

Department of Legislative Services
Maryland General Assembly
2023 Session

FISCAL AND POLICY NOTE
Third Reader

House Bill 279

(Delegate Cullison)

Health and Government Operations

Finance

Prescription Drug Affordability Board - Upper Payment Limits

This emergency bill reinstates provisions of law regarding the authority of the Prescription Drug Affordability Board (PDAB) to set upper payment limits and related requirements, including an appeals process. By December 1, 2026, PDAB, in consultation with its stakeholder council, must 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.

Fiscal Summary

State Effect: To the extent upper payment limits are implemented and reduce drug prices, State expenditures decrease. Revenues are not affected.

Local Effect: To the extent upper payment limits are implemented and reduce drug prices, local government health care expenditures decrease. Revenues are not affected.

Small Business Effect: None.

Analysis

Bill Summary:

Upper Payment Limits – Plan of Action

If the board 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 the FDA's prescription drug shortage list.

Appeals

A person aggrieved by an upper payment limit set by the board may request an appeal within 30 days after the board makes the decision to set the limit. The board must hear the appeal and make a final decision within 60 days after the appeal is requested. Any person aggrieved by a final decision of the board may petition for judicial review under the Administrative Procedure Act.

Current Law: Established by Chapter 692 of 2019, PDAB comprises five members – one each appointed by the Governor, the President of the Senate, the Speaker of the House of Delegates, and the Attorney General and one appointed jointly by the President of the Senate and the Speaker of the House of Delegates, who must serve as chair. The board must also have three alternate members to participate when a member is recused. At least one member of the board must have specified expertise. PDAB must make specified determinations, collect data, and identify specified prescription drug products that may cause affordability issues; PDAB may conduct a cost review of each identified drug product.

Section 3 of Chapter 692 included substantially the same provisions relating to upper payment limits (including the requirement to submit the plan of action for approval), the appeals process, and the reporting requirement that are included in the bill. PDAB was authorized to set upper payment limits on or after January 1, 2022. However, Section 3 of the Act was contingent on receipt of approval of the plan of action for implementing a process for setting upper payment limits by January 1, 2023. As a plan of action was neither drafted nor approved by this date, these provisions terminated.

Additional Comments: In June 2022, PDAB submitted a one-time [study](#) of the operation of the generic drug market in the State. The study recommended that PDAB, with its State partners, should (1) evaluate policies to identify and address affordability challenges for generic drugs with high prices or high price increases; (2) explore opportunities to collect data to better understand and address specified issues; (3) evaluate waste-free formularies as a policy to promote savings through generic drugs; (4) explore policies to address drug shortages in Maryland; and (5) explore partnerships and policies to support a safe and robust supply chain for generic drugs in Maryland.

In December 2022, PDAB submitted its annual cost review [report](#) as required, which detailed price trends for prescription drug products, Maryland drug price and spending trends for 2018 through 2020, and Maryland's cost review experience to date. Because the cost review process remains under development, no actual cost reviews were completed in 2022.

Additional Information

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

Designated Cross File: SB 202 (Senator Feldman) - Finance.

Information Source(s): Judiciary (Administrative Office of the Courts); Baltimore City Community College; University System of Maryland; Department of Public Safety and Correctional Services; Office of Administrative Hearings; Maryland Insurance Administration; Prescription Drug Affordability Board; Department of Legislative Services

Fiscal Note History: First Reader - February 1, 2023
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