HB 424

Department of Legislative Services

Maryland General Assembly
2025 Session

FISCAL AND POLICY NOTE
Enrolled - Revised

House Bill 424 (Delegate Cullison, *et al.*)
Health and Government Operations Finance

Prescription Drug Affordability Board - Authority and Stakeholder Council Membership (Lowering Prescription Drug Costs for All Marylanders Now Act)

This bill repeals reporting requirements for the Prescription Drug Affordability Board (PDAB) regarding upper payment limits (UPLs). Instead, PDAB must determine whether it is in the best interest of the State to set UPLs for purchases and payor reimbursements of prescription drug products in the State that have led or will lead to an affordability challenge. If PDAB makes this determination, it must establish a specified process and set UPLs accordingly. The bill also (1) authorizes PDAB to reconsider a UPL for a drug that becomes a "current shortage"; (2) prohibits PDAB from taking specified actions that pertain to UPLs; (3) modifies the requirements and criteria for setting UPLs; (4) repeals obsolete language related to the Prescription Drug Affordability Fund (PDAF); (5) imposes additional reporting requirements on PDAB; and (6) adds new members to the Prescription Drug Affordability Stakeholder Council. **The bill's requirement that PDAB set UPLs for purchases and payor reimbursements is contingent on specified actions taking place by September 30, 2030.**

Fiscal Summary

State Effect: General fund expenditures for the Office of the Attorney General (OAG) increase by $106,700 in FY 2026. PDAB special fund expenditures increase by at least $264,900 in FY 2027; special fund revenues increase correspondingly. Future years reflect annualization and ongoing costs. The bill is not anticipated to materially affect the Maryland Department of Health (MDH) or the Department of Budget and Management (DBM), as discussed below.

(in dollars)	FY 2026	FY 2027	FY 2028	FY 2029	FY 2030
SF Revenue	$0	$264,900	$263,200	$268,200	$273,300
GF Expenditure	$106,700	$128,700	$134,300	$140,300	$146,300
SF Expenditure	$0	$264,900	$263,200	$268,200	$273,300
Net Effect	($106,700)	($128,700)	($134,300)	($140,300)	($146,300)

Note: () = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate increase; (-) = indeterminate decrease

Local Effect: The bill may result in some cost savings for local governments; however, the overall impact on local finances and operations is expected to be minimal.

Small Business Effect: Potential meaningful.

Analysis

Bill Summary:

Upper Payment Limits on Purchases and Payor Reimbursements

The bill repeals the requirement that PDAB, in consultation with its stakeholder council, report to specified committees of the General Assembly by December 1, 2026, on (1) the legality, obstacles, and benefits of setting UPLs on *all* purchases and payor reimbursements of prescription drug products in the State and (2) recommendations regarding whether the General Assembly should pass legislation to expand the authority of PDAB to set UPLs to all purchases and payor reimbursements of prescription drug products in the State.

Instead, the bill specifies that PDAB, in consultation with the stakeholder council, must determine whether, in addition to setting UPLs for prescription drug products purchased or paid for by or on behalf of a unit of State or local government, it is in the State's best interest for the board to establish a process for setting UPLs for purchases and payor reimbursements of prescription drug products in the State that, in the board's determination, have led or will lead to an affordability challenge.

When making this determination, PDAB must consider, if applicable, (1) contract and budget data provided to the board that demonstrates savings to the State or local governments as a result of specified UPLs; (2) the success of setting UPLs in other states; and (3) the expected savings from Medicare Maximum Fair Prices set by the federal Centers for Medicare and Medicaid Services.

If PDAB determines it is in the State's best interest to establish a process for setting UPLs for purchases and payor reimbursements of prescription drug products in the State that it concludes have led or will lead to an affordability challenge, the board must establish a process for setting UPLs in consultation with the stakeholder council. The process, to the extent appropriate, must use the action plan approved by the Legislative Policy Committee (LPC) and otherwise comply with all existing requirements for setting UPLs.

PDAB may set UPLs for purchases and payor reimbursements of prescription drug products in the State, except for (1) payor reimbursements under Medicare Part C and D; (2) purchases under the federal 340B Drug Pricing Program; and (3) purchases and payor

reimbursements by federal agencies or federal programs that the State is preempted from regulating by federal law.

Before establishing a UPL that applies to Medicaid, PDAB must confer with Medicaid to approve the application of the UPL by assessing whether the UPL will (1) conflict with the Medicaid Drug Debates Program, the Covered Outpatient Drug Rule (CMS-2345-FC), or any other federal requirements, as applicable and (2) require additional funding to be allocated to the Medicaid budget.

Upper Payment Limits for Prescription Drug Products in Short Supply

The bill repeals the requirement that PDAB's process for setting UPLs must prohibit the application of a UPL for a prescription drug product that is on the U.S. Food and Drug Administration (FDA) prescription drug shortage list. The bill also repeals the requirement that the board must (1) monitor the availability of any prescription drug product on which it sets a UPL and (2) reconsider or suspend the UPL if there becomes a shortage of that prescription drug product in the State.

However, if PDAB sets a UPL for a drug that becomes a "current shortage" (defined as a drug listed as current on FDA's Drug Shortage Database or otherwise determined by the board to be in short supply in the State), the board may reconsider the previously set UPL. PDAB may not apply a new UPL to a drug in a current shortage.

Changes to Setting Upper Payment Limits

Setting Upper Payment Limits in Accordance with Approved Plan of Action: The bill specifies that PDAB may set UPLs *through regulations* for prescription drug products purchased or paid for by or on behalf of a unit of State or local government.

Prohibited Board Actions: PDAB is prohibited from (1) enforcing a UPL against provider or pharmacy reimbursement requirements for Medicare Part C or D plans and (2) counting a pharmacy dispensing fee toward or subjecting a dispensing fee to a UPL.

Modifications to Criteria: In addition to the existing criteria that PDAB must consider when setting UPLs, the board must consider the effect a UPL will have on providers of 340B drugs and, for a UPL on a drug designated as a drug for a rare disease or condition, the impact of the UPL on patients with rare diseases.

Repeal of Requirements: The bill repeals requirements pertaining to UPLs that are obsolete in light of LPC's October 2024 approval of PDAB's action plan for establishing UPLs for prescription drugs identified as causing or likely to cause affordability challenges.

Repeal of Obsolete Language – Prescription Drug Affordability Fund

The bill repeals obsolete language that (1) requires PDAB to be established using special or general funds, which must be repaid to the State with funds from PDAF and (2) requires that, if the board receives funding from the Maryland Health Care Commission (MHCC), it must repay the funds over a three-year period beginning June 1, 2021. PDAB received general funds to repay MHCC and such repayment is complete.

Additional Reporting Requirements

If PDAB sets a new UPL, to the extent practicable, it must include – in the first annual report required after the UPL has been in effect for one year – information on the effects of the UPL, based on available timely data, for the following:

- patient out-of-pocket costs, including whether the UPL was associated with increases or decreases in what patients pay for prescription drug products;
- patient health insurance premiums, including whether the UPL is associated with increases or decreases in health insurance costs for patients;
- pharmacies operating in the State, including the impact on reimbursement rates and financial viability of retail and independent pharmacies;
- patient health insurance formularies, including whether the prescription drug product subject to the UPL remained on formularies;
- provider-administered medications subject to the UPL, including whether providers were able to acquire the affected prescription drug product at a rate to account for acquisition costs and whether there was an impact on provider reimbursement;
- patient access to the prescription drug product subject to the UPL, which may include information as specified;
- covered entity providers participating in the 340B Drug Discount Program, including the impact of the UPL on their operations and contracted pharmacies; and
- the biotechnology industry in the State, including the impact on pharmaceutical research and development, investment, and job growth.

PDAB may request information necessary to complete the required annual report from an affected entity. If contacted by PDAB for this purpose, an affected entity must make a good faith effort to provide the requested information.

Effective Dates

The bill generally takes effect October 1, 2025. However, Section 2 of the bill, which requires PDAB to set UPLs for purchases and payor reimbursements of prescription drug products in the State that have led or will lead to an affordability challenge if the board

establishes such a process, is contingent on other actions. Specifically, PDAB must set, through regulations, UPLs on two prescription drugs (in accordance with the approved action plan) and each UPL must be in effect for one year. Within five days of these conditions being met, PDAB must notify the Department of Legislative Services (DLS). If DLS receives this notice by September 30, 2030, the provision takes effect on the date the notice is received. If the notice is not received by this date, the provision terminates.

Current Law: Established by Chapter 692 of 2019, PDAB is required to study the entire pharmaceutical distribution and payment system in Maryland and the policy options being used in other states and countries to lower the list price of pharmaceuticals. This includes setting UPLs, using reverse auction marketplaces, and implementing a bulk purchasing process.

Prescription Drug Affordability Stakeholder Council

Chapter 692 also established a Prescription Drug Affordability Stakeholder Council. The purpose of the stakeholder council is to provide stakeholder input to assist PDAB in making decisions. The council comprises specified stakeholders appointed by the Governor, the President of the Senate, and the Speaker of the House. Collectively, members of the council must have knowledge in the following areas: the pharmaceutical business model; supply chain business models; the practice of medicine or clinical training; consumer or patient perspectives; health care costs, trends, and drivers; clinical and health services research; or the State's health care marketplace.

Upper Payment Limits – Action Plan

On October 22, 2024, LPC approved PDAB's action plan for establishing UPLs for prescription drugs identified as causing or likely to cause affordability challenges.

The action plan's approval was made in accordance with § 21-2C-13 of the Health-General Article, which specifies that if PDAB finds that it is in the State's best interest to establish a process for setting UPLs for prescription drug products that it determines have led or will lead to an affordability challenge, the board, in conjunction with the stakeholder council, must draft a plan of action for implementing the process that includes the criteria the board must use to set UPLs. The criteria must include consideration of (1) the cost of administering the prescription drug product; (2) the cost of delivering the prescription drug product to consumers; and (3) other relevant administrative costs related to the prescription drug product.

Implementation of Upper Payment Limits Following Action Plan Approval

Upon approval of an action plan, the board may set UPLs for prescription drug products that are (1) purchased or paid for by a unit of State or local government or an organization on behalf of a unit of State or local government, including State or county correctional facilities, State hospitals, and health clinics at State institutions of higher education; (2) paid for through a health benefit plan on behalf of a unit of State or local government, including a county, bicounty, or municipal employee health benefit plan; or (3) purchased for or paid for by the Maryland Medicaid program. The UPLs must be for prescription drug products that have led or will lead to an affordability challenge and be set in accordance with the criteria established in board regulations. The board must monitor the availability of any prescription drug product for which it sets a UPL. If there becomes a shortage of a prescription drug product in the State, the board must reconsider whether the UPL should be suspended or altered. A UPL may not be applied to a prescription drug product while the prescription drug product is on FDA's prescription drug shortage list.

Reporting Requirements

In accordance with § 21-2C-09 of the Health-General Article, by December 31, 2020, and annually thereafter, PDAB must submit, to specified committees of the General Assembly, a report that includes (1) price trends for prescription drug products; (2) the number of prescription drug products subject to board review, including the results of the review; and (3) any recommendations for legislation to make prescription drug products more affordable in the State.

By December 1, 2026, PDAB, in consultation with the stakeholder council, is required to report to specified committees of the General Assembly on (1) the legality, obstacles, and benefits of setting UPLs on all purchases and payor reimbursements of prescription drug products in the State and (2) recommendations regarding whether the General Assembly should pass legislation to expand the board's authority to set UPLs to all purchases and payor reimbursements of prescription drug products in the State.

Prescription Drug Affordability Fund and Annual Fee

PDAF provides funding for the board. The fund consists of fee revenue, money appropriated in the State budget, interest earnings, and any other money from any other source accepted for the benefit of the fund. The fund may be used only to provide funding for the board and related purposes, including administrative expenses and any costs expended by a State agency to implement the board's duties.

PDAB must assess and collect an annual fee on manufacturers that sell or offer for sale prescription drug products to persons in the State, as well as pharmacy benefit managers

(PBMs), carriers, and wholesale distributors that sell or offer for sale prescription drug products to persons in the State. The fee must be calculated in a fair and equitable manner and assessed and collected in accordance with criteria established in board regulations. Each entity assessed a fee must pay the fee by October 1 each year, but the board must allow entities to make partial payments. Any fee not paid within 30 days may be subject to an interest penalty. Total fees collected in each calendar year are capped at $2.0 million.

340B Drugs

The federal 340B Drug Pricing Program requires pharmaceutical manufacturers to sell outpatient drugs to covered entities (certain hospitals and federal grantees like health centers and clinics) at reduced prices in order to have their drugs covered under Medicaid.

State Fiscal Effect: This analysis assumes that PDAB, as it implements the bill, determines that it is in the State's best interest to set UPLs for purchases and payor reimbursements of prescription drug products in the State that have led or will lead to affordability challenges, subsequently establishes a process for setting such UPLs, and sets UPLs in accordance with that process. To the extent PDAB deviates from these assumptions, actual expenditures are lower than the estimates provided below.

Under the bill, beginning in fiscal 2027, PDAB special fund expenditures increase by at least $264,925 for personnel and contractual expenses; PDAF special fund revenues increase correspondingly. OAG general fund expenditures increase by $106,659 in fiscal 2026, increasing to $146,304 in fiscal 2030, for personnel to provide legal support to PDAB. The bill is not anticipated to materially affect the finances or operations of MDH or DBM.

Prescription Drug Affordability Board

PDAB is currently funded by an annual fee assessment. The board is authorized to assess and collect up to $2.0 million in fees annually. According to PDAB, the current annual assessment of approximately $1.2 million will not be sufficient to cover its costs under the bill beginning in fiscal 2027. Therefore, PDAB advises that it intends to revise its regulations to permit the board to increase its annual fee assessment on manufacturers, PBMs, carriers, and wholesale distributors. PDAB intends to have these revised regulations in place by July 1, 2026, so that the board can increase its fiscal 2027 assessment to adequately fund its operations.

Due to the requirements the bill imposes on PDAB, the board advises that it must hire one full-time program administrator, with a start date of July 1, 2026, to assist with planning, coordinating, implementing, and monitoring UPLs for all payors in the State. PDAB further advises that, beginning in fiscal 2027, its budget for consulting services

increases by a minimum of $150,000 annually to provide data, studies, and other information to the board as it considers implementing and later sets UPLs on purchases and payor reimbursements of prescription drug products in the State.

Position	1.0
Salary and Fringe Benefits	$107,269
Contractual Expenses	150,000
Operating Expenses	7,656
Minimum FY 2027 PDAB Expenditures	**$264,925**

Future year expenditures – which reflect minimum costs – reflect a full salary with annual increases and employee turnover as well as annual increases in ongoing operating expenses.

For purposes of this analysis, it is assumed that PDAF special fund revenues in fiscal 2027 (and beyond) increase by a corresponding amount to the increase in PDAB special fund expenditures. However, actual PDAF special fund revenues depend on how the board sets the annual fee assessment.

Office of the Attorney General

OAG is responsible for providing legal advice to PDAB. Under the bill, its legal work on behalf of PDAB is likely to include efforts to expand the scope of the board's authority, assist with rewriting board regulations, and advise the board on potential litigation challenges. Therefore, OAG advises that the bill's expansion of PDAB's authority to set UPLs likely requires additional resources. DLS concurs with this assessment.

Accordingly, OAG general fund expenditures increase by $106,659 in fiscal 2026, which accounts for the bill's October 1, 2025 effective date. This estimate reflects the cost of hiring one full time assistant attorney general to provide additional legal assistance to PDAB. It includes a salary, fringe benefits, one-time start-up costs, and operating expenses.

Position	1.0
Salary and Fringe Benefits	$99,290
Operating Expenses	7,369
FY 2026 OAG Expenditures	**$106,659**

Future year expenditures reflect a full salary with annual increases and employee turnover as well as annual increases in ongoing operating expenses.

Should OAG require additional resources to comply with the bill, it can request additional staffing through the annual budget process.

Maryland Department of Health

According to MDH, the bill is likely to have a minimal impact on the Maryland Medicaid program. While setting UPLs on certain prescription drug products could prevent MDH from receiving federal and supplemental rebates for those products, MDH advises that the bill, as written, sufficiently mitigates against this risk.

Department of Budget and Management

PDAB is already authorized to set UPLs on any purchases of prescription drug products made by the State Employee and Retiree Health and Welfare Benefits Program. Accordingly, DBM advises that the bill has no impact on the program at this time. However, DBM advises that the bill's implementation may cause disruptions to the program's operations in the future.

Local Effect: According to the Maryland Association of Counties (MACo), the bill is likely to have a negligible impact on county operations and expenditures. However, MACo advises that, once PDAB's UPLs are in place, there could be savings on pharmaceutical expenses in county budgets.

Small Business Effect: To the extent that implementing UPLs for purchases and payor reimbursements of prescription drug products in the State that PDAB determines have led or will lead to affordability challenges reduces drug prices, small business health care expenditures decrease.

Additional Information

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

Designated Cross File: SB 357 (Senator Gile, *et al.*) - Finance.

Information Source(s): Maryland Association of County Health Officers; Maryland Association of Counties; Maryland Municipal League; Office of the Attorney General; University System of Maryland; Morgan State University; Department of Budget and Management; Maryland Department of Health; Department of Public Safety and Correctional Services; Maryland Insurance Administration; Department of Legislative Services

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