September 12, 2025

The Honorable Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue Southwest
Washington, District of Columbia 20201

RE: Multi-stakeholder Comments to the Centers for Medicare and Medicaid Services re: *Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; etc.* (CMS-1832-P)

We represent a diverse coalition of stakeholders that span the healthcare and technology sectors, all of whom support the necessary expanded use of digital and connected health technologies. A growing evidence base continues to demonstrate that the responsible use of digital health solutions produces better patient outcomes, reduces costs, augments population health management, and improves the healthcare workforce experience. Digital health tools, increasingly powered by software-as-a-medical device (SaMD) that includes artificial intelligence (AI), leverage patient-generated health data (PGHD) and include cloud-enabled wireless remote monitoring solutions, to support medical and clinical decision-making, and chronic and acute care management. The use of these tools is also vital in supporting unserved and underserved populations' access to prevention, diagnosis, and treatment for both acute and chronic conditions.

Based on our commitment to the responsible use of digital health innovations, we write to provide our comments on CMS' proposed Medicare Physician Fee Schedule (PFS) and Quality Payment Program (QPP) rule for calendar year (CY) 2026.

We offer the following specific comments on CMS' draft CY 2025 PFS for CMS' consideration:

- **Transform the Medicare System Using Wearables and AI:** we highlight the transformative potential of AI in healthcare to enhance value-based care, improve population health, optimize clinical delivery, reduce administrative burden, and lower overall costs. We urge CMS to establish clear payment and incentive policies that leverage the power of wearables and the use of Patient Generated Health Data (PGHD) by wearable medical devices or general purpose platforms using software and associated AI tools. AI software has only begun to demonstrate its transformational impact in areas such as disease surveillance, fraud prevention, diagnostic applications, and patient care coordination. We encourage CMS to adopt modernized policies that properly classify Software as a Medical Device (SaMD) and medical AI tools as direct practice expenses rather than indirect software costs when practices incur expenses to use a technology in the provision of a given service. We also encourage a move toward national payment rates instead of fragmented contractor pricing. We stress that CMS has a critical opportunity in CY2026 to lead in updating its interpretation of payment methodologies to support safe and efficient integration of AI into Medicare, ensuring beneficiaries access cutting-edge digital medical innovations.
- **Remote Physiologic Monitoring (RPM) and Remote Therapeutic Monitoring (RTM):** CMS's 2026 proposed updates to the PFS for RPM and RTM continue positive momentum toward recognizing digital medical technologies and services, which is building experience and infrastructure to support the move towards value-based care models. We are grateful for the

addition of new codes representing shorter time and monitoring increments for equipment supply as well as treatment management services, allowing tailored care, especially for patients with acute conditions. CHI recommends that CMS' payment for both RPM and RTM reflect new time increments.

We also request that CMS permanently allow both new and established patients to access RPM / RTM and refine proposed limits to enhance multi-provider and multi-device care, while expanding RTM indications beyond current device and diagnostic restrictions and for the adoption of RUC-recommended reimbursement rates for mental health devices. Further, CMS should not Contractor Price RTM respiratory, nor cognitive behavioral therapy supply of equipment CPT codes. CMS should provide more clarity on its proposal to use OPPS geometric pricing in recognition of clinical realities needed to fully meet patient and provider needs.

- **Virtualization of Diabetes Prevention in Medicare:** CMS is proposing major changes to the Medicare Diabetes Prevention Program (MDPP), expanding coverage for virtual and asynchronous online delivery to increase access for beneficiaries, especially in rural areas, and streamline supplier requirements so virtual-only organizations can enroll and participate through 2029. These positive proposals include aligning MDPP with Center for Disease Control (CDC) standards, removing the necessity for in-person delivery capabilities, updating weight reporting to allow self-reported or digitally captured data, and establishing payment rates for online sessions. However, concerns remain regarding lower reimbursement compared to in-person programs (despite evidence that virtual delivery achieves similar or better outcomes) as well as the need for reimbursement of practice expenses related to home-use medical devices similar to those used for remote monitoring. We encourage CMS to ensure payment parity, expanded eligibility for virtual suppliers, improvements in beneficiary awareness, and removal of barriers that restrict access or provider compensation for asynchronous engagement.
- **The Proposed Ambulatory Specialty Model:** We support CMS's proposed Ambulatory Specialty Model (ASM) as a significant move toward specialty-driven value-based care. Especially for chronic conditions like heart failure and lower back pain, emphasizing the importance of digital health tools in improving outcomes and enabling early interventions. We urge for several key modifications, including revising the financial structure to avoid payment cuts for most providers, making participation voluntary rather than mandatory, and setting clear advance performance benchmarks. We highlight the potential of efficacious medical wearables that generate PGHD and AI to enhance disease prevention and care coordination within ASM, and urge CMS to incorporate incentives for wearable use and data integration. Overall, we see ASM as a foundational framework for integrating digital medical innovations into specialty care under Medicare, fostering improved quality and cost control through advanced, technology-enabled chronic disease management.
- **Medicare Telehealth Services:** We commend CMS' proposals to expand and streamline Medicare Telehealth Services, including simplifying the process for adding or removing services from the Telehealth Services List, eliminating provisional status, adding new behavioral health services, and lifting frequency limits on certain visits. We support CMS' permanent recognition of real-time audio-video supervision for most incident-to services which encourages broader access to audio-only telemental health for both new and established patients. We urge CMS to grant Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) maximum flexibility to use digital health tools beyond mental health, including for RPM, RTM, and chronic care services, while avoiding unnecessary in-person requirements. Further, we request that CMS minimize paperwork burdens, and to protect provider safety and privacy by continuing to allow distant practitioners to bill from their enrolled practice location.

- **Direct Supervision via Virtual Modalities:** We appreciate CMS' steps to expand the use of virtual supervision by allowing supervising physicians or practitioners to be present via real-time audio-video technology, and request that this policy be made permanent across as many services as possible. We also support CMS' proposal to permanently authorize direct supervision via audio-video beginning January 1, 2026, for most services under 42 C.F.R. § 410.26 and § 410.32.
- **Digital Mental Health Treatment (DMHT):** Numerous innovations in digital therapeutics are enabling safe and effective treatments across a wide range of health conditions, and we do not support CMS' proposal to broadly include those technologies under one HCPCS code. CMS should not expand indications currently under G0552 beyond FDA 882.5801. As digital therapeutic medical devices continue to evolve in scope and sophistication, there is an urgent need to create codes that adequately represent these technologies. Accordingly, CMS should adopt RUC recommended valuation and pay for CPT cognitive behavioral therapy remote monitoring codes (98XX6, 98978), and set national rates for DMHT HCPCS codes.

Further, we offer the following input on the draft CY 2025 QPP rule for CMS' consideration:

- **Merit-based Incentive Payment System:** We encourage CMS to facilitate and reward the flexible and broad use of digital medical technologies, from remote monitoring to AI, throughout the Merit-based Incentive Payment System (MIPS), especially in its Promoting Interoperability (PI) component. CMS should avoid overburdensome MIPS PI program compliance and reporting requirements that contribute to provider confusion and burnout while doing little to improve patient care. The agency should move away from technology-specific mandates that reduce eligible practitioners' ability to adopt and scale their use of digital health tools to best provide value to beneficiaries.
- **Alternative Payment Models:** We share CMS' goal of developing a vibrant Alternative Payment Model (APM) ecosystem that will drive value for all beneficiaries. Digital health innovations play a central role in successful APMs by allowing data sharing with their participating physicians. Digital technologies facilitate patient access to the optimal mix of in-person, virtual, and remote monitoring services that take advantage of the capabilities offered through medical wearables and AI. We urge CMS to utilize every opportunity available to move away from legacy measurement programs and towards a truly connected continuum of care through its implementation of the QPP.

We appreciate CMS' consideration of our input on the proposed PFS and QPP rule for CY2026, and for its proposals to leverage the extraordinary potential of digital health technologies. We encourage CMS' thoughtful consideration of our input and stand ready to assist further in any way that we can.

Sincerely,

Adherium Limited

American Society of Nephrology

Axeleos, Inc., Makers of MediGuard360 Sentinel

CircleLink Health

Compassion & Choices

Connected Health Initiative

Dogtown Media LLC

Epic Reach, LLC

Gateway Rehabilitation Center

GenieMD, Inc.

HealthFlow

HERO Health

Medical Society of Northern Virginia

MiCare Path

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Nova Insights Corp

Remote Care Partners Inc.

Resmed Corp.

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