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September 9, 2024

Chiquita Brooks-LaSure
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 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program (CMS-1807-P)

Dear Administrator Brooks-LaSure:

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 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program" (Proposed Rule), issued on July 10, 2024.

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's proposal to authorize Medicare payment for digital therapeutics that can improve millions of Americans' mental and behavioral health outcomes. Medicare beneficiaries face a severe mental health provider shortage, which threatens their ability to access the care they need. Like the overall population, America's seniors experience significant mental and behavioral health concerns – about 20% of Americans aged 65 or older report experiencing anxiety or depression,[1] while nearly 1 million adults over 65 live with a substance use disorder.[2] The Department of Health and Human Services Office of Inspector General (OIG) found fewer than 5 active mental health providers per 1,000 enrollees in 20

[1] https://www.kff.org/mental-health/issue-brief/the-implications-of-covid-19-for-mental-health-and-substance-use/
[2] https://nida.nih.gov/publications/drugfacts/substance-use-in-older-adults-drugfacts

counties that serve roughly 130 million Medicare patients.[3] The provider shortage is particularly dire for traditional Medicare, where OIG found less than 3 active mental health providers per 1,000 enrollees.[4] The lack of active mental health providers may lead to longer wait times or increased transportation burden for beneficiaries and a more significant burden on the mental health providers who accept Medicare.

AMCP supports authorizing payment for digital mental health treatment devices (DMHTs), which can augment traditional therapies by enabling patients to access proven treatments like cognitive behavioral therapy outside of a practitioner's office. With the proposal to pay for DMHTs, CMS recognizes that digital health technologies can improve the management of a patient's condition by delivering evidence-based treatments using software.

AMCP has advocated for Medicare coverage of DMHTs and, more broadly, prescription digital therapeutics (PDTx). Broader adoption of PDTx may improve health equity by closing gaps in access to mental, physical, or neurological treatment; reducing patients' burdens to find transportation, child and elder care, or take time off work; and improving chronic disease management.[5] While there is growing evidence of PDTx impact on patient outcomes and healthcare spending, our health coverage systems have not caught up with these innovative technologies. CMS is poised to establish payment and coding standards that will enable expanded PDTx coverage across all payer types. AMCP shares recommendations informed by multistakeholder workshops[6,7] and a focus group of payer representatives with experience covering PDTx.[8]

CMS proposes to authorize payment to billing practitioners for DMHTs furnished incident to or integral to professional behavioral health services in conjunction with ongoing treatment. AMCP agrees with the proposal to limit eligibility to digital therapeutics that have been cleared or authorized by the Food and Drug Administration (FDA). This safeguard ensures that patients will only receive access to products that have been reviewed for safety and efficacy. However, the Proposed Rule excludes most PDTx that have been cleared or authorized by the Food & Drug Administration (FDA) to treat, manage, or diagnose a mental, physical, or neurological condition. AMCP believes that CMS should use its authority to pay for any PDTx that meets the following conditions:

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[3] https://oig.hhs.gov/documents/evaluation/9844/OEI-02-22-00050.pdf
[4] Ibid.
[5] Blount, M. et al. (2023). "Leveraging digital health tools to advance health equity." Morehouse School of Medicine. https://www.msm.edu/Research/research_centersandinstitutes/NCPC/DigitalTechnologySurvey/LeveragingDigitalHealthTools_DHTSFinalReport.pdf.
[6] "AMCP Partnership Forum: Digital therapeutics – what are they and where do they fit in pharmacy and medical benefits?" (2020). *Journal of Managed Care & Specialty Pharmacy,* Vol. 26, No. 5. https://doi.org/10.18553%2Fjmcp.2020.19418.
[7] "AMCP Partnership Forum: The evolving role of digital therapeutics." (2022). *Journal of Managed Care & Specialty Pharmacy,* Vol. 28, No. 7. https://doi.org/10.18553/jmcp.2022.22093.
[8] "Operational Readiness for Covering Prescription Digital Therapeutics." (2024). Academy of Managed Care Pharmacy. https://www.amcp.org/sites/default/files/2024-06/2024-AMCP-Brief-Operational-Readiness-Covering-Prescription-Digital-Therapeutics.pdf.

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, cleared, 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.

CMS should clarify which products will be classified as DMHTs if the agency does not believe its payment authority under the incident to pathway extends beyond mental health products. CMS proposes covering DMHTs that are cleared by the FDA as a computerized behavioral therapy (CBT) device for psychiatric disorders under 21 CFR 882.5801. AMCP is concerned that limiting the products eligible for payment under this proposal to those cleared under 21 CFR 882.5801 may limit patient access to products that are indicated to treat mental disorders but were cleared under a different FDA pathway. The FDA adopted a "fit for purpose" approach to Software as a Medical Device (SaMD) regulations for computerized therapies, which means that many SaMD products (including PDTx or DMHTs) are categorized based on the conditions they are intended to treat.[9] While several CBT devices fall under the 882.5801 regulation, including products indicated for substance use disorders, insomnia, and depressive disorders,[10] many PDTx that use CBT would not be eligible for payment under the Proposed Rule. AMCP estimates that 5 products have been cleared under the 21 CFR 882.5801 pathway:

a) ReSET and ReSET-O, indicated to treat substance use disorders and opioid use disorders, respectively
b) Somryst, indicated to treat chronic insomnia
c) Rejoyn, indicated to treat major depressive disorder
d) Mamalift Plus, indicated to treat postpartum depression symptoms

Several products listed above may not be available to Medicare beneficiaries; this list includes products that were developed by a company that filed for Chapter 11 bankruptcy in April 2023.[11] Meanwhile, the Proposed Rule does not parse whether Medicare will pay for mental health products with other FDA classifications. For instance, Freespira is an adjunctive treatment for symptoms associated with panic disorder or post-traumatic stress disorder to be used under the direction of a healthcare professional.[12] Patients are referred to this product by behavioral health professionals to treat the physical symptoms of mental health disorders that are recognized in the Diagnostic and Statistical Manual of Mental Disorders-5 (DSM). However, the FDA regulates Freespira as a biofeedback device under the 21 CFR 882.5050 regulation. CMS

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[9] Watson, A. et al. (2023). "FDA regulations and prescription digital therapeutics: Evolving with the technologies they regulate." *Frontiers in Digital Health,* Vol. 5. https://doi.org/10.3389%2Ffdgth.2023.1086219.
[10] "Product Code Classification Database". United States Food & Drug Administration. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/TextResults.cfm.
[11] These products were initially removed from the market due to the bankruptcy but have since been acquired by another company and relaunched. https://www.statnews.com/2024/08/22/pear-pursuecare-reset-digital-therapeutic-substance-abuse/
[12] "510(k) summary: K180173." (2018). United States Food & Drug Administration. https://www.accessdata.fda.gov/cdrh_docs/pdf18/K180173.pdf.

should consult with the FDA to determine which SaMDs should be considered DMHT, regardless of the regulation under which the product was initially cleared.

AMCP encourages CMS to clarify how DMHTs will be valued under this new framework. CMS proposes to establish 3 new Healthcare Common Procedure Coding System (HCPCS) codes for DMHTs that mirror the codes used for remote therapeutic monitoring (RTM) services. The first code, GMBT1, encompasses the supply of the DMHT and initial patient education and onboarding, while the following two codes, GMBT2 and GMBT3, pay practitioners for treatment management services associated with the DMHT. AMCP is concerned that the supply code 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 significant regional variation in the payment amount, which could inhibit access in certain markets. CMS should work with PDTx manufacturers and the Medicare Administrative Contractors to determine appropriate payment rates for DMHTs.

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