

Department of Legislative Services
 Maryland General Assembly
 2025 Session

FISCAL AND POLICY NOTE
 First Reader

House Bill 424 (Delegates Cullison and White Holland)
 Health and Government Operations

Prescription Drug Affordability Board - Authority for Upper Payment Limits
 (Lowering Prescription Drug Costs for All Marylanders Now Act)

This bill repeals existing 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 *all purchases and payor reimbursements of prescription drug products in the State*, as specified. If PDAB makes this determination, it must establish a specified process and set UPLs in accordance with the process. The bill also (1) authorizes PDAB to reconsider a UPL for a drug that becomes a “current shortage”; (2) prohibits the board from taking specified actions that pertain to UPLs; (3) modifies the requirements and criteria for setting UPLs; and (4) repeals obsolete language related to the Prescription Drug Affordability Fund (PDAF). **The bill generally takes effect October 1, 2025; the requirement that PDAB set UPLs for all purchases and payor reimbursements is contingent on specified actions taking place by December 31, 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 All 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 *all 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 the board determines it is in the State's best interest to establish a process for setting UPLs for all 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.

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
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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, the bill specifies that, 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 establish a new UPL for a current shortage.

Changes to Setting Upper Payment Limits

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 the UPL will have on providers of 340B drugs.

Repeal of Requirements: The bill repeals requirements pertaining to UPLs that are obsolete in light of the 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.

Effective Dates

The bill generally takes effect October 1, 2025. However, Section 2 of the bill, which requires PDAB to set UPLs for all purchases and payor reimbursements of prescription drug products in the State if the board establishes such a process, is contingent on other actions. Specifically, PDAB must set 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 31, 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.

Upper Payment Limits – Action Plan

On October 22, 2024, the 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

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 all purchases and payor reimbursements of prescription drug products in the State, 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 under the bill 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 all 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	<u>7,656</u>
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	<u>7,369</u>
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

MDH advises that the bill may have a substantial, but indeterminate impact on the Maryland Medicaid program. According to MDH, setting UPLs on certain prescription drug products could prevent it from receiving federal and supplemental rebates for those products. MDH notes that any prescription drugs that are purchased out of compliance with federal requirements would have to be covered with State general fund expenditures.

DLS advises that, under existing law, purchases of prescription drug products by Medicaid are already subject to the imposition of UPLs by PDAB. According to PDAB, the existing policies it has adopted for the implementation of UPLs do not put any federal matching dollars for Medicaid at risk. Unless PDAB alters its policies and procedures related to UPLs (if and when it expands UPLs to all purchases and payor reimbursements of prescription drug products in the State), PDAB advises that Medicaid's eligibility for federal funds should not be at risk. DLS concurs with PDAB's assessment and advises that the bill is unlikely to have a material impact on Medicaid's finances or operations.

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 all purchases and payor reimbursements of prescription drug products in the State 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 (Senators Gile and Feldman) - 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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