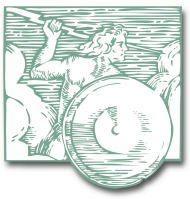

A E G I S

June 16, 2025

Centers for Medicare & Medicaid Services
Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC)
Department of Health and Human Services
File Code: CMS-0042-NC

RE: **Request for Information: Health Technology Ecosystem**

The AEGIS.net, Inc. team of healthcare interoperability specification experts, thought leaders and implementers are honored to respond to this important Request for information (RFI). We applaud the CMS and ASTP/ONC teams for recognizing the need to ask these important questions about how to accelerate adoption of FHIR-based standards and implementation guides (IGs) as fuel to accelerate healthcare interoperability for the benefit of all taxpayer/stakeholders: payers, providers, researchers and patients. We appreciate your mission focus.

We have provided answers on the topics to which we can add the greatest value given our current focus. As a prelude, we humbly submit thoughts about questions not directly asked, but which we feel are in the spirit of the RFI objectives.

Given that CMS and ASTP/ONC seek to encourage, through rule-making and regulation, wider adoption of health IT technology and their supporting standards and specifications, we see an opportunity to leverage the CMS and HL7 Connectathon events to more effectively further these objectives. We suggest seeking:

- Objective data on maturity of industry adoption of (for example) each FHIR IG
    - How many organizations have implemented a given IG or use case?
- Objective measurement of current coverage.
    - Which business requirements are actually being implemented in each IG?
    - What percentage of the overall requirements does that represent? Is that enough? Are the requirements satisfying final rules being implemented?
- Stakeholders require both testing artifacts (such as FHIR Test Plan, Test Cases, and FHIR TestScripts) conformance requirements to align with the full IG Publishing process. This would allow for better calibration of these testing artifacts across the implementation community.
- Leverage current best-in-breed commercial-off-the-shelf (COTS) supported FHIR Testing approaches which leverage FHIR TestScript.

Being armed with this kind of objective evidence of adoption velocity and maturity will empower CMS and ASTP/ONC teams to make data-driven assessments of interoperability progress and risks. We would be happy to help make this a reality for you and US taxpayers.

AEGIS Team Responses

Payers

PA-2

How can CMS encourage payers to accelerate the implementation and utilization of APIs for patients, providers, and other payers, similar to the Blue Button 2.0 and Data at the Point of Care APIs released by CMS?

CMS is in a unique position to offer financial incentives to providers (and their EHR vendors) to drive the adoption and utilization of these additional APIs--a key strategy for driving improved data quality. CMS can also set the example by modifying their APIs to conform to the applicable FHIR IGs to kickstart the adoption flywheel and benefit all payers.

PA-3

How can CMS encourage payers to accept digital identity credentials (for example, CLEAR, ID.me, Login.gov) from patients and their partners instead of proprietary logins?

There is a sound business case to be made--especially since these commercial options are compliant with the same NIST SP 800-63 specifications called for in the CMS Access Control Handbook. Many consumers are already required to use these commercial platforms for digital identity credentials, so payers should welcome the opportunity to select from those options rather than continuing investing in proprietary login infrastructure. To further encourage that decision, CMS could create a rule requiring payers to demonstrate conformance to NIST SP 800-63 for their patient/caregiver logins.

PA-4

What would be the value to payers of a nationwide provider directory that included FHIR end points and used digital identity credentials?

Establishing a directory of endpoints is as essential to FHIR/Interoperability as DNS was to making the World Wide Web viable. A great value of a nationwide provider directory over the patchwork of existing directories for providers, HIEs, etc. would be in the consolidated view of all pathways to clinical information.

PA-7

How can CMS encourage payers to submit information blocking complaints to ASTP/ONC's InformationBlocking Portal? What would be the impact? Would it advance or negatively impact data exchange?

Looking at the ASTP/ONC Information Blocking Portal, along with Information Blocking Data about submitted information blocking claims, could lead one to assume that such claims are not welcome from payers. Modifying the Portal UX to make it clear that claims are welcome from payers would likely be helpful. Another suggestion is to reach out to payers to provide encouragement to submit those claims.

We believe that regardless of who submits a claim, the impact of increased claim volume by all stakeholders would provide tangible evidence that CMS and ASTP/ONC are actively enforcing Information Blocking rules, and the impact on data exchange would be to discourage future information blocking and increase data exchange volume.

Vendors/Data Providers/Networks

TD-4

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

CMS can use a combination of its encouragement levers to drive greater use of publicly-available standards-based APIs. Resuming enforcement of previously delayed final rules is a step we encourage. We suggest tuning this enforcement, as necessary to ensure that required APIs (such as Patient Access, Provider Directory, and Prior Authorization APIs) are published, discoverable, standards-conformant, and expose complete and accurate data. CMS can use its public platform lever by establishing a certification program and publicly listing high-performing APIs to guide developers toward higher quality data. A third lever is more directly financial, and can likely be most effective after CMS teams can measure the differences in key metrics between activity using the public APIs vs legacy/proprietary APIs. Armed with that information CMS can offer incentives that are budget-positive for taxpayers.

From Mario's text below:

We see strategic investment by CMS in improving the standards development/ implementation/validation lifecycle as perhaps the most powerful lever for sustained impact on driving increased adoption of standards-based publicly available APIs. We have seen this result in FHIR IGs that are more readily implementable by development teams who can make faster progress when rigorous test cases are created and understood by IG authors and developers, along with automated conformance testing included in development workflow. This combination provides objective measurement to stakeholders of individual implementation progress and IG adoption rates, creating a virtuous cycle that further encourages IG adoption.

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?

Establishing a directory of endpoints is as essential to FHIR/Interoperability as DNS was to making the World Wide Web viable. A great value of a nationwide provider directory over the patchwork of existing directories for providers, HIEs, etc. would be in the consolidated view of all pathways to clinical information.

Allowing a party to find the organization they are interested in, then to discover all the electronic pathways to it, would be valuable, in that they could then decide which path(s) are the most beneficial/appropriate in terms of supported interoperability use cases and standards, cost, service level agreements, governance, etc. Such a consolidated view would not require replacing existing HIE directories; rather it could draw from those as primary sources. We recommend that this directory be published and maintained by CMS or a selected contractor then tested and validated by a third party.

TD-6

What unique interoperability functions does TEFCA perform?
Our perspective is that TEFCA is less about providing unique interoperability functions and more about functioning as a regulatory lever to compel interoperability.

a. What existing alternatives should be considered?

We find it interesting that existing nationwide HIEs like eHealth Exchange, Carequality and CommonWell have all rushed to become QHINs under TEFCA. This suggests that the regulatory lever is working, but it makes us wonder if the concentration of approaches is wise.

b. Are there redundant standards, protocols or channels or both that should be consolidated?
The standards chosen by TEFCA are good as far as they go. However, we are in favor of facilitated FHIR over brokered transactions.

TD-7

To what degree has USCDI improved interoperability and exchange and what are its limitations?
To the degree that USCDI defines a set of baseline expectations, it has improved interoperability. To the degree that additions seem to be driven by a chicken-and-egg assessment of what data elements are already in use, it seems to slow down the advancement of interoperoperability improvements.

a. Does it contain the full extent of data elements you need?
For some use cases no.

b. If not, is it because of limitations in the definition of the USCDI format or the way it is utilized?
JL: The USCDI format is not very straightforward to determine how to map from a given data element to the required standards. Secondary guidance materials like the HL7 Basic Provenance Guide would be very helpful.

c. If so, would adding more data elements to USCDI add value or create scoping challenges? How could such challenges be addressed?
Problems arise when adding data elements to USCDI is when they are not universally needed. In that case, the data elements being required should be conditioned on support for particular use cases.

d. Given improvements in language models, would you prefer a non-proprietary but less structured formats that might improve data coverage even if it requires more processing by the receiver?
Large language models (LLMs) offer great promise for extracting information from less structured data formats, but at this early stage of LLM evolution, we advocate

well-defined data structures to ensure patient safety and avoid imposing another processing layer to the solution stack.

TD-9

Regarding certification of health IT:
a. What are the benefits of redefining certification to prioritize API-enabled capabilities over software functionality?
To advance interoperability, prioritizing API-enabled functionality is an imperative, not an option. Software functionality in isolation does nothing to advance the exchange of healthcare information or ensure patient care coordination across an integrated care delivery team(s).

b. What would be the drawbacks?
Mandating API functionality alone, without setting any expectations about other software functionality, could become a hindrance to interoperability and a convenient excuse for engaging in information blocking. To avoid this, API expectations should include the specification of data transformations required to support API functionality.

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)?
We recommend making support of exchanging data from all aspects of the patient's chart (for example, faxed records, free text, discrete data) a foundational requirement for health IT certification, followed by rulemaking that (after a reasonable transition period) classifies the lack of such support as information blocking.

But certification criteria should not stop at defining expectations for what data should be in API payloads. We cannot simply test data (profile conformance); we need to test the EHR's ability to support message orchestration, bi-directonal care coordination, message organization (TODO: define this for them…) and the ability to support operations, such as pub/sub, consent, prior auth (burden reduction rules)

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?
Add this requirement to existing data quality reporting criteria that are associated with CMS reimbursement rates.

e. How could EHRs capable of bulk data transfer be used to reduce the burden on providers for reporting quality performance data to CMS? What capabilities are needed to show benefit? What concerns are there with this approach?

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?
We recommend that ASTP/ONC encourage technology vendors and EHR implementations to support a full complement of US Core profiles. Current (g)(10) certification criteria allow EHR vendors to claim compliance by testing just a few of the profiles. Our recommendation US Core profile(s) not supported should result in the certification exemption(s)/exclusion(s), noting the profile(s) for which the vendor has not demonstrated conformance.

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?
As a team observing hundreds of organizations struggle to implement requirements that are standardized, we feel strongly that a lack of standardization is a hindrance to Health IT innovation, and we see every day that the absence of specificity (in standards language) drives unpredictable results. A standardized EHI export standard would create a foundational data capability that could be an catalyst for multiple interoperability use cases. We recommend that ASTP/ONC and CMS drive a process for defining standardized API specifications for EHI export using the FHIR data model.

b. Are there specific workflow aspects that could be improved?
We feel that an EHI Export API would create a scalable workflow where (in many cases) no automated workflow exists at all. A self-serve could eliminate wait times for the EHI requestor and vastly reduce the burden for the EHI holder.

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

TD-12

Should CMS endorse non-CMS data sources and networks, and if so, what criteria or metrics should CMS consider?
Yes, we recommend that CMS carefully evaluate non-CMS networks, and we encourage you to also engage with your federal partners to evaluate the potential benefits to US taxpayers of that participation helping us realize the vision of a truly nationwide health information exchange network.

TD-13

What new opportunities and advancements could emerge with APIs providing access to the entirety of a patient's electronic health information (EHI)?
Information is power--to patients, implementers, clinicians and researchers. We feel that APIs providing the entirety of a patient's EHI will empower these stakeholders to gain new insights that will improve patient care and accelerate research breakthroughs.

a. What are the primary obstacles to this?
Health IT vendor roadmaps are driven by financial incentives and regulatory requirements. The absence of these is the primary obstacle.

b. What are the primary tradeoffs between USCDI and full EHI, especially given more flexible data processing capabilities today?
With the ongoing emergence of AI tools, the entirety of a patient's EHI will be extracted soon--with, or without, the cooperation of the health IT vendors. Given this, it is in the best interests of all stakeholders, including commercial payers, health IT vendors and CMS, to see official (fully vetted and certified) APIs emerge.

TD-15

Regarding bulk FHIR APIs:
a. How would increased use of bulk FHIR improve use cases and data flow?
Increasing the use of Bulk FHIR is essential for its adoption and refinement. A good analogy is network effects. The more Bulk FHIR is used, the more valuable it becomes,

encouraging additional use cases and refinement, which drives additional adoption and increasing standardization of data flow.

b. What are the potential disadvantages of their use
To realize this potential, more work needs to be done exploring how to best prepare and share data so that the requestor can utilize multiple requests to improve speed and address connectivity and error/recovery conditions. This effort could also require data alignment exercises, crossing multiple versions, and incorporate alternative standards and specifications.

TD-16

What are the tradeoffs of maintaining point-to-point models vs. shared network infrastructure?
As long as the edge systems have implemented the same standards and have a sufficiently robust implementation, point-to-point can work quite well, and we prefer it for FHIR. Shared/brokered communication has a few value adds (API adaptation, network management), but it is often oversold in terms of benefits (for example, scaling up communication partners is presented as difficult, but with proper governance, it should be analogous to adding entries to an address book), and can incur its own costs (latency, cost, lock in). Ideally, systems should be able to choose which they wish to implement.

a. Do current rules encourage scalable network participation?
JL: We are aware of some policies in another, non-CMS body, that created an artificial barrier to scalability by requiring additional effort for each addition to a network by the existing network member, leading to a call for a hub to mitigate the policy impact.

b. What changes would improve alignment (for example, API unification, reciprocal access)?
JL: The key aspect to manage in point to point architectures is rolling out changes and additional capabilities to the standard APIs.

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?
Like it or not, vendors, data providers and networks (along with their stakeholders) react to the rules and incentives created (and enforced) by CMS and ASTP/ONC. In an ideal US healthcare system, all actors would respond to their primary goal of optimizing for

patient outcomes, and most try. Nevertheless, the health IT community has been trained to respond to rules, incentives and penalties. We recommend you these levers to achieve the usage and outcomes you seek.