June 16, 2025

Stephanie Carlton
Deputy Administrator, Centers for Medicare & Medicaid Services

Dr. Thomas Keane
Assistant Secretary for Technology Policy, National
Coordinator for Health Information Technology

Department of Human Services
Attention: CMS-0042-NC
7500 Security Boulevard
Baltimore, MD 21244-1850

*Submitted Electronically Via Regulations.gov*

*RE:* [RIN 0938-AV68; CMS-0042-NC] Request for Information; Health Technology Ecosystem

Dear Deputy Administrator Carlton and Assistant Secretary Keane:

Thank you for the opportunity to respond to the Centers for Medicare and Medicaid Services'(CMS) RFI on the Health Technology Ecosystem. ADVION will be providing responses to Section E, which focuses on technology vendors, data providers, and networks. ADVION is a national organization representing health information technology (health IT) companies that develop and distribute full clinical electronic health records (EHRs), billing and point-of-care health IT systems and other software solutions serving the majority of Long Term and Post Acute Care providers (i.e., assisted living facilities (ALF), Home Health Agencies (HHAs), Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Skilled Nursing Facilities (SNFs)). ADVION also represents rehabilitation therapy companies; providers of clinical laboratory and portable x-ray services; suppliers of complex medical equipment and other specialized supplies. ADVION is a founding member of the Long Term & Post-Acute Care Health IT Collaborative, which was formed in 2005 to advance health IT issues by encouraging coordination among provider organizations, policymakers, vendors, payers and other stakeholders.

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E. Technology Vendors, Data Providers, and Networks

Ecosystem

TD-1: What short term (in the next 2 years) and longer-term steps can CMS take to stimulate developer interest in building digital health products for Medicare beneficiaries and caregivers?

Short-Term (Next 2 Years):

- Launch pilot programs and demonstration projects that provide real-world testing environments and incentives for developers to build digital health products tailored to Medicare beneficiaries and caregivers.
- Offer financial incentives, such as grants or challenge prizes, for solutions addressing usability, accessibility, and integration with existing Medicare systems.
- Simplify and clarify regulatory requirements to reduce barriers to entry for new developers.
- Enhance technical assistance and provide robust documentation, sandboxes, and developer support to lower the learning curve.
- Engage with stakeholders including patients, caregivers, and vendors early and often to ensure products meet real-world needs.

Longer-Term:

- Incorporate successful digital health products into CMS programs and payment models, creating sustainable demand for innovation.
- Continue to modernize data standards and invest in foundational infrastructure, such as national provider directories and interoperable APIs.
- Foster alignment with value-based care initiatives and support the evolution of standards to keep pace with technology and policy changes.

Data Access, Interoperability, and Standards Challenges

TD-2: CMS Data to Stimulate Developer Interest-

What additional data would be most valuable if made available through CMS APIs?

- USCDI Certification Data: Providing access to USCDI (United States Core Data for Interoperability) certification information would enable developers to build applications that align with national interoperability standards, supporting both "pull" (on-demand) and "push" (event-driven) workflows.
- Specific Data APIs by Certification Lens: APIs tailored to specific certification requirements would help developers meet regulatory needs more efficiently.

- NHSN Reporting Data: Streamlining the National Healthcare Safety Network (NHSN) reporting process by automating data uploads rather than relying on manual entry would address a significant pain point for providers.
- MDS Data and Item Sets: Making Minimum Data Set (MDS) data and related item sets accessible via API would support innovation in long-term care and post-acute care settings.

a. What data sources are most valuable alongside the data available through the Blue Button 2.0 API?

- Mandatory Blue Button Utilization: Given the current low utilization rates, requiring the use of Blue Button 2.0 for relevant programs could drive adoption and ensure more consistent access to patient data.
- Enhanced Connectivity Resources: Improving the infrastructure and support for connectivity would help developers integrate Blue Button data more effectively with other valuable data sources.

b. What obstacles prevent accessing these data sources today?

- Limited Patient Access: Many individuals are not aware of or do not know how to access their health data, which limits the practical use of available APIs.
- Usability Challenges: Even when data is available, the lack of user-friendly tools and workflows makes it difficult for both patients and developers to make use of the information.

c. What other APIs should CMS and ASTP/ONC consider including in program policies to unleash innovation and support patients and providers?

- iQIES API Expansion: Expanding API access to the Internet Quality Improvement and Evaluation System (iQIES) would enable broader data sharing and support for quality improvement initiatives in healthcare.

Digital Identity

TD-3. Regarding digital identity implementation:

a. What are the challenges and benefits?
   - Digital identity solutions can break down when individuals are unable to verify their identity, such as in cases where a proxy or caregiver needs access on their behalf. Even with legal documents like a Power of Attorney (POA), enabling proxy access remains a significant pain point and operational gap.

- The process often requires the individual to first identify themselves and then explicitly grant access to a proxy, which can be cumbersome for patients and caregivers.
- Digital identity provides a trusted, standardized way to confirm that a patient is who they claim to be, enhancing security and reducing the risk of fraud or misidentification in healthcare settings.

b. How would requiring digital identity credentials (for example, CLEAR, Login.gov, ID.me, other NIST 800-63-3 IAL2/AAL2 CSPs) impact cybersecurity and data exchange?

- Mandating digital identity credentials (such as CLEAR, Login.gov, ID.me, or other NIST 800-63-3 IAL2/AAL2 compliant providers) can improve cybersecurity by ensuring only authorized individuals access sensitive health data.

- However, requiring these credentials solely to drive adoption does not guarantee better data exchange, especially if records remain inaccessible due to privacy restrictions or sealed records.
- It is important not to introduce additional steps for providers, as this could delay access to patient records and negatively impact care delivery. Such requirements may be more appropriate for patient access rather than for providers who need timely information to deliver care.

c. What impact would mandatory use of the OpenID Connect identity protocol have? Slow down information, if implemented on top of blue button a sys that isn't implemented already it will slow down even less.
- Making the use of the OpenID Connect identity protocol mandatory could slow down information exchange, particularly if implemented on top of systems like Blue Button that are not yet fully deployed or optimized for such protocols.
- The additional authentication layer may introduce friction, further reducing efficiency in environments where rapid data access is critical.

Technical Standards and Certification

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

- Require the use of open standards (e.g., FHIR, REST, OAuth) for all CMS-funded or certified health IT systems.

- Provide clear, accessible documentation and reference implementations for APIs, reducing the technical burden on developers.

- Enforce transparency in API business and technical documentation, including terms of access, fee structures, and registration processes.
- Penalize or restrict the use of proprietary APIs that create vendor lock-in or hinder interoperability, while rewarding systems that adopt open APIs.
- Support the development and adoption of a common data model to ensure consistency and reduce complexity across APIs.

TD-5: How could a nationwide provider directory of FHIR endpoints improve access to health information for patients, providers, and payers? Who should publish such a directory, and should users bear a cost?

- A nationwide provider directory of FHIR endpoints could improve access to health information for patients, providers, and payers. Current directories often lack the necessary information to make FHIR scalable. Having URLs that do not actually provide access is not beneficial. The directory should be maintained by an appropriate authority, but it is not specified who should publish it or whether users should bear a cost.

TD-6: What unique interoperability functions does TEFCA perform?

- TEFCA provides a single, nationwide framework for health information exchange, reducing the need for multiple, individual agreements between entities.
- Establishes Qualified Health Information Networks (QHINs) as an onramp for secure, standardized data exchange across diverse stakeholders.
- Simplifies legal and technical aspects of data sharing by setting common rules, governance, and technical standards.
- Enables more efficient, secure, and consistent flow of information across healthcare settings, including support for patient access and care coordination.

    a. What existing alternatives should be considered?
    - DirectTrust, Carequality, and private HIEs offer alternative frameworks for data exchange, though they may lack TEFCA's national scope and standardization.

    b. Are there redundant standards, protocols or channels or both that should be consolidated?
    - The current landscape includes overlapping standards and protocols (e.g., IHE XCA, proprietary APIs, various point-to-point connections) that could be consolidated under TEFCA to reduce duplication and administrative burden.

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

- USCDI has driven significant improvements in interoperability by standardizing core data elements for exchange across certified health IT systems.
- It provides a flexible, evolving framework that supports new use cases and aligns with FHIR US Core implementation guides.
- Limitations include gaps in certain domains (e.g., laboratory data, device identifiers, portable medical orders) and challenges with implementation in settings not subject to ONC certification, such as long-term care.
- Some required data elements may not align with existing regulatory assessments, risking duplication or workflow conflicts.

a. Does it contain the full extent of data elements you need?

- USCDI does not always contain the full set of data elements needed for all use cases, particularly in specialized or evolving domains.

b. If not, is it because of limitations in the definition of the USCDI format or the way it is utilized?

- Gaps stem from both the scope of the USCDI format and the variability in how it is implemented in practice.

c. If so, would adding more data elements to USCDI add value or create scoping challenges? How could such challenges be addressed?

- Expanding USCDI could add value but also risks scoping challenges, such as increased complexity and implementation burden. These can be addressed by phased adoption, modular compliance pathways, and robust stakeholder engagement.

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?

- Advances in language models make less structured, non-proprietary formats more feasible, but these require more processing by receivers and may reduce data reliability. Stakeholders may prefer a hybrid approach: structured data for core elements and flexible formats for emerging needs.

TD-8: What are the most effective certification criteria and standards under the ONC Health IT Certification Program?

- The most effective certification criteria and standards under the ONC Health IT Certification Program were those implemented around 2010-2012, particularly security items such as audit trails. These were beneficial in ensuring security and accountability. There is a need for everyone to meet these entry-level security standards.

TD-9: Regarding certification of health IT:

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

- Prioritizing API-enabled capabilities in certification would make the process more transparent and honest about the intended outcomes. Open, scalable API certification is encouraged, with proof of data sharing as a key outcome.

b. What would be the drawbacks?

- Redefining certification could require significant changes to programs like MIPS and may expose systems in ways that are not meaningful if not carefully implemented.

c. How could ASTP/ONC revise health IT certification criteria to require APIs to consistently support exchanging data from all aspects of the patient's chart (for example, faxed records, free text, discrete data)?

- Certain API's can be used in the national framework like TEFCA, which would lend itself for this to be accomplished within this trusted framework.

d. What policy changes could CMS make so providers are motivated to respond to API-based data requests with best possible coverage and quality of data?

- Mandating the use of APIs in a scalable way, aligning with frameworks like TEFCA, and ensuring providers can respond to API-based data requests without additional effort is recommended.

e. How could EHRs capable of bulk data transfer be used to reduce the burden on providers for reporting quality performance data to CMS?

- CMS would have to use their own program to pair down API needed for quality reporting this is hard to do with disparate systems.

What capabilities are needed to show benefit?

- Standards-Based, Interoperable APIs: EHRs must support open, scalable APIs (such as HL7 FHIR Bulk Data) that can export all relevant data elements needed for quality reporting, including structured, unstructured, and scanned/faxed documents.

- Automated Data Extraction and Submission: Systems should enable automated extraction and submission of large volumes of patient data, minimizing manual chart review and data entry by providers.
- Data Mapping and Normalization Tools: Robust tools are needed to ensure data from disparate sources is accurately mapped, normalized, and interpreted for reporting purposes.
- Timely and Flexible Reporting: The ability to generate and submit reports quickly and flexibly, including support for frequent and on-demand reporting cycles, is essential for reducing provider burden.
- Security and Privacy Controls: Strong protocols must be in place to protect sensitive health information during bulk transfers, ensuring compliance with privacy regulations.
- Integration with Clinical Workflows: Bulk data transfer processes should be integrated into existing clinical and administrative workflows to minimize additional effort for providers and staff.
- Support for Multiple Data Sources and Registries: EHRs should be capable of interfacing with various registries, reporting programs, and health information exchanges to support comprehensive quality reporting.

What concerns are there with this approach?

- Concerns with this approach range from variability across disparate systems, data quality/integrity issues, resource burden for provider, information blocking/API limits, security/privacy risks, cost/vendor practices, data migration complexity.

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?

- While EHRs may have the technical capability to allow access, some vendors use information blocking exceptions to circumvent API access requirements. APIs should be required to support data exchange across all aspects of the patient's chart, including faxed records, free text, and discrete data, within a national framework like TEFCA.

TD-11: As of January 1, 2024, many health IT developers with products certified through the ONC Health IT Certification Program are required to include the capability to perform an electronic health information export or "EHI export" for a single patient as well as for patient populations (45 CFR 170.315(b)(10)). Such health IT developers are also required to publicly describe the format of the EHI export. Notably, how EHI export was accomplished was left entirely to the health IT developer. Now that this capability has been in production for over a year, CMS and ASTP/ONC seek input on the following:

a. Should this capability be revised to specify standardized API requirements for EHI export? How?

- The current EHI export capability is broad and can cause headaches due to variability in how data is specified and mapped (e.g., allergies). Standardization would be helpful but could also constrain vendors and increase costs.

b. Are there specific workflow aspects that could be improved?

- There is a need for a standard way to access data across vendors, but simply mandating a new standard does not fix fundamental reconciliation and trust issues in data mapping.

c. Should CMS consider policy changes to support this capability's use?

- Policy changes could encourage or require integration of EHI export functionality into routine clinical and administrative workflows, making it easier for users to trigger exports and utilize the data without extensive technical support.

Data Exchange

TD-12: Should CMS endorse non-CMS data sources and networks, and if so, what criteria or metrics should CMS consider?

- CMS should consider endorsing non-CMS data sources and networks if they meet criteria such as data quality, interoperability, security, alignment with federal standards, and proven value for patient care and quality measurement.
- Metrics could include coverage, reliability, timeliness, and the ability to support CMS program requirements.

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

- APIs providing access to all of a patient's EHI enable more comprehensive care coordination, patient engagement, and secondary uses such as analytics and public health reporting.
- Support for longitudinal records and benchmarking across care settings is enhanced.

a. What are the primary obstacles to this?

- Variability in data capture and standardization, technical limitations of legacy systems, privacy and security concerns, and potential for information overload.

b. What are the primary tradeoffs between USCDI and full EHI, especially given more flexible data processing capabilities today?

- USCDI offers a standardized, manageable set of data elements, while full EHI access provides greater data depth but can increase complexity and processing demands.
- Flexible data processing capabilities (e.g., AI, language models) can help manage unstructured data but may introduce new challenges around data quality and trust.

TD-14: Regarding networks' use of FHIR APIs:

a. How many endpoints is your network connected to for patient data sharing? What types, categories, geographies of endpoints do you cover? Are they searchable by National Provider Identifier (NPI) or organizational ID?

- The number and types of endpoints vary by network; some support hundreds to thousands of endpoints, covering hospitals, clinics, and payers across multiple geographies. Many are searchable by NPI or organizational ID.

b. How are these connections established (for example, FHIR (g)(10) endpoints, TEFCA/Integrating the Health Enterprise (IHE) XCA, or proprietary APIs)?

- Connections are established via FHIR (g)(10) endpoints, TEFCA/IHE XCA protocols, or proprietary APIs, depending on network capabilities and partner requirements.

c. Do you interconnect with other networks? Under what frameworks (for example, TEFCA, private agreements)?

- Networks may interconnect under TEFCA, Carequality, or through private agreements, with increasing adoption of standardized frameworks for broader interoperability.

TD-15: Regarding bulk FHIR APIs:

a. How would increased use of bulk FHIR improve use cases and data flow?
- Bulk FHIR APIs enable efficient data extraction for population health, research, and quality measurement use cases, improving scalability and reducing manual data pulls.

b. What are the potential disadvantages of their use?

- Risks include increased privacy and security concerns, technical challenges in handling large data volumes, and potential for inconsistent implementation across systems.

TD-16: What are the tradeoffs of maintaining point-to-point models vs. shared network infrastructure?

a. Do current rules encourage scalable network participation?

- Point-to-point models offer customized connections but are resource-intensive and do not scale well. Shared network infrastructure (e.g., TEFCA, QHINs) enables broader, more efficient participation and reduces duplication of effort.

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

- Current rules are moving toward encouraging scalable network participation, but further alignment such as API unification and reciprocal access requirements would improve efficiency and reduce barriers.

TD-17: Given operational costs, what role should CMS or ASTP/ONC or both have in ensuring viability of healthcare data sharing networks, including enough supply and demand, that results in usage and outcomes?

- Funding and Incentives: CMS and ASTP/ONC should provide targeted funding, grants, and technical assistance to support the operational costs of healthcare data sharing networks, especially for under-resourced and rural providers. This includes supporting infrastructure upgrades (such as broadband and secure data centers) and subsidizing participation fees for smaller entities to ensure equitable access and network viability.
- Policy and Regulatory Support: Clear policies should mandate participation in data sharing networks for organizations receiving federal funding or participating in CMS programs, driving both supply and demand to achieve a critical mass of participants and data liquidity.
- Standardization and Interoperability: Investment in and enforcement of open, standards-based APIs (such as FHIR) and common data models are necessary to reduce integration costs and technical barriers, making it easier for vendors and providers to join and utilize networks.
- Stakeholder Engagement and Technical Resources: Ongoing engagement with technology vendors, providers, and data aggregators is essential to identify gaps and needs. Providing robust technical resources, sandboxes, and analytic tools supports onboarding and sustained participation.
- Monitoring and Outcomes Measurement: Transparent metrics on network usage, data quality, and outcomes should be developed and published to demonstrate value and encourage continued participation. These insights can refine incentive structures and technical support.

Compliance

TD-18: Information blocking:

a. Could you, as a technology vendor, provide examples for the types of practices you have experienced that may constitute information blocking. Please include both situations of non-responsiveness as well as situations that may cause a failure or unusable response?

- EHR vendors or providers may fail to respond to legitimate requests for electronic health information (EHI) in a timely manner, delaying access for patients or other providers.
- Requests for data export or interface setup may be ignored or excessively delayed, hindering data portability and workflow efficiency.
- Data may be provided in non-standard or proprietary formats that cannot be readily used by the requester, even when standards-based options are available.
- Excessive fees may be imposed for data access, export, or interface use, which are not reasonably related to the cost of providing the service.
- Access to EHI may be restricted by limiting the duration or scope of access, such as only allowing access for a short window or to a subset of data elements.
- Contractual terms may prohibit or discourage interoperability, such as preventing clients from migrating data to a competing platform or requiring burdensome licensing or training requirements.

b. What additional policies could ASTP/ONC and CMS implement to further discourage healthcare providers from engaging in information blocking practices?

- Strengthen Enforcement and Penalties: Expand and publicize enforcement of civil monetary penalties of those found to have committed information blocking.
- Increase Transparency: Require public reporting of entities found to have engaged in information blocking, including details of violations and corrective actions taken.
- Clarify and Expand Exceptions: Provide clearer guidance on allowable exceptions to information blocking, reducing ambiguity and closing loopholes that may be exploited to justify non-compliance.
- Mandate Standardized Data Formats: Require all certified health IT systems to support export and exchange of EHI using open, standards-based formats (such as FHIR and USCDI), minimizing the risk of unusable or proprietary responses.
- Facilitate Patient and Provider Education: Launch educational initiatives to inform patients and providers of their rights under information blocking regulations and how to report suspected violations.
- Streamline Complaint and Investigation Processes: Make it easier for stakeholders to report information blocking and for regulators to investigate and act on complaints in a timely manner.

c. Are there specific categories of healthcare actors covered under the definition of information blocking in section 3022(a)(1) of the Public Health Service Act (PHSA) that lack information blocking disincentives?

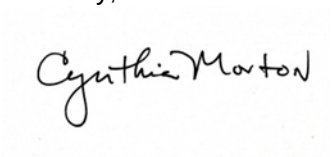
- Coverage under PHSA Section 3022(a)(1): Information blocking actors include health care providers, health IT developers, health information networks, and health information exchanges.
- Disincentive Gaps: Health IT developers and health information networks/exchanges are subject to civil monetary penalties, but health care providers have historically faced less

direct financial risk. Recent rules allow for broader disincentives for providers, but the scope and application of these penalties are still evolving.

- Potentially Under-Regulated Actors: Certain provider types or smaller organizations may not face meaningful disincentives if they are not subject to CMS payment programs or if enforcement resources are limited. There may also be gaps for actors not directly involved in CMS programs or those operating outside the ONC Health IT Certification Program.

Thank you again for allowing us to provide responses on this RFI. I am available to provide additional input or clarification and can be reached at 202 803-2385 or Cynthia@ADVIONadvocates.org.

Sincerely,



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