CMS Request for Information: Health Technology Ecosystem

TD-4: How can CMS better encourage use of open, standards-based, publicly available APIs over proprietary APIs?

Over the past decade, CMS has implemented programs and rules to promote the adoption of health information technology (IT), particularly through its leadership in driving electronic health record (EHR) adoption and interoperability. Initiatives such as the Promoting Interoperability Programs (formerly known as Meaningful Use), as well as regulatory efforts like the CMS Interoperability and Patient Access Final Rule, have been pivotal. The 21st Century Cures Act Final Rule (enforced by ATSP and supported by CMS) built on the foundation of these programs and rules by requiring developers and payers to support standards-based APIs using HL7® FHIR®. These efforts marked a major policy shift toward patient access, data liquidity, and innovation through APIs.

Building on the Cures Act, CMS can help accelerate the maturation of data standards, not only through regulation, but also by supporting collaborative, public-private efforts that ease administrative burden and improve the patient and provider experience. Open, standards-based, publicly available APIs are critical infrastructure for achieving real-time interoperability, enabling patient-centered care, fostering innovation, and reducing cost and burden across the healthcare continuum.

Recommendations for Advancing Standards-Based APIs

1. Expand Scope and Use Cases

CMS should take a more active role in supporting the implementation and use of open-source, standards-based APIs across clinical, operational, administrative, as well as public and population use cases. This includes extending API requirements to support prior authorization, scheduling, and payment workflows, and ensuring alignment with emerging HL7 implementation guides (IGs), such as US Core, and those being developed through Accelerators such as the Da Vinci Project, CARIN Alliance, FAST, and others.

2. Invest in Open-Source Infrastructure

CMS should prioritize the development, support, and promotion of open-source tools that implement API standards, such as FHIR reference implementations and Software Development Kits (SDKs). Reference implementations can serve as blueprints for compliant APIs, enabling health IT developers, particularly those in small or resource-limited organizations, to adopt standards without building solutions from scratch. SDKs offer prebuilt functionality and consistent logic that reduce variability in implementation and promote interoperability across systems. Reusable libraries, testing frameworks, and conformance tools will help dramatically reduce the technical and financial barriers to implementation for both private and public sector entities. Open- source testing tools, such as those aligned with ASTP's certification criteria, help organizations validate conformance to the specifications.

CMS can further support open-source tool development by funding the development and maintenance of critical open-source components, offering technical assistance to implementers, and promoting reuse of government-funded codebases across federal programs and state

Medicaid agencies. This approach fosters transparency, trust, and collaboration, ensuring broader participation and a more level playing field across diverse stakeholders.

3. Align Regulations and Incentives

CMS should continue to use regulations and incentive programs to encourage industry-wide use of open standards-based APIs and ensure consistency, interoperability, and accountability, while reducing reliance on proprietary solutions.

This includes continuing to build on and mature the API requirements defined in CMS-0057-F, adopting certification and testing tools, and expanding API requirements into new areas such as:

- Estimates and price transparency
- Quality and value-based care metrics
- Public health reporting and emergency response
- Referrals and care coordination
- Real-time benefit checking (including pharmacy)
- Clinical decision support
- Chronic disease prevention and management

CMS should continue to require that the currently defined APIs be made publicly discoverable and accessible, with openly available documentation, sandbox environments, and infrastructure for endpoint discovery (e.g., a provider directory of FHIR endpoints).

Beyond regulation, CMS could link API use to participation in value-based care programs (e.g., ACO REACH, MIPS, and the Quality Payment Program) and offer bonus payments or increased reimbursement for organizations demonstrating effective API usage. Additional supports such as grants or low-interest loans could aid safety-net providers, rural hospitals, and Medicaid plans in API implementation.

Early adopter programs and implementation pilots could further refine strategies, generate best practices, and demonstrate real-world success, especially when paired with technical support and regulatory flexibility.

4. Enable Scalable Data Access for Population Health

One major opportunity CMS could address is the limited scalability and adoption of specifications like FHIR Bulk API, which in practice often fall short of performance and usability expectations. CMS and ASTP should invest in long-term support for frameworks such as FHIR Bulk Data Access API, SMART on FHIR, US Core IG, and other HL7 IGs and position them as core infrastructure for a computable health ecosystem.

One of the critical gaps in real-world FHIR implementations is the inability to perform crosspatient queries based on population-level criteria. Typical workflows retrieve patient-specific information. However, quality measurement and public health reporting require identification and monitoring of patient cohorts. CMS quality programs require capabilities such as:

- Identifying all relevant patients within a defined timeframe (e.g., inpatient encounters)
- Detecting reportable conditions or measure criteria
- Submitting line-level and aggregate data

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Tools such as CDC's NHSNLink, a FHIR-based, open-source application originally developed for public health surveillance, offer a compelling model. NHSNLink dynamically identifies patient cohorts and triggers targeted data acquisition. CMS could adapt this to automate aspects of digital quality reporting, streamline EHR data flows, and reduce manual chart review burden.

5. Foster Industry Collaboration and Standards Development

CMS should invest in and promote the continued development of industry-led and governmentsupported standards. Development of scalable open standards requires involvement from a wide range of stakeholders. CMS's leadership has helped accelerate and focus open standards development and ensure alignment with CMS goals, not just the interests of individual vendors.

Through collaboration with HL7 Accelerators and initiatives like USCDI+, CMS can define the necessary API functionality for the ecosystem. This will help ensure open APIs are not only available but capable of replacing proprietary interfaces for key use cases such as public health reporting, regulatory data exchange, and payer-provider interoperability.

Through continued leadership, policy alignment, and clear expectations around standards-based interoperability, CMS can drive the transition toward a truly connected health ecosystem. By investing in the infrastructure, regulatory framework, and collaborative tools necessary for robust API implementation, CMS can unlock the full potential of technologies like AI to reduce burden, enhance clinical decision-making, and enable patient-centered, data-driven care.

TD-5: How could a nationwide provider directory of FHIR endpoints improve access to health information for patients, providers, and payers?

A nationwide directory of FHIR endpoints would significantly improve access to health information by creating a centralized, standardized lookup service that benefits patients, providers, and payers alike. Such a directory would help patients locate providers whose systems support interoperable data exchange, assist clinicians with streamlined referrals and care coordination, and enable payers to aggregate data more efficiently. Currently, initiatives like those led by the Registered Coordinating Entity (RCE), and more recently the CMS/ASTP-supported National Directory of Healthcare Providers & Services (NDH), provide some directory services at the organizational level, but they often lack essential metadata, such as authentication protocols, supported FHIR versions, and endpoint-specific connection details.

CMS should facilitate a network of state and local (organizational) provider directories integrated with the national CMS directory. The <u>Oklahoma QHP pilot</u> has yielded a promising framework for this provider-directory API model. Individual directories may contain individual provider-level information, such as services offered, credentials, and network participation. This additional detail would support more granular and equitable access to health information.

The NDH initiative, if implemented comprehensively, could serve as a foundational public utility that underpins national interoperability. Ideally, the national directory should be governed by a neutral public entity and made freely accessible to users. Further, a network of organizational directories APIs has the potential to empower organizations to dramatically improve provider credentialling (i.e., verification of provider data) and facilitate scheduling and other value-added services and search capabilities offered to network providers and patients. Treating the NDH as a public utility would lower barriers to participation and support broader interoperability goals across the healthcare system.

Lantana CONSULTING GROUP At its core, a national directory of FHIR endpoints can facilitate reliable and automated discovery of where to send or retrieve health information. This seemingly simple function becomes transformative when scaled to encompass the nation's health systems and data partners. For example, it enables:

- Automated Public Health Reporting: Tools like NHSNLink demonstrate how FHIRbased query engines can automatically extract and evaluate structured clinical data from EHR systems, format it into required public health reports, and securely submit it to national registries such as NHSN. A comprehensive FHIR endpoint directory expands this capability from isolated pilots to a scalable, nationwide network.
- Digital Quality Measurement at Scale: Access to interoperable FHIR endpoints allows for real-time acquisition of data needed for digital quality measures (dQMs), enabling more timely and accurate performance assessments.
- Consumer-Centered Care Navigation: Patients benefit from improved care coordination when their health data can be located and exchanged across the providers and services they interact with. A trusted, accessible directory removes barriers to sharing longitudinal records and empowers patients to participate more actively in their care.

While essential, a directory alone is insufficient to realize these benefits. Two additional pillars are critical:

The UDAP (Unified Data Access Profiles) implementation guide (IG) introduces workflows that extend OAuth 2.0 for both consumer-facing applications and B2B use cases. UDAP enables:

- Automated client application registration
- Authentication of ecosystem participants using asymmetric cryptographic keys and digital certificates
- Exchange of trust and metadata among organizations

UDAP provides the security framework necessary for scalable, trusted, and policy-aligned data exchange across independent organizations. This security framework is a prerequisite for enabling meaningful data liquidity through any national FHIR directory.

The value of a provider directory is multiplied when endpoint discovery can be paired with functionality for population-level or cross-system querying. Public health surveillance, crisis response (e.g., during pandemics), and national reporting initiatives require data aggregation from multiple facilities. Capabilities such as those demonstrated in CDC's NHSNLink, including real-time query execution, cross-EHR data synthesis, and direct submission to federal systems, illustrate the transformative potential when such queries are supported by a unified network of known, authenticated endpoints.

With a national FHIR endpoint directory, supported by UDAP and designed for scalable, multisource queries, healthcare stakeholders can achieve:

- Near-real-time situational awareness during public health emergencies, using consistent, automated data extraction from any EHR connected to the trusted network
- Continuous quality improvement, where digital measures can be evaluated without the delays, gaps, and inconsistencies introduced by manual reporting and data siloing
- Streamlined burden reduction, aligning with CMS's longstanding work to reduce provider burden through standards-based automation and data reuse



TD-7: To what degree has USCDI improved interoperability and exchange and what are its limitations?

- a. Does it contain the full extent of data elements you need? (this actually received a 12 but I think we need to answer this to address the one below which scored a 15)
- **b.** If not, is it because of limitations in the definition of the USCDI format or the way it is utilized?
- c. If so, would adding more data elements to USCDI add value or create scoping challenges? How could such challenges be addressed?
- d. Given improvements in language models, would you prefer a non-proprietary but less structured format that might improve data coverage even if it requires more processing by the receiver?

USCDI has made measurable contributions to advance interoperability, especially when paired with FHIR APIs and implementation guides (IGs). This combination has been particularly effective in use cases like digital quality measurement, where standardized data elements simplify reporting and improve comparability. However, despite these successes, significant gaps remain in the representation of rich, contextual clinical information. Key data types such as medication administration, longitudinal care plans, social risk factors, and narrative clinical notes are either missing or inadequately defined, which limits their utility for advanced analytics and population health use cases.

In response to the specific sub-questions, the USCDI does not yet contain the full range of data elements needed for comprehensive interoperability. This is due to both structural limitations within the USCDI format and variability in its implementation across systems. While expanding USCDI could provide substantial value, it may also introduce scope management and adoption challenges. These could be addressed through tiered inclusion criteria or by piloting emerging data classes in controlled environments before formal incorporation. To support more consistent implementation, CMS could consider aligning USCDI version adoption timelines with regulatory requirements tied to FHIR US Core profiles-for example, through the Patient Access, Provider Access, or Payer-to-Payer APIs. This would give providers and vendors clear expectations and compliance deadlines, while preserving USCDI's broader role as a consensusbased standard. Such alignment would help mitigate variability in adoption and reduce uncertainty for implementers. Strategies like tiered inclusion criteria, piloting emerging data classes, and aligning USCDI adoption with FHIR regulatory timelines could enhance data comprehensiveness, even if they place greater processing demands on data receivers. Ultimately, CMS should continue to evolve USCDI in ways that balance structure with flexibility, ensuring the standard remains adaptive to the ecosystem's changing requirements.

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? ASTP should prioritize both the completeness and usability of data made accessible via APIs, as well as the removal of technical, semantic, and financial barriers that limit meaningful use.

Expanding API access to high-impact datasets not currently included in routine data sharing, such as Medication Administration (Med Admin) data, is critical. Unlike prescription or dispensing data, Med Admin captures what medications were administered to patients, along with precise timing. These data are foundational for clinical decision-making, medication reconciliation, and treatment adherence monitoring, yet it is often unavailable through existing certified APIs. Its inclusion, either through new endpoints or enhancement of current certified API scopes, would reduce fragmentation and align with the statutory requirement to provide access to *all data elements* in a patient's electronic health record.

ASTP should consider requiring certified APIs to expose underutilized but clinically valuable FHIR resources, such as Med Admin, Care Plan, care coordination notes, and data elements that collect social non-medical factors (like housing, transportation, education, etc.) data. These data types are essential for holistic, patient-centered care and are increasingly important in population health, public health reporting, quality programs, and for identifying opportunities to support Healthy America priorities. Certification criteria should ensure that these elements are accessible through standardized API endpoints wherever they exist in certified health IT.

ASTP should address semantic interoperability challenges that persist even when data are technically accessible. Many APIs surface data are encoded with local, proprietary codes rather than standardized vocabularies such as SNOMED CT or LOINC. This undermines the intent of the Cures Act to support data *use without special effort*. To address this, ASTP should require certified developers to implement translation capabilities that map local codes to national standards using FHIR ConceptMap or other shared artifacts. A standardized structure and implementation pattern should be defined, and conformance should be part of certification. Even where perfect alignment is not possible, requiring APIs to support approximate mappings and expose underlying codes ensure greater transparency and interoperability.

Additionally, the current state of Bulk FHIR APIs—despite their potential to support populationlevel queries—often falls short of the "without special effort" bar. Developers cite performance challenges, inconsistent support across vendors, and high fees that limit accessibility. For example, some EHR vendors charge providers \$10,000 or more annually per API instance, even when those APIs are technically required by certification. ASTP should issue implementation guidance that defines performance expectations and consider incorporating cost and accessibility metrics into certification surveillance. CMS and ASTP could jointly fund pilot or early adopter projects and provide targeted support to help small vendors implement performant, low-barrier FHIR APIs.

To foster a developer-friendly ecosystem, ASTP should promote consistent implementation patterns for advanced capabilities such as cross-patient querying, real-time data subscriptions, and longitudinal record retrieval. Current patient-level API constraints inhibit analytics, care coordination, and public health use cases. Certification criteria should evolve to reflect these realities and ensure that APIs are not only functionally present but practically usable for diverse applications.

Taken together, these steps would make certified APIs more robust, objective, and aligned with the goals of the 21st Century Cures Act. Without these enhancements, "without special effort" risks becoming a theoretical standard rather than a reality for developers, providers, and patients.

TD-13: What new opportunities and advancements could emerge with APIs providing access to the entirety of a patient's electronic health information (EHI)?

Enabling API-based access to the full scope of a patient's electronic health information (EHI) would be transformative across the healthcare ecosystem. Clinicians would be better equipped to make informed, timely decisions, drawing on comprehensive longitudinal records that include not only medical histories and treatments but also future care plans and prescriptive recommendations. Such access would facilitate improved care coordination, reduce redundancies, and help avoid errors caused by fragmented or incomplete information. For public health agencies, full access to EHI could enable richer public health surveillance, faster response to emerging threats, and more effective program targeting.

Patients, too, would benefit from increased transparency and control over their health information, fostering trust and enabling informed decision-making. Payers and researchers would gain a more holistic view of care patterns, supporting better risk stratification, quality improvement, and value-based care initiatives. Importantly, the ability to access fully computable EHI through APIs would accelerate the development of novel digital tools, analytics platforms, and AI-powered applications, thereby catalyzing innovation across the health IT ecosystem.

Expanded access to complete EHI also enables powerful advancements through natural language processing (NLP) and AI. NLP can extract structured insights from clinical notes and unstructured documentation—areas traditionally overlooked or inconsistently interpreted in electronic reporting. This supports more accurate quality measurement, more complete risk adjustment, and automated reporting, reducing the administrative burden on providers. AI models, trained on longitudinal EHI, can further enhance predictive analytics and clinical decision support, aiding CMS in initiatives that target early intervention, chronic disease management, and disparities in care. These tools can also help CMS better evaluate population-level trends and outcomes.

Comprehensive EHI access through APIs will provide the foundational data needed for digital infrastructure to adapt quickly as clinical workflows, regulatory programs, and data sources evolve. By enabling systems to draw from a complete and current dataset, EHI access supports faster integration of new use cases, supports dynamic decision-making, and streamlines compliance with changing requirements. Health IT systems and tools, such as EHR platforms, data aggregators, and analytics applications, that are built using modular, standards-based architectures, robust governance, and agile deployment models will be well-positioned to support CMS's strategic goals around interoperability, burden reduction, equity, and high-quality outcomes in a rapidly shifting healthcare landscape.

To fully realize the opportunities of API-based access to complete EHI, health IT systems must evolve to handle the scale, complexity, and variability of this data. As data payload sizes grow, the demand will increase for applications that are scalable, configurable, and use case–aware— applications that can extract and enhance the value of EHI while respecting privacy, security, and

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utility. These systems must be capable of transporting, transforming, evaluating, and storing large volumes of data at high speeds (velocity) without compromising performance or integrity.

The variety of health data—from structured to unstructured, FHIR to legacy formats—requires flexible solutions that can ingest and harmonize data across systems. Configurable transformation pipelines that extend beyond a single standard will be critical to ensure semantic alignment and analytical readiness.

Ensuring veracity—the accuracy, completeness, and trustworthiness of data—is another key area for innovation. Applications that support real-time validation, error reporting, and feedback loops will help both senders and receivers maintain data quality and usability at scale.

Lastly, variability in data—due to clinical workflows, system changes, or patient behavior demands systems that are adaptable. Future-ready applications will incorporate dynamic requirements management, unlocking new API-enabled use cases as data environments, policies, and care delivery models evolve.

CMS and ASTP should view comprehensive EHI access not simply as a policy goal but as foundational infrastructure for a connected, efficient, and patient-centered healthcare system. Supporting this access will require robust technical frameworks, clear privacy protections, and a coordinated policy strategy to ensure the benefits are fully realized.

