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Dr. Mehmet Oz
Administrator, Centers for Medicare & Medicaid Services (CMS)
US Department of Health and Human Services
Baltimore, Maryland 21244

Dr. Thomas Keane
Assistant Secretary for Technology Policy (ASTP)
Office of the National Coordinator for Health Information Technology (ONC)
US Department of Health and Human Services
Washington, DC 20201

Re: Request for Information – Health Technology Ecosystem

Dear Dr. Oz and Dr. Keane,

Milken Institute Health is honored to provide its expert response to the Request for Information: Health Technology Ecosystem [CMS-0042-NC].

As a nonprofit, nonpartisan think tank, the Milken Institute believes in the power of capital markets to address urgent social and economic challenges, thereby improving lives. Its guiding belief is that societies thrive when they cultivate an educated, healthy workforce, foster transparent and efficient capital markets, and sustain effective social institutions. Milken Institute Health shapes and advances innovative solutions to accelerate biomedical innovation and access, improve prevention and wellness, catalyze a more nutritious, sustainable, and resilient food system, and advance healthy aging and financial security for older adults.

We appreciate CMS providing the opportunity to respond to the agency's ongoing efforts to modernize its data environment and advance a patient-centered, technology-enabled health-care system, thereby empowering beneficiaries. We write at what we believe is an inflection point: the threshold of a data-driven renaissance in American health care. If every component of the Department of Health and Human Services can speak a common digital language, CMS can catalyze an enterprise-wide transformation that both safeguards taxpayer dollars and accelerates patient access to lifesaving innovation.

Older adults and family caregivers seeking to use technology for health and home care must typically stitch together suites of devices and apps, and much of the data generated doesn't reach health-care providers. Opportunities for earlier intervention can be missed, along with potential insights into how to better support the entire continuum of stages and health statuses that older adults experience, which fluctuate over time.

Milken Institute Health also wants to highlight pivotal issues that require CMS's immediate attention. Chronic diseases have become a leading cause of preventable death in the United States, consuming a substantial share of health-care spending while diminishing quality of life and productivity. As our population ages, the burdens of cancer, diabetes, cardiovascular disease, and dementia climb ever higher, compounding strains on our health-care system.

CMS leadership can spark a new era of biomedical innovation and its access, one that breaks down barriers to care and guarantees effective and efficient access for every American. Milken Institute Health is dedicated to amplifying the voices of patients and caregivers in transforming our health-care system. We stand ready to partner with CMS on this critical mission, uniting our expertise and resources to deliver transformative solutions for communities across the nation.

Summary of Recommendations:

I. Establish a secure, interoperable CMS-FDA data platform that links clinical, claims, and electronic health record (EHR) information to accelerate evidence generation, streamline approvals, refine payment policies, strengthen safety oversight, and speed equitable patient access to innovative therapies.
II. Convene experts to craft a person-centered roadmap that links digital health tools to older adults' prevention, detection, and chronic care needs, thereby accelerating adoption by and independence of older adults.
III. Spearhead a certified "digital front door" by working with industry experts to define actionable home-generated data elements and model data flows, enabling interoperable platforms, dashboards, and marketplaces that unify fragmented digital-health information and tools for coordinated, personalized care.
IV. Launch state-led evidence pilots and update Medicare/Medicaid payments—including Medicare Advantage supplemental benefits and Program for All-Inclusive Care for the Elderly (PACE)—to measure and fund connected-home technologies that improve outcomes, accelerating national uptake.

Streamlining Data from Approval to Access

Recommendation 1. Establish a shared digital nervous system for CMS and the FDA.

CMS maintains one of the nation's largest collections of clinical and claims data, encompassing Medicare, Medicaid, Children's Health Insurance Program, and Marketplace beneficiaries; however, much of this data remains in separate systems.[1] Treating these data as a shared, interoperable resource that is timely and longitudinal would allow CMS to link separate datasets into a single evidence stream supporting decisions across the care continuum.

We believe that the FDA's increasing use of pragmatic, decentralized, and point-of-care study designs depends on capturing real-world data where patients receive care. A fully interoperable CMS–FDA data platform would better connect clinical research with routine practice, helping to extend trial opportunities to rural and underserved communities that are often underrepresented in studies. Combined claims and EHR data could also reinforce post-marketing clinical research, supporting timely labeling updates and more reliable detection of safety signals.[2]

With linked cost and outcome information, CMS would be in a stronger position to refine payment policies. Manufacturers could move forward on a clearer, evidence-based path that builds on collaborations such as the Transitional Coverage for Emerging Technologies (TCET) framework while meeting post-approval evidence commitments. Shared learning platforms—drawing on models like the Health Care Payment Learning & Action Network—could limit duplicative contracting and foster collaboration among patients, clinicians, and regulators, helping to shorten the cycle from research to practice.

Developing a secure, interoperable data infrastructure between the CMS and the FDA could shorten the time between product approval and patient access, reduce unnecessary spending, and enhance public confidence through transparent data stewardship and consistent oversight of safety and quality of medical products and health care.

The Milken Institute Health launched ENRICH-CT (Enabling Networks of Research Infrastructure for Community Health Through Clinical Trials)[3] in collaboration with over 60 organizations, aiming to enhance access to better evidence-generation mechanisms for clinical studies and the value assessment of innovative medical products in

low-resource settings. The Milken Institute is ready to partner with the agency to utilize this active public-private partnership to test models to enable the clinical research utilizing interoperable data for streamlined biomedical research and development (R&D), regulatory, and access.

Building the Health Technology Ecosystem for Older Adults

Health care is moving care outside of the four walls of the hospital and clinician's office and into the home, where an array of digital tools is now available to older adults supporting a variety of needs. These needs range from health care to daily life, and technologies include everything from remote patient monitoring for specific medical conditions to health wearables and apps focused on prevention and well-being to passive home sensing technologies supporting safety and care management.

While many point solutions now exist, data and devices remain fragmented. Systems don't yet provide an integrated experience for older adults and their families. Information doesn't flow easily between consumer and provider-facing devices and apps, and many digital tools simply don't work together due to a lack of interoperability. Older adults and family caregivers seeking to use technology for health and home care must typically stitch together suites of devices and apps, and much of the data generated doesn't reach health-care providers. Opportunities for earlier intervention can be missed, along with potential insights into how to better support the entire continuum of stages and health statuses that older adults experience, which fluctuate over time.

The field of digital health tools is also crowded, making it difficult for older adults and care providers to parse relevant options. More than 350,000 mobile health apps and thousands of monitoring technologies are currently available.[4] With numerous available point solutions—apps, services, and devices targeting a single issue or performing a standalone function—stakeholders are seeking connections, bundles, and consolidation (i.e., fewer tools that do more).

These conditions impact adoption. Only about half of adults aged 55 and older use assistive or health-related technology to help them age in place, and tools are often introduced reactively.[5] Cost and lack of insurance coverage or other payment sources make them out of reach for many. To realize the promise of health technology for healthy longevity and aging at home, concerted effort is needed to organize, grow, and support the ecosystem.

Recommendation 2. Respond to the needs and preferences of older adults in the development and deployment of digital health tools (PC-5).

Half of adults aged 50 and above don't believe that technology enables them to lead a healthy life, and two-thirds don't feel that technology today is designed with their age in mind.[6] Characterizing use cases to articulate how digital health technologies meet the specific needs and preferences of older adults can encourage adoption and reduce implementation barriers.

Use cases should reflect the lived experiences of older adults, focusing on prevention and well-being, early detection of health issues, and effective management of chronic conditions. Taxonomies of solution types can then be matched to use cases to guide stakeholders and encourage alignment of point solutions into integrated suites of tools. This user-centered approach enables adults, caregivers, and providers to select appropriate tools, informing the development and adoption of technology.

CMS can support use case development by convening a multidisciplinary working group of experts—including gerontologists, health-care professionals, and technologists—to establish clear goals and standards for connected care solutions and develop a person-centered roadmap for self-care and caregiving solutions. A comprehensive, person-centered roadmap that aligns the wants and needs of older adults with connected care solutions supporting self-care and informal caregiving could provide practical steps for integrating health technology into daily life, promoting prevention, independence, and quality of life.

Recommendation 3. Create infrastructure to unify data and generate meaningful insights from older adults (PC-6).

Point solutions do not typically exchange data or connect with a cohesive system to help manage care across different digital health tools. Data fragmentation limits accessibility, flow, and the ability to derive meaningful insights. Social determinants of health and activities of daily living data that many consumer-facing tools generate are difficult to codify into EHR modules, and providers face barriers to utilizing these data for decision-making without advancements in artificial intelligence. These conditions indicate the need for a digital front door that unifies data and solutions.

A digital front door approach leverages data platforms, visual dashboards, and digital marketplaces to foster a cohesive ecosystem. Data platforms integrate data from digital health tools, EHRs, and from heterogeneous Internet of Things products for personalization, insights, and timely intervention. Visual dashboards provide a cohesive system to help coordinate care across different digital health tools and smart home devices. Digital marketplaces facilitate seamless navigation to relevant tools and bundles, connecting users (e.g., older adults, family caregivers, health-care systems/providers).

To accelerate progress on the digital front door, CMS can work with relevant industry experts to define a set of priority data points (i.e., meaningful, actionable, and feasible) generated in the home environment by digital health tools and create model data flows for sharing them with health-care providers. CMS could then explore how the data set can become a baseline tool and be incorporated into certification. The mCode—Minimal Common Oncology Data—initiative provides an illustrative example. mCode established a set of elements forming the basic data collected on patients with cancer for inclusion in EHRs.[7] The recently adopted United States Core Data for Interoperability Plus Cancer (USCDI+Cancer) defines how these data are exchanged and enables capture of the key cancer-related elements in a patient's EHR.[8] Together, mCode and USCDI+Cancer provide a framework from a related field for digital health tools supporting older adults aging at home.

Recommendation 4. Facilitate access and adoption by older adults and their care teams (PC-7).

Measuring what works, for whom, and when creates an evidence base that stakeholders can use to guide decision-making, from formulating policies to individual care plans. Tangible, measurable benefits help build a case for integrating technologies that support healthy longevity and aging at home into value-based care, guiding the selection and payment of solutions in various scenarios and supporting broader access to them. Overall, quantifying the impact for each stakeholder (e.g., older adult, caregiver, care team, health system, tech innovator, community partner) demonstrates the value proposition for connected care in the home, helping drive adoption.

Uncertainty of reimbursement through health insurance creates adoption friction, especially when coupled with limited alternative avenues for older adults and caregivers to defray the costs. Adoption at scale will require innovation within Medicare and Medicaid, as well as blending and braiding of sources of financial support beyond what government health insurance covers.

Support for coordinated and rapid assessments of technologies can help build the evidence base through real-world data. A states-as-laboratories approach is promising. It could bring together state aging and health agencies to formulate research protocols that quantify impacts on health outcomes and costs and identify suites of technologies matching the needs of populations, with the goal of launching programs that generate evidence and put innovations in the hands of older adults and caregivers.

The New York State Office for the Aging (NYSOFA)'s NYS Innovations in Aging offers a demonstrative example. Since 2018, NYSOFA has fostered more than 20 partnerships with AgeTech start-ups and innovators to improve older adult social, physical, and mental well-being. The program requires its partners to measure and demonstrate the impact of

their interventions to prove efficacy. The evidence is positive and promising, and includes reduced hospitalization and emergency visits, reduced depression, increased social engagement, improved life satisfaction, and improved caregiver support.[9]

Federal programs offer immediate opportunities to support access to digital health tools for older adults through incremental changes in reimbursement. For example, exploring how Medicare Advantage supplemental benefits could be leveraged in new ways, such as expanding allowable home modifications to include infrastructure enabling connected care and the types of technology plans cover for prevention. PACE also has the potential to increase access to comprehensive home-based technology for dual-eligible adults aging at home. These near-term solutions could be developed alongside longer-term strategies, such as building upon existing Medicare alternative payment models currently being tested with providers or creating new ones.

More information on these recommendations, along with additional recommendations not covered here, is contained in our report, *The Future of Connected Care: Enabling Healthy Longevity and Aging at Home*.[10] Over the past year, our initiative on the future of connected care in the home has engaged leaders across health, technology, housing, policy, and research to develop consensus-informed solutions that support older adults and caregivers.

Milken Institute Health Expertise Related to CMS's Priorities

For more than 30 years, the Institute has served as a trusted thought partner for policymakers. Below, we outline our programmatic focus areas where we can support and collaborate with the CMS on its transformative journey.

Elevate Patient Voice in CMS Decision-Making

Unmet medical need is the cornerstone of incentives fueling new biomedical innovation, yet its meaning varies among stakeholders, causing confusion and weakening its ability to identify critical societal health challenges. By clarifying and unifying this concept, CMS can harness breakthrough technologies and pioneering payment models to better target and address these unmet needs, driving transformative improvements in health outcomes for vulnerable communities.

Multiple factors shape what is deemed most urgent, including disease epidemiology, value assessments, cost considerations, payer strategies, clinical guidelines, diagnostic practices, and the perspectives of patients and caregivers. Patient experience data is crucial for understanding the "real-world perspectives" on unmet health needs, disease impacts, and the value of medical products and health care. Since the passage of the 21st Century Cures Act, patient-focused drug development has undergone significant evolution in medical product R&D and has strengthened regulatory evaluation. CMS has already taken steps to incorporate patient and caregiver insights into health-care quality assessments, and the Medicare Drug Price Negotiation Program opens an even greater opportunity to deepen that engagement.

CMS can establish a scientific, systemic framework and streamlined infrastructure, including the potential for a dedicated CMS Office of Patient Engagement for partnering with patients, caregivers, and advocacy organizations. The framework and infrastructure can help CMS determine access to medical products according to the needs of the product's beneficiaries, both patients and caregivers.[11]

For over 20 years, the Milken Institute Health has led an alliance of over 180 patient and disease organizations focused on advancing medical research and access to medicines to deliver better health outcomes for patients.[12] The Milken Institute stands ready to work alongside CMS, securing the necessary resources, building staff capacity, and creating rigorous measures that fully capture patients' experiences and priorities—ultimately transforming our health-care system to serve every American more effectively.

Stop Chronic Illness Through Preventive Health Care

CMS can redefine America's health-care landscape by championing prevention-first policies that reduce the burden of preventable chronic conditions and improve outcomes through vaccination, early screenings, and diagnosis. The Milken Institute Health established Project Prevent in May 2024 to identify principles for successful preventive health-care delivery and promising, scalable platforms that have succeeded in various settings.[13] Subsequently, we have launched a Collaborative of over 27 organizations across sectors and industries committed to scaling prevention.

Getting people to make better choices is resource-intensive and extremely hard. To boost awareness, referrals, and timely screening to stop chronic illness in its tracks, we must also systematically recognize non-physician providers who work closely with communities and patients, such as community health workers, pharmacists, and even caregivers, particularly in dementia care.

We urge support of value-driven reimbursement reforms that empower non-physician providers to reach under-engaged populations, bridging critical gaps in care. Establishing a consistent reimbursement policy for preventive counseling and incorporating preventive measures into value-based payment models will ensure that prevention and access to care remain top priorities.[14]

Pioneer a New Era of Dementia Care

Dementia is complex, costly, underdiagnosed, and stigmatized. Alzheimer's disease is the cause of 60-80% of dementia. Care and services spent for people living with Alzheimer's disease and related disorders (ADRD) are estimated to cost Medicare $164 billion and Medicaid $68 billion annually, which amounts to 16% and 8% of the budget, respectively. Medicare beneficiaries with ADRD incur costs three times the average, in addition to the annual out-of-pocket expenses experienced by families, estimated at $9,000 per year.[15]

Over the next 10 years, the Alzheimer's Association estimates that the prevalence of Alzheimer's Disease alone will rise to nearly 10 million Americans age 65+, resulting in nearly $400 billion in direct costs to CMS by 2035. These costs do not include the costs incurred by family caregivers, who shoulder the intense care needs of their loved one and often need to reduce work hours or step away altogether, impacting not only their own financial security and health but also reducing state and federal tax revenues.

Investment in ADRD detection, diagnosis, treatment, and care is an urgent need. Bending these cost curves is possible if we can delay the onset of disease symptoms. A one-year delay in the onset of Alzheimer's disease could result in $113 billion in reduced formal and informal care costs, while a three-year or five-year delay would result in projected savings of $415 billion and $599 billion, respectively, by 2050.[16]

The Milken Institute launched the Alliance to Improve Dementia Care[17] in 2020 and convenes a coalition of over 135 organizations from the public, private, and nonprofit sectors to transform and improve the fragmented care systems that people at risk for or living with dementia and their caregivers must navigate. The Alliance drives forward initiatives to 1) Promote prevention and early detection and diagnosis, 2) Build workforce and systems capacity to accelerate adoption of innovations in diagnostics and treatments, and 3) Scale comprehensive dementia-care models.

The Alliance is ready to collaborate with CMS to accelerate the adoption of key advancements in the field, including the first FDA-approved disease-modifying therapies, novel detection and diagnostic technologies (e.g., blood tests and digital cognitive assessments), and new payment models such as the CMS Innovation Center (CMMI) Guiding an Improved Dementia Experience (GUIDE) model.

Advance Nutrition for a Healthier Nation

Bold leadership at CMS can revolutionize America's fight against diet-related chronic diseases. Programs like North Carolina's Healthy Opportunities Pilots—utilizing evidence-based, non-medical interventions focused on nutritious food—have achieved lower health-care costs (resulting in a monthly savings of $85 per participant) and improved health outcomes. These successes demonstrate that integrating nutritional support into health-care yields significant returns on investment.

Milken Institute Health has united more than 40 thought leaders—from health insurance and food retail to health care and nonprofits—through its Food Is Medicine Task Force.[18] We stand ready to partner with CMS to champion the critical role of healthy food in serving under-resourced and rural communities, transforming patient care, and strengthening our nation's health.

Conclusion

By establishing a shared, interoperable data infrastructure that bridges CMS's vast database with the FDA's clinical data, policymakers can shorten the cycle from approval to patient access, enhance safety monitoring, and inform value-based payment models with timely, longitudinal insights. Simultaneously, a concerted effort to organize and support the digital health ecosystem for older adults—through user-centered use-case roadmaps, a certified "digital front door," and state-led evidence pilots coupled with modernized Medicare and Medicaid payment pathways—will drive adoption, reduce barriers, and ultimately empower individuals, caregivers, and providers to integrate connected-care solutions that promote prevention, independence, and healthy longevity.

We stand at a truly defining moment in American health care. Historically, CMS has welcomed beneficiary feedback, but now more than ever, a scientific and systemic framework is needed to transform those conversations into direct catalysts for change. By establishing an official structure that enables patients, caregivers, and patient organizations to engage with CMS, we can amplify the voices that matter most while fostering a closer alliance with the FDA, thereby avoiding duplicative processes in generating evidence for safety, efficacy, and value.

As chronic diseases increasingly affect younger demographics each year, and rural, resource-constrained communities continue to face limited choices, CMS leadership can guide CMMI to test innovative payment models and assess their real-world impact on a smaller scale before expanding successful strategies to all Americans. The prevention-first mindset—powered by telehealth access, early detection, and incentivizing healthy lifestyles and nutritious food—will dramatically reduce hospitalizations, boost health outcomes, and contain runaway health-care spending.

The Milken Institute stands ready to provide additional detail on our recommendations and serve as an ongoing resource to CMS. This is our chance to set bold targets, redefine patient engagement, and infuse every corner of our health-care system with vision and clarity—ultimately ensuring a healthier, more vibrant future for every American.

Sincerely,

Esther Krofah
Executive Vice President, Health
Milken Institute

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