

June 16, 2025

Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Request for Information; Health Technology Ecosystem [CMS-0042-NC]

Introduction

Flexion is a technology and consulting firm with more than 25 years of experience delivering modern, human-centered solutions in the public sector. Flexion helps organizations adapt and grow by building high-quality software solutions that are easy to use, modify, and modernize. Our approach creates flexible options at every level, enabling agencies to respond efficiently to evolving business needs, user demands, and emerging technologies. Our team has partnered with federal agencies such as the Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) on a wide range of health technology projects. We focus on interoperability, data integration, digital product development, and operational transformation.

Flexion is pleased to respond to the CMS Request for Information (RFI) regarding the Health Technology Ecosystem. We believe our experience delivering innovative solutions to federal health programs uniquely positions us to offer valuable input to CMS on key topics in this RFI.

Background

This RFI explores how CMS can best support health technology innovation to advance care delivery, patient engagement, program integrity, and interoperability. Flexion's comments below are organized by RFI section and we have included comments for RFI questions that we feel reflect our organization's broad experience in healthcare technology consulting.

Comments on Selected RFI Questions

Patients and Caregivers: Patient Needs

PC-2

It is rare, if not impossible, to access all of an individual's health information from a single location. A typical individual will likely have a separate health information portal for each provider they visit. Some portals, especially if they use the same underlying EHR software, have limited ability to share data with each other. However, more likely than not, patients need to log in to multiple portals to gain a comprehensive view of their health data.

Moreover, different health systems have different limitations as to what can be viewed through their portals. Sometimes, a patient can access certain information, such as imaging results or procedure notes, from one portal but not another. The inconsistency between provider portals can be confusing and irritating to a user.

A user-friendly solution that would allow data sharing and data aggregation between providers to provide patients with a single view of all of their health data would be helpful. Insisting that providers use the full capabilities of their patient portal software would also be beneficial to patients, so that they can be assured that they are viewing the entirety of their medical records.

PC-3

Fasten Health [<https://www.fastenhealth.com>] is one organization that is building a user-facing application to aggregate health information from multiple health systems. This application relies on data being available in FHIR format. Though the Fasten Health application is still in early stages and is not yet user-friendly, the goal remains to have a place where any patient, including Medicare beneficiaries and their caregivers, can easily find all of their relevant medical information across multiple providers. It is critical to continue supporting additional data being required to be available in FHIR format through rule making. USCDI is very helpful in making applications like Fasten Health a reality.

PC-4

Some features that would be useful to have in an app: A way to easily get accurate cost estimates for medical procedures and visits without needing to know CPT codes and taking into account a patient's insurance, better provider search tools including the ability to find sub-specialty practitioners, the ability to update portions of a patient's own medical record such as family history, and direct access to claims and the associated data for the claims.

PC-5

CMS can be a trusted partner in vetting health products, tools, and applications. It can be tough to weed out poor products and applications. Having a process to review these things for privacy and security, especially, can help patients and caregivers make a more informed decision about the products they use.

PC-6

Specifically, thinking about Medicare beneficiary users and their caregivers, one good way to make digital health products accessible and easy to use is to mandate the use of “plain language”. The medical industry is filled with jargon and hard-to-understand terminology. Using plain language will help in the comprehensibility of what patients and caregivers read through a digital health product. These products also need to be designed with accessibility in mind. Using current accessibility guidelines for visual, cognitive, and other aspects of a product will help bring the product to a wider range of patients. Patients with a disability are often more involved with the healthcare system in general than non-disabled individuals, and these products must be made with this in mind.

PC-7

A good way to gather real-world data is to deliberately seek out user feedback and expert reviews. Users will be able to relate to whether or not a product was helpful to them, while experts will be able to relate to whether or not a product is accurate and secure.

Patients and Caregivers: Data Access and Integration

PC-8

A commonly available piece of health data is the provider note or after-visit summary. These are critical pieces of information for any patient to help them understand what was decided at their provider visit.

It can be hard to get claims and pricing data, especially when having it integrated into a single app with other health data. Integrated quality scores would be helpful as well. Patients can also use some consistency in clinical data that is available across providers. Likely, this will require apps to be able to integrate with different providers and insurance companies and potentially other organizations as well. CMS can potentially assist with this from the rule-making side of things.

There are a number of challenges here. Limited funding is an issue. Not having the correct expertise on staff can be a challenge as well. Sometimes, the changes required to meet accessibility, interoperability, and integration goals are too much of an effort. Interoperability and integration can be hard when different organizations are not using the same standards for their data or their APIs.

PC-9

Other data sources that would be useful to include in the Blue Button API are provider data sources. Being able to tie in information about a provider directly with Medicare claims data can be helpful for the end user.

PC-12

Other valuable operational health data use cases for patients are:

- The ability to easily view prior authorization decisions that are easily understandable will help promote timely care and avoid emergency situations.
- Comprehensive upper limit cost guarantees for procedures that include everything a patient is responsible for.
- Pharmacy information, including the ability to clearly understand alternative medication choices and out-of-pocket costs.

Patients and Caregivers: Information Blocking and Digital Identity

PC-13

It's likely that patients and caregivers aren't sufficiently informed as to their rights to retrieve their own health data. ASTP/ONC and the federal government in general should do more to promote knowledge sharing for patients and caregivers so that they understand these rights. Anecdotally, there is also evidence that insurance companies and other organizations don't always know these rules. Education for everyone involved in healthcare to ensure that patients and caregivers can access all of their health information is warranted.

It is unknown as to the effect this would have on data exchange, but the hope is that this will influence all organizations that have health information to provide easy ways for people to retrieve that health information.

PC-14

There are many pros and cons for and against making widespread use of digital identity credentials. There are many arguments against requiring digital identity credentials for anything. However, understanding a person's identity is critical to ensure correctness within health information systems.

There are a number of compelling identity credential systems available today. One, notably, is login.gov. [Login.gov](https://login.gov) has a robust identity verification process and monitoring, and is built to be a one-stop shop for identity services from a federal government perspective. A major benefit to using a system such as this is that patient records across multiple health systems can be more easily matched to the correct patient. This can be extremely beneficial for individuals who see numerous health care providers or for individuals who must seek health-related services away

from their home area. This can increase the ability of providers to gain an accurate picture of someone's full health situation and can increase the ability for patients to correctly retrieve their own health data. Decreases in errors owing to similar patient names or decreases in duplicative tests across multiple providers can be realized.

There are some downsides that should be noted, however. There are concerns that having a common digital identifier will lead to health information being shared in spaces where it shouldn't be shared. Having a digital identity will make it easier for services and coverage to be denied. Or even that the federal government will use this information to link people's statuses across other federal systems. Careful vetting of identity providers needs to occur to weed out potential bad actors who may be harvesting identity information for nefarious purposes.

CMS and other trustworthy organizations need to determine (or build) a small number of Credentialing Service Providers that can be trusted.

Providers: Digital Health Apps

PR-1

It's a great idea for CMS and its partners to encourage providers to use more digital health products for their patients. However, smaller providers, and especially providers in rural areas, can be at a significant disadvantage when trying to integrate these products with their own systems.

It can take a fair amount of technical knowledge and know-how to be able to integrate a product with an EHR system. A small or rural provider may not have someone on staff with that knowledge, and they may not be able to afford a contractor to do the work. Oftentimes, the creator of the digital health product can offer services to perform the installation and/or integration, but that may be cost-prohibitive as well.

It is hard to say whether or not a provider should have any real responsibility when recommending digital health products to a patient. Providers may or may not have enough technical expertise to make judgment calls about a product other than whether or not the product "seems like a good product". It would be better to have a third party (a verified third party, the federal government, or a federal agency) publish recommendations that can be trusted by providers and the public.

PR-2

There are a couple of obstacles to useful and innovative applications for physician workflows. One is that anecdotally, physicians and other providers see these applications as a barrier to patient care. They do not find these applications useful. Another is that it seems that healthcare startups and other companies that are developing these physician workflow applications do so in a vacuum. They do not work with actual providers to understand what problems need to be solved and what things will be helpful.

PR-3

From the perspective of healthcare delivery, there are already rules in place that patients are to be provided all of their health data from a provider when they ask. Regardless of the actual storage format, providers generally have a way to make this data available. The real issue is interoperability.

Different provider systems, even using the same underlying EHR or other software, may store data in different ways. Without customization, this can limit direct interoperability between systems. The challenge here is, where does that customization happen? A software vendor could provide customization for interoperability at that level. An integration engine can sit in front of the vendor EHR software that can transform messages and data. Or, an intermediary can be used to provide the interoperability. No matter the choice made, the solution can require a significant amount of time, effort, and funding.

One technical barrier to interoperability is the concept of identity. Different systems will have different ways of identifying patients in their systems. This makes it hard to verify patients from system to system. As the patient is everything, how can there be true interoperability between any system if there is no agreement on how a person is identified?

Solutions to full interoperability of all data formats can range from custom transformation at one of multiple levels, as previously mentioned in this section, all the way to mandating all data be in one specific format. No matter the solution, the implication is that a significant cost is attached. Many providers and many systems will need to make changes. These changes have the potential to be very expensive.

Providers: Data Exchange

PR-8

Getting the necessary clinical quality data that CMS needs can be challenging. There are many measures, and each measure needs slightly different data. There are a couple of different options for simplifying the responsibilities of providers.

For each of these options, an enabler is that CMS performs the clinical quality measure calculations with the data sent. It would be in CMS's interest to store clinical quality measures in a publicly accessible repository so that there is transparency of what the quality measures measure, and then CMS runs the calculations. This simplifies provider responsibility so that only CMS has to worry about performing the calculations.

One option to get data to CMS involves sending real-time data feeds of relevant clinical data to CMS. The current FHIR specifications around quality measures have the ability for a provider to

query as to what data is required for each measure. Using this, a provider can provide the appropriate data in real-time when it appears in the system. CMS can consume these data feeds and perform real-time measure calculations, which would allow providers to see their current measure scores right away.

Another option would be for CMS to create a SMART on FHIR application that providers would install into their EHR systems. This SMART on FHIR application would do all the work to query the EHR to retrieve all the necessary data for quality measures and send it automatically to CMS.

Bulk FHIR exports can be used similarly.

No matter the solution, there remains a large potential liability in sending so much PHI data to CMS. These processes would need to be scrutinized significantly from a security perspective to ensure that the data is handled properly. Any information leak from these processes would be incredibly damaging.

Providers: Digital Identity

PR-9

Many people should already see the convenience in having a single digital identity. The use of OAuth 2.0 is prevalent across the industry. It should not be much of a stretch to use a single, or one of a small number of, digital identity providers as a means to log in to any provider software system.

While technical changes to do this may be minimal, providers may need an incentive to make the change available to users. This also may be somewhat out of individual providers' hands as a provider is entirely dependent upon the vendor of the software they use.

Patient privacy certainly needs to be balanced with convenience. Services such as login.gov should be able to accomplish this. A CSP should be transparent with the data it stores on an individual and an individual should be able to provide consent. If a patient would prefer, they should not be forced to use a CSP if an EHR system provides one. They could simply choose to use a login provided by the EHR.

PR-10

Providers will certainly have challenges getting all of their patients to use a single digital identity solution. Not all patients will want to use one due to security or privacy concerns. However, there seems to be a benefit such that this could enable better provider-to-provider data sharing, and always being able to correctly identify a patient.

One downside is that if the single digital identity for an individual is compromised, the impact may be higher because that single identity grants access to more data than if it were just a login to a single provider system.

Payers

PA-1

One limitation of TEFCA is that not all use cases are currently supported. It will certainly take some time before a larger number of payer-related use cases are supported. Until then, some payers may opt not to join a TEFCA network.

PA-3

CMS could provide a clear recommendation of a single credential that should be used and accepted because it has been fully vetted. This should help payers make modifications to accept the credentials from patients and partners.

PA-5

There is anecdotal evidence that payers and providers are very reluctant to share data with each other. If this is true, then this is the issue that needs to be solved first.

Technology Vendors, Data Providers, and Networks: Ecosystem

TD-1

One potential mechanism to stimulate developer interest in building digital health products for Medicare beneficiaries is to create a number of contracts for building out pieces of work for CMS. Some of these contracts should be set aside for small businesses, and some for large businesses. All of this work should either directly build new products for Medicare or build pieces of framework that will expose more data so that other third-party product organizations will be interested in building products that use the data. Specifically, exposing more data in FHIR format will be beneficial, and publicizing this will encourage developers to think about new products of value.

TD-2

One piece of valuable data that could be made available through CMS APIs is provider data. Being able to access the full view of providers across the country can be extremely helpful to tie multiple datasets together. This could be a custom CMS API, but a good way to approach this might be to use the National Directory FHIR Implementation Guide to promote further use of FHIR.

EHR systems can be data providers as well. However, this ecosystem can be tough to get into. The vendors typically require a lot of review and credentialing. In addition, it can be expensive to gain access to their internal app stores. This can add some obstacles in the way of third-party developers creating solutions that tie together EHR data and CMS data into cohesive applications run either in the EHR vendor app store or independently.

Technology Vendors, Data Providers, and Networks: Digital Identity

TD-3

Requiring digital identity credentials should be seen as a positive step. For use cases that absolutely require a known identity, it can be time-saving to have a single point that provides the proper identity vetting that can be reused across multiple applications and systems. One type of use case that should bear a bit more thought is how to create digital identity credentials for systems. Much of the data exchange that occurs is machine-to-machine rather than person-to-machine. At this time, a large amount of that exchange uses OAuth with tokens to perform the authentication. While this is secure and works well, if digital identity credentials are mandated for people, from a consistency perspective, shouldn't we require the same for machine-to-machine interactions?

OpenID Connect (OIDC) is a well-known protocol built on top of OAuth 2.0 that has a lot of use across the industry. Using OIDC can greatly simplify authentication using proven mechanisms. Mandating the use of OIDC would have a positive effect.

Technology Vendors, Data Providers, and Networks: Technical Standards and Certification

TD-5

Having a national directory of FHIR endpoints will be beneficial for everyone. The discovery of data capabilities that are FHIR compatible is tough at the current moment. A lot of product insight and innovation can come from understanding what endpoints are available. It would be good for the federal government to implement, publish, and maintain this directory. If not the federal government, then a trustworthy third party. This should be open source and at no cost to any user. It would be good for it to be at no cost to have a listing in the directory as well, but if funding is required, then perhaps a small cost for listings. The goal is to make this easy to add to and easy to consume from.

TD-7

The current state of LLMs is certainly an improvement upon the models of the near past, but they are still not reliable enough to get correct results out of less structured data at a rate near 100%. One can argue that even with LLMs, structured data is preferred. Also, the security of LLMs is not at the level one would like when working with so much PHI.

FHIR, as a structured data format, has been developed for over 10 years and is fairly mature at this point. The industry will likely not support another new data format at the current time.

TD-11

It would be good for the EHI export rule to specify a standard format and API requirements. The bulk FHIR API could be a good start. The Implementation Guide is maturing rapidly and FHIR is a good, mature data format choice. Removing the guesswork with potentially differing formats and APIs to retrieve exported data will be helpful.

Conclusion

Flexion appreciates the opportunity to comment on the Health Technology Ecosystem RFI. We are committed to supporting CMS's efforts to modernize healthcare technology, improve access and outcomes, and foster innovation through open standards and data sharing. We look forward to further engagement and partnership to achieve these goals.

Sincerely,

A handwritten signature in black ink, appearing to read 'Scott Fradkin', with a stylized, cursive script.

Scott Fradkin
Delivery Leader
Flexion, Inc.