# **Department of Legislative Services**

Maryland General Assembly 2024 Session

### FISCAL AND POLICY NOTE First Reader

(Senator Lam)

Senate Bill 990 Finance

#### Maryland Medical Assistance Program and Health Insurance - Step Therapy, Fail-First Protocols, and Prior Authorization - Prescription Drugs to Treat Serious Mental Illness

This bill prohibits insurers, nonprofit health services plans, and health maintenance organizations (collectively known as carriers), as well as Medicaid from applying a prior authorization requirement, fail-first protocol, or step therapy protocol for a prescription drug used to treat a diagnosis of specified mental health conditions. The bill's Medicaid provisions take effect July 1, 2024, subject to a specified termination provision. Provisions relating to carriers take effect January 1, 2025, and apply to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after that date.

### **Fiscal Summary**

**State Effect:** Minimal increase in special fund revenues for the Maryland Insurance Administration in FY 2025 only from the \$125 rate and form filing fee; review of filings can be handled with existing resources. Medicaid expenditures increase by a significant amount (50% general funds, 50% federal funds) in FY 2025 and 2026, as discussed below; federal fund revenues increase correspondingly. No impact on the State Employee and Retiree Health and Welfare Benefits Program, as discussed below. **This bill increases the cost of an entitlement program beginning in FY 2025.** 

**Local Effect:** Potential increase in health insurance costs for local governments that purchase fully insured health plans. Revenues are not affected.

Small Business Effect: Potential meaningful.

# Analysis

**Bill Summary:** A prior authorization requirement, fail-first protocol, or step therapy protocol may not be imposed for a prescription drug used to treat a diagnosis of (1) bipolar disorder; (2) schizophrenia; (3) major depression; (4) post-traumatic stress disorder; or (5) a medication-induced movement disorder associated with the treatment of a serious mental illness.

By January 31, 2026, and then each January 1 through 2030, the Maryland Department of Health (MDH) must report to the Department of Legislative Services (DLS) on any cost increase to Medicaid from the immediately preceding fiscal year resulting from the bill. By April 30 of the year in which a report is submitted, DLS must determine, based on the report, whether the bill resulted in a cost increase to Medicaid of more than \$2.0 million from the immediately preceding fiscal year. If DLS determines that Medicaid costs have increased by more than this amount, the Medicaid provisions of the bill must terminate that April 30.

# **Current Law:**

# Step Therapy/Fail-first Protocols

"Step therapy or fail-first protocol" means a protocol established by a carrier that requires a prescription drug or sequence of prescription drugs to be used by an insured or enrollee before a prescription drug ordered by a prescriber is covered.

A carrier may not impose a step therapy or fail-first protocol if the step therapy drug has not been approved by U.S. Food and Drug Administration for the medical condition being treated (*i.e.*, off-label use) or a prescriber provides supporting medical information to the carrier or pharmacy benefits manager (PBM) that a prescription drug covered by the carrier or PBM (1) was ordered for the insured or enrollee within the past 180 days and (2) based on the professional judgment of the prescriber, was effective in treating the insured or enrollee.

A carrier is also prohibited from imposing a step therapy or fail-first protocol if the prescription drug is used to treat the insured's or enrollee's stage four advanced metastatic cancer and use of the prescription drug is consistent with specified indications and supported by peer-reviewed medical literature.

### Prior Authorizations for Prescription Drugs

Chapter 549 of 2019 established requirements for prior authorization for a prescription for a chronic condition and requires specified entities to (1) maintain a database of information SB 990/ Page 2

relating to prior authorization requests filed electronically; (2) provide a specific explanation when denying a prior authorization; (3) honor certain prior authorizations for a specified time period and under specified circumstances; and (4) provide specified notice of a new prior authorization requirement for a prescription drug. If a carrier requires a prior authorization for a prescription drug, the prior authorization request must allow a health care provider to indicate whether a prescription drug is to be used to treat a chronic condition. If a health care provider indicates as such, a carrier may not request a reauthorization for a repeat prescription for one year or for the standard course of treatment for the chronic condition, whichever is less.

### **State Fiscal Effect:**

# Medicaid

Many drugs used primarily for serious mental health diagnoses are also being prescribed for the treatment of other conditions or off-label use. At this time, there is no federal mandate requiring a diagnosis to be included on a prescription. Therefore, prescriptions as presented to the pharmacy do not include diagnosis, and this information is not otherwise readily available at the time a prescription is filled. To implement the bill, MDH advises that it would need to eliminate all prior authorization requirements from these classes of drugs so that, whenever such a drug is prescribed, it would automatically be authorized. MDH advises that this will result in an increase in the number of prescriptions being filled and, accordingly, increased Medicaid expenditures.

By removing step therapy, fail-first, and prior authorization for specified drugs, MDH anticipates that utilization will shift from generic to brand-name drugs or from lower net cost brand-name drugs to higher net cost brand-name drugs, increasing the overall cost per prescription. MDH also anticipates a decrease in supplemental rebates as manufacturers will no longer have an incentive to offer such rebates to have their brand-name drugs included on the Medicaid preferred drug list. Receipt of fewer supplemental rebates results in higher net expenditures for Medicaid prescription drugs.

Currently, total net costs for Medicaid for prescription drugs used to treat the diagnoses specified under the bill amount to \$81.2 million per year. Under the bill, MDH projects significant cost increases as discussed above (as much as \$125.3 million annually in total funds). Thus, MDH expenditures increase by a significant but indeterminate amount (50% general funds/50% federal funds) in fiscal 2025 and 2026 to comply with the bill. Federal revenues increase correspondingly.

The bill includes a termination provision triggered if DLS determines, by April 30, that the bill resulted in a cost increase to Medicaid of more than \$2.0 million from the immediately preceding fiscal year. Thus, based on the estimated impact on Medicaid expenditures under

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this analysis (likely well in excess of \$2.0 million), the bill likely terminates April 30, 2026, after the initial report is presented. Thus, there is likely no effect beginning in fiscal 2027.

MDH additionally advises that the federal Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act requires states to implement claims review processes for individuals prescribed opioids and antipsychotics. States must monitor appropriate prescribing of antipsychotic medication to children, and report on monitoring activities for children in foster care or children younger than 18. MDH's current prior authorization policies are in compliance with the federal SUPPORT Act. Implementation of the bill may impact this compliance, putting federal matching dollars at risk.

### State Employee and Retiree Health and Welfare Benefits Program

The Department of Budget and Management advises that the State Employee and Retiree Health and Welfare Benefits Program does not currently have prior authorization or step therapy rules in place for the mental health conditions indicated in the bill. Thus, there is no fiscal impact on the program at this time.

Small Business Effect: To the extent the bill increases the cost of health insurance, small businesses with nongrandfathered small employer plans may incur increased premiums.

# **Additional Information**

**Recent Prior Introductions:** Similar legislation has not been introduced in the last three years.

**Designated Cross File:** HB 1423 (Delegates S. Johnson and A. Johnson) - Health and Government Operations.

**Information Source(s):** Department of Budget and Management; Maryland Department of Health; Maryland Insurance Administration; Department of Legislative Services

**Fiscal Note History:** First Reader - March 6, 2024 rh/ljm

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