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The Honorable Mehmet C. Oz, MD, FACS
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: RIN 0938-AV50

Dear Dr. Oz:

The Consumer Technology Association (CTA®) appreciates the opportunity to comment on the Calendar Year 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies proposed rule.

As North America's largest technology trade association, CTA is the tech sector. Our members are the world's leading innovators – from startups to global brands helping support more than 18 million American jobs. CTA owns and produces CES® – the most powerful tech event in the world. CTA is the trade association representing more than 1200 companies in the U.S. technology industry. Eighty percent of CTA companies are small businesses and startups; others are among the world's best-known brands. We provide members with policy advocacy, market research, technical education and standards development.

CTA's Health Division advances consumer-based, technology-enabled health solutions to improve health outcomes and reduce overall health care costs. The Division includes telehealth providers, personal health wearable companies, digital health technology companies, healthcare payers, health systems, and biopharmaceutical innovators. Our members use technology to improve nutrition, fitness, mental health, lifestyle management, care access, care coordination, and more – and they are poised to lead the next wave of American innovation with cutting-edge health technology.

General Comments

On February 13, 2025, President Trump signed Executive Order (EO) "Establishing the President's Make America Healthy Again Commission."[1] The Executive Order highlights the heavy burden chronic diseases places on patients, families and the U.S. healthcare system. We commend CMS for their leadership in enacting policies that promote technology as an important way to accomplish the goals of the EO, including the "Make Health Tech Great Again" event to highlight voluntary commitments from industry to improve data interoperability, reduce friction and administrative costs. Paired with the Administration's focus on establishing the U.S. as a leader in AI, we are at a critical time to execute on technology's promise to improve treatments, develop new cures and ultimately lower unnecessary health care spending.

[1] Establishing the President's Make America Healthy Again Commission – The White House

Telehealth

CTA supports the proposal to streamline the review process for adding codes to the Medicare Telehealth Services List. We agree with CMS that Steps 1 – 3 of the process are sufficient and removing Steps 4 and 5 will reduce administrative burden.

CTA also supports CMS' proposal to permanently adopt a definition of direct supervision that allows "immediate availability" of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), for all services described under § 410.26, except for services that have a 000, 010, or 090 global surgery indicator.

Digital Mental Health Treatment

CTA has been a strong supporter of the new Digital Mental Health Treatment (DMHT) codes and believes they further the Administration's goals of expanding access to tools for treatment and management of chronic conditions. These codes allow for reimbursement for certain prescription digital therapeutic (PDT) products. PDTs are evidence-based software products designed to manage, prevent, or treat diseases, often integrating sensors or wearables into therapeutic systems. They are proven first-line treatments for conditions like insomnia[2], major depressive disorder[3], chronic pain[4], urinary incontinence[5], and amblyopia[6] that offer an alternative modality for delivering medically necessary interventions. PDTs are typically accessed through apps or specialized hardware, often prescribed by healthcare providers or dispensed by pharmacies and medical equipment suppliers.

PDTs can play a key role in addressing chronic diseases and mental health challenges—critical issues highlighted by the "Establishing the President's Make America Healthy Again Commission" EO.[7] Nearly half of Americans live in areas with a mental health workforce shortage[8], and nearly half of practitioners (46%) said they have been unable to meet the demand for treatment and nearly three-quarters (72%) have longer waitlists than before the pandemic[9]. PDTs can help alleviate these challenges by expanding access to mental health care, particularly in underserved areas, offering remote, personalized treatment and enabling providers to monitor patient progress between visits. By integrating PDTs into mainstream healthcare, the U.S. can reduce healthcare costs, improve patient outcomes, and shift towards more sustainable models focused on long-term health and well-being. A recent review of clinical evidence found that PDTs used in conjunction with usual care produces clinically meaningful improvements in depression and anxiety symptoms that exceed care outcomes alone.[10]

Last year, CMS established HCPCS codes G0552, G0553, and G0554 to reimburse for the provider time and supply of PDTs cleared or approved by the FDA classified at § 882.5801. While CTA supported this, we urged CMS to expand reimbursement for all FDA cleared or approved PDTs.

Since the establishment of the new DMHT HCPCS codes, we have heard of some challenges in the operationalization of these codes. First, CMS did not set a national price for the codes, which is understandable given that it is a new category. However, without guidance, the Medicare Administrative

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[2] Sleepio is the first-ever digital therapeutic to receive NICE guidance, confirming clinical and cost effectiveness
[3] In the Mirai clinical trial of patients with MDD, when added to an ADT, Rejoyn reduced symptoms without side effects
[4] Darnall BD et al. Self-Administered Skills-Based Virtual Reality Intervention for Chronic Pain: Randomized Controlled Pilot Study. JMIR Form Res 2020.
[5] Weinstein, Milena M. MD et al. Digital Therapeutic Device for Urinary Incontinence: A Randomized Controlled Trial. Obstetrics & Gynecology 139(4):p 606-615, April 2022.
[6] Xiao, S et al. Randomized Controlled Trial of a Dichoptic Digital Therapeutic for Amblyopia. Ophthalmology, 29(1):p. 77-85, April 2022.
[7] Establishing the President's Make America Healthy Again Commission – The White House
[8] https://www.kff.org/medicaid/issue-brief/a-look-at-strategies-to-address-behavioral-health-workforce-shortages-findings-from-a-survey-of-state-medicaid-programs/
[9] https://www.apa.org/news/press/releases/2022/11/mental-health-care-strains
[10] "Virtual Solutions for Depression and Anxiety," Peterson Health Technology Institute. May 2025.

Contractors (MACs) are reimbursing at vastly differing levels for these codes. Without predictability and accurate pricing, providers will not make these products available to their patients. We urge CMS to issue guidance to MACs and require them to base pricing of the DMHT codes on invoices submitted by providers.

As mentioned above, CTA believes CMS should expand reimbursement to all FDA cleared or approved PDTs; therefore, we support the proposed expansion of reimbursement to those classified at § 882.5803 Digital therapy device for Attention Deficit Hyperactivity Disorder (ADHD). We also encourage CMS to further expand reimbursement, as mentioned in the proposed rule, to Computerized behavioral therapy devices for treating symptoms of gastrointestinal conditions at § 876.5960; Digital therapy devices to reduce sleep disturbance for psychiatric conditions at § 882.5705; and Computerized behavioral therapy device for the treatment of fibromyalgia symptoms to be codified at § 882.5804. While we do support expanding reimbursement for additional FDA cleared or approved PDTs, we encourage CMS to consider establishing additional G codes to help establish more accurate pricing. For example, CMS could establish distinct G codes based on FDA classification.

CTA is encouraged by CMS' embrace of digital health tools like PDTs to clinically proven interventions for those with chronic conditions. We look forward to continuing to work with the agency to ensure continued access to care.

Comment Solicitation on Payment Policy for Software as a Service (SaaS)

CTA commends CMS for recognizing that the current PE methodology does not accurately account for innovative health software technologies like artificial intelligence (AI). As White House Office of Science and Technology Policy Director Michael Kratsios said "AI technology is already enhancing the digital revolution in sectors such as health care and agriculture, and further enabling new industries such as robotics, drones, and self-driving vehicles." Unfortunately, AI adoption in health care has been hampered by lack of predictable reimbursement policies. CMS has long acknowledged this issue and has yet to propose updated methodology or undertake work to address the issue. To date, FDA has approved more than 1200 AI-enabled medical devices.[11] It is past time to establish new policies that will ensure Medicare beneficiaries have access to innovative technology tools that are medically reasonable, necessary and demonstrably improve care.

Ultimately, CMS must move away from time-based reimbursement codes that incentivize inefficient clinician workflows. CTA supports recent steps HHS has taken to support value-based payment systems as we believe this will be crucial to AI and other software-based tools reaching their full potential and utilization in the Medicare program. When constructing such a payment system, CMS should explore using existing data on performance-based contracting arrangements that are collected by entities such as Group Purchasing Organizations like CTA member company Premier Inc.

CMS specifically asks for examples of how AI is being used to address chronic disease currently. Please find examples from CTA member companies below:

- **Curai Health** deploys machine learning into clinical workflows to extend clinicians' abilities to care for their patients, with a focus on chronic disease management, including hypertension, diabetes, and anxiety/depression. As a primary care provider, Curai also leverages AI to drive behavior change at scale, using advanced models to identify personal barriers to health goals and support consumers in overcoming obstacles with clinically informed protocols.

- **Hippocratic AI** leverages advanced machine learning to support chronic disease management, including hypertension and chronic kidney disease. Through AI-driven outreach, patients receive timely assessments, monitoring, and escalations to clinical teams as needed. This proactive approach helps improve patient outcomes by addressing both medical and social determinants of health.

- AI and ML are also being integrated into traditional medical devices like continuous glucose monitors (CGMs) to help Americans better manage their health, like the CGM systems developed by **Dexcom**. These systems, including the first over-the-counter CGM, utilize generative AI to deliver personalized,

[11] https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-enabled-medical-devices

consumer-centered care. By incorporating advanced AI technologies, Dexcom's CGMs empower millions of Americans—both with and without diabetes—to make more informed health choices, track their glucose levels in real time, and create lasting lifestyle changes that improve their overall well-being.

- **Verily Lightpath** is designed to be a proactive, personalized, dynamic and responsive chronic care platform, which is fueled by continuous data integration and AI. Lightpath pairs health coaches and an advanced licensed clinical team including endocrinologists, pharmacists, primary care physicians, nurses and registered dietitians, through an affiliated medical group. This allows Lightpath to serve a variety of acuity levels within a single solution based on member need. Lightpath's care modules and pathways are dynamic and personalized and use AI as a self-learning system. The intent is to help members achieve their goals by driving behavior change through rapid feedback loops. This means Lightpath can help members overcome barriers, either in partnership with their current providers, or by working with our advanced clinical care teams.

Prevention and Management of Chronic Disease – Request for Information

Within this request for information (RFI), CMS is keying in on an important issue – Medicare generally does not provide reimbursement for "wellness" tools. However, with the advancement in technology and the growth of FDA cleared or approved software functions being incorporated into consumer tools like consumer wearables, the line between wellness product and medical device are being blurred. Examples of CTA members leading consumer wearable innovation include:

- **Samsung** has been a key innovator in this space, releasing the first FDA-cleared obstructive sleep apnea risk detection feature for consumer wearables. By leveraging photoplethysmography (PPG) technology, Samsung's Galaxy Watch can identify breathing interruptions during sleep. With nearly 80% of sleep apnea cases going undetected, such widespread consumer-grade devices with advanced technology have the potential to improve millions of lives and reduce the clinical burdens associated with chronic conditions.

- **Google** is a leading innovator in the consumer wearables space through its Pixel Watch and Fitbit devices, which are designed to provide comprehensive health and wellness insights. Leveraging advanced sensor technology, Fitbit devices offer continuous heart rate tracking, detailed sleep stage analysis, and stress management tools. For example, the Fitbit Sense 2 includes an Electrodermal Activity (EDA) sensor to detect electrodermal activity responses, which may indicate stress. The Google Pixel Watch, building on Fitbit's expertise, integrates seamlessly with Android, offering enhanced connectivity and the precision of Google's health algorithms. A key differentiating feature is the deep integration of Google's AI and machine learning capabilities, which power personalized insights and health recommendations, going beyond basic tracking to provide actionable guidance for improving overall well-being. This comprehensive ecosystem helps users understand their health holistically, promoting proactive lifestyle management and early detection of potential issues. These offerings integrate with Google's Health Connect, which is a platform designed to help Android users securely store non-clinical health and fitness data on their phones and easily share it with their preferred apps. Health Connect now supports Personal Health Records (PHR), including new clinical categories like problems & conditions, medications, allergies, immunizations, and lab results, accessible through new Android Health APIs.

- **Oura Ring** supports chronic disease management by empowering users and their care teams with objective physiological monitoring combined with behavioral insight, enabling proactive care that is scalable, cost-effective, and patient-centered. Oura Ring provides a convenient, comfortable, and accurate way to track health data 24/7, with battery life of up to 8 days. It tracks heart rate and heart rate variability, respiratory rate, skin temperature trends, and other biometrics that can signal cardiovascular risk, autonomic dysfunction, or infection or inflammation. Many chronic conditions are rooted in behavioral patterns—poor sleep, sedentary behavior, and stress. Oura Ring provides personalized, real-time feedback on sleep quality and patterns, activity, and recovery. While Oura Members with chronic diseases are able to self-monitor at home, they also bring their Oura data into

care conversations. Continuous engagement by patients and providers with Oura can help reverse underlying healthcare issues by encouraging sustained behavior change, ultimately reducing burden on health systems.

While there is a hardware component, the overall device itself would not meet requirements under the Durable Medical Equipment program, nor are software components separately reimbursed under the Fee Schedule, despite being FDA cleared/approved.

Further, there are more examples of wearable products that may be reimbursed by Medicare, but in limited use cases. For example, CGMs are reimbursed by Medicare, but only for Medicare beneficiaries with insulin-dependent diabetes or who have a history of problems with hypoglycemia; yet recent advancements in CGM technology have increased their potential benefit for those with non-insulin dependent Type 2 diabetes and even those with pre-diabetes.

While CMS may be constrained by statute in terms of what can be reimbursed under the Fee Schedule, CMS should consider new pilots and demonstration projects under the Center for Medicare and Medicaid Innovation (CMMI) that would study and potentially make recommendations for coverage for health products that are generally considered "wellness" products but may have clinically validated functions for certain populations – like CGMs for those with prediabetes.

Remote Patient Monitoring

CTA supports CMS' proposal to adopt new CPT codes 99XX4, 98XX5, and 98XX6 to support reimbursement of remote physiological monitoring and remote therapeutic monitoring with 2 – 15 days of data collection in a 30-day period. While RPM and RTM are especially helpful for management of chronic conditions, they also are helpful in certain scenarios for management of acute conditions as well – for example, post-hospital discharge. However, CTA does have concerns with CMS' proposal to value the new supply codes the same as existing RPM and RTM codes that require 16 – 30 days of data collection. By having two distinct time-based codes (i.e., 2-15 days of data and 16 or more days of data), CMS can more accurately pay for the actual use of equipment, track utilization, and ensure program integrity.

CTA is concerned with CMS' statement that using OPPS cost data to value CPT RPM codes 99XX4 and 99454 and CPT RTM codes 98XX5 and 98977 may be more accurate than the PE inputs recommended by the RUC. CMS should clarify its plans to modernize the practice expense calculation to improve practice expense for codes like 99454, and that the use of OPPS data is an interim measure until that work is complete. We also request that the payment methodology set for CY2026 remain static (not updated with cost statistics) using the CY2026 data until such time as CMS is able to more meaningfully reform and modernize the calculation of practice expense for codes like 99454. In the meantime, instead of using CY2025 OPPS data, we request that CMS use the Total Geometric Mean for CY 2026 as recently released in the OPPS proposed rule to calculate the PE RVU under this new methodology since that is the most updated available data.

Medicare Diabetes Prevention Program

CTA has, for many years, urged CMS to allow for virtual suppliers of the Medicare Diabetes Prevention Program (MDPP); therefore, we are encouraged to see the proposal to test the inclusion of an asynchronous delivery modality and allow MDPP suppliers to deliver the Set of MDPP services online through December 31, 2029. Before finalizing, we encourage CMS to make some adjustments, including:

- CMS should limit eligible virtual suppliers to organizations with "Full" or "Full Plus" CDC recognition status. This would expand access while ensuring only high-quality virtual suppliers are eligible to participate.

- CMS should establish a fair pricing structure for online providers, which could include:
    - **Outcomes-based reimbursement vs. completion-based reimbursement:** CMS could base reimbursement on weight-loss outcomes vs. whether or not a beneficiary has completed the program.

    - **Virtual supplier-specific reimbursement**: CMS could re-weight payments to account for virtual suppliers that furnish connected weight scales to MDPP beneficiaries.
    - **Payment parity**: G9886 (In Person) and G9887 (Distance) are both compensated at $25. G9871 should be compensated at the same rate and allow virtual MDPP suppliers the opportunity to receive the same payment amount as suppliers furnishing services in-person.

- CMS should expand and align weight collection requirements for asynchronous, online modalities to align with CDC DPRM standards. We recommend CMS align with CDC DPRP standards that use the "first and last recorded weights during the Core and Core Maintenance phases" to determine starting and final weight / weight loss during the member's participation in the program.

- In order to increase participation in MDPP, CMS should update Medicare.gov and other publicly facing beneficiary documents and websites to promote timely access to new virtual MDPP modalities.

- CMS should not require live lifestyle coaching interactions in order to receive payment for asynchronous virtual delivery of MDPP. Virtual providers cannot control whether or not a beneficiary chooses to respond or engage with a coach. Having availability and offering coaching should satisfy this requirement.

Conclusion

Digital health is key to achieving the Administration's Make America Healthy Again goals of chronic disease prevention, management and treatment, as well as increasing access and decreasing unnecessary costs in the health care system. We look forward to continuing to work with CMS to ensure all Medicare beneficiaries have access to innovative new technology.

Sincerely,

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