Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013, Baltimore, MD 21244

June 16, 2025

RE: CMS-0042-NC, Request for Information; Health Technology Ecosystem (RIN 0938-AV68)
[Filed Electronically]

Thank you for the opportunity to submit the following comments in response to the Request for Information; Health Technology Ecosystem. Drummond Group is a respected test lab and certification body, fully authorized for testing and certification of Health IT by the Office of the National Coordinator under the Health IT Certification Program. As a recognized industry leader and ONC-ACB, we have unique insight into healthcare technology, the state of interoperability, and common end user challenges.

We appreciate your consideration of our comments and look forward to our continued work within the healthcare community to advance our nation's healthcare system.

Sincerely,

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# Request for Information; Health Technology Ecosystem

*CMS-0042-NC*

## Patients

| **Data Access and Integration** |
|---|
| (PC-8c) What specific opportunities and challenges exist to improve accessibility, interoperability and integration of clinical data from different sources to enable more meaningful clinical research and generation of actionable evidence? |
| **Drummond Response:**<br>We believe FHIR certification requirements should be updated to recommend or require that FHIR-enabled Health IT applications support FHIR 4 Create and Update operations. CMS should consider promoting other industry use cases where CDEX and Bulk FHIR are being used or proposed for clinical data integration from different sources. |
| (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?<br>▪ (PC-10a) Provide specific examples<br>▪ (PC-10b) What changes would you suggest?<br>▪ (PC-10c) What use cases could have a significant impact if implemented through TEFCA?<br>▪ (PC-10d) What standards are you aware of that are currently working well to advance access and existing exchange purposes?<br>▪ (PC-10e) What standards are you aware of that are not currently in wide use, but could improve data access and integration?<br>▪ (PC-10f) Are there redundant standards, protocols, or channels that should be consolidated?<br>▪ (PC-10g) Are there adequate alternatives outside of TEFCA for achieving widespread patient access to their health information? |
| **Drummond Response:**<br>The TEFCA Common Agreement should be modified to require support for FHIR 4 enabled data exchange, facilitating QHINs to support provider-payer FHIR business use cases at scale for prior authorization, patient cost transparency, CDEX-based clinical data exchange, payer-to-payer data exchange, and other use cases for FHIR data exchange. |

TEFCA should also be modified to support FAST services like Directory, Consent, Identity, and Security Authentication. Networked FHIR services, such as a QHIN, must be able to route data exchange between providers and payers using FHIR standards to support interoperable health data exchange.

(PC-11) How are health information exchanges (HIEs) currently helping to advance patient access to health information in the real world?

- (PC-11a) How valuable, available, and accurate do you find the data they share to be?
- (PC-11b) What changes would you suggest?
- (PC-11c) Are there particular examples of high-performing HIE models that you believe should be propagated across markets?
- (PC-11d) What is the ongoing role of HIEs amidst other entities facilitating data exchange and broader frameworks for data exchange (for example, vendor health information networks, TEFCA, private exchange networks, etc.)?

**Drummond Response:**
HIEs are important aggregators of patient data and should be required to support FHIR standards similar to providers and payers. As such, we believe HIEs should also be subject to testing and certification requirements like the producers and consumers of patient health data.

## Information Blocking and Digital Identity

(PC-14) Regarding digital identity credentials (for example, CLEAR, Login.gov, ID.me, other NIST 800–63–3 IAL2/AAL2 credentialing service providers (CSP)):
a. What are the challenges today in getting patients/caregivers to sign up and use digital identity credentials?
b. What could be the benefits to patients/caregivers if digital identity credentials were more widely used?
c. What are the potential downsides?
d. How would encouraging the use of CSPs improve access to health information?
e. What role should CMS/payers, providers, and app developers have in driving adoption?
f. How can CMS encourage patients to get digital identity credentials?

**Drummond Response:**
The current need for patients to have and maintain credentials for every provider and payer portal is not a scalable and realistic future for patient access to health information or for the authorized exchange of data between providers and payers. We believe digital identity credentials for patients from CSPs are necessary if we want to see widespread adoption of heath data exchange and access. In addition to one credential per patient accepted everywhere, digital identity credentials would solve the persistent patient matching problem.

CMS can encourage patient digital identity credentials by making rulemaking that requires providers and payers to use digital identity credentials in FHIR APIs for patient and provider access, as well as other FHIR business data exchange use cases such as prior authorization, payer-to-payer data exchange, and patient cost transparency.

## 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?

**Drummond Response:**
Similar to the initial Meaningful Use incentives that stimulated the adoption of digital medical record transformation and adoption of EHR technology, both payers and providers (and their solution developers) should be financially incentivized to adopt FHIR standards that enable transformative interoperability and standardized data exchange.

We also believe incentives should extend to specialties and suppliers of DME, imaging providers, lab order fulfillment, and others so that the full healthcare ecosystem is included in standardized FHIR data exchange.

(TD-2) Regarding CMS Data, to stimulate developer interest--
a. What additional data would be most valuable if made available through CMS APIs?
b. What data sources are most valuable alongside the data available through the Blue Button 2.0 API?
c. What obstacles prevent accessing these data sources today?
d. What other APIs should CMS and ASTP/ONC consider including in program policies to unleash innovation and support patients and providers?

**Drummond Response:**
To stimulate developer interest, consider promoting the development of Billing APIs and modern replacements for outdated messaging protocols like Direct/Edge. Encourage adoption of Documentation Templates and Rules (DTR) standards to streamline the creation of clinical documentation for pre-claim and post-claim reviews. Additionally, updating HIPAA regulations to explicitly support FHIR-based data exchange between covered entities would enable broader interoperability and innovation.

## Digital Identity

(TD-3) Regarding digital identity implementation:
a. What are the challenges and benefits?
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?
c. What impact would mandatory use of the OpenID Connect identity protocol have?

**Drummond Response:**
There are currently different approaches to handling CSPs and digital identity. We recommend a standardized unified approach between TEFCA, SMART and UDAP.

## Technical Standards and Certification

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

**Drummond Response:**
CMS can promote the adoption of open, standards-based publicly available APIs by continuing its participation in HL7-led development of new FHIR standards, issuing regulations that mandate the use of FHIR APIs, and requiring both provider and payer solutions to undergo testing and certification through ONC-Authorized Test Labs (ONC-ATLs) and Certification Bodies (ONC-ACBs). This will help ensure interoperability across the healthcare ecosystem.

(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?

**Drummond Response:**
Nationwide directories would enable networked FHIR entities, such as QHINs, to more efficiently look up and route FHIR data exchange traffic between payers and providers in a standardized manner.

TD-6. What unique interoperability functions does TEFCA perform?
a. What existing alternatives should be considered?
b. Are there redundant standards, protocols or channels or both that should be consolidated?

**Drummond Response:**

We believe that the TEFCA Common Agreement should mandate the support and use of HL7 FHIR standards that include FAST services.

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?
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?

**Drummond Response:**
We believe USCDI should continue to serve as the foundational set of standardized data elements, with the flexibility to incorporate additional elements tailored to specific use cases through the USCDI+ framework. Certification could be structured to require the core USCDI set, with optional USCDI+ modules available to address more specialized data exchange needs.

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

**Drummond Response:**
170.315(g)(10) Standardized API for Patient and Population Services has been impactful in accelerating the industry's progress towards interoperability by mandating use of FHIR standards and open APIs for certified technology and empowering patients with access to their data.

170.315(b)(11) Decision Support Interventions is also valuable in supporting the industry's shift toward greater interoperability by establishing standardized requirements for the integration and operation of clinical decision support (CDS) within certified health IT systems and an important step in providing needed structure for integrating predictive tools responsibly.

TD-9. Regarding certification of health IT:
a. What are the benefits of redefining certification to prioritize API-enabled capabilities over software functionality?
b. What would be the drawbacks? 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)?

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?
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?

**Drummond Response:**
Prioritizing API-certified capabilities, particularly those based on FHIR, supports a more interoperable and modern health IT ecosystem. Testing API-related criteria is essential to ensure real-world functionality and trust. While some non-API criteria could be managed through self-attestation, key requirements related to patient portal and e-Prescribing still warrant rigorous testing. Eliminating these requirements risks weakening oversight by ONC-ACBs and may compromise patient safety and standards compliance.

We recommend implementing CMS policies that require certification for payers and third-party application developers to promote more consistent, standards-based data exchange and help extend privacy and security protections beyond EHRs to the broader health data ecosystem.

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:
c. Should this capability be revised to specify standardized API requirements for EHI export?
b. Are there specific workflow aspects that could be improved?
c. Should CMS consider policy changes to support this capability's use?

**Drummond Response:**
Establishing a FHIR-based standard for EHI export would facilitate a more streamlined and consistent process for health IT developers.

## Data Exchange

TD-13. What new opportunities and advancements could emerge with APIs providing access to the entirety of a patient's electronic health information (EHI)?
a. What are the primary obstacles to this?
b. What are the primary tradeoffs between USCDI and full EHI, especially given more flexible data processing capabilities today?

**Drummond Response:**
While full access to a patient's electronic health record remains the ideal, a primary obstacle is the absence of comprehensive FHIR implementation guides across all clinical specialties, which limit consistent and standardized data exchange.

TD-15. Regarding bulk FHIR APIs:
a. How would increased use of bulk FHIR improve use cases and data flow?
b. What are the potential disadvantages of their use?

**Drummond Response:**
We strongly believe the submission of claims data should be moved to FHIR technology. The use of bulk FHIR would enable providers to submit claims and clinical reason documentation to payers more efficiently using FHIR APIs.

TD-16. What are the tradeoffs of maintaining point-to-point models vs. shared network infrastructure?
a. Do current rules encourage scalable network participation?
b. What changes would improve alignment (for example, API unification, reciprocal access)?

**Drummond Response:**
While point-to-point models are important to establish a baseline of FHIR interoperability and demonstrate the potential for transforming interoperable health data exchange, point-to-point models for FHIR data exchange limit the scalability of FHIR.

Shared network infrastructure is critical to connecting a meaningful volume of payers and providers in the marketplace and scaling to millions of transactions per day. The TEFCA Common Agreement does encourage scalable network participation; however, the agreement should be modified to require support for FHIR 4 enabled data exchange and FAST services intended to enable scalable FHIR transactions. This concept should apply to HIEs, clearinghouses and other shared network infrastructure.