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September 5, 2025

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted electronically via regulations.gov

Re: Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program (CMS-1832-P)

Dear Administrator Oz:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to the "Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program" (Proposed Rule), issued on July 16, 2025.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

AMCP and its members applaud CMS for continuing to expand patient access to innovative digital therapeutics that improve chronic disease management. This includes prescription digital therapeutics (PDTs), digital therapeutics that have been determined by the FDA to require a prescription from a qualified health care professional. Last year, the agency created a pathway for practitioners to bill for certain digital therapeutics that are indicated to treat mental health conditions under Medicare Part B. Starting this year, practitioners may bill for digital mental health treatment (DMHT) devices furnished incident to professional behavioral health services used in conjunction with ongoing behavioral health care treatment. CMS established three new Healthcare Common Procedure Coding System (HCPCS) G-codes for DMHT devices, which relate to the supply of a product, initial education and onboarding, and monthly treatment management services. Coverage was initially limited to digital therapeutics that were cleared under the 510(k) pathway or granted De Novo authorization and classified by the Food and

Drug Administration (FDA) as a "Computerized behavioral therapy device for psychiatric disorders" under 21 CFR 882.5801. When the DMHT pathway was proposed in the 2025 fee schedule, AMCP and other stakeholders expressed concern that this definition would exclude several PDTs that are indicated to treat or manage mental health conditions classified under separate FDA codes. The DMHT pathway also categorically excludes PDTs that could help millions of Medicare beneficiaries manage chronic conditions like diabetes, irritable bowel syndrome, and chronic pain.

In the Proposed Rule, CMS proposes to expand its payment policies for HCPCS codes G0552, G0553, and G0554 to also make payment for DMHT devices cleared under section 510(k) of the Federal Food, Drug & Cosmetic Act or granted De Novo authorization by FDA and in each instance classified at § 882.5803 Digital therapy device for Attention Deficit Hyperactivity Disorder (ADHD). AMCP applauds CMS for recognizing the potential that additional digital therapeutic devices may offer in increasing patients' access to treatment for behavioral health conditions, including ADHD. The CDC estimates that roughly 6% of U.S. adults aged 18 and older and 11.4% of U.S. children have received an ADHD diagnosis.[1,2] AMCP agrees with the agency's intent to limit payment eligibility to digital therapeutics that have been cleared or authorized by FDA, to ensure that DMHT devices are safe and beneficial for patients.

Nonetheless, AMCP is concerned that CMS' proposal to limit coverage only to products cleared under 21 CFR 882.5801 and 21 CFR 882.5803 is unnecessarily burdensome and may restrict patients' access to dozens of additional DMHTs that are indicated to treat mental disorders but were cleared under a different FDA pathway. Although FDA clearance, approval, or De Novo authorization for a product signifies its safety and efficacy, CMS' proposed guidelines disregard the rigorous, evidence-based review process that FDA utilizes in clearing devices classified outside of 21 CFR 882.5801 and 21 CFR 882.5803 for use by the American public.

In response to the CY 2025 physician fee schedule proposed rule, AMCP estimated that five existing products had been cleared under the 21 CFR 882.5801 pathway: ReSET and ReSET-O, indicated to treat substance use disorders and opioid use disorders, respectively; Somryst, indicated to treat chronic insomnia; Rejoyn, indicated to treat major depressive disorder; and Mamalift Plus, indicated to treat postpartum depression symptoms.[3] Under the CY 2026 proposed fee schedule, AMCP estimates that the expanded payment policy would accommodate one additional DMHT device cleared under the 21 CFR 882.5803 pathway, EndeavorRx. Unfortunately, Akili Interactive, the manufacturer of EndeavorRx, was forced to shift to a nonprescription model for its digital therapeutic in 2023, while also letting go of roughly 40% of its workforce due to financial constraints and a lack of uptake.[4] Without an existing public payer reimbursement framework, PDT developers are unable to sustain research and

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[1] "Attention-Deficit/Hyperactivity Disorder Diagnosis, Treatment, and Telehealth Use in Adults — National Center for Health Statistics Rapid Surveys System, United States, October–November 2023." https://www.cdc.gov/mmwr/volumes/73/wr/mm7340a1.htm#:~:text=Discussion,used%20telehealth%20for%20ADHD%20services.

[2] "ADHD Prevalence Among U.S. Children and Adolescents in 2022: Diagnosis, Severity, Co-Occurring Disorders, and Treatment." https://pubmed.ncbi.nlm.nih.gov/38778436/

[3] https://www.amcp.org/sites/default/files/2024-09/AMCP_Comments_2025_Fee_Schedule.pdf

[4] "Akili to lay off 46% of its staff, explore strategic options amid sluggish sales" https://www.statnews.com/2024/04/30/akili-interactive-digital-therapeutics-firm-announce-layoffs-restructuring/

development into these innovative products. This follows the path of other PDT manufacturers such as Better Therapeutics and Pear Therapeutics, who each received FDA clearance for their products but were subsequently forced to shutter operations.[5] [6]

CMS anticipates that expanding payment policies for digital therapeutics will be an iterative process and recognizes that the platforms and technologies for digital therapeutics are rapidly evolving. AMCP appreciates CMS's willingness to accommodate interested parties' recommendations to make payment for FDA-authorized devices under other classifications. AMCP believes that CMS should use its authority to pay for any PDTs that meet the following conditions:

a) Intended to treat, manage, or diagnose a disease, disorder, condition, or injury by generating and delivering a medical intervention that has a demonstrable positive therapeutic impact on a patient's health;
b) Reviewed and cleared, approved, or authorized by the FDA;
c) Require a prescription from a qualified healthcare professional; and
d) Furnished incident to a professional health service in conjunction with ongoing treatment of a mental, physical, or neurological condition.

In the proposed rule, CMS requests feedback on the need to establish coding and payment policies for devices classified under the following FDA regulation sections: 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. AMCP encourages CMS to expand its coding framework to include devices regulated under § 876.5960, § 882.5705, and § 882.5804. Several existing digital therapeutic products fit within these frameworks and are well positioned to treat patients suffering from these chronic conditions. This includes:

- Mahana IBS, a prescription mobile application designed to deliver 3 months of gut-directed cognitive behavioral therapy to treat irritable bowel syndrome (IBS), cleared under § 876.5960 [7],
- Regulora, also cleared to treat IBS under § 876.5960, [8]
- NightWare, indicated to reduce sleep disturbance related to nightmares through vibrotactile feedback during sleep cycle, cleared under § 882.5705, [9] and

[5] "Pear Therapeutics sold for parts at $6 million auction." https://www.statnews.com/2023/05/19/pear-therapeutics-auction/
[6] "Digital diabetes app maker Better Therapeutics shutters operations, lays off staff." https://www.fiercebiotech.com/medtech/digital-diabetes-app-maker-better-therapeutics-shutters-operations-lays-staff
[7] "Real-world outcomes for a digital prescription mobile application for adults with irritable bowel syndrome." https://pubmed.ncbi.nlm.nih.gov/38689434/
[8] "What to Know About Regulora, the FDA-Cleared Digital Therapeutic for IBS." https://www.goodrx.com/conditions/irritable-bowel-syndrome/fda-clears-regulora-ibs?srsltid=AfmBOooIUrglHu1qLEzUAb9QWFC-xMSd_jWpBXMceusI-etPnNyUdJWF
[9] "DE NOVO CLASSIFICATION REQUEST FOR NIGHTWARE KIT (APPLE IPHONE, APPLE WATCH, APPLE IPHONE CHARGING CABLE, APPLE WATCH CHARGING CABLE)" https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN200033.pdf

- Stanza, indicated for the treatment of fibromyalgia symptoms in adult patients, cleared under § 882.5804. [10]

CMS states that Medicare FFS claims data for HCPCS codes G0552, G0553, and G0554 have remained low in volume since the codes were established in the CY 2025 PFS final rule, finding that the incident to pathway may not align with direct-to-consumer delivery and payment models that existed before the final rule was issued. AMCP agrees that these codes may not be appropriate for products that vary in terms of overhead costs, conditions treated, and the length of time for a course of therapy. Medicare Administrative Contractor pricing may also lead to variation in payment amounts, which could inhibit access in certain markets. CMS should work with PDT manufacturers and the Medicare Administrative Contractors to determine appropriate payment rates for DMHTs. This would also alleviate future coding challenges, should CMS decide to provide payment for devices regulated under § 876.5960, § 882.5705, and § 882.5804.

AMCP believes that there are dozens of additional PDTs well suited to combatting other chronic conditions, including diabetes, chronic lower back pain, urinary and fecal incontinence and stroke. Unfortunately, the prolonged timeline that novel technologies must face to receive Medicare coverage following FDA review significantly inhibits patient access to critical treatments.[11] On average, medical device manufacturers wait five years after FDA authorization to receive nationwide coverage, coding, and payment.[12] AMCP encourages the agency to continue to explore expedited coverage pathways for PDTs, in addition to or expanding upon the existing Transitional Coverage for Emerging Technologies program. AMCP also praises the White House and CMS for their commitment to "Make Health Tech Great Again," as the administration takes significant steps toward building a smarter, more secure, and more personalized healthcare experience for America's patients.[13]

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with CMS. If you have any questions regarding AMCP's comments or would like further information, please contact AMCP's Manager of Regulatory Affairs, Vicky Jucelin, at vjucelin@amcp.org or (571) 858-5320.

Sincerely,

Susan A. Cantrell, MHL, RPh, CAE
Chief Executive Officer

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[10] "FDA Authorizes Stanza to Treat Fibromyalgia Symptoms." https://swingtherapeutics.com/swing-therapeutics-fda-stanza-to-treat-fibromyalgia-symptoms/

[11] "Dr. Oz stresses need for faster Medicare coverage of new devices during confirmation hearing." https://www.medtechdive.com/news/dr-oz-tcet-medicare-coverage-medical-devices/742611/

[12] "The Need for Transitional Coverage for Emerging Technologies." https://healthpolicy.duke.edu/sites/default/files/2022-04/TCET%20Webinar_Slides%203.28.22.pdf

[13] " White House, Tech Leaders Commit to Create Patient-Centric Healthcare Ecosystem." https://www.cms.gov/newsroom/press-releases/white-house-tech-leaders-commit-create-patient-centric-healthcare-ecosystem