

Department of Legislative Services
 Maryland General Assembly
 2020 Session

FISCAL AND POLICY NOTE
Third Reader - Revised

House Bill 1100

(Delegate Pendergrass, *et al.*)

Health and Government Operations

Finance

Prescription Drug Affordability Board – Meetings, Legal Advisor, Reports, and Technical Changes

This bill repeals the requirement that the Prescription Drug Affordability Board hire legal counsel. Instead, the bill specifies that the Attorney General is the legal adviser to the board and must designate an assistant Attorney General as counsel to the board. The bill clarifies that the board may set upper payment limits in accordance with a specified plan of action. The bill also reduces the frequency by which the board is required to meet from at least once every six weeks to at least four times per year and delays the date by which the board must complete specified actions. **The bill takes effect June 1, 2020.**

Fiscal Summary

State Effect: No effect in FY 2020. General fund expenditures increase for the Office of the Attorney General (OAG) by \$105,900 in FY 2021 to designate an assistant Attorney General as counsel to the board. Special fund expenditures for the board decrease, potentially correspondingly, beginning in FY 2021; the Governor’s proposed FY 2021 budget includes \$750,000 and five positions for the board in the Maryland Health Care Commission (MHCC) budget. Future years reflect annualization and elimination of one-time costs. Revenues are not affected.

(in dollars)	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
Revenues	\$0	\$0	\$0	\$0	\$0
GF Expenditure	105,900	97,200	99,600	103,000	106,500
SF Expenditure	(-)	(-)	(-)	(-)	(-)
Net Effect	(\$-)	(\$-)	(\$-)	(\$-)	(\$-)

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

Local Effect: None.

Small Business Effect: None.

Analysis

Bill Summary: As needed, the Attorney General may assign additional assistant Attorneys General to the board. The counsel to the board may not have a duty other than to give the legal aid, advice, and counsel required by the board, supervise the other assistant Attorneys General assigned to the board, and perform for the board the duties that the Attorney General assigns. After the Attorney General designates the counsel to the board, the Attorney General may not reassign the counsel without consulting the board.

The bill delays, from December 31, 2020, to December 31, 2021, the date by which the board must:

- study and report on the entire pharmaceutical distribution and payment system in the State and policy options being used in other states and countries to lower the list price of pharmaceuticals;
- collect and review publicly available information regarding prescription drug product manufacturers, health insurance carriers, health maintenance organizations, managed care organizations, wholesale distributors, and pharmacy benefits managers;
- identify states that require reporting on the cost of prescription drug products and initiate a process of entering into memoranda of understanding with the states to aid in the collection of transparency data for prescription drug products; and
- jointly with the State-designated health information exchange (HIE), study how the HIE can provide de-identified provider and patient data to the board and report findings and recommendations to the General Assembly.

The bill delays, from June 1, 2020, to June 1, 2022, the date by which the board must conduct a study of the operation of the generic drug market in the United States that includes a review of physician-administered drugs and considers specified factors and report its findings to the General Assembly.

Current Law: Chapter 692 of 2019 established the Prescription Drug Affordability Board. The board must make specified determinations, collect data, and identify specified prescription drug products that may cause affordability issues; may conduct a cost review of each identified drug product; and, if warranted, must draft a plan of action that includes the criteria to set upper payment limits for prescription drug products. The plan of action must be approved either by the Legislative Policy Committee (LPC) or by the Governor and the Attorney General. If approved, the board may set upper payment limits for

specified populations beginning January 1, 2022. The Act also established a Prescription Drug Affordability Stakeholder Council.

The board 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. The chair of the board must hire an executive director, general counsel, and staff for the board, who must receive a salary as provided in the budget of the board. The chair must develop a five-year budget and staffing plan for the board's approval.

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 for setting upper payment limits 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.

If a plan of action is drafted, by July 1, 2021, the board must submit the plan of action to 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.

If the plan of action is approved by LPC or the Governor and the Attorney General, then beginning January 1, 2022, 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 U.S. Food and Drug Administration's prescription drug shortage list.

If the board has not received approval of the plan of action by January 1, 2023, these provisions are null and void.

Background: The board has conducted two meetings (January 13 and February 24), with a third meeting scheduled for April 20, 2020. By December 31, 2020, the board, in consultation with the stakeholder council, must study (1) the entire pharmaceutical distribution and payment system in the State and (2) policy options being used in other states and countries to lower the list price of pharmaceuticals, including setting upper payment limits, using a reverse auction marketplace, and implementing a bulk purchasing process. The board must report its findings and recommendations (and any legislation required to implement the recommendations) to specified committees of the General Assembly.

Also by December 31, 2020, the board must (1) collect and review publicly available information regarding prescription drug product manufacturers, health insurance carriers, health maintenance organizations, managed care organizations, wholesale distributors, and pharmacy benefits managers; (2) identify states that require reporting on the cost of prescription drug products; and (3) initiate a process of entering into memoranda of understanding with the states to aid in the collection of transparency data for prescription drug products.

Based on the information collected and the data obtained from other states, the board, in consultation with the stakeholder council, must adopt regulations to (1) establish methods for collecting additional data necessary to carry out its duties and (2) identify circumstances under which the cost of a prescription drug product may create or has created affordability challenges for the State health care system and patients.

State Expenditures: General fund expenditures for OAG increase by \$105,931 in fiscal 2021, which accounts for a 30-day start-up delay from the bill's June 1, 2020 effective date. This estimate reflects the cost of hiring one assistant Attorney General to serve as counsel to the board. It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Position	1
Salary and Fringe Benefits	\$100,406
One-time Start-up Expenses	4,890
Ongoing Operating Expenses	<u>635</u>
Total FY 2021 OAG Expenditures	\$105,931

Future year expenditures reflect a full salary with annual increases and employee turnover and ongoing operating expenses. To the extent OAG assigns additional assistant Attorneys General to the board, OAG general fund expenditures may increase further.

Although general funds were anticipated to be used when the board was established, that funding was ultimately not provided. Instead, the Governor’s proposed fiscal 2021 budget includes \$750,000 and five positions for the board in the MHCC budget. No staff, including general counsel, have been hired for the board to date. Accordingly, this analysis does not reflect a reduction in general fund expenditures under the assumption that MHCC would otherwise continue to provide funding until the board could sustain itself. Beginning in fiscal 2021, special fund expenditures intended for the board’s general counsel position decrease – to the extent that funding is not redirected for other purposes. The amount of the decrease for the board may correspond with the increase in costs for OAG. However, due to the bill’s extension for completion of certain actions, costs that would otherwise have been incurred in fiscal 2020 or 2021 may be delayed to fiscal 2022. This impact has not been quantified in this analysis.

Additional Information

Prior Introductions: None.

Designated Cross File: None.

Information Source(s): Baltimore, Carroll, Harford, Montgomery, Queen Anne’s, and St. Mary’s counties; Maryland Association of Counties; Office of the Attorney General; Maryland Department of Health; Department of Legislative Services

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