HB 340

Department of Legislative Services

Maryland General Assembly
2024 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 340 (Delegates Cullison and White Holland)
Health and Government Operations

Prescription Drug Affordability Board - Authority for Upper Payment Limits and Funding (The 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. Instead, on or after October 1, 2024, PDAB must determine whether it is in the best interest of the State to set upper payment limits for *all purchases and payor reimbursements of prescription drug products in the State*, as specified. If PDAB determines that this is in the best interest of the State, the board must establish a specified process for setting such upper payment limits and then actually set upper payment limits in accordance with the process. For fiscal 2025 and annually thereafter, the Governor must include in the annual budget bill an appropriation of at least $1.0 million for the Prescription Drug Affordability Fund (PDAF). The bill specifies the order in which PDAB must spend monies in the fund and includes a reversion provision for unexpended general fund appropriations.

Fiscal Summary

State Effect: No fiscal effect in FY 2025, as discussed below. Beginning in FY 2026, although a general fund appropriation of at least $1.0 million must be made to the fund, this analysis assumes no material fiscal impact due to the assumed subsequent reversion of the entire appropriation at year-end, as discussed below. Nevertheless, those monies are not available to be appropriated for other purposes. **This bill establishes a mandated appropriation beginning in FY 2026.**

Local Effect: None.

Small Business Effect: Potential meaningful.

Analysis

Bill Summary:

Funding

Each year, PDAB must first use any annual fee revenues collected by the board and any other non-State funds in PDAF before using the mandated appropriation. Any unspent portion of the mandated appropriation may not be transferred by budget amendment or otherwise to any other fund and must revert to the general fund.

The bill repeals obsolete language that (1) requires the board 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.

Upper Payment Limits

The bill repeals the requirement that PDAB, in consultation with its stakeholder council, must, by December 1, 2026, report to specified committees of the General Assembly on (1) the legality, obstacles, and benefits of setting upper payment limits 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 upper payment limits to all purchases and payor reimbursements of prescription drug products in the State.

Instead, on or after October 1, 2024, and only if a plan of action has been approved, PDAB, in consultation with the stakeholder council, must determine whether to set additional upper payment limits. Specifically, in addition to setting upper payment limits for only certain prescription drug products (those purchased or paid for by specified State or local government entities, paid for through a health benefit plan on behalf of a State or local government entity, purchased for or paid for by Medicaid, as provided under current law), PDAP must determine if it is in the best interest of the State for the board to establish a process for setting upper payment limits for *all purchases and payor reimbursements of prescription drug products in the State* that the board determines have led or will lead to an affordability challenge.

When making this determination, PDAB must consider, if available, contract and budget data provided to the board that demonstrates savings to the State or local governments as a result of any upper payment limits it may set for prescription drug products (1) purchased or paid for by specified State or local government entities; (2) paid for through a health

benefit plan on behalf of a State or local government entity; or (3) purchased for or paid for by Medicaid.

If PDAB determines that setting upper payment limits for *all purchases and payor reimbursements of prescription drug products in the State* that the board determines have led or will lead to an affordability challenge is in the best interest of the State, the board, in consultation with the stakeholder council, must establish a process for setting such upper payment limits. The process must, to the extent appropriate, use the approved plan of action and otherwise comply with statutory requirements for setting upper payment limits.

If PDAB establishes a process to set such upper payment limits, the board must set such upper payment limits in accordance with the process.

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 upper payment limits, using reverse auction marketplaces, and implementing a bulk purchasing process. Following its various studies, PDAB will publish a report on its findings and recommendations, including any necessary legislative action.

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 any 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, pharmacy benefits managers, 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.

Upper Payment Limits – Plan of Action

If PDAB finds that it is in the best interest of the State to establish a process for setting upper payment limits 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 upper payment limits. 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.

The process for setting upper payment limits must (1) prohibit the application of an upper payment limit for a prescription drug product that is on the U.S. Food and Drug Administration (FDA) prescription drug shortage list and (2) require the board to monitor the availability of any prescription drug product for which it sets an upper payment limit and, if there becomes a shortage of the prescription drug product in the State, reconsider or suspend the upper payment limit.

If a plan of action is drafted, the board must submit the plan of action to the Legislative Policy Committee (LPC) for approval. LPC must have 45 days to approve the plan of action. If LPC does not approve the plan of action, the board must submit the plan of action to the Governor and the Attorney General for approval. The Governor and the Attorney General must have 45 days to approve the plan of action. The board may not set upper payment limits unless the plan is approved by either (1) LPC or (2) the Governor and the Attorney General.

Implementation of Upper Payment Limits If Plan of Action Approved

If a plan of action is approved, the board may set upper payment limits 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 upper payment limits 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 an upper payment limit. If there becomes a shortage of a prescription drug product in the State, the board must reconsider whether the upper payment limit should be suspended or altered. An upper payment limit may not be applied to a prescription drug product while the prescription drug product is on FDA's prescription drug shortage list.

State Fiscal Effect: 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. PDAB advises that the current annual assessment collected is approximately $1.2 million and that those fee revenues adequately cover board costs. Accordingly, the board does not have plans to

increase the assessment in the near term; even under the bill, PDAB advises it does not anticipate significant new expenditures.

Regardless, the bill establishes a mandated appropriation of $1.0 million for PDAF beginning in fiscal 2026 (and attempts to do so for fiscal 2025). The bill also establishes that the board must spend its annual fee assessment revenues (and any other non-State funds in PDAF) *before* using the mandated appropriation. Given this requirement, the board's current funding position, and the bill's October 1, 2024 effective date, this analysis assumes that discretionary funding is not provided in fiscal 2025. Thus, there is no fiscal impact anticipated in fiscal 2025.

Beginning in fiscal 2026, at least $1.0 million in general funds must be *appropriated* to PDAF each year. However, due to the expectation that such funding is not needed – at least not in the near term, these additional monies are not likely to be expended. Instead, the full $1.0 million in general funds is assumed to revert, as required under the bill, at year-end to the general fund. Under this assumption, aside from not being available for other purposes, the mandated appropriation has no net impact on the general fund. Indeed, the same $1.0 million may be recycled each year.

Special fund revenues and expenditures would increase beginning in fiscal 2026 if the general fund appropriation were utilized, which is not expected. Even so, special fund revenues and expenditures could increase to the extent the board collects additional revenue through the assessment to cover any costs associated with the bill.

Small Business Effect: To the extent that implementing upper payment limits for all purchases and payor reimbursements of prescription drug products in the State reduces drug prices, small business health care expenditures decrease.

Additional Comments: In December 2023, PDAB submitted its *Annual Cost Review Report* as required. The report detailed price trends for prescription drug products and Maryland's cost review experience to date. The board did not recommend additional legislation at the time but noted that it will continue to explore policy and legislative initiatives to make prescription drugs more affordable for Marylanders. Final board regulations to implement the cost review study process took effect December 25, 2023, and the board's work in identifying and selecting drugs for the cost review study is expected to begin in early 2024.

Additional Information

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

Designated Cross File: SB 388 (Senator Gile, *et al.*) - Finance and Budget and Taxation.

Information Source(s): Prescription Drug Affordability Board; Maryland Department of Health; Maryland Insurance Administration; Department of Legislative Services

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