

ISSUE BRIEF

ACCESS TO PRESCRIPTION DIGITAL THERAPEUTICS ACT (S.723/H.R. 1458)

BACKGROUND

The Access to Prescription Digital Therapeutics Act of 2023 (S. 723/H.R. 1458) is an important bipartisan bill that will improve care for millions of Americans by expanding coverage of prescription digital therapeutics (PDTs). A growing class of treatment, PDTs are software-based therapies that deliver a clinical benefit to patients, either alone or in combination with other treatments. However, many PDTs do not currently fit into one of the statutorily defined coverage categories for the Medicare or Medicaid programs. This leaves beneficiaries of those programs, which include some of America's most vulnerable populations, without access to these cost-effective and accessible treatments. The CY 2025 Medicare Physician Fee Schedule (PFS) established the first defined coverage framework for a subset of PDTs indicated for behavioral health conditions. The products covered under the PFS, known as digital mental health treatment devices (DMHTs), must be furnished incident to professional behavioral health services in conjunction with ongoing treatment. AMCP estimates that five products would be eligible for coverage under the PFS, which excludes many PDTs already cleared or authorized by the FDA. This bill will expand the number of PDTs eligible for coverage under Medicare and Medicaid, as well as direct the Centers for Medicare & Medicaid Services (CMS) to establish additional payment methodologies and product-specific Healthcare Common Procedure Coding System (HCPCS) codes. Like other prescription therapies, PDTs are tested for safety and efficacy in randomized clinical trials, reviewed and approved by the Food & Drug Administration (FDA), and prescribed by a health care provider. PDTs treat a wide variety of diseases and conditions, including mental and behavioral health issues, substance and opioid use disorders, Parkinson's disease, and diabetes. Many can be used on a mobile phone, which helps improve patient outcomes by displaying care reminders and allowing patients to access their therapies in any setting. Although private health payers may elect to cover PDTs, the current landscape is a patchwork of reimbursement strategies and coding practices. This leads to confusion and underutilization.



AMCP Urges Passage of the Access to Prescription Digital Therapeutics Act of 2023

AMCP supports the Access to Prescription Digital Therapeutics Act of 2023. Expanding coverage of PDTs will improve care for millions of American patients and help standardize reimbursement practices and coding of these therapies across both public and private payers. This bill will help ensure that the greatest number of patients possible are receiving innovative, modern care, which is especially vital for closing care gaps caused by specialist shortages or geographic obstacles.

As private payers continue to expand coverage, lack of a comprehensive benefit category is creating a disparity of access for Medicare and Medicaid beneficiaries.

AMCP urges Members of Congress to cosponsor and ultimately enact the *Access to Prescription Digital Therapeutics Act of 2023* (S. 723/H.R. 1458) to authorize stable, comprehensive coverage under Medicare and Medicaid, thereby increasing patient access and quality of care.

