



June 16, 2025

Secretary Robert F. Kennedy, Jr.
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Subject: Response to Request for Information; Health Technology Ecosystem
(CMS-0042-NC)

Dear Secretary Kennedy,

On behalf of the [Digital Medicine Society \(DiMe\)](#), thank you for the opportunity to respond to the Request for Information on the Health Technology Ecosystem. DiMe is a global non-profit and the professional home for digital medicine. We advance the safe, effective, and ethical use of digital solutions to redefine healthcare and improve lives. We do this by convening experts from every sector across healthcare, technology, research, and policy to tackle the toughest challenges facing modern medicine and deliver actionable, open-source resources on a technology timeline.

In this response, we offer high-level comments to support the Assistant Secretary for Technology Policy (ASTP) / Office of the National Coordinator for Health IT (ONC) and the Centers for Medicare & Medicaid Services (CMS) in achieving the bold vision outlined in this RFI. We leave specific implementation comments to our many partner organizations across the healthcare and technology ecosystem. Our intention is to offer macro-level insights rooted in evidence and experience, and reference specific questions in the RFI where relevant.

Of note, we are also submitting a separate response focused exclusively on the value of [the DiMe Seal](#) - a symbol of quality and trust, awarded to digital health software products that demonstrate performance against a comprehensive framework of standards and best practices in evidence, usability, privacy, and security - to the health technology ecosystem.

1. Healthcare's digital currency is data, and it must be the right data



We applaud the agencies for recognizing that data is the fiat currency of modern healthcare. Precision medicine, value-based care, and artificial intelligence rely on high-quality, high-velocity, and representative data. However, relying solely on electronic health record (EHR) and claims data will not meet the needs of a modern, responsive, and sustainable healthcare system.

To truly deliver on the promise of a digital era in healthcare, we must expand the definition of meaningful health data to include:

- Patient-generated health data (PGHD)
- Social determinants of health (SDOH)
- Remote patient monitoring (RPM) data
- Self-reported outcomes
- Genomic and other -omics data

The EHR was originally built for billing and should not be retrofitted to meet all data needs. As referenced in Question TD-2, CMS APIs must evolve to support access to these data types. Otherwise, developers and care teams will continue to work within narrow and incomplete parameters that do not reflect the full picture of a person's health.

2. Empowering patients requires more than simply access to data

Enhancing patient access to data is essential, but it is not sufficient. Expecting patients to serve as the central hub for the immense data demands of our \$4.8 trillion healthcare system is unrealistic. Many individuals, whether managing their own care or that of a loved one, lack the time, digital literacy, or tools to take on this responsibility. True empowerment does not stem solely from access to data. It comes from healthcare systems designed to deliver meaningful **solutions** built around patient needs and values, supported by real-time data flows and analytics, and delivered through clinically informed, digitally enabled care pathways. This must be our vision for a truly patient-centered system in the digital age.

The RFI rightly highlights common pain points such as appointment scheduling and electronic form completion. These are real frustrations, but they are not the most urgent or consequential challenges patients face.

I offer a personal example. I am currently receiving treatment for late-stage colon cancer. While headlines now recognize the rise of colorectal cancer in younger patients, my care team is forced to make life-or-death decisions based on data drawn from populations that do not include me. There is no infrastructure to help us learn from the growing number of patients like me. We are not just missing data—we are missing the opportunity to act on it.



3. The value of the patient-centric learning health system

We strongly support the goal of a patient-centric learning health system. In the digital era, where data can be used and reused with appropriate permissions, the learning health system must be patient-centered. Anything less would be a missed opportunity.

To make this high-value vision actionable, we urge ASTP/ONC and CMS to:

- Prioritize data streams that reflect what patients value most in their care and outcomes
- Integrate FDA into conversations about post-market surveillance, particularly in the context of digital and AI-enabled medical products (See PC-7)
- Support the use of new data types, such as patient-generated health data (PGHD), social determinants of health (SDOH), and enhanced demographic data, to evaluate real-world performance, safety, and cost-effectiveness

4. Value-based care requires the right tools and incentives

The RFI rightly highlights digital health as essential to the future of value-based care. However, we urge a shift away from a technology-first mindset. In an era of rapid innovation and ever-expanding data streams, technological advancement alone will not solve healthcare's most pressing challenges. We must begin by addressing the greatest patient and societal needs, and then determine which data and digital tools are best suited to meet those needs.

For example, Question PC-12 suggests that increased data access will improve outcomes, such as by enabling better scheduling. However, expanded scheduling tools are of little help when there are too few primary care providers accepting new patients. Similarly, Question PC-10 focuses on giving patients access to their health records. Yet access without context or support is not the same as better care.

Technology will not fulfill the goals of the RFI - enhancing care experiences, reducing costs, increasing access, preventing disease, and improving outcomes - unless we use it intentionally. To advance value-based care, we must recognize the unique role digital technologies can play in generating high-resolution, high-value data that help us better identify and manage risk.

Digital health technologies (DHTs) can support individuals with or at risk for cardiometabolic diseases by continuously monitoring vital parameters, behaviors such as diet and exercise, and adherence to medications. These tools can also expand the types of outcomes we track, moving beyond traditional point-in-time clinical metrics such as HbA1c and office-based blood pressure. In mental health, DHTs offer a



much-needed alternative to outdated clinical measures that often fall short in diagnosing and managing common conditions.

But these innovations will not translate into better outcomes unless we update the policy frameworks that determine what gets supported and reimbursed. Right now:

- Virtual-first care models are often excluded because their homegrown EHRs do not meet certification requirements designed for brick-and-mortar systems
- Asynchronous care and services delivered by professionals like health coaches or community-based therapists are rarely reimbursed
- Remote patient monitoring tools that are not regulated as medical devices fall outside traditional reimbursement structures, even when they deliver demonstrable value

This status quo disincentivizes the very care models most capable of improving outcomes, increasing equity, and meeting patients where they are.

One particularly urgent opportunity is supporting aging in place. With [nearly 90 million Americans over age 50](#) reporting substantial comfort with leveraging technology to help them age comfortably in their place of choice, we must act now to harness new digital health tools, smart home automation, and innovative care models. The demand is clear. Meeting it with thoughtful, scalable, and patient-centered digital solutions will transform how older adults access care and support wherever they choose to live.

5. Certification and Standards Must Reflect Today's Health System

In the technical standards and certification section, we respond to three areas:

- **TD-1 (Incentives):** Incentives should support asynchronous care, services provided by non-QHPs, and the use of validated digital tools, even if they fall outside legacy classifications. Reimbursement policy must be harmonized across APM and non-APM organizations to ensure system-wide impact
- **TD-7 (USCDI):** DiMe's work as a founding host of CancerX demonstrates how to develop USCDI+ data elements that are sustainable and relevant. We used a [structured approach](#) to identify the most important data elements for the Enhancing Oncology Model, based on clinical utility and research needs. This is a replicable framework for broader efforts to expand USCDI+
- **TD-9 (Certification):** Certification should prioritize API-enabled capabilities over rigid software requirements. A modern certification program must reflect the rapid pace of innovation and the need for adaptability



Conclusion

The health technology ecosystem must evolve to deliver on the promise of better health for all. This means:

- Expanding the definition of valuable health data
- Prioritizing solutions over data access alone
- Designing learning systems that reflect patient needs and enable efficiencies in medical product development and monitoring
- Incentivizing care models that are working in the real world
- Modernizing certification and reimbursement frameworks

We commend ASTP/ONC and CMS for issuing this thoughtful RFI and would welcome the opportunity to continue supporting this important work.

Sincerely,

Jennifer Goldsack

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