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Mehmet Oz, M.D., Administrator, Centers for Medicare & Medicaid Services
Thomas Keane, M.D., Assistant Secretary for Technology Policy and National Coordinator for Health Information Technology
U.S. Centers for Medicare & Medicaid Services, Department of Health and Human Services
Attention: HHS-0042-NC
7500 Security Boulevard
Baltimore, MD 21244-1850

Sent electronically via: regulations.gov
RE: Request for Information; Health Technology Ecosystem (HHS-0042-NC)

Dear Dr. Oz and Dr. Keane:

McKesson Corporation ("McKesson") appreciates the opportunity to provide comments in response to the Request for Information (RFI) on the Health Technology Ecosystem (HHS-0042-NC), issued by the Department of Health and Human Services (HHS), including the Centers for Medicare & Medicaid Services (CMS) and the Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator for Health Information Technology (ONC) (collectively referred to here as "HHS").

About McKesson

McKesson is a global leader in healthcare supply chain management solutions, community pharmacy, community oncology and specialty care, and healthcare information technology solutions. McKesson partners with pharmaceutical manufacturers, providers, pharmacies, payers, federal, state, and local governments, and other organizations in healthcare to advance health outcomes for *all*.

As a diversified healthcare leader, our solutions help patients access life-changing therapies, create a real difference for patients with cancer, and equip pharmacies, health systems and clinics with technologies to operate more effectively. Our provider and pharmacy partners operate in communities that include some of the most underserved urban and rural areas of the U.S. As we work across our partners and customers, McKesson strives to ensure that its views on improving healthcare prioritize what's best for the patient.

GENERAL COMMENTS

McKesson commends HHS for their continued leadership in modernizing the digital infrastructure that supports patient care, innovation, and system-wide efficiency. We share the Administration's vision for a more connected and responsive health technology environment—one that enables patients to access and share their health information, supports providers with actionable data, and fosters innovation through clear, consistent, and scalable standards.

We are uniquely positioned to support patients in making informed decisions and achieving better outcomes. However, current regulatory and legal frameworks may limit our ability to fully deliver on that potential. Durable, patient-centered policy frameworks are essential to achieving this vision. These frameworks should be designed to endure over time, providing stability and clarity for patients, providers, and innovators alike. They should empower the private sector to innovate within guardrails that protect patient information and build trust—especially for use cases that rely on Health Information Portability and Accountability Act (HIPAA) regulated data and emerging technologies like artificial intelligence (AI).

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Our recommendations reflect this philosophy and are grounded in the following priorities:

Ensuring access to critical data for high-value use cases: HHS should require real-time access to benefit, cost, and prior authorization data through standardized Application Programming Interface (APIs) (e.g., HL7 Fast Healthcare Interoperability Resources [FHIR], National Council for Prescription Drug Programs [NCPDP]) and support tools like real-time benefit tools (RTBTs) that empower patients and providers to make informed decisions.

Supporting hybrid interoperability frameworks: While Trusted Exchange Framework and Common Agreement (TEFCA) is a critical step forward, HHS should also recognize alternative models and proxies that meet "gold standard" interoperability thresholds, particularly for non-traditional actors like pharmacies and emerging digital health tools.

Addressing information blocking asymmetries: HHS should ensure that payers are held to the same standards as providers, and that pharmacists are not penalized for lacking access to certified electronic health records (EHRs) or TEFCA networks.

Modernizing certification and data standards: HHS should expand certification pathways to include non-EHR technologies and support dual-standard interoperability (e.g., HL7 and NCPDP) to ensure broad participation across the ecosystem.

McKesson's data policy efforts are grounded in a commitment to improving outcomes for all, while always putting the patient first. We appreciate HHS and ASTP's inclusive approach to shaping the future of health technology and look forward to offering specific recommendations that build on these foundational principles.

SPECIFIC COMMENTS IN RESPONSE TO THE RFI QUESTIONS

Empowering Patients Through Data and Transparency (PC-1, PC-4, PC-5, PC-7, PR-1-3)

Modernizing the health technology ecosystem requires not only technical interoperability but also policy frameworks that empower patients to access, manage, and share their health information with confidence. Durable, patient-centered policy frameworks are essential to fostering trust, ensuring patient safety and transparency to all options to support affordable care, reducing friction, and ensuring that digital health tools are accessible, equitable, and effective.

RECOMMENDATION

- **Clarify patient data ownership and access rights:** HHS should affirm that patients—not commercial entities—own their health data and should be able to direct its use across platforms of their choosing. Current limitations often stem from contractual or structural barriers imposed by covered entities, not from HIPAA itself. These constraints hinder innovation and limit the utility of digital tools designed to improve affordability, adherence, and care navigation.
- **Modernize HIPAA to support affordability and transparency**: The HIPAA Privacy Rule, finalized in 2003 (well before the widespread adoption of digital health technologies) governs how Covered Entities (CEs) and their Business Associates (BAs) collect, use, disclose, and safeguard Protected Health Information (PHI). Originally, BAs were only indirectly accountable for HIPAA compliance through contractual obligations in Business Associate Agreements (BAAs). These agreements not only bind BAs to HIPAA's requirements but also restrict their use and disclosure of PHI to the specific functions authorized by the CE. In 2013, the HITECH Act extended direct liability to BAs for HIPAA violations. However, it did not expand their authority to use PHI independently, even when such use could benefit patients. As a result, CEs, such as

healthcare providers, health plans, and clearinghouses, remain the sole gatekeepers of PHI across the U.S. healthcare system. This structure limits the ability of other qualified healthcare organizations to use data in ways that could meaningfully support patients (for example, by promoting price transparency or guiding patients through complex care journeys) unless explicitly permitted by a CE. Given the evolution of digital health and decentralized care models, HHS should consider modernizing this framework. Specifically, HHS could issue guidance clarifying that certain independent uses of PHI by BAs (particularly those aligned with Treatment, Payment, or Healthcare Operations) may fall under the "proper management and administration" exception in HIPAA. This would allow organizations already bound by HIPAA to use and disclose PHI in ways that mirror how others in the ecosystem can operate, enabling more transparency, reducing friction in care delivery, and supporting unbiased, patient-centered decision-making.

Ensuring Access to Actionable and Transparent Information (PC-1, PC-2)

As healthcare entities expand their digital capabilities, implement AI and other emerging technologies, and leverage their data assets to improve individualized healthcare treatment options, it is imperative that patients have timely access to accurate information and data they need to effectively participate in their own care. Patients must also have the ability to share this information with providers, caregivers and other partners of their choosing in real-time, with minimal hurdles. A critical first step in unlocking the power of patient data is determining what data elements address essential use cases.

1. Benefit and Cost Transparency (PC-3, PC-4, PR-7)

We support HHS's finalized requirement that Medicare Part D sponsors implement at least one RTBT capable of integrating with a prescriber's e-prescribing system or EHR. While this is a critical step forward, misaligned incentives and information blocking prevent patients, their caregivers, and providers from accessing the information needed to make informed care decisions seamlessly and in real-time. Enhancements are necessary to ensure that RTBTs and benefit data serve their intended purpose: empowering patients with transparent, actionable information to make informed decisions about their care.

RECOMMENDATIONS

- **Require RTBT implementation across all payer types**: Ensure that both commercial and public payers implement RTBT capabilities that support patient- and provider-facing tools**.**
- **Mandate a standardized set of data elements**: Include out-of-pocket costs, therapeutic alternatives, prior authorization information (i.e., flags, criteria, determinations, status) and criteria, benefit accumulators, and eligibility details to ensure consistency and usability across platforms.
- **Ensure standardized API-based access**: Require that RTBT and eligibility data be made available in a standardized format via open APIs that align with proven interoperable standards (e.g., HL7 FHIR and NCPDP), enabling integration with third-party applications that support affordability, adherence, and care navigation.
- **Enable data sharing with affordability tools**: Allow RTBT data to flow to tools that help patients identify lower-cost alternatives and connect with savings programs—such as patient assistance programs (PAPs)—even when those options fall outside of the payer's formulary.

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2. *Prior Authorization (PR-5, PR-7)*

We commend HHS for advancing prior authorization reform and mandating use of FHIR-based Prior Authorization APIs, machine-readable documentation requirements, and real-time status updates across Medicare Advantage, Medicaid, the Children's Health Insurance Program (CHIP), and Qualified Health Plans (QHPs) on the Federally Facilitated Exchanges. These provisions represent a critical step forward in reducing administrative burden and improving patient access to timely care. However, additional action is needed to ensure that the finalized requirements are not only implemented but also leveraged to their full potential across the healthcare ecosystem.

RECOMMENDATIONS

- **Support consistent implementation across all payer types**: Ensure that commercial payers and self-insured plans adopt standardized prior authorization APIs to avoid fragmentation, including transparent and real-time access to prior authorization criteria.
- **Promote certification and adoption across the ecosystem**: Encourage EHR vendors and third-party developers to adopt certified prior authorization APIs to ensure interoperability across platforms and care settings.
- **Align with broader federal interoperability efforts**: Coordinate with initiatives such as TEFCA and United States Core Data for Interoperability+ (USCDI+) to streamline data exchange, reduce duplicative efforts, and ensure consistency across regulatory frameworks.

3. *Enabling Clinical Research and Evidence Generation (PC-8, PC-9)*

We strongly support HHS's goal to expand access to clinical and non-clinical data to support research, innovation, and evidence generation. To achieve this, we recommend a multi-pronged approach that ensures data is not only standardized and accessible, but also shareable in real-time via open APIs. While HHS has made progress through initiatives like Blue Button 2.0, the current scope is limited to basic demographic and claims data. We must expand the data ecosystem to enable meaningful research and innovation.

RECOMMENDATIONS

Expanded data should include:

- **Clinical data:** lab values, encounter notes, imaging, genomics, and patient-reported outcomes.
- **Non-clinical data:** environmental factors affecting health and outcomes, pharmacy and adherence data, and care navigation interactions.
- **Operational data**: appointment availability, provider capacity, and care team composition.

Provider Interoperability Frameworks (PR-1-14, TD-8, TD-9)

Seamless, standards-based data exchange is foundational to improving care coordination, reducing administrative burden, and enabling innovation. However, the current interoperability landscape—particularly the TEFCA framework—poses challenges for many stakeholders, especially those outside the traditional EHR ecosystem and may reinforce incumbent advantages. The high cost and complexity of onboarding, combined with a centralized governance model, can serve as a de facto "good housekeeping" seal of approval—one that is often out of reach for smaller providers, innovators, and community-based organizations. This dynamic discourages participation and limits the diversity of actors in the ecosystem.

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To address these concerns, we support a hybrid interoperability model that allows for multiple, standards-based pathways to participate in national exchange. This includes TEFCA, but also alternative models that are more agile, inclusive, and better suited to non-traditional actors.

RECOMMENDATIONS

- **Advance hybrid interoperability frameworks or governance models**: Support the coexistence of TEFCA with alternative exchange frameworks that enable multi-directional data exchange across clinical, public health, and community-based organizations.
- **Expand and streamline ASTP/ONC Health IT Certifications:** Create modular, use-case-specific certification pathways for non-EHR technologies—including care coordination platforms, remote monitoring tools, and digital therapeutics to reduce entry barriers and provide a meaningful trust signal for interoperability readiness.
- **Lower participation costs:** Explore grant, pilot, or incentive programs to subsidize digital infrastructure development for under-resourced providers and innovators.
- **Ensure inclusive TEFCA governance**: Require transparent, accountable governance of Qualified Health Information Networks (QHINs) with mechanisms for stakeholder input, particularly from sectors like pharmacy, behavioral health, and long-term care.
- **Prevent anti-competitive practices:** Establish safeguards against exclusive contracting, data throttling, or preferential access that could limit innovation or patient access.
- **Mandate payer API certification:** Align CMS and ASTP/ONC policies to require certification of payer-facing interoperability APIs, ensuring that all actors—not just providers—are held to consistent standards.
- **Enable modern exchange architectures:** Recognize the importance of non-FHIR standards (e.g., NCPDP SCRIPT, SCRIPT-ePA, and telecommunications standards) to ensure broad participation across sectors like pharmacy, behavioral health, and long-term care.

Information Blocking (PC-13, PR-12-14, PA-7)

Information blocking regulations were designed to ensure that patients and providers have timely, unimpeded access to electronic health information (EHI). However, the current implementation has created inconsistencies in how different actors are treated—particularly pharmacists and payers—raising concerns about fairness, feasibility, and the broader impact on interoperability.

Pharmacists are designated as actors under the Cures Act, yet many lack access to certified EHRs or participation in TEFCA networks. Without clear guidance or technical pathways to compliance, these structural limitations risk excluding pharmacists from data exchange or exposing them to enforcement despite their limited control over infrastructure. Pharmacists must be supported—not penalized—for their unique interoperability challenges.

At the same time, payers are not currently held to the same information blocking standards as providers, despite their central role in managing and exchanging patient data. This regulatory asymmetry undermines the goal of a level playing field and limits patients' ability to access a complete, longitudinal health record. Ensuring that payers are subject to consistent expectations is essential to advancing equitable, system-wide interoperability.

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RECOMMENDATIONS

- **Include payers as actors under information blocking rules**: HHS should formally designate health plans as actors to ensure parity in data exchange obligations and close current regulatory gaps.
- **Issue guidance for pharmacists:** HHS should clarify that pharmacists who lack access to certified EHRs or TEFCA networks will not be penalized under information blocking enforcement. This would promote fairness and support innovation in pharmacy-based care delivery.
- **Support equitable infrastructure access:** HHS should explore funding or technical assistance programs to help pharmacies and other under-resourced actors gain access to certified APIs and exchange networks.
- **Clarify obligations for intermediaries**: Entities that control access to data—such as EHR vendors or QHINs—should be required to support equitable exchange with pharmacy systems and other non-traditional actors.

Data Standards and Interoperability (TD-1-8, VB-1-3, VB-6, VB-11-13)

A modern interoperability strategy must support a range of data standards and exchange formats to reflect the diversity of actors, workflows, and care settings across the healthcare ecosystem. While HL7 FHIR has become foundational for many interoperability initiatives, it is not sufficient on its own. A flexible, multi-standard interoperability model is essential to ensure that all stakeholders—including pharmacies, specialty providers, and digital health tools—can participate meaningfully in data exchange.

USCDI has helped establish a baseline for structured data sharing, but it remains limited in scope for many real-world use cases. Specialty care, oncology care, emerging cell and gene therapies, pharmacy, and value-based care (VBC) models often require access to data elements not currently included in USCDI, such as medication adherence, social risk factors, and care team composition. Without these elements, it is difficult to support advanced analytics, personalized care, or equitable participation in alternative payment models.

Moreover, any new mandates related to data standards or APIs must account for the operational realities of smaller providers and innovators. Transitioning to new formats—whether FHIR-based or otherwise—requires time, resources, and technical support.

RECOMMENDATIONS

- **Advance a multi-standard interoperability model:** HHS should formally recognize that interoperability must extend beyond FHIR to include other widely used standards such as NCPDP SCRIPT, and telecommunications protocols. This is essential to ensure broad participation across sectors like pharmacy, behavioral health, and long-term care.
- **Support dual-standard APIs and translation layers**: Encourage the development of APIs and middleware that support both FHIR and non-FHIR standards (e.g., NCPDP), enabling gradual transitions without disrupting existing workflows.
- **Expand USCDI to support specialty and VBC use cases:** Prioritize the inclusion of data elements relevant to specialty care, oncology care, cell and gene therapy, chronic disease management, and environmental factors affecting health and outcomes to support more inclusive and effective value-based care.

- **Allow for phased implementation timelines**: Any new data standard or API requirements should include realistic transition periods and technical assistance, particularly for under-resourced providers and innovators.
- **Extend ASTP/ONC certification to non-EHR technologies**: Modular certification pathways should be available for digital health tools, care coordination platforms, and specialty systems that operate outside of traditional EHRs.

Patient Identity and Matching (PR-14, TD-6)

Accurate patient identity matching is foundational to interoperability, yet the U.S. healthcare system still lacks a universal, scalable solution. Fragmented identity management across payers, providers, and digital health platforms leads to mismatched records, duplicate entries, and gaps in care coordination—especially in pharmacy, specialty care, and community-based settings.

While several promising models have emerged—including the NCPDP Universal Patient Identifier (UPI)—we caution against mandating a single, centralized solution. Instead, HHS should support a flexible, standards-based approach that allows for multiple, privacy-protective identity strategies to coexist and evolve. This will foster innovation while ensuring that identity solutions are adaptable to different care settings and technology environments.

Importantly, any identity solution must be low-cost or no-cost to patients. Patients should not be expected to pay for access to their own data or to enroll in identity services in order to benefit from interoperability. Equity and accessibility must be core design principles.

RECOMMENDATIONS

- **Support a flexible, multi-solution approach to patient identity**: Avoid mandating a single identifier or architecture. Instead, support multiple standards-based solutions—such as the NCPDP UPI—that can be adopted based on context and infrastructure.
- **Ensure affordability for patients**: Identity solutions must be free or low-cost to patients. No individual should be required to pay to access or share their own health information.
- **Encourage payer-provider alignment**: Promote consistent identity management practices across payers and providers to reduce mismatches and improve data quality.
- **Incentivize infrastructure upgrades**: Provide funding or technical assistance to help under-resourced providers and pharmacies implement real-time identity verification and consent management tools.

Value-Based Care (VB-1-4, VB-11-15)

HHS has long recognized that modernizing payment and delivery models is essential to advancing whole-person care, improving outcomes, and reducing costs. Embedding foundational technologies—such as tools that support real-time, patient-centered decision-making—into care delivery is critical to realizing this vision and empowering providers to deliver measurable improvements in care.

RECOMMENDATIONS

- **Encourage foundational technologies through** Center for Medicare and Medicaid Innovation **(CMMI) models:** HHS should require or incentivize CMMI participants to offer core digital tools to patients and providers as part of their participation. These tools—such as RTBTs and care

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coordination platforms—should be evaluated based on their clinical and operational utility, not defined prescriptively.

- **Modernize Alternative Payment Models (APMs) to reflect digital innovation**: APMs should reward the use of technologies that support risk stratification, longitudinal care management, and patient engagement. This includes AI-driven analytics, remote monitoring, and patient-generated health data. These capabilities are essential to delivering high-quality, coordinated care and should be recognized as core enablers of value.
- **Advance interoperability as a VBC enabler:** Seamless data exchange is foundational to VBC. HHS should support a phased approach to interoperability that allows for dual use of NCPDP and HL7 standards, particularly in pharmacy and benefit systems. Certification criteria should evolve to reflect emerging technologies without increasing provider burden.
- **Recognize pharmacy as a care team member:** Pharmacies play a critical role in VBC, especially in medication adherence, chronic disease management, and the use of RTBTs. Federal policy should ensure that pharmacy data standards are fully supported and integrated into VBC models.
- **Promote digital identity and access infrastructure**: Investment in infrastructure that supports secure, patient-directed data exchange—including digital identity credentials and FHIR endpoint directories—is essential for enabling patients to navigate care and for providers to deliver coordinated services.
- **Align certification with VBC outcomes:** Certification programs should prioritize capabilities that directly support VBC, such as closed-loop referrals, social determinants of health capture, and patient-reported outcomes. Certification should be streamlined to reduce administrative burden while ensuring accountability.

Conclusion

McKesson believes that patient-centered healthcare interoperability can transform care delivery, improve outcomes for all, and empower patients to be active participants in their healthcare journey. Our recommendations are common-sense outgrowths of the Department's completed and continuing efforts to promote interoperability, improve care coordination, and increase transparency in an otherwise siloed and opaque system that has stood too long in the way of value-based care. We have identified both immediate actions that HHS can take to improve healthcare delivery, and policy pathways that establish a durable framework to support the responsible and sustained advancement of health technology. We look forward to working with HHS to advance these opportunities in the months ahead. If you have questions or need further information, please contact Fauzea Hussain, Vice President of Public Policy, at Fauzea.Hussain@McKesson.com.

Sincerely,

Rich Buckley