange ensures that Apps and solutions can target receiving just the data needed for the patient care and build adaptable flows that meet the needs of every stakeholder in the patient's care.

b. What changes would you suggest?



- 1. Focus on expanding to new use cases outside of clinician to clinical treatment purpose of use, to truly enable all the patients data, throughout their healthcare journey to be shared to the right stakeholders and available, near real time to the patient. This includes payment, and operations data. Accelerating the IAS use case with consents, to allow for patients to share all data they want to including clinical and payment, with App vendors will allow for an app eco system to evolve on help patients have fully actionable data such as cost, location, copays, vouchers, discounts, prior authorizations etc that can help them understand which treatment options and services are best suited to their circumstance.
- Accelerate sharing of data via FHIR over a trusted exchange and help accelerate the
 necessary components to ensure that this can scale, such as FAST security IG and make
 the location of the data searchable and discoverable via a Nationwide endpoint
 directory.
- 3. Ensure claims and coverage data available via FHIR APIs near real time, as it enables innovation, and helps the patient make the right decision for their health circumstance.
- 4. Where appropriate allow for sharing of data in bulk via the networks to ensure data liquidity for B2B processes that require large data sets, such as those needed for population health and quality metrics.
- c. What use cases could have a significant impact if implemented through TEFCA?

Individual Access Services would be important as this flow enables the patient to participate in a network that shares their data. Patients can become a key source of truth to validate items such as which medications are currently active, ensuring that they are a full participant in the data exchanges.

Operation purpose of use becoming mandatory would allow for Payers to be full participants in TEFCA. Payers provide information that is key to ensuring that the care itself is cost effective and is providing quality outcomes.



d. What standards are you aware of that are currently working well to advance access and existing exchange purposes?

Bulk FHIR APIs and CDS Hooks are currently working well to advance access and existing exchange purposes. Performant Bulk FHIR APIs would unlock many flows that are not possible to scale today and they are available across many EHR solutions. Bulk on FHIR is necessary for many B2B flows, such as Provider to Payer exchange, however, today these at large EHR vendors are not provided in a performant manner for the necessary volume of data. And access to test sandboxes is not always easy for developers to obtain.

Many EHR vendors also institute Bulk FHIR as backend processes have a low priority and run at low transaction times. This means queries can take up to days to run and many have not implemented the \$export function to enable the end to end process. Additionally, most have not implemented \$import to make the data exchange seamless.

Many EHRs require the creation of a Patient Group to identify the cohort to run, but do not provide an easy mechanism via FHIR to create that Group as seen in listings on Lantern. Vendors should provide benchmark data on their process times for exporting and importing bulk data via FHIR, this will ensure that there is transparency on limitations of EHR solutions and expose where there may be a need for augmenting with alternatives such as cloud enabled data management. EHR vendors should allow for creation of groups via FHIR, and implement at a minimum \$export operation.

CDS Hooks is already unlocking process flows such as real time Prior Authorizations within the EHR, without requiring onerous and expensive implementations, or vendor lock-in to EHR specific platforms. CDS hooks need to be expanded to accelerate common processes such as scheduling and adoption of necessary hooks required in the DaVinic flow such as order-select.

e. What standards are you aware of that are not currently in wide use, but could improve data access and integration?



<u>FAST Security IG and FHIR Subscriptions:</u> FAST Security IG (UDAP), and FHIR Subscriptions would unlock many data flows that are not available today without onerous data integration efforts.

FAST Security IG is required to enable sharing of data via FHIR in a scalable way across a trusted network. Without this component, access to each endpoint will require a time consuming and costly manual registration process.

FHIR Subscriptions could allow for real time event listening, without requiring the expensive, outdated and time consuming infrastructure required today to integrate into B2B process flows through HL7 V2.

f. Are there redundant standards, protocols, or channels that should be consolidated?

Many of the existing standards that require onerous and manual efforts. For instance to set up a HL7 V2 exchange a VPN is required. This is a manual and laborious process, requiring multiple back and forths to ensure data is flowing correctly. Moving to FHIR subscriptions, great write back via FHIR and CDS Hooks would enable these flows to happen via one standard.

g. Are there adequate alternatives outside of TEFCA for achieving widespread patient access to their health information?

Today there are alternatives to TEFCA for patient access, but these are onerous, requiring a patient to individually login to multiple patient chart portals, requiring them to be able to locate their providers, get a login account from that provider, not always an easy process, remember and maintain multiple accounts and passwords, and requiring a share all or none approach. As a result patients are not able to access and manage their healthcare data. Even when available without tremendous effort. This has led to the term 'portalitis' to describe this phenomena. Today while some networks such as CommonWell have demonstrated successful pilots to enable patients to get their data via IAS, the purpose of use, expanding this to true nationwide data exchange, is hampered by the lack of a single accessible login being available across all the major EHR vendors.



Outside of TEFCA, there is no alternative that today that could easily and rapidly scale nationwide to provide access to all patients data, and not be specific to one network. TEFCA, not only is nationwide, is an open trusted framework and covers all patients that are covered via the 3 nationwide networks today.

TEFCA is further along in envisioning and planning support for the components needed to enable patients to participate in Networks, including mandating use of UDAP. TEFCA today is driving other networks to envision how to operationalize other use cases beyond the Clinician to clinician treatment workflow. Without this driver we may see the industry take a step back.

C. Providers, 2. Data Exchange, PR-5

Which of the following FHIR APIs and capabilities do you already support or utilize in your provider organization's systems, directly or through an intermediary? For each, describe the transaction model, use case, whether you use individual queries or bulk transactions, and any constraints:

<u>a. Patient Access API:</u> We support this in provider organizations for our clients. The utilization would be individual queries related to a single patient per session.

Many applications would like for data to be maintained over time which involves managing a refresh token, which can be an inconsistent and frustrating experience for a patient when it expires - if a refresh token is even available.

Some EHR vendors use the desire to have a refresh token to submit applications to review an approval process that is out of step with regulations.

Our experience is that many patient facing apps require manual steps to activate at a given health system. For some EHR vendors, under certain use cases, this can be downloaded, but not in all cases. When automatic download and configuration is not an option, the distribution of the application is a significant barrier to use and adoption.

<u>b. Standardized API for Patient and Population Services:</u> We do not utilize or support BulkFHIR but it is on our roadmap.



We often find that current EHR implementations do not make Bulk FHIR an attractive option for use cases that we've seen from our clients: consuming large patient populations for registries and maintaining those data sets over time. Issues include:

- Inappropriate (non-system to system) authentication protocols.
- Vague warning about "performance problems" for the population transfers these APIs are intended to support.
- Inconsistent support for accurate population selection.
- Manual creation and curation of patient populations that are desired / relevant.

We work around these limitations using other means to access much of the benefits of population level exchanges via means other than bulk FHIR.

<u>c. Provider Directory API:</u> We do not use provider directory API services today, but could support consumption of these APIs for our clients.

<u>d. Provider Access API</u>: We consume Provider Access APIs for our clients. Our use cases range from SMART on FHIR applications to bulk data transfer.

We find that access to these APIs has significant operational overhead and variance by EHR vendor. In all cases, manual setup at the health system is required in order for Provider Access APIs to be functional, effectively and unnecessarily gating these applications in an IT queue or technical limitations of a small clinic office's staff. These limitations impose a serious distribution challenge on any vendor and long delays or a significant burden to activate the application at small and medium sized treatment locations.

Variance in authentication, specifically refresh token behavior can be a serious technical burden to manage for a vendor.

Finally, some EHRs impose rate limits or other restrictions that are simply not viable for an application at scale, further complicating technical and operational implementation and adoption of these solutions.

<u>e. Payer-to-Payer API:</u> We do not use Payer-to-Payer API services today, but could support consumption of these APIs for our clients.

<u>f. Prior Authorization API:</u> We support Da Vinci flows in production today. This includes Da Vinci flows for the payer, but mapped to underlying X12 message types for the health system.



Because our support does not require EHR support for Da Vinci flows or FHIR, and only requires our payer customer to integrate with our platform using the prior authorization APIs we do not have experience with the operational burdens associated with integrating via the Da Vinci flows at health systems.

g. Bulk FHIR—Do you support Group ID-based access filtering for population-specific queries?

We can support Group-ID based filtering for our clients if necessary. We've never seen an EHR system support this that was well matched to client needs and have other approaches to accomplish Group ID (or other population filter criteria) filtering to facilitate population level data exchange.

h. SMART on FHIR—Do you support both EHR-launched and standalone app access? What does the process for application deployment entail?

We support both EHR launched and standalone SMART on FHIR application access for our clients. For our clients we issue an appropriate authentication credential and provide a single endpoint they interact with - we will handle the SMART on FHIR handshake with the EHR on their behalf. Typically a single registration of their application with us is sufficient.

The application deployment process varies at each health system. Some friction we and our clients encounter:

- EHRs may have a review and approval process per application.
- Some EHRs require beta periods at *each* health system deployed.
- Manual configuration is always required to deploy except in certain stand-alone patient facing application use cases.

<u>i. CDS Hooks (for clinical decision support integrations):</u> We have just related support for CDS Hooks, to support prior authorization and best practice suggestions in clinical workflows for our clients.

So far, our experience is that EHR level support for CDS hooks is limited, but a number of major EHR vendors have signaled their intention to support. We have clients contracted for this functionality, but it is not yet live in production.

E. Technology Vendors, Data Providers, and Networks, 3. Technical Standards and Certification, TD-4



How can CMS better encourage use of open, standards-based, publicly available APIs over proprietary APIs?

Encouraging the widespread adoption of open, standards-based, publicly available APIs over proprietary solutions is fundamental to achieving true healthcare interoperability. At Redox, our platform is purpose-built to navigate the complexities of healthcare data exchange, abstracting away proprietary variations to enable seamless, standards-based communication. We recognize the challenges and opportunities in this space and offer the following recommendations to CMS:

- 1. Broaden Incentives for Open API Adoption: CMS should significantly increase the scope of incentives to drive broader participation in programs that mandate open, standards-based APIs. Current incentives, while a good start, often don't fully account for the investment required to transition from legacy, proprietary systems. Expanded incentives should:
- Reward comprehensive API implementation: Go beyond basic compliance. Incentivize
 systems that not only expose data via open APIs but also consume and act on data
 received through these channels, demonstrating a true commitment to bi-directional
 interoperability.
- **Support diverse system types:** Extend incentives beyond EHRs to include payers, labs, pharmacies, public health agencies, and other critical healthcare entities. The network effect of interoperability only truly materializes when all key players participate.
- Offer tiered incentives for advanced capabilities: Recognize and reward systems that implement more complex and valuable API use cases, such as those supporting write-back capabilities, bulk data exchange, or real-time event notifications, which are crucial for dynamic workflows.
- 2. Address Operational Burden of Application Distribution: The current environment of "health system by health system" implementation and certification creates immense operational friction. CMS can mitigate this by:
- Standardizing Trust Frameworks and Certification: Beyond technical standards, CMS should foster a national "trust community" for health applications. This means moving beyond individual EHR vendor certification programs or proprietary "gates" to a more unified model for application vetting and onboarding. Redox currently manages connections to over 90 EHRs and thousands of organizations, navigating these



- fragmented processes daily. A standardized, federally-backed trust framework would drastically reduce this burden.
- Preventing Impractical Non-Functional Limitations: CMS must establish guidelines to
 prevent health systems or EHR vendors from imposing arbitrary or impractical
 non-functional limitations on open APIs (e.g., excessively low global API calls per minute
 per application). Such limitations stifle innovation and prevent real-time, data-intensive
 applications from functioning effectively. Clear performance expectations for mandated
 APIs are critical.
- Leverage Intermediaries for Scale: Acknowledge and encourage the role of
 interoperability platforms like Redox. We abstract away the complexities of disparate
 EHR versions, data formats (HL7v2, FHIR, X12, etc.), and connectivity methods. By
 normalizing data into a consistent, standards-based format (including FHIR), Redox
 allows applications to connect once and reach a vast network, dramatically reducing the
 "health system by health system" burden for developers. This accelerates go-to-market
 for new applications and reduces operational overhead for both developers and health
 systems.
- 3. Expand the Supported API Set for Full User Experiences: Current API mandates are a strong foundation, but a truly transformative ecosystem requires a broader set of APIs that enable comprehensive user experiences. CMS should:
- Prioritize Clinically and Operationally Relevant APIs: Expand the mandated API set beyond patient access to include APIs critical for clinical workflows (e.g., discrete lab orders, medication reconciliation, patient intake forms, care plan updates, real-time alerts) and operational efficiencies (e.g., scheduling, referral management, prior authorization decision support). This will enable applications to drive more complete and impactful user experiences.
- **Embrace Bi-directional Exchange:** While read access is important, the true power of APIs lies in bi-directional data exchange. CMS should increasingly mandate write-back capabilities where appropriate, enabling applications to contribute data back to the system of record, thus closing critical workflow loops.
- Foster API Design for Workflow Integration: Encourage API designs that align with clinical and administrative workflows, rather than simply exposing static data. This means promoting APIs that support events, subscriptions, and bulk data transfer where relevant, moving beyond simple GET requests to enable dynamic, responsive applications.



Redox is uniquely positioned to support CMS in these endeavors. Our platform provides a robust, secure, and scalable foundation for organizations to connect to and leverage open, standards-based APIs, including FHIR. We translate and normalize data across disparate systems, provide advanced security and monitoring, and offer developer-friendly tools, effectively becoming the "interoperability layer" that accelerates the adoption of these critical standards across the healthcare landscape. Our commitment to secure, seamless data exchange aligns perfectly with CMS's vision for a more interconnected healthcare future.

E. Technology Vendors, Data Providers, and Networks, 3. Technical Standards and Certification, TD-9

Regarding certification of health IT:

a. What are the benefits of redefining certification to prioritize API-enabled capabilities over software functionality?

There are three primary benefits:

- 1. Agentic AI via MCP is built on top of APIs. By prioritizing API capabilities you are also prioritizing Agentic AI capabilities.
- 2. By prioritizing API enabled capabilities, you must wrestle with certifying workflows via APIs which could significantly increase the value of API consuming applications.
- 3. You separate the UI from the underlying data stores and business roles, which could open the door to more experimentation in the user experience and open up more competition for the users instead of them being locked into the EHR. Effectively this could split EHRs into a backend API and a front end where many more groups could compete with the frontend without requiring enterprise level investment in the product development and deployment before getting into user hands.

b. What would be the drawbacks?

Existing regulation exposes a significant portion of the patient chart via open, standards based APIs. Therefore, the most likely direction for increased API enabled capabilities would be prioritizing RESTful FHIR APIs for writeback.

But FHIR is a standard of conceptual data models, and today software is used to drive **workflow** via spurts of data flow corresponding to complex and opaque business rules, often driven by a combination of provider needs, institutional interpretation of compliance requirements, and overly byzantine payer, including CMS, reimbursement requirements.



Simply prioritizing FHIR APIs without addressing the reality that most EHRs today drive workflows *and* the forces that shape those workflows are broken will at best result in poor adoption and at worse create significant operational friction at providers.

E. Technology Vendors, Data Providers, and Networks, 3. Technical Standards and Certification, TD-10

For EHR and other developers subject to the ONC Health IT Certification Program, what further steps should ASTP/ONC consider to implement the 21st Century Cures Act's API condition of certification (42 U.S.C. 300jj-11(c)(5)(D)(iv)) that requires a developer's APIs to allow health information to be accessed, exchanged, and used without special effort, including providing access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws?

Addressing the operational burdens around distribution and deployment of applications is critical to fully realize the "without special effort" mandate of the 21st Century Cures Act's API condition of certification. While significant progress has been made with standardized APIs (e.g., FHIR) and SMART App Launch, the practical realities of integrating with diverse EHR environments continue to pose considerable friction for developers and, by extension, limit the adoption of innovative health applications.

To further implement the "without special effort" requirement, ASTP/ONC should consider the following steps:

1. Standardized, Centralized Application Registration and Configuration:

- Mandate Universal App Store/Catalog: ONC should mandate the development and adoption of a national, standardized "App Store" or catalog for certified health IT applications. This platform would serve as a centralized registry where developers can list their applications, specify their data access requirements (FHIR scopes), and provide necessary metadata for deployment.
- Automated Site-Specific Registration: The "App Store" should facilitate
 automated, programmatic registration of applications with individual EHR
 instances. This means moving beyond manual processes where each healthcare
 organization (HCO) or EHR instance requires a separate, often unique,
 registration and approval workflow. A standardized API for application
 registration and management (akin to OAuth 2.0 dynamic client registration)
 should be developed and enforced, allowing developers to register their apps



- once and deploy them across multiple EHR instances with minimal manual intervention.
- Pre-negotiated Scopes and Authorization Profiles: For common use cases, ONC should define and encourage standardized sets of FHIR scopes and authorization profiles. This would streamline the approval process by providing EHRs with clear, pre-defined security postures for widely adopted application types, reducing the need for site-specific security reviews for each application.
- Centralized Credential Management: Explore models for more centralized or federated credential management for applications, reducing the burden on individual developers to manage unique client IDs and secrets for every EHR instance they integrate with. This could involve trust frameworks or a distributed ledger technology to attest to application identity and security posture.

2. Enforcement of Realistic and Consistent API Rate Limits:

- Minimum Baseline Rate Limits: ONC should establish and enforce minimum baseline API rate limits as part of the certification criteria. These minimums must be substantially higher than current common practice, which often sees unacceptably low limits (e.g., 500 requests per hour per application or per tenant). The current limits stifle innovation and make population-level data access, research, and advanced analytics practically impossible.
- Tiered and Negotiable Rate Limits: While setting minimums, the regulation should also encourage EHR vendors to implement tiered rate limits, allowing developers to negotiate higher limits based on legitimate use cases and data volume needs. The process for requesting and approving these increases should be transparent, standardized, and timely, with clear criteria for approval.
- Real-Time Rate Limit Monitoring and Feedback: EHRs should be required to
 provide developers with real-time feedback on their API usage and remaining
 rate limits via standardized HTTP headers or dedicated API endpoints. This allows
 applications to dynamically adjust their request patterns and avoid hitting limits,
 improving application resilience and data flow.
- Penalties for Undue Restrictions: Implement clear penalties for EHR vendors
 who impose unreasonable or discriminatory rate limits that impede
 interoperability or constitute information blocking. The current lack of a strong
 enforcement mechanism for such limitations allows EHRs to control the "pipes"
 in a way that hinders innovation.

3. Mandatory and Standardized Refresh Token Lifecycles:

 Guaranteed Long-Lived Refresh Tokens: The certification program must mandate that EHRs issue refresh tokens with a minimum, substantial validity period (e.g., 1



year or more) for confidential client applications. The current variability, including instances where refresh tokens are not provided or have absurdly short lifespans, creates significant operational overhead for maintaining continuous data access.

- Standardized Refresh Token Renewal: A consistent and standardized mechanism for refreshing access and refresh tokens, adhering to established OAuth 2.0 best practices, must be enforced. This includes clearly defined error handling for expired or invalid tokens and predictable renewal flows.
- Eliminate Manual Re-authorization: The "without special effort" clause implies
 that once an application is authorized by a patient or system administrator, it
 should not require frequent manual re-authorization unless there is a change in
 scope or a security event. The frequent need for manual re-authentication due to
 short-lived tokens or lack of refresh token support is a direct violation of this
 principle.
- Audit and Enforcement of Token Management: ONC should actively audit EHRs' token management practices to ensure compliance with these requirements and investigate instances where refresh token policies unduly burden developers or limit continuous data access.

By addressing these operational burdens through concrete regulatory steps, ASTP/ONC can significantly reduce the "special effort" required for application distribution and deployment, fostering a more vibrant and innovative health IT ecosystem that truly prioritizes seamless health information exchange for the benefit of patients and providers.

E. Technology Vendors, Data Providers, and Networks, 4. Data Exchange, TD-16

What are the tradeoffs of maintaining point-to-point models vs. shared network infrastructure?

Maintaining point-to-point (P2P) integration models, where each system directly connects to every other system it needs to exchange data with, offers a degree of tailored control and immediate problem-solving for specific use cases. In the short term, for a limited number of integrations, it can appear cost-effective and provide direct connectivity. However, these benefits quickly diminish as the number of integrations grows.

The fundamental tradeoffs lie in scalability, maintainability, and the ability to foster a truly interoperable healthcare ecosystem. P2P models lead to a combinatorial explosion of connections, creating a complex, brittle, and expensive spaghetti architecture. Each new integration requires custom development, testing, and ongoing maintenance, leading to



significant technical debt. This approach hinders agility, making it difficult to introduce new technologies or adapt to evolving regulatory requirements. Furthermore, visibility into data flow and overall system health becomes incredibly challenging without a centralized monitoring and management framework.

In contrast, a shared network infrastructure, built upon standardized APIs and common data models, offers a scalable, resilient, and manageable solution. While the initial investment in establishing such an infrastructure, including robust governance and shared services, can be higher, the long-term benefits in terms of reduced development costs, improved data quality, enhanced security, and accelerated innovation far outweigh the upfront expenditure. A shared network fosters a "connect once, access many" paradigm, drastically reducing the complexity and cost of adding new participants or use cases.

a. Do current rules encourage scalable network participation?

Currently, the rules, while aiming for interoperability, **do not sufficiently encourage scalable network participation**, and often inadvertently reinforce the challenges inherent in P2P models.

Existing challenges include:

- Very limited use case support due to the need for high consensus among disparate
 actors with misaligned incentives: Achieving broader use cases, such as comprehensive
 care coordination across multiple providers and payers, or population health
 management, requires a level of consensus among diverse stakeholders with competing
 interests. Without a strong central authority or clear incentives for collaboration on a
 shared infrastructure, this consensus is difficult to achieve, leading to fragmented
 solutions.
- Some rules (e.g., providers able to invoice payers an arbitrary amount per record) that are logistical nightmares even if one agrees with the principle: Regulations that permit or encourage transactional, per-record billing for data exchange set on an institution by institution basis create significant administrative burden and disincentives for high-volume, real-time data sharing. This model is antithetical to the seamless, always-on data flow required for truly scalable network participation.
- A lack of effective governance forcing groups to play by the rules, e.g., openly admitting
 they are adjusting the standards for data exchange of the network they agreed to: The
 absence of robust, transparent, and enforceable governance mechanisms allows
 individual actors or groups to deviate from agreed-upon standards or selectively
 implement interoperability requirements. This "shadow IT" or informal standards



adjustment undermines the very foundation of a shared network, reintroducing P2P complexities and undermining trust. Without clear accountability and consequences for non-compliance, the promise of a unified network remains elusive.

b. What changes would improve alignment (for example, API unification, reciprocal access)?

To foster a truly scalable and effective shared network infrastructure for healthcare interoperability, the following changes are crucial:

• Mandatory API Unification and Standardization:

- Enforce FHIR-first Mandate: While CMS has encouraged FHIR, a stronger
 mandate for all regulated entities to expose and consume data via standardized
 FHIR APIs, specifically US Core profiles, should be established. This includes a
 clear roadmap for evolving to the latest stable FHIR releases. This should,
 specifically not allow a workaround of "exchanging a CCD via a binary FHIR
 resource" as a FHIR based data exchange.
- Standardize API Security and Authentication: Beyond basic OAuth 2.0 and OpenID Connect, specific profiles and best practices for identity management, consent management, and data access control within the healthcare context must be standardized and enforced across all APIs. This reduces implementation variability and strengthens security.
- Unified API Endpoints and Discovery: CMS should consider establishing a
 mechanism for standardized API endpoint discovery, similar to a DNS for
 healthcare APIs. This would allow systems to programmatically discover available
 data services and their capabilities, drastically simplifying integration.
- Require Granular Data Element Exchange: Move beyond document-centric
 exchange to granular data element exchange via FHIR resources. This enables
 systems to consume only the data they need, reducing overhead and improving
 data usability for specific applications (e.g., predictive analytics, AI/ML).

Mandatory Reciprocal Data Access and Data Liquidity:

- "No Data Silos" Mandate: Regulations should unequivocally prohibit information blocking and promote a culture of data liquidity. This means not only requiring data export but also reciprocal access, where entities that consume data are also obligated to make relevant data available back to the network.
- Patient-Mediated Data Exchange (PMDE) Empowerment: Further empower
 patients as the central orchestrators of their health data. This includes robust



- support for third-party applications connecting to APIs, clear patient consent mechanisms, and the ability for patients to direct their health information to any authorized entity or application.
- Payer-to-Payer and Provider-to-Provider Data Exchange Incentives: Beyond current payer-to-payer mandates, strong incentives and potentially requirements for direct, real-time data exchange between providers (e.g., hospitals to skilled nursing facilities) and between payers (e.g., for continuity of care when a patient changes plans) using standardized APIs should be implemented.

• <u>Strengthened Governance and Enforcement:</u>

- Establish a National Healthcare Interoperability Authority (NHIA): This
 independent body, with representatives from CMS, ONC, industry, and patient
 advocacy groups, would be responsible for continuous standard development,
 enforcement of interoperability rules, dispute resolution, and auditing for
 compliance. The NHIA would have the authority to impose meaningful penalties
 for non-compliance and information blocking.
- Transparent Compliance Reporting and Public Dashboards: Require all regulated entities to publicly report on their interoperability capabilities and compliance with standards. CMS could maintain a national dashboard highlighting compliance rates and information blocking instances, fostering transparency and accountability.
- Shift from "Per Record" to "Network Participation" Value: Reorient financial incentives away from per-record charges towards value-based care models that inherently reward seamless, comprehensive data exchange. This could involve direct financial incentives for participating in certified shared networks, or penalties for maintaining data silos that impede care coordination.
- Investment in Shared National Services: CMS should lead or facilitate investment in critical shared national services that underpin a robust network, such as a national provider directory with real-time updates, master patient index services, and consent management frameworks that can be leveraged by all participants.

By adopting these tech-forward changes, CMS can transition the healthcare industry from a fragmented P2P landscape to a truly integrated and scalable shared network infrastructure, ultimately improving patient care, reducing administrative burden, and fostering innovation

Conclusion



Redox appreciates the Administration's thoughtful and comprehensive approach to advancing interoperability across the healthcare system and we kindly thank you for considering our comments. The questions posed in this RFI reflect a strong understanding of the practical and systemic challenges that providers, payers, developers, and most importantly, patients continue to face in accessing and exchanging health data. As a platform that supports a wide range of healthcare organizations and use cases, we recognize both the progress made and the work still ahead to make seamless data exchange a reality. We are encouraged by CMS's continued leadership on these issues and welcome the opportunity to support this effort with insights from our experience working across the ecosystem.

Sincerely,

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