

Department of Legislative Services
Maryland General Assembly
2023 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 441

(Senator Lam)

Finance

Maryland Medical Assistance Program - Prescription Digital Therapeutics

This bill requires Medicaid, subject to the limitations of the State budget, to provide coverage for “prescription digital therapeutics.”

Fiscal Summary

State Effect: Medicaid expenditures increase by an indeterminate amount beginning in FY 2024 (51.5% federal funds, 48.5% general funds) to provide coverage of prescription digital therapeutics. Federal fund revenues increase accordingly. **This bill increases the cost of an entitlement program beginning in FY 2024.**

Local Effect: None.

Small Business Effect: None.

Analysis

Bill Summary: “Prescription digital therapeutics” means a product, device, Internet application, or any other technology that (1) is approved, cleared or classified by the U.S. Food and Drug Administration (FDA), as specified; (2) has an approved or cleared indication for the prevention, management, or treatment of a medical disease, condition, or disorder; (3) primarily uses software to achieve its intended result; and (4) can be dispensed only in accordance with a prescription.

Current Law: Medicaid generally covers children, pregnant women, elderly or disabled individuals, low-income parents, and childless adults. To qualify for Medicaid, applicants must pass certain income and asset tests. Effective January 1, 2014, Medicaid coverage

was expanded to persons with household incomes up to 138% of federal poverty guidelines, as authorized under the federal Patient Protection and Affordable Care Act.

State Fiscal Effect: Medicaid expenditures increase by an indeterminate amount beginning in fiscal 2024 (51.5% federal funds, 48.5% general funds) to provide coverage of digital prescription therapeutics. Federal fund revenues increase accordingly.

Digital prescription therapeutics supplement rather than supplant existing treatments and services. Thus, while they may improve patient outcomes, the Maryland Department of Health (MDH) advises that they are not anticipated to reduce costs or substitute for other services. For example, Pear Therapeutics' FDA-cleared application reSET is designed to treat substance use disorder through software that augments in-person counseling and cognitive behavioral therapy. MDH further advises that there is limited data on the current and potential uptake of prescription digital therapeutics in the Maryland Medicaid population on which to estimate potential utilization. Any coverage of digital prescription therapeutics would be subject to a 51.5% federal matching rate, decreasing to a 50% federal matching rate beginning in calendar 2025.

Additional Comments: Digital therapeutics are regulated as medical devices by the Digital Health Center of Excellence in the FDA's Center for Devices and Radiological Health. Digital therapeutics work in a variety of ways, from calculating insulin doses to delivering cognitive behavioral therapy, and can help track and manage symptoms as well as improve medication adherence. These products are often accessed through a smartphone or tablet and can be used independently or in concert with other treatments. At least 26 digital therapeutics are currently available that are intended to manage or treat anxiety, attention deficit/hyperactivity disorder, chronic pain, diabetes, depression, hypertension, insomnia, migraines, nicotine dependence, panic disorders, and substance use disorders.

Florida's Medicaid program recently added Pear Therapeutics' reSET and reSET-O (prescription digital therapeutics intended for substance use disorder and opioid use disorder, respectively) to the program's preferred drug list. California Medicaid has contracted with Pear Therapeutics for a pilot program to help individuals in a 24-week outpatient program for stimulant use disorder.

Additional Information

Prior Introductions: Similar legislation has not been introduced within the last three years.

Designated Cross File: HB 813 (Delegate S. Johnson) - Health and Government Operations.

Information Source(s): U.S. Food and Drug Administration; Maryland Department of Health; Department of Legislative Services

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km/ljm

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