



June 16, 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: CMS-0042-NC

Dear Administrator Oz:

On behalf of the Academy of Managed Care Pharmacy (AMCP), thank you for the opportunity to respond to the request for information on the Health Technology Ecosystem [CMS-0042-NC] from Centers for Medicare & Medicaid Services (CMS). We appreciate CMS's leadership in advancing digital health innovation to improve patient care, support caregivers, and modernize the Medicare and Medicaid programs.

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.

Digital Health Products – Prescription Digital Therapeutics

As CMS explores strategies to increase the adoption of digital health tools, AMCP urges CMS to support broader coverage of prescription digital therapeutics (PDTs) under Medicare and Medicaid. PDTs represent an emerging class of software-based treatments that deliver clinically validated therapeutic benefits, either independently or in combination with other interventions.¹ These products can play a transformative role in improving access, especially for patients with behavioral health conditions or chronic diseases.

In 2022, CMS took an important step by establishing two HCPCS Level II A-codes for PDTs related to cognitive behavioral therapy and visual therapy. However, these codes are used to reimburse physicians and are not generally used to process pharmacy claims. Because many PDTs are patient-administered—similar to oral medications—enabling pharmacy benefit

¹ <https://www.amcp.org/sites/default/files/2024-12/PDT-Principles.pdf>

coverage would better reflect their use, support care integration, and reduce administrative burden.

More recently, the CY 2025 Medicare Physician Fee Schedule (PFS) established a coverage pathway for a subset of PDTs identified as digital mental health treatment devices (DMHTs). While this represents meaningful progress, the current policy is limited to devices furnished “incident to” professional behavioral health services as part of ongoing treatment. Based on our analysis, only approximately five FDA-cleared products would meet this standard, leaving many effective and FDA-authorized PDTs without a viable coverage pathway.

Although AMCP does not support mandating coverage of specific PDTs, CMS should broaden the coverage framework to allow managed care organizations (MCOs) the ability to cover any PDTs that have received FDA clearance or approval. This would accelerate adoption and ensure equitable access to these innovative therapies.

Conclusion

We commend CMS for its commitment to modernizing access to digital health tools and appreciate the opportunity to provide input. AMCP stands ready to collaborate with CMS on its efforts to expand access to prescription digital therapeutics and to ensure that Medicare and Medicaid beneficiaries benefit from the full range of clinically effective, digitally enabled therapies.

Should you have any questions or require additional information, please contact Vicky Jucelin, AMCP’s Manager of Regulatory Affairs, at vjucelin@amcp.org or (571) 858-5320.

Sincerely,



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