Public Comment on CMS–0042–NC: Request for Information on Health Technology Ecosystem

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I am James Cummings — a digital health policy expert, caregiver, and father of three — **including two sons with distinct rare diseases**. This dual perspective, as both a professional working in health IT and a parent navigating the system for two very different conditions, informs my deep understanding of where healthcare interoperability succeeds, and where it repeatedly fails patients and families.

As a health policy and technology expert and the parent of two young children with rare diseases, I submit this comment in response to CMS-0042-NC to strongly advocate for the advancement of a truly patient-centric digital health ecosystem. The opportunity to shape national policy around data interoperability and digital health tools must center the needs of the most underserved—and simultaneously most motivated—populations: rare and undiagnosed disease communities.

I. Technological Catalysts for Systemic Change

The health technology ecosystem envisioned by CMS and ONC must move beyond digitized workflows and embrace technologies that catalyze a cultural transformation. FHIR®-based APIs, longitudinal health record aggregation, and large language models (LLMs) offer an opportunity to reallocate epistemic authority in healthcare.

FHIR enables structured data exchange and real-time access to electronic health information (EHI), while LLMs such as GPT-4 or Med-PaLM translate this into understandable summaries and patient-generated queries. Together, they allow caregivers to become critical contributors to diagnostic accuracy and treatment planning.

Importantly, the development and deployment of the **National Provider Directory (NPD)** is a critical catalyzing step that this administration must prioritize. A centralized, verified directory of digital endpoints (including FHIR API addresses) is essential to **enforce interoperability mandates**. If a provider cannot be reached via a known FHIR API, there is no technical or policy lever to ensure compliance. **Enforcement is the incentive** in interoperability; and enforcement must be measurable and transparent. The NPD provides this accountability. As discussed in the June 3rd ONC/ASTP Listening Session at HHS, enforcement—not just enablement—is the repeating theme. Providers, vendors, and health

systems must be required to participate in this directory and keep endpoint information current.

II. Breaking Paternalism Through Participatory Education

Our current system is entrenched in paternalism, limiting patients to passive roles even when they are the most consistent and motivated actors in their health journey. This is most evident in rare disease care, where parents of affected children often become de facto experts.

Consumer-facing apps powered by LLMs can educate patients using their own data. They maximize time between appointments and reduce knowledge asymmetry, initiating a cultural rewiring where education is not a program but a structural change.

To correct this, CMS must recognize the sociological role of policy and technology as educational interventions. Mandating the use of interoperable standards (FHIR), the right to EHI exports, and the facilitation of patient-contributed data (PGHD, PROs, SDOH) into unified longitudinal records is not only a technical achievement—it is a re-education of the healthcare system to acknowledge the epistemic value of patients.

Education, in this context, is not a program—it is a cultural rewiring. The implementation of consumer-facing health data tools with embedded LLMs (to interpret, summarize, or query health records) fosters this shift at scale. These tools will serve as educational scaffolds for patients and clinicians alike, reducing asymmetries of knowledge and helping usher in a collaborative care paradigm.

III. Precision Medicine and Translational Science Implications

Precision medicine relies on granular, longitudinal data aggregated across clinical encounters, patient behaviors, and biological inputs. Today, the majority of this data remains inaccessible to researchers due to: siloed EMRs, lack of standards enforcement, and absence of patient-mediated data sharing pathways.

Patients are the only common node across fragmented providers, EMRs, and institutions. Their consent-driven data aggregation, supported by FHIR APIs and bulk data access, will enable more accurate cohort discovery and equitable AI training. Widespread adoption of EHI Export APIs and expansion of USCDI is essential to ensure the necessary data breadth.

The cultural shift to empower patient aggregation and sharing of full EHI—complemented with wearable, genomic, environmental, and patient-reported data—would revolutionize cohort discovery and observational research. This is especially true for rare and undiagnosed diseases, where n=1 and cross-institutional collaboration are the norm.

FHIR-based infrastructure, bulk data APIs, and TEFCA participation must extend to include consumer applications as nodes in the research data ecosystem.

Furthermore, LLMs will play an increasing role in translational science by surfacing hypothesis-generating patterns from multimodal health data. Their accuracy and equity, however, depend on ingesting diverse, representative datasets—which are currently impossible without full consumer access to and sharing of health records.

IV. The National Provider Directory and Enforcement

CMS's prioritization of the National Provider Directory (NPD) marks a critical step toward practical interoperability enforcement. It ensures providers are 'wired in' and accountable. Effective enforcement—not just incentives—is the backbone of all successful interoperability policy. As underscored during the June 3 ONC/ASTP listening session, providers must be able to demonstrate API functionality as a condition for compliance.

V. Challenges with Current Data Exchange Network Models

While TEFCA and other health data exchange networks offer promise, **they remain flawed by design due to business model conflicts, privacy restrictions, and the lack of meaningful proxy access standards.** Widespread digital identity initiatives and patient matching algorithms, while important in theory, are currently **a distraction** from urgent near-term implementation priorities. These initiatives consistently fail to address the most common use cases in real-world care: proxies.

Parents of young children and caregivers of elderly relatives are the most active health consumers. Any solution that sidelines their role is structurally flawed. By excluding proxy access as a baseline use case, we introduce hurdles to near-term success and long-term system resilience.

Proxy access is **paramount**. The most active healthcare consumers are caregivers to children and aging parents—the very populations who consume the majority of healthcare services. **90% of lifetime health costs occur in the last 10%** of life, and yet proxy access mechanisms remain an afterthought in nearly all current interoperability infrastructure.

Without explicit inclusion of proxy access in both policy and implementation models, we are building a house on sand. **Interoperability cannot be achieved without enabling caregivers.** Focusing resources on identity verification or matching without solving for caregivers introduces hurdles that stall adoption and weaken the entire framework. CMS must instead use caregiver-led and rare disease communities as**q**, not an edge case.

VI. Early Adopter Pilots: Rare Disease Communities as Models

CMS should explicitly fund and design early adopter programs focused on rare disease communities. These communities:

- Are highly motivated and data-literate due to necessity;
- Face high uncertainty and lack of guidelines in traditional care pathways;
- Already participate in registries, biobanks, and digital health communities;
- Offer unique early feedback on usability, interoperability, and accessibility issues.

In policy terms, early adopter pilots serve a translational role between rulemaking and enforcement. When paired with structured implementation support and open reporting mechanisms, these communities can spotlight effective patterns for national scale: from API adoption to PGHD integration, to real-world evaluation of digital health tools under Medicare coverage.

Rare disease communities embody high motivation, digital literacy, and necessity. They already participate in registries and have extensive experience navigating fragmented care. Empowering them as early adopters will allow CMS to validate interoperability and AI-enabled tools under real-world pressure.

These pilots also offer an organic mechanism for surfacing what works, identifying policy gaps, and informing scalable enforcement strategies across Medicare and Medicaid populations.

VII. Recommendations

1. **Implement consumer-mediated FHIR APIs for full EHI export and aggregation** into personal health records or apps under consumer control.
2. **Support integration of patient-contributed data—**including PGHD, wearable data, genomic info, and unstructured narrative—into EHRs through standardized interfaces.
3. **Require LLM explainability tools** to be integrated into certified personal health applications to assist in education and care navigation.
4. **Launch early adopter pilot programs** focused on rare disease families to test consumer-facing interoperability, digital navigation tools, and AI-assistive capabilities.
5. **Support longitudinal cohort aggregation models** built on consumer data sharing to facilitate observational research and accelerate precision medicine.
6. **Enforce information blocking provisions** where providers or vendors impede patient-mediated data aggregation across systems.
7. **Fund, build, and maintain the National Provider Directory** as the enforcement backbone of interoperability. Providers without FHIR APIs or with missing digital endpoints should face programmatic disincentives.
8. **Prioritize EHI Export APIs and full EHI access**, not just USCDI elements. CMS must support and require **standardized EHI Export APIs** to facilitate complete longitudinal records across systems. Expanding USCDI must also accompany a parallel push to operationalize full EHI access, including narrative notes, PDFs, and diagnostic media.

Closing

The consumer-driven future of healthcare is inevitable—and already underway. Our collective obligation is to ensure it arrives sooner, with stronger protections and smarter tools. Empowered patients are the catalysts of translational science, equity, and diagnostic excellence.

In a learning health system, patient participation is not optional—it is foundational. If the U.S. healthcare system is to become equitable, precise, and economically sustainable, it must empower patients and caregivers with the tools, access, and dignity they need to contribute meaningfully.

This consumer behavior is not a trend—it is an inevitable evolutionary trajectory. As more people confront their own mortality or that of loved ones, they will demand participatory roles in care and outcomes. **All patients will take an active role in their mortality and health outcomes.** This CMS administration has a unique opportunity to accelerate that transition—making the inevitable happen sooner, with dignity, safety, and science leading the way.

As a caregiver to **two children with different rare diseases**, I've had to confront—and overcome—the failures of our fractured data systems from multiple angles. Their differences highlight just how important complete, accessible, and longitudinal data is across conditions, systems, and stages of life. I bring this perspective not only as a father, but as someone working to shape the very policies that could spare others the same burden.

Respectfully,
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Participatory Health