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June 16, 2025

The Honorable Robert F. Kennedy, Jr. Secretary U.S. Department of Health and Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201

To: Dr. Mehmet Oz, Administrator, Centers for Medicare & Medicaid Services

We welcome the opportunity to provide comments on the *Request for Information Health Technology Ecosystem – document 2025-0871.*

We appreciate the Centers for Medicare and Medicaid Services (CMS) and Assistant Secretary for Technology Policy and National Coordinator for Health Information Technology (ASTP/ONC) efforts to lead infrastructure progress to cultivate the digital health market, increasing beneficiary access to effective digital capabilities needed to make informed health decisions, and increasing data interoperability for all stakeholders contributing to health outcomes.

For more than four decades, the <u>Massachusetts Health Data Consortium (MHDC)</u> has been the trusted and objective facilitator of health information and technology transformation in Massachusetts as well as across the country. With its merger with the New England Healthcare Exchange Network (NEHEN), MHDC provides a range of health data innovations, insights, and services to over 4,000 health professionals across more than 200 organizations. Its mission is to inform and empower the individual in their health journey and reduce the burden healthcare imposes on patients and their families, providers, and payers. MHDC realizes this mission by assisting health organizations in navigating regulations, sharing health data securely and effectively, and reducing the burden and cost of inefficiency.

MHDC convened its payer and provider members to provide input into developing a response to this RFI. MHDC members represent a broad cross-section of healthcare stakeholders in Massachusetts and beyond, participating in both Medicare and Medicaid (MassHealth) programs as well as commercial lines of business. MHDC members are committed to advancing interoperability and automation to gain efficiencies and improve our healthcare system, and we believe that regional and state-led initiatives such as ours can serve as powerful accelerators for national progress. We use this frame of thinking as we craft our response to this timely RFI.

General Comments and Key Recommendations:

MHDC supports effective and responsible technology adoption that can empower patients to make better decisions for their health and well-being. Since most healthcare services are local, we believe that public-private partnerships and the inclusion of representatives from all local stakeholders, such as providers, payers, regulators, and system developers, are crucial to creating an innovative and competitive marketplace that facilitates health data exchange while also granting the autonomy local markets require to build innovative solutions. National level solutions, e.g., TEFCA, are not purpose-built for commerce, the driving force behind creating a health data economy.

We address in this RFI the foundations of a robust healthcare technology ecosystem, namely:

- Consumers need a new and innovative digital health economy where transparent, high-fidelity, real-time data fuels the technology innovation required to achieve major advances in clinical and cost effectiveness.
- Innovation is essential to achieve data liquidity and establish a new digital healthcare ecosystem. This ecosystem will utilize open standards to exchange health data at scale and provide patients with information when and where they need it.
- Current regulations are not advancing the health data economy sufficiently. CMS and ASTP/ONC must prioritize commerce as the engine of innovation, aligning priorities to minimize friction, reduce costs, and alleviate the burden associated with exchanging health data in the present.
- Patients, providers, and payers must have access to clinical and claims data to reduce administrative burden, innovate risk-sharing contracts between providers and payers, and permit true value-based care.
- The market needs a federated, standards-based digital identity framework. Existing efforts and methods to match patients within provider networks and their health plans are burdensome, expensive, and still prone to error.
- CMS should accelerate the creation of national directory services that support full interoperability among healthcare stakeholders.
- CMS should shift focus to incentivize or reward participation in state-based data-sharing initiatives and to realign national and regional initiatives (e.g., TEFCA, HIEs) to promote more payer-provider-patient interoperability.
- CMS should enforce data blocking among patients, providers and payers with substantial financial penalties for those actors who engage in information-blocking practices.

Digital Health Applications:

MHDC believes in CMS's vision to create a new digital health economy, and leveraging open standards is the logical way to achieve this vision at scale.

Accelerate Adoption of FHIR-Based APIs for Real-Time Data Exchange. The use of Fast Healthcare Interoperability Resource (FHIR) Application Programming Interfaces (APIs) allows for real time data exchange of the right data at the right time with authorized stakeholders. This on-demand capability of FHIR empowers patients to access their health information when and where they need it, reduce their exposure to excessive costs and unnecessary services, manage their care team, and schedule their appointments.

Patients require the ability to manage their health data with providers, payers, health advocates, and care coordinators in the application(s) they choose rather than in the manner that legacy provider and payer systems support. Health data is not centralized, and portals are no longer the answer to achieve meaningful access. They provide patients with a partial view of their data, without providing dynamic tools and guidance for patients to interpret the information and make better informed healthcare decisions. Health data "liquidity" is required to support patients using applications (apps) in real time or as close to real time as possible. This challenge is multiplied for patients with multiple chronic conditions who must access multiple portals to manage their health data. Patients' information is siloed without an

easy way to view it comprehensively or share it with care team members. All healthcare stakeholders, including payers and system developers, must shift focus from investing in improving health data exchange to support their business transactions, to sharing data with payers and patients to improve the patient's healthcare experience. FHIR-based APIs enable more flexible and necessary health data exchange for patients. Once data is more readily available, we will see increasing innovation and adoption of patient-centered health applications.

Quality Reporting & Clinical Data Exchange. Solutions to promote a robust digital health economy would include FHIR-based API implementation for real-time clinical data exchange across all CMS-sponsored programs. Enabling real-time health data and quality reporting through FHIR APIs offers a material opportunity to reduce administrative burden and improve care delivery. At present, providers often rely on retrospective, manual data extraction and submission processes that are time-consuming, error-prone, and disconnected from clinical workflows. By contrast, real-time, API-enabled reporting allows quality data to be captured and transmitted directly from point-of-care, automatically, and in standardized formats.

This reduces the need for duplicative documentation, ordering of tests, chart abstraction, and manual reconciliation efforts, saving significant time for clinical and administrative staff. Facilities can streamline compliance by reporting once through interoperable systems that satisfy multiple program requirements. Additionally, real-time feedback enables providers to identify gaps in care more quickly, improving responsiveness and outcomes while also aligning reporting more closely with clinical realities.

Widespread adoption of FHIR APIs will also allow CMS to move toward continuous quality measurement, which supports more agile payment models and policy development—further reducing reliance on quarterly or annual reporting cycles. Overall, this shift can dramatically reduce reporting complexity, lower costs, and ease the burden on frontline clinicians and health systems, enabling them to focus more fully on delivering high-quality, patient-centered care.

Promote Interoperability. Rather than imposing additional regulations, Medicare could promote interoperability by encouraging voluntary certification programs for technologies (e.g., digital health apps, remote monitoring) to ensure safe and secure interoperability without adding extra regulatory steps. Medicare can align with best practices and industry standards that enable interoperability, inform innovation, align with modern and more established frameworks, streamline reporting, promote public-private partnerships, improve AI algorithms, accelerate a focus on clinical effectiveness, and inform ongoing dialogue. This approach avoids additional regulatory burdens while fostering innovation and quality improvements.

Medicare could incentivize or reward participation in existing data-sharing initiatives, such as statebased initiatives, e.g., MHDC in Massachusetts (NEHEN 3.0), UHIN in Utah, and to national initiatives (TEFCA) that facilitate provider, payer, and patient data access. Medicare must also support API-based access to Medicare data, like the Blue Button 2.0, to encourage digital health innovation without prescribing every detail. Medicare programs should also apply to wearable technology developers to ensure patients' own health data is available and may be freely accessed and shared--with their consent--to achieve or improve their care. The advancement of artificial intelligence will provoke medical device developers to collect patient health data and create services at a cost to patients. Patients must have the right to their own health data without paying for it. Medicare could also collaborate with industry groups, technology vendors, and provider associations to develop implementation guides, toolkits, and best practice resources that align Medicare requirements with industry norms. It could also launch pilot programs with selected industry partners to co-design and test standards-based solutions. For example, a telemedicine pilot could align Medicare coverage with existing American Telemedicine Association best practices, ensuring alignment with established clinical guidelines.

Instead of requiring the use of specific technologies, Medicare could recognize technology as an enabler rather than a requirement. It could leave the choice of tools up to providers, focusing on interfaces, APIs, outcomes, and patient experience instead of mandating specific apps, devices, or platforms. For instance, Medicare could focus on required integration of FHIR APIs and metrics like care coordination success and patient health outcomes for integrated care systems rather than dictating which care management software must be used.

In summary, Medicare can align with best practices and industry standards using APIs by emphasizing flexibility, aligning with existing frameworks, investing in state-based multi-stakeholder initiatives, and directing policy toward streamlined reporting, interoperability, outcome-focused requirements, and ongoing dialogue. This approach avoids additional regulatory burdens while fostering innovation and quality improvements. Standardization through APIs would also assist with prior authorization and patient information collection.

Data Exchange:

Open, Transparent Health Data. MHDC believes the true benefit of health data exchange is to provide the patient with their own health information in a manner that is easy, transparent, and available in real time. This could be achieved using open standards adopted by all actors, including payers, providers, HIEs, and system developers, to achieve a lower cost of care with better health outcomes.

Mandate Standardized Data Exchange to Support Key CMS Functions. CMS should mandate the use of nationally recognized data standards, such as the U.S. Core Data for Interoperability+ (USCDI+) and FHIR, to support critical CMS functions including risk adjustment, payment integrity, and automated quality measure reporting. Standardized data exchange ensures that clinical and administrative data can flow seamlessly and consistently across systems, eliminating the need for manual data abstraction, reformatting, and duplicative submissions.

For risk adjustment, standardized data enables the timely and accurate capture of patient complexity, improving fairness in reimbursement without requiring providers to perform additional chart reviews. Interoperable documentation also improves payment integrity processes, enabling auditability, reducing the likelihood of overpayments, underpayments, or disputes—and minimizing costly reconciliations. For quality reporting, standards like FHIR support automated extraction of clinical quality measures (e.g., HEDIS, CAHPS, eCQMs) directly from electronic health records, reducing time-consuming manual reporting and enhancing data accuracy. Together, these efficiencies reduce administrative overhead, lower compliance costs, and free up provider and facility resources to focus more fully on delivering high-quality patient care.

Need For Provider Directories. The need for a national provider directory using FHIR endpoints is not mutually exclusive to digital identity credentialling, as discussed in the RFI. The credentialing process is not the same as provider identification for data exchange. Plans must be able to identify a provider to comply with the CMS Interoperability and Prior Authorization Final Rule (CMS-0057 F); this requires the

use of APIs with FHIR digital endpoints to exchange the data. Without the provider identifier, plans would be forced to exchange data point-to-point instead of at scale to meet the volume of requests to exchange health data. This would result in additional expenses and an overall burden on plans.

CMS and ASTP/ONC should continue the effort to lead the establishment, maintenance, and governance of publicly available, free, and machine-readable national directory services crucial for enabling nationwide health information exchange and interoperability. Effective, scalable interoperability across a diverse national landscape requires common, trusted, and easily accessible infrastructure for discovering participants, their capabilities, and their electronic endpoints. This reduces friction for all stakeholders, from application developers to Health Information Networks (HINs) and individual patients seeking to connect.

Trusted Exchange Framework and Common Agreement (TEFCA). Diversify the organizations entrusted with data exchange by shifting regulatory investment on large, centralized national exchanges for provider-to-provider data exchange, e.g., TEFCA, to a federation of national, state, and regional networks. By leveraging the interoperability standards and policy floor set at the federal level—such as FHIR and USCDI—local efforts can design flexible, scalable tools that address real-world barriers and reduce administrative burden for the participants in their unique ecosystems. This approach allows for more effective feedback loops, encourages true multistakeholder collaboration, and fosters innovation that aligns both community needs and national goals. Multistakeholder groups such as MHDC are effectively working together to reduce duplication, harmonize requirements, and tailor solutions to the specific needs of their populations. A coordinated shift that pairs technological advancement with regulatory flexibility will better support the diverse realities of care delivery and ensure that quality improvement efforts are both practical and sustainable.

CMS should work with local exchanges to develop regional, common frameworks to exchange data. Regional and state-based programs along with vendors, payers, providers, and associations can partner with CMS and ASTP/ONC to ensure the needs of local markets are being served.

MHDC believes we must reduce the abrasion and investment in the national exchanges to ensure the needs of the community are being met. We are not seeing the adoption of TEFCA today as a provider-payer-patient exchange but as a provider-to-provider exchange. To engage payers, additional use cases will need to include information for payment and operations in a broader context. Regional or state HIEs have the potential to play a central role in data exchange in regional communities where trust and support tend to be higher, facilitating more data exchanges. TEFCA should be voluntary and focus on efforts where there are gaps in state-based initiatives.

Patient Access and Integration - Digital identity:

Create A Trusted Digital Credential. Providers and plans spend significant time and resources to verify a patient's identity, which causes additional cost and loss of resources in the healthcare system today. Patients should be able to voluntarily identify themselves in a trusted way without the need to create separate portal accounts with every data holder who currently stores their health information. Individuals seeking their health information could then use that same, trusted "identity-proofing" digital credential to access their health information across multiple payers and providers. A federated, trusted framework should be established using industry-proven standards to digitally credential a patient. We have seen this in the banking and airline industries; the same should apply to healthcare.

MHDC supports the creation and use of a federated, trusted framework for the verification of Digital Identity. One such framework is the <u>Carin Alliances Person Centered Trust Framework</u>.^{*i*} A person-centric approach to health data access would allow patients to prove their identities once and be issued a credential that different systems can accept. However, a method to establish trust is required so that the multiple relying parties (data holders) that did not perform the "identity proofing" can trust the patient's identity. A trust framework provides value here. Federating trust creates a mechanism for a third party (external to the relying organization) to rely upon the identity asserted by an external third party in a way that is dynamic and automated but reliable.

MHDC supports the recommendations of the Leavitt Partners White Paper <u>Kill The Clip Board</u>,ⁱⁱ that underscores the importance of integrating identity-proofed digital credentials into national infrastructure to support scalable, secure data exchange and that similar principles should apply to patient digital identity as well – enabling individuals to use a single, trusted credential across multiple systems to access their health data securely and efficiently.

Need For Education. There are misperceptions among patients today that using digital credentials is an invasion of privacy. Digital identity is an electronic "key," or representation of a patient's identity, without revealing private health data. Digital identity verification can be used to access apps, patient portals, and secure access to electronic health records. CMS should invest in coordinated public education campaigns to build understanding and trust in digital identity credentials. Patients must be educated on how digital identity enhances access, security, and privacy—not threatens it.

Information Blocking:

The 21st Century Cures Act information blocking provisions apply to healthcare providers, health IT developers of certified health IT (HIT), and HIEs/HINs, yet providers are heavily reliant upon their system vendors and developers to provide them with the capability to make health information available. MHDC members report experiences with system developers continuing to focus on their strategic business efforts to monetize health data versus sharing the data. The adoption and use of bulk FHIR would enable data exchange at high volumes; however, many vendors are still not accepting this functionality. These barriers prevent third parties from building patient-facing applications and tools that patients will use to make informed healthcare decisions. Patients need access to their health information when and where they need it, as opposed to being constrained by the limits of legacy provider and payer systems. This is adding to the lack of trust and causing friction with providers, payers, and patients.

MHDC believes all actors should be disincentivized from data blocking; however, the rule must be enforced. Monetary disincentives as well as public reporting may serve as a deterrent for all actors. HIT certification should also continue to ensure system developers are open to sharing information. A reporting mechanism should be available to patients, providers, and payers to report that the information to which they're entitled is being blocked. A web-based tool should assist in easing the reporting of data blockers by all patients, providers and others as appropriate.

CMS should also establish a program dedicated to patient engagement and raising awareness about information blocking. We've observed some providers utilizing the HIPAA Privacy and Security rules as an excuse to withhold health information. This often stems from a lack of comprehension regarding what data can and cannot be shared. Consequently, a public web and app-based Resource Center should be created for providers, patients, and the industry. This center should provide materials and use cases that illustrate what data can be shared. This initiative would be beneficial for both providers and

patients. Medical and Provider Associations, as well as other relevant stakeholders, could utilize this as a valuable training resource.

Closing

We are grateful for the chance to share our perspective on behalf of the MHDC community. We eagerly anticipate opportunities to support CMS, ASTP/ONC, and other stakeholders as they work to develop and expand the digital health market. This includes ensuring that beneficiaries have access to the necessary digital capabilities to make informed health decisions and improving data interoperability for all stakeholders, ultimately leading to better health outcomes. We welcome the opportunity to meet with CMS and ASTP/ONC as appropriate to share our experience and review our suggestions.

Sincerely yours,

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Denny Brennan Executive Director

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