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Submitted via regulations.gov
Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services, Department of Health and Human Services,
Attention: CMS-2025-0050-0031
P.O. Box 8016
Baltimore, MD 21244-8016

June 16, 2025

Re: Request for Information; Health Technology Ecosystem (CMS-2025-0050-0031)

Dear Administrator Oz,

The Robert J. Margolis, MD Institute for Health Policy at Duke University (Duke-Margolis Institute) appreciates this opportunity to comment on the Centers of Medicare and Medicaid Services' Request for Information; Health Technology Ecosystem (CMS-2025-0050-0031), henceforth known as the RFI.

About the Duke-Margolis Institute

Established with a founding gift through the Robert and Lisa Margolis Family Foundation, the Duke-Margolis Institute aims to generate and analyze evidence across health policy and practice to support the triple aim of health care–improving the experience of care, the health of populations, and reducing per capita cost. The Duke-Margolis Institute's activities reflect its broad multidisciplinary capabilities, fueled by Duke University's entrepreneurial culture. It is a university-wide program with staff and offices in both Durham, North Carolina, and Washington, DC, and collaborates with experts on health care policy and practice from across the country and around the world.

The mission of the Duke-Margolis Institute is to improve health and the value of health care through practical, innovative, and evidence-based policy solutions. The Institute's work includes identifying effective delivery and payment reform approaches that support the transition to value-based care and collaborating with expert stakeholders to identify pathways to increase the value of biomedical innovation to patients – both through better health outcomes and lower overall health care spending. Duke-Margolis and University-wide faculty and staff have extensive experience in analyzing data to develop practical policy solutions and insights into Centers for Medicare & Medicaid Services' programs.

Introduction

In this Request for Information (RFI) on the Health Technology Ecosystem (CMS-2025-0050-0031), CMS and ASTP/ONC show a commitment to advancing a patient-centered digital health ecosystem that empowers Medicare beneficiaries and improves current health technology infrastructure. The RFI focuses on enhancing functionality, reducing barriers to data access, and supporting value-based care.

Duke-Margolis believes that this RFI is an important strategic step for the agency. It aligns with the CMS Innovation Center's strategy refresh, which highlighted a focus on unlocking data access through innovative technology that empowers patients to meet their health goals. Duke-Margolis hosted a

recent public CMMI strategy launch webinar, during which we received questions and comment related to the many important topics CMS raises in this RFI. Duke-Margolis's ongoing efforts to contribute to the health technology ecosystem include:

- Multistakeholder approach to modernizing risk adjustment and performance measurement through utilizing clinical and pharmacy data already within electronic health records to enhance payment accuracy, reduce administrative burden, and promote prevention-oriented care for Medicare beneficiaries.
- Supporting the Health Care Payment Learning and Action Network (HCP-LAN), including its new Technology-Enabled Health Care Workgroup that will focus on developing, incentivizing, and implementing use cases for consumer-facing health care applications and address barriers to interoperability. The HCPLAN is co-led by the Director of Duke-Margolis, Dr. Mark McClellan, to with a goal of creating a clear value proposition and implementation pathway for technology in health care.
- Advancing the use of secure, anonymized data from CMS, and other payers and providers, to support rapid assessment and learning to accelerate health care reform. For example, in 2024, Duke-Margolis responded to CMS's Request for Information on the Medicare Advantage data (CMS-4207-NC), recommending that CMS promote researcher access to data by implementing and supporting a collaborative process with researchers and other key stakeholders to identify a path forward to enhance data capabilities in MA and continue to strengthen the program.

Duke-Margolis is aligned with the broader vision of the 21st Century Cures Act to enhance patient access to health information and remove barriers to data exchange and information blocking for both patients and providers. In order to unlock the potential of technology in healthcare that will positively influence patient outcomes, Duke-Margolis encourages CMS to leverage supporting policies, such as those in the Shared Savings Program and other payment systems, to incentivize provider, payer, and other stakeholder investment in strong data infrastructure to advance efficient, interoperable data exchange through policy levers that encourage the adoption of interoperable processes. We provide detailed responses to the RFI along the following themes:

- Proposing a Strategic Vision for Tech-Enabled Care
- Evaluating Efficacy of Digital Health Tools (DHTs)
- Encouraging Implementation and Scaling of Effective Digital Health Tools Through Meaningful Incentives
- Simplifying Data Exchange to Reduce Reporting and Measurement Burden

A Strategic Vision for Tech-Enabled Care

The current US health care delivery system has been challenged in availing itself of recent technological advancements that other industries have been able to due to a variety of legal, technical, administrative, and financial barriers. For example, technology vendors have obligations to promote interoperability of the data and ensuring its security, while also obtaining a return on their investments. Providers collect, store, and analyze data for quality improvement activities and (usually fee-for-service) business purposes, while patients advocate for data rights, privacy, and support for using data and technology to improve their care.

The health technology landscape for providers remains challenging to navigate; administrative burden associated with changing regulatory requirements and inconsistent policies across payers (especially non-FFS, "value-based" payers) is a large pain point. While implementing technology improvements can benefit clinical operations through some gains in efficiency, they can be difficult to integrate into clinical workflows and often lead to burden increases in the short run. Health systems are also interested in achieving increases in productivity and health value through applying AI, though there is not agreement on which tools to prioritize, for what purposes, and how to reliably measure impact. Finally, cost is a significant barrier. Implementing technology in health systems is resource-intensive, requiring providers to make tradeoffs in what they choose to invest in based on their population health needs, resulting in an increasing digital divide between larger, better-resourced health systems and smaller, less-resourced ones. Therefore, some issues are not technical but stem from misaligned business incentives and motives, and policy change is the mechanism to help foster alignment. Overall, as we describe below, clear business cases are needed to support sufficient data exchange and effective tech-enabled interventions, which are likely to be most effective when implemented through a stepwise approach.

1. A foundational priority for enhancing tech-enabled care is strengthening the flows through existing building blocks of a common data infrastructure. This involves incentives and supports for advancing key data exchange and interoperability for multiple purposes, through leveraging the investment and burgeoning progress with existing interoperability projects, including normalizing bulk FHIR exchange (including provider-payer exchange), United States Core Data for Interoperability (USCDI) standards, and the Trusted Exchange Framework and Common Agreement (TEFCA) on a larger scale. By encouraging, requiring, and/or incentivizing more entities to participate in bulk fashion, CMS can help health care organizations succeed across multiple digital health initiatives. CMS has a unique position and ability to align and catalyze efforts in data and technology. Its strategy towards technology should aim for alignment and synergies in advancing multiple priorities based on a common interoperable foundation, while also considering consent, security, and privacy issues for patient data.

2. Alongside a clearer path for a routine, functional common data infrastructure, CMS and industry can then build, and scale health care delivery based on the foundational building blocks, supported by a clear business case for demonstrating evidence of effectiveness of tech-enabled tools. For example, bulk FHIR currently supports the exchange of interoperable data, but it will require more support to enable valid, fit-for-purpose data in high priority opportunities, including data exchange for quality improvement and quality reporting. As CMS is aware, providers have struggled implementing EHR-abstracted electronic Clinical Quality Measures (eCQMs) for a variety of issues, as a consequence the migration to FHIR has been challenged. Scaling FHIR capabilities more broadly would accelerate efforts to implement digital Quality Measures (dQMs), which alleviate admin burden by providing a mechanism for automated data exchange across multiple sources. Strong common data infrastructure can benefit other CMS programs and initiatives, such as the HCPLAN Technology-Enabled Health Care Workgroup and CMMI's Rapid Cycle Innovation Program (RCIP). Such investments can also accelerate the adoption and uptake of transformative therapies, which will rely on efficient care delivery systems and a reliable capacity to track patients and their outcomes over time to realize the

potential for better management and reduced burden of chronic diseases. Other key processes in healthcare delivery that stand to benefit from a strong data infrastructure include risk adjustment; care coordination involving mobile, satellite, and centralized provider systems; clinical decision support; quality measures; value-based payments; post-market product surveillance; learning health systems; real-world evidence studies; and standardizing AI and other software tools to achieve optimal patient outcomes.

3. CMS should concurrently support policy reforms to increase alignment across different healthcare delivery models and payment programs. By engaging health care organizations in priority use case and incentive alignment across Traditional Medicare, Medicare Advantage (MA), and state and commercial programs – while recognizing that challenges, priorities, and incentives differ across the programs – CMS can enable more successful digital health adoption and care reforms with broader impact, such as more access to mental health care and strategies and help controlling chronic disease like diabetes and hypertension. There are opportunities across both primary, secondary, and tertiary prevention. For example, leveraging pharmacy apps that have been shown to improve medication adherence and reduce exacerbations, but policies would be differentially implemented for an ACO verse an MA plan that may have an integrated pharmacy benefits manager.

In conclusion, CMS should consider a pathway to achieve successes in tech-enabled care and digital health tools by strengthening existing initiatives towards a common data infrastructure, identifying applicable use cases and programs, and scaling and aligning these efforts across different programs and patient populations. To operationalize this approach, Duke-Margolis offers our responses and considerations to the CMS technology ecosystem RFI below, categorized across the following themes.

Evaluating Efficacy of Digital Health Tools (DHTs)

These comments refer primarily to PC-5a and PR-4, which focus on evaluating the efficacy of patient-facing DHTs and CMS's potential role in reviewing or approving these products based on their efficacy, quality, or impact on health outcomes. Evaluations of DHTs' ability to sustainably improve patient health outcomes, particularly patient-facing tools not under FDA authority, can be challenging for individual product developers to implement. They are often poorly controlled, short-term, and do not provide findings that clearly address the business needs of payers or providers (i.e., confident return on effort and financial costs of adoption). Despite a range of private-sector efforts, there is still no broadly accepted framework or scaled platform for addressing these impact questions, leading to inconsistent methodologies and criteria for adoption. Applications that require myriad manual inputs or have unfriendly user design result in low engagement. This absence of a unified approach contributes to duplicative efforts and inconsistent adoption across the industry.

In light of this, Duke-Margolis proposes the following considerations for CMS.

- Oversight in DHT Evaluation. CMS should consider guidance on what evidence is needed to support reimbursement and payment for DHTs. The Food and Drug Administration (FDA) must authorize medical devices used for the diagnosis or treatment of a specific disease. However, many DHTs do not meet the definition of a medical device and are not under FDA authority, and for others, the FDA has chosen to exercise enforcement discretion by not requiring pre-market review. Thus, there is a need to align on mechanisms to streamline coverage and payment for DHT use and to ensure that those coverage and payment mechanisms incentivize competition on patient engagement and outcomes. Because of the substantial differences in payment and incentive structures across CMS programs, different approaches will likely be needed for Traditional Medicare, Traditional Medicare with alternative payment models (like the Shared Savings Program), Medicare Advantage, and CMS guidance and support for state Medicaid programs. Traditional Medicare has covered some DHTs through chronic care management codes, but the broadness of these codes results in uniform reimbursement regardless of a tool's complexity or effectiveness, with many tools remaining uncovered. In accountable care programs with person-based payments, CMS has more flexibility. However, a stronger focus on developing high quality evidence could help create a clearer pathway to pay for tools that improve patient outcomes or reduce costs, such as the Medicare Diabetes Prevention Program and virtual solutions for depression and anxiety.
- Standards of Evidence Generation. CMS can develop standards of evidence around the "reasonable and necessary" threshold to incentivize the development and effective use of high-quality digital tools, focusing first on high-impact use cases. In conjunction with other Federal agencies and the private sector, CMS can encourage the establishment of a framework for quality evidence generation that emphasizes DHT usability, sustained engagement, and proven impact on health outcomes and costs to help providers, patients, and product developers better assess which products are most effective in particular circumstances.
- Opportunity to Evaluate through Rapid Learning Assessments. A pathway to evaluate (and eventually scale) high-priority DHT use cases more quickly through rapid-cycle assessments can help assess which interventions or tools work in diverse contexts more quickly. This includes advancing methods to share data and experience across providers, plans, and use contexts to identify the best products that would result in positive health outcomes, reduced costs, increased convenience for patients, and products that patients would most likely use over time. Identifying and promoting opportunities through partnering with health systems and providers (e.g., through HCPLAN), can function as both a mechanism for evidence generation and potential future distribution pathways for DHTs.

Effective evaluation and coverage of DHTs requires collaboration among CMS, digital health technology evaluators (e.g. Peterson Health Tech Institute), FDA (when applicable), health IT developers, patients, and providers to define evaluation criteria tailored to product type, patient population, and use case. Engaging developers early ensures that products will align on evidence requirements, enabling only proven effective DHTs to qualify for payer reimbursement and provider use. These recommendations can help address the current fragmentation in DHT evaluation, promote the adoption of highly effective tools in appropriate contexts, and improve patient outcomes while reducing costs.

Encouraging Implementation and Scaling of Effective Digital Health Tools Through Meaningful Incentives

These comments address questions PC-6, TD-1, VB-1, VB-2, PR-1, and PR-2, which focus on strategies to promote adoption and scaling of effective DHTs once standardized efficacy is established. As described above, barriers including limited evidence of effectiveness and inconsistent or unclear reimbursement supports create barriers to adoption, including for value-based care organizations and providers. Emerging evidence shows that DHTs have the potential to support patients in maintaining and improving their health, specifically for conditions like cardiovascular diseases (e.g. diabetes, hypertension), weight management (an underlying risk factor for many conditions), and early hearing loss. Tech-enabled care offers promising solutions to support and provide evidence on optimal health outcomes in-between visits and interactions with providers.

To begin encouraging implementation and scaling of effective DHTs, CMS can take into account the following considerations.

- Integrate Successful DHT Use Cases: Highlight successful use cases and pilots through collaborations such as the HCPLAN Technology-Enabled Care Workgroup to demonstrate real-world impact and strategies for overcoming barriers. CMS can help multiple payers encourage effective DHT adoption by promoting the discussion and assessment of coverage and payment strategies for DHTs based on their evidence level and risk sharing, encouraging wider adoption, trust, and coverage for these tools.
- CMMI Model Design & Implementation Guidance: Support the development of CMS guidance that facilitates the adoption of DHTs across specific disease/health risk areas for patient populations and incentivize data sharing to accelerate evidence development and product refinement. CMS can leverage interoperable technologies and sources of nuanced data, such as qualified clinical disease registries or longitudinal patient tracking by health systems, to build use-case evidence in alignment with real-world evidence initiatives. Mechanisms like Coverage with Evidence Development (CED) to support to local coverage determinations and MA plan coverage decisions can further enable this approach. As we have noted, risk-based contracting with DHT product developers to support the implementation and evaluation of DHTs can be further enablers of this approach.
- Payment Incentives: Continue to explore solutions or tools that move away from relying on provider time and number of services for payment and move toward payment systems that provide flexible revenue streams that afford providers the ability to invest in the necessary, whole-person care infrastructure. This is particularly important for medical specialties with access challenges, where DHTs can help enhance care between visits.
- Stratifying Payment Mechanisms Based on Program Payment Structures. As mentioned earlier, CMS should also be aware that incentives and coverage for DHTs will vary depending on the program, i.e., traditional Medicare versus Medicare Advantage.

Stakeholder buy-in is critical to foster a paradigm shift in the perception of medicine and medical treatments. This requires clearly communicating and demonstrating the benefits and ROI of DHTs for patients, providers, payers (including MA plans), and health systems. By establishing an adequate

incentive architecture, CMS can rapidly scale DHT adoption while addressing the historical funding challenges through shared financial responsibility.

Simplifying Data Exchange to Reduce Reporting and Measurement Burden

These comments refer primarily to questions PC-3, PR-7, PR-8, PC-8, PC-11, TD-4, TD-5, PA-5, and PA-7, which focus on improving health data exchange through interoperability and open standards to simplify clinical reporting and measurement processes for providers and payers. The current state of health data exchange remains largely fragmented, with providers facing duplicative and burdensome reporting requirements and standards/formats. Opportunities to leverage Health Information Exchanges (HIEs) and bulk FHIR-based APIs are increasing, thanks to the continuing evolution of CMS interoperability requirements and incentives. But at present, adoption and uptake of large-scale automated reliance on these interoperable systems has been challenging. For example, many organizations are reluctant to invest in the cost of reporting eCQMs, which are abstracted out of the EHR, since bulk FHIR-based methods could potentially replace more burdensome site-specific abstraction work. Dominant hospital EHR systems like Epic and Cerner have different customizations and fee structures that may present challenges for bulk data exchange, while the outpatient EHR market often lacks sufficient customization for appropriate data analysis, reporting, or sharing. A critical goal of a unified approach is to clearly align efforts with simplifying data exchange to improve care, specifically through adopting bulk-FHIR based reporting and measurement to streamline processes, providing stronger incentives for stakeholders, and reducing administrative burden on providers.

In light of this goal, Duke-Margolis proposes the following considerations.

- Coordination with Other Agencies and Partners. In addition to the FDA, CMS should collaborate with the Assistant Secretary for Technology Policy (ASTP) Office to ensure that data sets capture not only outcomes that matter to patients and providers but also key risk predictors that can target and refine tools. Additionally, coordination should support the inclusion of data on relevant treatments—such as use or non-use of prescription medications—that may impact patient outcomes. ASTP can also facilitate further developments and socialization of USCDI to achieve these goals.
- Advance Interoperability to Advance Quality Improvement and Measurement Efforts. As mentioned in the strategic vision, CMS should support existing interoperability initiatives to advance multiple CMS program goals. Leveraging bulk FHIR and TEFCA can facilitate data exchange and access to multiple data types (e.g., EHR, claims, clinical, encounter). Unlocking this access supports providers and patients through more reliable, timely and complete access to information for improving care. It also advances CMS' Universal Foundation vision and would advance progress in CMS' strategic roadmap towards dQMs (i.e., a more efficient alternative to previous eCQM requirements) and incorporating disparate data sources into quality reporting. For example, CMS can consider laying out a clearer pathway, potentially including quality incentives and pilots, for physicians and health plans to adopt standardized key data elements, structures, and transfers using APIs. Prioritized elements would be those identified in the work described above, to advance digital- and AI-enabled care that improves outcomes and reduces costs. This would ease the burden that health systems have faced reporting particular eCQMs

through the EHR. CMS can also standardize quality measurement reporting across software systems to facilitate multi-payer alignment and reduce duplication.

- Build on Successful Use Cases. Improved data exchange can help improve and scale existing efforts that already show some promising results. The Diabetes Prevention Program (DPP) reduced participants' chances of developing type 2 diabetes by 58%, though the program has not been widely adopted. The DPP provides a model for digital health and AI reimbursement by combining base payments for participation in the digital health program with outcomes-based payments tied to weight loss and improved glucose control. While there are nascent efforts to test AI tools for DPP, improved, seamless data exchange could alleviate the cost burden of implementation, allowing greater opportunities to scale DPP adoption.
- Leverage Existing CMS Networks and Partnerships. CMS should leverage public-private partnerships, such as the HCPLAN Tech-Enabled Health Care Workgroup, to coordinate interoperability and reporting efforts across multiple stakeholders and industries. NCQA's Bulk FHIR API Quality Coalition is another public-private partnership effort that convenes payers and providers to mass pilot bulk FHIR implementation and expansion in the future. Public-private partnerships can build trust, create buy-in, and align implementation across providers, payers, EHR developers, Health Information Exchanges (HIEs), and data warehouses. Providing opportunities for bi-directional communication and feedback between policymakers and partners is critical to identifying and addressing barriers, as well as sharing and scaling best practices (such as through rapid learning efforts).

Conclusion

We appreciate the opportunity to provide feedback to CMS. Duke-Margolis encourages CMS to consider a stepwise approach to tech-enabled care and digital health tools by strengthening existing initiatives towards a common data infrastructure, identifying applicable use cases and programs, and scaling and aligning these efforts across different programs and patient populations. If you have questions or require additional information, please contact Frank McStay at Frank.McStay@Duke.edu.

Best Regards,

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