Department of Legislative Services

Maryland General Assembly
2025 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 111 (Senator Lam)
Finance

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

This bill prohibits insurers, nonprofit health service 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. A prior authorization requirement may be imposed if required under specified federal law. **The bill's Medicaid provisions take effect July 1, 2025, subject to a specified termination provision. Provisions relating to carriers take effect January 1, 2026, 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 2026 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 2026 and 2027, as discussed below; federal fund revenues increase correspondingly. State Employee and Retiree Health and Welfare Benefits Program costs increase in FY 2026 and 2027 and subsequent years, as discussed below. **This bill increases the cost of an entitlement program beginning in FY 2026.**

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 (PTSD); or (5) a medication-induced movement disorder associated with the treatment of a serious mental illness. A prior authorization requirement may be applied if required under 42 U.S.C. § 1396(a) (State plans for medical assistance).

By January 31, 2027, and then each January 1 through 2031, 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 $2.0 million, 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 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

Behavioral health drugs associated with the treatment of a serious mental illness, including those used to treat bipolar disorder, schizophrenia, major depression, and PTSD, are carved out of the Medicaid managed care organization (MCO) pharmacy benefit, and paid for on a fee-for-service (FFS) basis. Medication-induced motion disorder drugs are covered by both FFS and MCOs. These drugs often have prior authorization requirements.

MDH currently allows for a 30-day emergency supply of atypical antipsychotic drugs not on the preferred drug list to ensure that individuals will not have a gap in their medications while prior authorization issues are being resolved. In addition, MDH has a grandfather policy in place to ensure that individuals who have been on a prescribed drug before they enroll in Maryland Medicaid are able to receive a supply of that drug while their prescription undergoes the prior authorization process.

Many drugs used primarily for serious mental health diagnoses are also prescribed for other conditions or off-label use. At this time, 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.

An estimated 466,622 Medicaid recipients (including 414,700 adults) have been diagnosed with one of the conditions specified in the bill. Total net costs for Medicaid for prescription drugs used to treat those diagnoses are $81.2 million per year (or an estimated $72.2 million for adults).

Under the bill, MDH projects significant cost increases as discussed above (as much as $109.1 million annually in total funds). This does not reflect any costs associated with movement disorder medications. Thus, MDH expenditures increase by a significant but indeterminate amount (50% general funds/50% federal funds) in fiscal 2026 and 2027 to comply with the bill. Federal revenues increase correspondingly. Expenditures may be offset by savings from reduced delays in treatment and reduced medical costs such as provider visits and hospitalizations.

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 this analysis (likely well in excess of $2.0 million), the bill likely terminates April 30, 2027, after the initial report is presented. Thus, there is likely no effect beginning in fiscal 2028.

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. The federal Consolidated Appropriations Act, 2024 extended and expanded SUPPORT Act policies and requires monitoring and management of antipsychotic medication for adults receiving home- and community-based services and residing in institutional care settings beginning in March 2026. MDH notes that the bill may create challenges to align with these provisions.

State Employee and Retiree Health and Welfare Benefits Program

The Department of Budget and Management (DBM) advises that the State Employee and Retiree Health and Welfare Benefits Program currently has prior authorization or step

therapy rules in place for five drugs associated with the mental health conditions indicated in the bill. Using current utilization data through November 2024, the estimated annual incremental impact of the bill on the program is between $500,000 and $1.0 million after rebates (0.15% to 0.3% of total cost). Thus, expenditures for the State Employee and Retiree Health and Welfare Benefits Program could increase by as much as $500,000 in fiscal 2026 (to reflect the January 1, 2026 effective date), and by as much as $1.0 million annually thereafter. DBM further advises that the bill could have longer-term cost implications as it would prohibit the State's future ability to expand prior authorization or step therapy.

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 been introduced within the last three years. See SB 990 and HB 1423 of 2024.

Designated Cross File: HB 382 (Delegate S. Johnson, *et al.*) - Health and Government Operations.

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

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