

June 16, 2025

Anna McCollister Project Lead & Co-Chair Consumer Engagement Strategy Workgroup

Dr. Mehmet Oz, Administrator Centers for Medicare and Medicaid Services

P.O. Box 8016 Baltimore, MD 21244-8016

Re: Request for Information; Health Technology Ecosystem

Attention: [CMS-0042-NC] RIN 0938-AV68

Submitted electronically to <a href="http://www.regulations.gov">http://www.regulations.gov</a>

Dear Administrator Oz:

As the project lead and co-chair for the Sequoia Project's Consumer Engagement Strategy Workgroup, I am submitting a series of comments, insights and recommendations in response to the Request for Information: Health Technology Ecosystem.

As a patient who lives with complex chronic health conditions, I have spent many years advocating for improvements in data standards, patient data access, medical device and electronic health data interoperability, data liquidity and accelerated innovation in

health technology. Within that context, I find the timing, tenor and direction of the RFI encouraging and motivating. The direction of the questions indicates a sincere desire by CMS under the Trump Administration to seriously consider and address the growing burdens associated with the complexity of care for patients and caregivers by leveraging digital tools and processes that have been successfully incorporated into the functions of other industries.

#### Overview

Despite the substantial gains made in health information policy, medical devices and digital health tools over the years, we still have a long way to go. While some aspects of accessing data have become easier for some, in many respects the complexity, responsibility and corresponding workload for patients has increased.

When we launched the <u>Consumer Engagement Strategy Workgroup</u> for the Sequoia Project in March 2024, we began by documenting and characterizing the many layers of patient data dysfunction as experienced from the perspective of patients and caregivers. We built on the work of the Sequoia Project's Consumer Voices Workgroup, a year-long focus group of patients. In addition, we conducted one-on-one interviews with patients and caregivers and reviewed published research and media coverage about patient data access issues. The stories shared were replete with seemingly unnecessary bureaucratic processes, requirements and costly duplicative needs for information and testing.

Facing this burden amidst a time of fear, pain and often overwhelm, patients and caregivers expressed frustration, anger, defeat and a sense of learned helplessness against a "system" that seemed uninterested in or incapable of being sensitive to the burdens faced by patients who simply wanted to stay healthy and get care. None of the problems identified were impossible to fix. What was missing was the lack of incentives to fix them.

What our research documented was not a revelation to anybody who lives with complex illness and is forced to interact with our healthcare system. While patient care may be the business of health care, addressing patient needs, promoting patient health and supporting patient autonomy and agency are not a priority within the "system" as it operates today.

During our Workgroup kick-off meeting, we identified four core pillars of patient data needs, summarized in aspirational statements of what we hope all patients can someday say. These "user stories" serve to guide our work, which is focused on developing solutions to support the creation of an ecosystem that enables and empowers patients. They include:

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> My provider and patient portal makes clear what data is and is not shared with other providers in that health system or other health

#### Personal Health Data - What Patients Need

Personal Access	Care Team Access	Usefulness	Awareness and Education
All of my health information is readily accessible to me and my caregivers in one place when I need it	All of my data is readily accessible to all of my care team through their EHR, regardless of their practice affiliation	I can understand my data and health information makes sense to me	I understand my rights to data access, how and by whom my data is used and can advocate for myself and others
My patient portal makes it easy to find my visit reports, lab results, prescriptions and physician notes I can access all of my health information from all of my	All of my physicians have access to all of the data about me that I choose to make available through their office electronic health record	My information is easy to read without straining my eyes It is easy for me to see which of my lab values are out of range or if a specific test is negative or	My provider makes it easy for me to understand my rights to data use and takes measures to ensure that I am able to exercise those rights in a timely manner.
physicians through a personal health hub of my choosing It's easy for me to be able to do what I need with my data to manage my health and care.	It's easy for me to share all of my data with the providers, apps and researchers I choose I am able to choose to not share specific types of health data with	positive My information is provided to me in language that is understandable to somebody without a medical degree	My data access rights are clearly articulated in my patient portal and provider's office, so that I can see and understand them within the context in which that knowledge is relevant
-	certain providers	My information is accurate and its	5

For the past year, our workgroup has been exploring each of these pillars of patient data need, inviting expert speakers to highlight what is currently possible, what is not and identifying specific barriers that are perpetuating the state of patient data dysfunction. Along the way, we realized that while some of the remaining barriers are the unintended consequence of policy, much of the "friction" introduced into the system that increases patient data burden relates to very fixable processes and operations that are not deemed priorities by provider practices, institutions and their vendors. As a result, a patient facing a health crisis is confronted with a system that is not set up to meet their needs. Administrative staff or overworked providers are forced to help the patient figure it out as they go. This inefficiency increases workload not just for patients but for practice and hospital staff and often fails to be sufficiently timely to meet the needs of patients in urgent need of data and/or care. In the best case scenario, tests are often repeated to get the needed data. In the worst case, precious time is lost, care is provided without the needed data and decisions are made without context necessary to ensure the best result.

easy for me to correct

#### Solving the "Last Mile Problem" for Patient Data Access

Our workgroup is developing a set of best practices and recommendations for how to address these process and operational challenges, which we call *"solving the last mile problem" for patient data access*. We plan to publish the best practices for public comment in the coming weeks. Once the best practices are finalized, our plan includes the development of an industry-wide pledge to build support for adopting these best practices, which we will launch later in 2025. As part of our activities, we also plan to identify opportunities for corresponding policy considerations. Some of those are included in our responses to your questions below. In the meantime, we

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welcome the opportunity that CMS has provided for us to provide input into how the Trump Administration can not only solve issues related to patient data dysfunction but enable health technology to evolve and unleash new opportunities for patients to manage their care and maintain their health.

Thank you for issuing this forward-thinking RFI. On behalf of our workgroup, I am excited for the directions you are signaling through this process. Our comments to the specific questions are below.

Sincerely,

Anna McCollister

Member, Health IT Advisory Committee Project Lead and Co-Chair, The Sequoia Project's Consumer Engagement Strategy Workgroup

#### PC-1. What health management or care navigation apps would help you understand and manage your (or your loved ones) health needs, as well as the actions you should take?

a. What are the top things you would like to be able to do for your or your loved ones' health that can be enabled by digital health products?

#### **Data Access**

Most patients would prefer to focus on life and health, rather than on health care, doctor's appointments, medication refills and access to data.

Today, many patients are still forced to serve as their own "health information exchange" of one, manually accessing, aggregating, organizing, updating and transporting their data from one health provider to the next. For patients with longterm, complex or chronic disease, which is the case for many Medicare patients, this can be a difficult, tedious, time-consuming and overwhelming process.

#### **Personal Data Access**

As noted in the four pillars of patient need listed previously in our comments, from the outset our workgroup identified four affirmative statements patients should be able to make related to personal data access. These include:

- All of my health information is readily accessible to me and my caregivers in one place when I need it
- My patient portal makes it easy to find my visit reports, lab results, prescriptions and physician notes
- I can access all of my health information from all of my physicians through a personal health hub of my choosing
- It's easy for me to be able to do what I need with my data to manage my health and care.

These statements represent the most basic needs of any patient, caregiver or parent. All of them are achievable with our current technology.

Specific policy considerations to facilitate:

**Safe Harbor for IAS and Patient Matching –** While TEFCA guarantees individuals the right to access their data through TEFCA Individual Access Services (IAS), very few

patients or patient-chosen PHRs have been able to use IAS successfully. The primary barrier blocking effective IAS is the issue of "patient matching". As it currently stands, the HHS Office of Civil Rights (OCR) has maintained a stance that any inadvertent release of data to the wrong patient will be subject to enforcement action. While at face value this seems to protect patients, in fact it actually causes unnecessary harm and risk by preventing patient data access through TEFCA. Hospitals or providers who are concerned about enforcement action refuse to enable patient access to data through TEFCA if they have any concerns they might send "John Smith" data that belongs to another person in the same city with the same name. This issue is solved daily by providers who send and receive data using frameworks, such as TEFCA and CareQuality. In those instances, both the sender and receiver are "covered entities", so there is no risk of an enforcement action if the wrong data is sent.

HHS' OCR could eliminate this barrier by creating a "safe harbor" rule that establishes a HITRUST- like gold standard of steps that providers can implement to ensure they are sending the right data to the right patient. If this gold standard process is implemented, any provider who inadvertently sent data on the wrong patient would not be subject to OCR enforcement action. Providing a "safe harbor" for providers will enable PHRs and other apps to evolve to help solve many of the unnecessarily complex patient data access issues.

**Medical Device Data APIs** – Require any company that manufacturers an in-patient or out-patient medical device that is covered by CMS to provide access to real-time data streams through accessible APIs. Currently, much of the data generated by medical devices remains siloed and stored in ways that are not readily accessible by patients. Even when data is available through apps, such as Apple Health, the company restricts other companies' access to the Software Development Kit (SDK) needed to enable the data to feed seamlessly into other apps in real time. This greatly limits the development of newer, better tools and apps that can use data from multiple data streams to provide patients with more comprehensive insights needed to improve their care. Similarly, some imaging device companies, such as those who manufacturer devices used for ophthalmological diagnostics, refuse to allow access to the raw data files for images. This makes it difficult for ophthalmology images to be readily incorporated into EHRs. It also restricts the ability for researchers to improve diagnostic methods or create Albased improvements in diagnostic accuracy. These device companies, by limiting access to data, are preventing the development of newer, better tools that could improve patients' lives, decrease patient burden and facilitate better understanding and care.

#### Care Team Data Access

As referenced above, enabling provider access to all of a patient's health data is a basic patient data need. Our workgroup established four affirmative "user stories" about care team data access to guide our activities. These include:

- All of my data is readily accessible to all of my care team through their EHR, regardless of their practice affiliation
- All of my physicians have access to all of the data about me that I choose to make available through their office electronic health record
- It's easy for me to share all of my data with the providers, apps and researchers I choose
- I am able to choose to not share specific types of health data with certain providers

We applaud the efforts ASTP/ONC and CMS have taken to encourage and improve health data interoperability. We encourage CMS to continue these efforts to increase health data interoperability among providers, ensuring each of the patient's providers, regardless of where they practice, can access patient data without requiring patients to be the courier. Specifically CMS could consider:

- Increasing the adoption of FHIR-based data exchange by including more data classes and elements within USCDI at faster rates of adoption.
- Require access to diagnostic tests and images through a readily accessible platform, such as the patient portal or PHR, which would enable the patient to be able to download their data or direct it to a personal health record, online storage folder or another provider, without the need to engage with medical records departments. This would ensure hospitals and providers are compliant with the information blocking rule's requirement to make digital files accessible in a timely manner. It would also help prevent unnecessary, costly repeats to diagnostic tests and images.

### b. If you had a personal assistant to support your health needs, what are the top things you would ask them to help with? In your response, please consider tasks that could be supported or facilitated by software solutions in the future.

The type of support needed or desired by patients varies by the patient, their disease complexity, personal preferences and technical capabilities. Our research for the workgroup suggests key areas of need are:

- Data collection, aggregation, updating and sharing with other doctors, family members, researchers or health apps. The technology and methods to accomplish this have been used by other industries for years through user agreements and APIs. Patients and entrepreneurs have attempted to create these tools, but an array of policy barriers and "privacy protections" have prevented the type of seamless data liquidity needed to empower patients to efficiently manage their health and care and support research for their community.
- Scheduling appointments with physicians or specialists needed to care for new or evolving health care needs. Several barriers prevent this from being readily implemented through technology, but the administrative burden for gaining access to new and specialist physicians is substantial.
- Managing prescription refills from various physicians through retail, online and/or specialty pharmacies. This would include monitoring supply on hand, ensuring refills are sent through by physicians in sufficient time, managing the process of prior authorization and tracking the medication or device supply chain status of the pharmacy amidst shortages.

### PC-2. Do you have easy access to your own and all your loved ones' health information in one location (for example, in a single patient portal or another software system)?

#### a. If so, what are some examples of benefits it has provided?

## b. If not, in what contexts or for what workflows would it be most valuable to ( printed page 21037) use one portal or system to access all such health information?

As stated above, from the outset of our workgroup, we established four core pillars of patient data need. For each pillar, we listed four "user stories" that we hoped that our work could help support achieving.

Personal data access is critically important for patients and caregivers. The specific needs and uses for any individual will vary considerably, based on the individual's health, capabilities, disease complexity and treatments. What works perfectly for one patient will be woefully inadequate for another. There is no single tool or app that will support the needs of all patients. *What is essential is the need for easily accessible, freely "liquid" data that can flow, at the patient's discretion and direction.* The data needs to be readily exchangeable among providers, but it also is vitally essential that all of a patient's electronic health information is available to patients, not just through portals but through API-based data exchange that can enable data to be instantly retrieved by a patient's chosen method or shared through smart phones,

personal computers or Web-based platforms. Prioritizing patient need for data access will simultaneously stimulate the type of data liquidity needed to improve data access for providers and researchers.

c. Were there particular data types, such as x-rays or specific test results, that were unavailable? What are the obstacles to accessing your own or your loved ones' complete health information electronically and using it for managing health conditions or finding the best care (for example, limitations in functionality, user friendliness, or access to basic technology infrastructure)?

Our workgroup documented a broad array of patient data dysfunction across the healthcare system. The obstacles were varied, but included:

- Information barriers information related to accessing health data is scattered throughout a hospital or provider institution's websites. The information needs to be consolidated into a cohesive patient data resource center that considers the needs of the patient to understand clearly what they need to do to access their data and arms them with the context, information and tools to enable patient agency in obtaining their data in a timely manner without significant effort and burden.
- Process barriers In many cases, providers seemingly have failed to consider the various steps necessary to facilitate easy patient data access, especially for data that is not accessible through the portal. Some examples:
  - Forcing patients to print information, scan documents or fax forms to doctors is a significant burden and barrier for many who may not have access to a functional printer, scanner or fax machine.
  - Providing images in CD or USB A/B formats, which are increasingly obsolete for most home and office computer systems.
  - Requiring patients to interact with medical records departments who are unaware of the information blocking rule's requirement that electronic data be provided in a timely manner. Many continue to cite the HIPAA data access rule requirements that give providers 30 days to provide the information needed to patients, refusing to provide data or images to patients until the patients have mailed in a check and the check has cleared, after which they have 30 days to provide the records.
  - Requiring payment by paper check. As referenced above, many providers still require patients to mail or hand deliver a paper check to gain access to their data, despite the fact that providers willingly accept credit or debit card payments for services. The check requirement is an unnecessary and cumbersome barrier that introduces significant friction for patients and delays access to data.

PC-5. What can CMS and its partners do to encourage patient and caregiver interest in these digital health products?

- a. What role, if any, should CMS have in reviewing or approving digital health products on the basis of their efficacy, quality or impact or both on health outcomes (not approving in the sense of a coverage determination)? What criteria should be used if there is a review process? What technology solutions, policy changes, or program design changes can increase patient and caregiver adoption of digital health products (for example, enhancements to data access, reimbursement adjustments, or new beneficiary communications)?
- b. What changes would enable timely access to high quality CMS and provider generated data on patients?

#### **Quality Measures for Patient User Experience**

Over the past decade, CMS has invested heavily in establishing and implementing a series of quality measures aimed at improving patient care. While most of the measures are appropriately focused on outcomes, a small set of measures have focused on patient experience. Measures such as the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) and the corresponding outpatient version, OAS CAHPS, have resulted in noticeable improvements in patient experiences in the clinical environment.

CMS should build on the success of these two measures by establishing standards for user experience related to data access, information navigation and administrative processes. Once standards are established, CMS should require all providers, pharmacies, device companies and other entities that receive payment from CMS to conduct user experience testing and submit their results to CMS as part of the incentive payment system. User experience testing is ubiquitous throughout software development and user-centered design. These methods can be harnessed and incorporated into quality measures to improve user experience related to administrative concerns and patient data access.

#### PC-6. What features are most important to make digital health products accessible and easy to use for Medicare beneficiaries and caregivers, particularly those with limited prior experience using digital tools and services?

As referenced above, rather than developing proscriptive requirements about user workflow or interfaces that might limit creativity and innovation, CMS should incentivize care burden reduction through user experience quality measures. It's essential for

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entrepreneurs and innovators to have the flexibility to solve problems in new ways. A quality measure based on user experience with digital interfaces linked to care, data access and administration ensures a focus on patient burden reduction without limiting how that burden reduction might be achieved.

# PC-7. If CMS were to collect real-world data on digital health products' impact on health outcomes and related costs once they are released into the market, what would be the best means of doing so?

Per the recommendation above, CMS should require user experience testing and reporting for all providers, vendors, pharmacies, insurance companies, device manufacturers and others who receive direct or indirect payment from CMS. These requirements should be incorporated into the CMS incentive payment system.

#### 2. Data Access and Integration

### PC-8. In your experience, what health data is readily available and valuable to patients or their caregivers or both?

- a. What data is valuable, but hard for patients and caregivers, or app developers and other technical vendors, to access for appropriate and valuable use (for example, claims data, clinical data, encounter notes, operative reports, appointment schedules, prices)
- b. What are specific sources, other than claims and clinical data, that would be of highest value, and why?
- c. 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?

For many patients, data remains siloed and segmented. For those with complex health conditions and multiple providers, data remains scattered across a variety of portals, apps and pharmacies. Attempts to access data through apps like Apple Health are thwarted by barriers, such as expiring "trust tokens" and device manufacturers' policies that delay access to real-time data from medical devices. These barriers make it difficult for third party developers to create tools and apps that make data access

easy, seamless and tailored to the needs of individual patients or groups of patients. One-size-fits-all solutions often meet the needs of nobody. Specific examples of difficult to access data include:

- **Imaging data –** x-rays, MRIs, echocardiograms, ultrasounds, etc. Imaging data should be readily accessible to patients via their portal or through other API-based exchange methods that could route the images to phone- or web-based apps.
- Ophthalmological images retinal scans and other images collected in-office by ophthalmologists at the point of care. These images are not currently incorporated into the patient portal or EHR. In addition, manufacturers of these devices restrict access to the raw data for researchers interested in developing improved methods for diagnosis and treatment.
- Sensor data real-time data from sensors, such as continuous glucose monitors, is restricted by the manufacturers who unnecessarily restrict access to their SDK and create a three-hour delay for other apps to access the data. This delay makes it impossible for third-party developers to create useful apps that integrate CGM data.
- Home-based and remote monitoring data data from digital scales, blood pressure cuffs, home-based EEGs and watch-based sensors is accessible to patients but scattered in different platforms. None of it is readily accessible to physicians or incorporated into existing EHR systems. This lack of incorporation of this critical, patient-generated data will limit the development of useful AI-derived clinical analysis of patients with complex disease and potentially introduce unnecessary harms.
- Pharmacy supply chain data information about which pharmacies have specific medications in stock and in what doses. Drug shortages and supply chain issues create substantial burdens for patients who are forced to call from pharmacy to pharmacy to identify a store that has their medication in stock. Often, pharmacists say they will order the medication for the next day, but the medication does not arrive as ordered. All of the data about medication stocks, distribution and transportation is accessible in structured format through APIs. Pharmacists, physicians and patients should be able to access that data through apps that connect to the already established logistical APIs.

#### PC-10. How is the Trusted Exchange Framework and Common Agreement<sup>™</sup> (TEFCA<sup>™</sup>) currently helping to advance patient access to health information in the real world?

#### a. Please provide specific examples.

#### b. What changes would you suggest?

As referenced above, the inclusion of IAS in TEFCA was important, but the promise has not been realized due to concerns over "patient matching". Creating a "safe harbor" policy that would identify a gold standard of patient matching approaches and provide providers with an assurance that they would not be subject to enforcement action would be helpful.

#### 3. Information Blocking and Digital Identity

#### PC-13. How can CMS encourage patients and caregivers to submit information blocking complaints to ASTP/ONC's Information Blocking Portal? What would be the impact? Would increasing reporting of complaints advance or negatively impact data exchange?

CMS should consider requiring all providers and institutions that receive funding from CMS to create a centralized patient data resource center, which includes all of the information needed by patients related to data access, rights, data exchange and privacy. Within that resource center, include a requirement that providers have a call-out button that patients can click that will take them directly to the ASTP/ONC form for reporting information blocking.

By making it easier for patients to report information blocking, CMS would incentivize providers and their vendors to ensure they comply with the information blocking rule's requirement that all patient data in electronic formats is readily accessible in a timely manner.

#### About The Sequoia Project

The Sequoia Project is a non-profit, 501(c)(3) public-private collaborative that advances the interoperability of electronic health information for the public good. The Sequoia Project has a long history of enabling nationwide interoperability through sustainable initiatives. We work with stakeholders from across healthcare and health IT to identify, prioritize, and collaboratively address the most pressing and impactful challenges to nationwide health information sharing.

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The Sequoia Project's Interoperability Matters initiative brings together providers, consumers, caregivers, payers, health IT companies, health information networks, federal agencies, and other stakeholders to focus on creating practical, consensusdriven approaches that result in substantial progress in interoperability health information sharing from a practical perspective. Our Interoperability Matters workgroups provide participants with an opportunity to engage with other leaders in health IT on a range of topics, including Consumer Engagement Strategy, Privacy & Consent, Payer-to-Payer FHIR API Implementation Data Usability, Public Health, Pharmacy Interoperability and Information Sharing.