



June 11, 2025

Administrator Mehmet Oz
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

**RE: ATA Action Response to Centers for Medicare and Medicaid Request for Information
Information Health Technology Ecosystem (CMS-0042-NC)**

Dear Administrator Oz,

On behalf of ATA Action, we are pleased to offer the below comments in response to the Centers for Medicare and Medicaid (“CMS” or the “Agency”) request for information with the goal of removing unnecessary barriers to digital health access and promoting health care innovation.

ATA Action, the American Telemedicine Association’s affiliated trade association, is focused on ensuring all individuals have permanent access to digital health products and services across the care continuum. ATA Action supports the enactment of state and federal digital health coverage and appropriate payment policies to secure digital health access for all Americans, including those in rural and underserved communities. ATA Action recognizes that digital health products and services have the potential to truly transform the health care delivery system – by improving patient outcomes, enhancing safety and effectiveness of care, addressing health disparities, and reducing costs – if only allowed to flourish.

We are excited to share with you that ATA Action acquired the Digital Therapeutics Alliance (DTA) on March 31, 2025. The DTA was the leading international nonprofit trade organization focused on expanding access to digital therapeutics. Through this acquisition, ATA Action expanded its advocacy efforts to support digital health tools such as digital therapeutics, digital diagnostics, remote monitoring devices, and artificial intelligence by forming the Advancing Digital Health Coalition.

As a preliminary matter, we recognize the importance of the Agency’s deregulation efforts and encourage the removal of unnecessary digital health barriers while prioritizing regulations and guidance that encourage innovation. We also thank the Agency for its ongoing efforts to increase beneficiary access to effective digital capabilities. As further discussed below, we believe that a combination of deregulation and targeted guidance is necessary to promote health care innovation and digital health adoption.

**1. Collaborate with Congress to ensure continuation of Medicare telehealth
flexibilities**

At the beginning of 2025, Congress extended the following flexibilities through September 30, 2025:



- Waiving originating and geographic sites
- Audio-only coverage
- Expansion of Medicare telehealth list to include therapists
- Allowing Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) to serve as distant sites
- Temporary waiver of telemental health in-person requirement
- Continuation of Acute Hospital Care at Home Program

ATA Action kindly requests CMS to work alongside Congress to make permanent or extend these flexibilities for as long as possible before the end of September. Following an extension, it is critical that CMS releases aligning regulatory guidance as soon as possible to reduce confusion amongst the industry.

2. Make Certain Telehealth Flexibilities Permanent

a. Permanently Allow Telehealth Providers to Use Practice Address (Not Personal) for Billing and Enrollment

Prior to the COVID-19 pandemic, CMS policy on a telehealth provider's distant site address was not clear. When discussing the distant site, the Medicare Claims Processing Manual, Chapter 12, Section 190.6.1 Submission of Telehealth Claims for Distant Site Practitioners and the MLN Booklet on Telehealth Services simply state that claims for telehealth services are submitted to the contractors that process claims for the performing practitioner's service area. However, "service area" was never explicitly defined. In response to requests for clarification on this topic, CMS responded that practitioners should enter "where they typically practice" on line 32 of the HCFA 1500 claim form the address and that should be their home address if that is the location of typical practice. Throughout the pandemic, CMS allowed providers across the country who render telehealth services to list a practice address rather than their home address on their Medicare enrollment and billing forms. **We applaud CMS for extending this flexibility through CY2025 and strongly urge the Agency to make it permanent.** As we have pointed out in previous comments to CMS, workplace violence is a leading cause of job dissatisfaction among providers, particularly nurses. Workplace violence incidents can lead to increased costs due to staff turnover, costs for treating injuries, and staff time away from work. One of ATA Action's top priorities is to ensure provider safety and security. A provider should not be required to list their home address on any Medicare form, especially one that will be published on a public facing platform. Additionally, if this flexibility were to revert back to the pre-pandemic policy there would be a tremendous influx of Medicare billing and enrollment forms that CMS may not have the resources or capacity to keep up with internally.

b. Make Removal of Certain Telehealth Frequency Limits Permanent

ATA Action seeks to remove arbitrary barriers that limit access to care such as telehealth frequency limitations, in-person, geographic proximity, or brick and mortar requirements. In last year's Medicare Physician Fee Schedule (PFS), CMS removed the telehealth frequency limitations for subsequent hospital inpatient/observation care (99231, 99232, 99233),



subsequent nursing facility visits (99307, 99308, 99309, 99310), and critical care consultation services (G0508, G0509), until the end of CY2025. We appreciate this extension but urge CMS to permanently remove these telehealth frequency limitations moving forward.

c. Make Direct Virtual Supervision via Telehealth Permanent For All Scenarios

ATA Action applauds CMS for extending the COVID-19 PHE definition of direct supervision, which allows a supervising provider to be considered “immediately available” through virtual presence, through the end of CY2025. We are also pleased that CMS made this definition permanent for a subset of low-risk, incident-to services typically performed entirely by auxiliary personnel. While these are steps in the right direction, ATA Action continues to urge CMS to make direct supervision via telehealth a permanent option across all scenarios. We recommend that CMS collaborate with stakeholders to identify the most appropriate services for this supervision method, with patient safety as the paramount concern. Providers should have the autonomy to determine when direct supervision via telehealth is clinically appropriate and consistent with the standard of care, and CMS should avoid imposing additional requirements for virtual supervision that do not apply to in-person supervision.

Further, we support CMS’s decision to continue to allow teaching physicians to have a virtual presence during a virtual, three-way telehealth visit, with the patient, resident, and teaching physician in separate locations through CY2025. Although, ATA Action asks CMS to permanently allow direct virtual supervision for teaching physicians during both virtual visits and non-virtual visits, specifically allowing in-person resident and patient visits to be supervised by a teaching provider who joins virtually.

3. Address Outdated Medicaid In-State Location Requirements

Long-standing Medicaid policies in some states require their licensed providers to have an in-state service address to be considered an in-state provider, despite the fact that the provider holds a valid in-state license. Medicaid agencies did not anticipate virtual care at scale, delivered by providers licensed in their state but practicing across state lines when many of the enrollment requirements were instituted. Consequently, provider entities are either denied enrollment by state Medicaid agencies or are required to adhere to onerous and unnecessary out-of-state provider enrollment rules.

Outdated structural deficiencies have mandated that a provider group service address be used, which is typically where the group is headquartered. While CMS and state Medicaid programs have already updated requirements to allow distant site providers to furnish telehealth services, they have not yet fixed brick-and-mortar service address requirements. For providers offering services via telehealth, the distant site -- where the provider is located -- is not necessarily the same as the service address. This dynamic is leading to confusion among state Medicaid agencies. Policies have not kept pace with technology. As a result, vulnerable patient populations miss out on the full scope of high-quality medical and specialty care that telehealth can enable, including easier access to affordable health care services delivered by wider and more robust provider networks. **States should ensure that so long as a health care provider**



is appropriately licensed in a state, by that state's licensing Board, they should not be treated as an out-of-state provider.

Further, telehealth providers should not be required to hold a license in the state where their provider group is located because the patient is not being seen at that service address. Providers encounter significant administrative burdens when delivering care to Medicaid beneficiaries. As states look to expand access and account for the significant expansion of telehealth services, state programs need guidance on how best to modernize and streamline provider enrollment while addressing the administrative burdens associated with furnishing telehealth services in Medicaid. As CMS looks to expand access to high quality telehealth, **we ask for your support in updating prior telehealth guidance to states to better communicate provider enrollment requirements under current law, identify where states have authority to modernize, and provide recommendations that would harmonize enrollment requirements, reduce regulatory and administrative burden, and enhance Medicaid provider networks.**

4. Promote Digital Health Innovation Through Appropriate Reimbursement

The absence of clear reimbursement pathways for prescription digital therapeutics (PDTs) and other digital health products and services hinders innovation and adoption. We strongly encourage CMS to eliminate or revise unnecessary limitations and requirements relevant to reimbursement for digital health, considering the unique qualities of the products and services and how they are delivered. A few specific examples are provided below for your consideration.

a. Remove Unnecessary Virtual Care Limitations on Medicare Diabetes Prevention Program

The Medicare Diabetes Prevention Program (MDPP) is a Medicare-covered initiative designed to help prevent or delay the onset of Type 2 diabetes in individuals at high risk. MDPP suppliers are organizations or entities that are approved by CMS to deliver the Diabetes Prevention Program, which typically involves group-based coaching, education, and support in areas such as nutrition, physical activity, and weight management.

Unfortunately, when expanded in 2018, CMS restricted access to MDPP benefits solely to in-person programs and elected not to authorize enrollment of CDC-recognized virtual DPP supplier organizations (in contrast to CDC policy, which recognizes virtual programs and providers). CMS should modernize the MDPP and align with the CDC National Diabetes Prevention Program and allow virtual suppliers to furnish critical diabetes prevention services to Medicare beneficiaries. Modernizing MDPP would make significant progress toward preventing the onset of Type 2 diabetes in Medicare beneficiaries with prediabetes. By helping individuals make lifestyle changes that reduce their risk of developing diabetes, the program has the potential to save the federal government and taxpayers billions of dollars.

We urge CMS to expand this program and allow all CDC-recognized delivery modalities, including virtual diabetes prevention platforms and suppliers, to participate in the Medicare Diabetes Prevention Program.



b. Withdraw Unduly Narrow Digital Mental Health Treatment Device Requirements

We applaud the Agency's decision to create the new G codes which apply to certain digital mental health treatments (DMHTs) and **encourage CMS to remove unnecessary limitations on G0552 (DMHT device code).**

Importantly, economic studies have shown the potential for DMHT devices to decrease overall medical spending.¹ Notably, the Peterson Health Technology Institute, an independent non-profit organization, recently found that using PDTs with conventional care in treating anxiety and depression, resulted in an estimated \$643 per user decrease in annual healthcare spending.² With respect to specific DMHT devices, studies have found the following:

- Treatment of substance use disorder patients using reSET for 6 months demonstrated 50% reduction in hospital encounters and >\$3,500 savings per patient.³
- A retrospective study of claims data showed a \$2,150 per patient savings due to changes in facility and clinical encounters while using reSET-O during a six-month period.⁴
- In a yearlong pilot study of using Freespira to treat PTSD anxiety, overall medical costs were reduced by 35% from \$548 to \$358 PMPM (per member per month).⁵
- A large real-world, retrospective cohort study found use of SleepioRx among 11,027 US adults was associated with a statistically significant annual healthcare cost saving of \$2,083 per person—a 42% reduction from baseline—compared with matched controls who

¹ Youn SJ, Jaso B, Eyllon M, Sah P, Hoyler G, Barnes JB, Jarama K, Murillo L, O'Dea H, Orth L, Pennine M, Rogers E, Welch G, Nordberg SS. Leveraging Implementation Science to Integrate Digital Mental Health Interventions as part of Routine Care in a Practice Research Network available at: <https://pubmed.ncbi.nlm.nih.gov/37615809/>

² Peterson Health Technology Institute, Virtual Solutions for Depression and Anxiety, May 2025 available at: <https://phti.org/assessment/virtual-solutions-anxiety-depression/>

³ Shah, Neel; Velez, Fulton F.; Colman, Samuel; Kauffman, Laura; Ruetsch, Charles; Anastassopoulos, Kathryn; et al. (2022). Real-world reductions in healthcare resource utilization over 6 months in patients with substance use disorders treated with a prescription digital therapeutic. Adis Journals. Media available at: <https://doi.org/10.6084/m9.figshare.19950266.v3>

⁴ Velez, F. F., Colman, S., Kauffman, L., Ruetsch, C., & Anastassopoulos, K. (2020). Real-world reduction in healthcare resource utilization following treatment of opioid use disorder with reSET-O, a novel prescription digital therapeutic. *Expert Review of Pharmacoeconomics & Outcomes Research*, 21(1), 69–76 available at: <https://doi.org/10.1080/14737167.2021.1840357>

⁵ Kaplan A, Mannarino AP, Nickell PV. Evaluating the Impact of Freespira on Panic Disorder Patients' Health Outcomes and Healthcare Costs within the Allegheny Health Network. *Appl Psychophysiol Biofeedback*. 2020 Sep;45(3):175-181. doi: 10.1007/s10484-020-09465-0. PMID: 32342249 available at: <https://pubmed.ncbi.nlm.nih.gov/32342249/>



received standard care; reductions were observed in both pharmacy (46%) and medical (15%) claim costs.⁶

- Treatment of chronic insomnia with Somryst showed a two-year cost reduction of \$2059 per patient.⁷ When costs were compared between patients treated with the digital therapeutic and a matched cohort on sleep medications, the savings increased exponentially; six treatments with Somryst were required to avoid a hospitalization or emergency department visit.⁸

There are a variety of DMHT devices currently available in the U.S. that are specific to a mental health disorder (e.g. major depressive disorder and PTSD) while others target physical conditions by addressing the mental health component (e.g. chronic pain, anxiety and irritable bowel syndrome) but only some of these digital therapeutics meet G0552 requirements. **We encourage CMS to expand the G0552 code to include devices that treat physical conditions with a mental health component, as well as many others that do not meet current device classification requirements.**

As we noted in our response to the CY 2025 proposed Medicare Physician Fee Schedule, we believe requiring clearance under 21 CFR 882.5801 is unduly narrow. This regulation, originally intended as a catch-all for computerized behavioral therapy devices, does not encompass the current diversity of products that could be used as DMHT devices. As a result of further innovation, FDA has since established additional regulatory device classifications tailored to different device types or indications for use and their respective patient risks and regulatory needs. Many of these new device classifications may be appropriately furnished “incident to” the services of a qualified health practitioner. These classifications include:

- Computerized Behavioral Therapy for the Treatment of Fibromyalgia Symptoms (21 CFR 885.5804)
- Computerized Behavioral Therapy Device for Treating Symptoms of Gastrointestinal Conditions (21 CFR 879.5960) Digital Therapeutic Software for Attention Deficit Hyperactivity Disorder (21 CFR 882.5803)
- Digital Therapy Device to Reduce Sleep Disturbance for Psychiatric Conditions (e.g., nightmare disorder, PTSD, etc.) (21 CFR 882.5705)

⁶ Miller, C., Bradley, D., Hall, S., Hayes, H., Chowdhury, S., & Sampson, C. (2025). Health care cost savings with digital cognitive behavioral therapy for insomnia (SleepioRx), a real-world evaluation at a population scale. *Journal of Managed Care + Specialty Pharmacy*, 31(3-a), S46.

⁷ Forma F, Knight TG, Thorndike FP, Xiong X, Baik R, Velez FF, Maricich YA, Malone DC. Real-World Evaluation of Clinical Response and Long-Term Healthcare Resource Utilization Patterns Following Treatment with a Digital Therapeutic for Chronic Insomnia. *Clinicoecon Outcomes Res.* 2022 Aug 10;14:537-546. doi: 10.2147/CEOR.S368780. PMID: 35983014; PMCID: PMC9379126.

⁸ Forma, F et al. EE364 Reduced Healthcare Resource Use in Patients With Chronic Insomnia After Treatment With a Digital Therapeutic With 2-Year Follow-Up Value in Health, Volume 25, Issue 12, S126 available at: [https://www.valueinhealthjournal.com/article/S1098-3015\(22\)02814-5/fulltext](https://www.valueinhealthjournal.com/article/S1098-3015(22)02814-5/fulltext)



As further innovation happens, FDA is likely to create new device categories tailored to new DMHT device types as technology and treatment modalities evolve. Limiting coding and payment to devices cleared under one specific regulation unnecessarily restricts access to these important devices and does not align with the Agency's goal of expanding access to these valuable behavioral health treatments.

c. Eliminate Unnecessary Limitations and Uncertainty Regarding Existing Benefit Categories for Digital Health Solutions

To promote innovation in health care, we strongly encourage CMS to continue reviewing coverage pathways and making modifications to coverage criteria and current reimbursement frameworks to accommodate the innovative and diverse characteristics of digital health solutions. While we recognize CMS is focused on de-regulation efforts, we note that lack of clarity regarding coverage of digital health products by Medicare and Medicaid can also stifle innovation due to the uncertainty it creates for investors and innovators and ask that CMS prioritize guidance in this area. For example, providing specific guidance regarding Medicare Advantage and Medicaid coverage of digital therapeutics and other digital health solutions.

A broad range of digital therapeutics are available without Medicare coverage for a variety of indications including diabetes, musculoskeletal, respiratory, neurological, women's health, irritable bowel syndrome, and more will continue to enter the U.S. market. We encourage the Agency to build upon its recent progress by expanding the types of digital health products that are covered when provided "incident to" a physician's services, and continuing to approve medical equipment coverage for innovative products beyond MedRhythm's InTandem and AppliedVR's RelieVRx.

d. Eliminate Arbitrary Restrictions on Remote Monitoring and Ensure Fair Payment

A critical issue for the remote monitoring (RM) industry has been the arbitrary 16-day data requirement for remote physiologic and remote therapeutic monitoring devices over a 30-day period. This restriction lacks clinical relevance, and industry feedback indicates that in some cases, 16 days of data can lead to inaccurate or misleading diagnoses and treatments. ATA Action has long urged CMS to address this limitation. In late 2024, the American Medical Association's CPT panel accepted a proposal to create two distinct device supply codes: one for 2-15 days of monitoring and another for 16 or more days. ATA Action strongly urges CMS to adopt these new codes and establish fair reimbursement rates.

Since the introduction of remote physiologic monitoring codes in 2019, average Medicare reimbursement for these services has decreased by between 7% and 28%, outpacing overall reductions in the Physician Fee Schedule conversion factor. This trend has led to significant challenges for providers, particularly those in rural areas, as geographic adjustments intended to align payments with local costs of living further reduce reimbursement. If CMS continues to decrease reimbursement rates, hospital systems and providers will not continue to utilize these critical technologies, and many RM organizations will shut down.

e. Address Existing Benefit Requirement for Transitional Coverage of Emerging Technologies

We applaud the efforts made by CMS to promote Medicare reimbursement of emerging technologies. Under the TCET final rule, Medicare reimbursement is limited to technologies that qualify under an existing benefit category. While this may allow for reimbursement of some products, there are many digital health products that do not fit into an existing benefit category. For example, as discussed above only a narrow range of SaMD PDTs are covered under the new DMHT G codes, and a limited number of therapeutic products with a device component have been given HCPCS codes due to the Agency's historic position that PDTs are not covered as durable medical equipment.

We encourage CMS to consider alternative requirements to an existing benefit category, or the establishment of a temporary code under existing benefit categories that allows for reimbursement for a limited time (e.g. 1-2 years) to allow CMS to further evaluate the technology and to the extent appropriate and feasible develop new codes and payment policies for permanent Medicare coverage.

We note that other countries have adopted a preliminary coverage period to encourage innovation while allowing for the government to evaluate the product for permanent coverage and establish pricing. For example, Germany's DiGA program allows for one year of coverage while manufacturers build their case for permanent coverage.⁹

5. Adopt Reasonable Durable Medical Equipment Requirements for Software Products

We strongly encourage CMS to revise its DME regulations and standards to address the needs of digital health companies. In particular, we suggest the Agency:

- Revise the accreditation standards to account for the unique qualities of digital health products;
- Address how digital health products can be covered under DME coverage policies;
- Align DME payment policy to account for the duration of digital health products in treatment plans with the understanding that transfer of title is not always warranted; and
- Establish criteria within the statutory requirements for DME that would enable appropriate digital health products (e.g. PDTs) to qualify (e.g. eliminating non-statutory limitations such as the ability to be rented or used by multiple patients).

⁹ More information about the DiGA program available at:
https://www.bfarm.de/EN/Medical-devices/Tasks/DiGA-and-DiPA/Digital-Health-Applications/_node.html



6. Address Unnecessary Contractor Obstacles

We suggest that the Agency's deregulation efforts include removing unnecessary hurdles created by MACs for digital health product reimbursement providing guidance to auditors to avoid the imposition of criteria and standards in excess of what is required by existing law, regulations, and guidance.

a. PTAN Numbers

Unique numbers like National Provider Identifiers (NPI) and Provider Transaction Access Numbers (PTAN) are used to verify providers and suppliers ("Providers") participating in Medicare. HIPAA transaction rules require that all Providers have a unique NPI that is utilized for all transactions including billing government payors, and as a result all Providers may go through the process of obtaining an NPI number.

When a provider utilizes tools made available by a local Medicare administrative contractor (MAC), a PTAN is also required. While this number is described as a "Medicare specific" requirement, **in practice lack of a PTAN limits a Provider's ability to participate in Medicaid and impacts the ability of managed care organizations to contract for the Provider's products/services.**

Suppliers of innovative products that do not fit squarely into existing benefit categories are unable to obtain PTAN numbers when the products and services they provide are not payable by Medicare. Specifically, we are aware of digital health product manufacturers who have obtained NPI numbers and are DMEPOS accredited whose requests for PTAN numbers have been denied.

We suggest that the limitations placed on obtaining PTANs be removed in the following scenarios:

- Providers with NPI numbers that are billing third party payors utilizing codes that are not payable by Medicare; and
- Providers that are DMEPOS accredited.

b. MAC G0552 Guidance

We believe in creating the G0552 device code the Agency indicated its intent to pay for devices meeting the requirements articulated in the CY 2025 Physician Fee Schedule (PFS). However, it has been brought to our attention that some MACs are questioning the necessity of payment for G0552 devices rather than establishing rates. With this in mind, we would like to reiterate our recommendations for MAC guidance with respect to the new DMHT codes by taking the following steps to ensure timely and accurate claims review, processing, and payment for G0552 devices:



- Provide guidance to the MACs regarding covered G0552 devices and considerations for valuation; and
- Instruct the MACs to develop a timely and transparent process for G0552 device claims review.

As we noted in our comments to the proposed CY 2025 PFS, manufacturers of DMHT devices incur significant research, development, and regulatory costs, which companies consider in establishing pricing to health care professionals for G0552 devices. As a result, we ask that these factors be taken into account by the MACs when establishing G0552 device rates.

7. Safe Harbor Proposal to Support Access-Enhancing Technologies

ATA Action urges the Department of Health and Human Services and the Centers for Medicare & Medicaid Services to consider modernizing the Anti-Kickback Statute (AKS) to better reflect today's healthcare delivery environment. Originally enacted in 1972, the AKS is a critical tool in preventing fraud and abuse, yet its broad and outdated language inadvertently hinders legitimate, technology-driven solutions that improve patient access and care efficiency. Online health information service providers—such as appointment booking platforms—serve a vital role in helping patients connect with appropriate providers, yet under current law, these services may fall into legal ambiguity due to perceived AKS violations.

To address this, we support the creation of a new safe harbor that would clarify permissible arrangements between providers and digital health platforms, provided appropriate safeguards are in place. ATA Action, alongside more than 30 organizations in the Health ACCESS Alliance, supports the bipartisan Health ACCESS Act, which would establish these guidelines. Such regulatory clarity will empower health systems, clinics, and independent providers to reduce no-show rates, optimize provider time, and offer timely, lower-cost care to patients—including those covered by federal programs—without risking legal repercussions. We respectfully request that HHS-OIG use its authority under Section 1128B(b) of the Social Security Act to enact a safe harbor reflecting these principles and enabling a more modern, equitable, and efficient healthcare system.

Thank you for the opportunity to respond to this important request for information. If you have any questions or would like to discuss further, please email me at kzebley@ataaction.org. We look forward to working with you to ensure all regulations and laws allow for continued innovation and do not impede access to care.

Kind regards,

A handwritten signature in black ink, appearing to read "Kyle Zebley", is written over a faint, light gray circular watermark that contains the text "ATA ACTION".

Kyle Zebley
Executive Director
ATA Action