

Department of Legislative Services
 Maryland General Assembly
 2019 Session

FISCAL AND POLICY NOTE
Third Reader - Revised

Senate Bill 759
 Finance

(Senators Klausmeier and Lam)

Health and Government Operations

Health - Prescription Drug Affordability Board

This bill establishes a Prescription Drug Affordability Board to protect State residents and other stakeholders from the high costs of prescription drug products. 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 recommend a strategy for making the drug more affordable in the State. The bill also establishes a stakeholder council to assist the board and multiple reporting requirements. The board must be established using general funds. By December 31, 2020, the board must determine and submit to specified committees of the General Assembly a recommendation for a funding source for the board. The Office of the Attorney General (OAG) may pursue any available remedy under State law when enforcing the bill. **The bill takes effect July 1, 2019.**

Fiscal Summary

State Effect: General fund expenditures increase by \$831,900 in FY 2020 to establish the board and implement the bill. The FY 2020 Medicaid budget restricts \$750,000 in general funds for this purpose, contingent on passage of SB 759/HB 768 of 2019. Future years reflect ongoing costs but do not factor in certain costs, including those associated with required reports. To the extent the bill reduces drug prices, State expenditures may decrease (not reflected below). Revenues are not materially affected.

(in dollars)	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Revenues	\$0	\$0	\$0	\$0	\$0
GF Expenditure	831,900	781,600	807,400	834,500	862,500
Net Effect	(\$831,900)	(\$781,600)	(\$807,400)	(\$834,500)	(\$862,500)

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

Local Effect: To the extent the bill reduces drug prices, local government health care expenditures may decrease. Revenues are not materially affected.

Small Business Effect: Meaningful.

Analysis

Bill Summary:

Prescription Drug Affordability Board

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. Members of the board may not receive compensation but are entitled to reimbursement for expenses under standard State travel regulations, as provided in the State budget.

The board must meet in open session at least once every six weeks to review prescription drug product information (unless there is none to review). Public notice of each board meeting must be provided at least two weeks in advance. Materials must be made available to the public at least one week in advance. The board must provide an opportunity for public comment at each open meeting and for provision of written comments on pending board decisions.

The board is subject to specified provisions of State procurement law, including minority business participation.

Funding for the Board

The board must be established using general funds, which must be repaid to the State. By December 31, 2020, the board must determine a funding source. The board must consider (1) assessing and collecting a fee on manufacturers, pharmacy benefits managers (PBMs), health insurance carriers, or other entities; (2) using rebates the State or local government receives from manufacturers; and (3) any other method it determines appropriate.

Prescription Drug Affordability Stakeholder Council

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.

Members of the stakeholder council may not receive compensation but are entitled to reimbursement for expenses under standard State travel regulations, as provided in the State budget.

Conflicts of Interest

The bill specifies by whom and at what times conflicts of interest must be disclosed. Conflicts of interest (including the nature, type, and magnitude) must be posted on the board's website unless the board member is recused from any final decision resulting from a review of a prescription drug product.

Members of the board must recuse themselves for specified conflicts of interest. Members and alternate members of the board, board staff, and third-party contractors are prohibited from accepting any gift or donation of services or property that indicates a potential conflict of interest or has the appearance of biasing the work of the board.

Identification and Collection of Data

By December 31, 2020, the board, in consultation with the stakeholder council, must:

- collect and review specified publicly available information;
- review any information requested from manufacturers and other specified entities;
- determine what additional data is necessary to carry out its duties and how to access the data;
- review and assess the pharmaceutical distribution and payment system in the State;
- monitor and review potential and actual federal changes to the pharmaceutical distribution and payment system;
- monitor and review federal regulations governing the Medicaid drug rebate program to support voluntary, value-based purchasing arrangements between states and manufacturers;
- assess the impact of potential and actual federal changes to the pharmaceutical distribution and payment system;

- monitor and review the impact of steps taken by specified State agencies to increase transparency and lower the cost of prescription drugs;
- study different causes of drug shortages and how drug shortages impact the cost of prescription drug products;
- study whether upper payment limits would be appropriate in addressing costs; and
- study other policy proposals to lower the cost of prescription drugs.

Also by December 31, 2020, the board must (1) identify states that require reporting on the cost of prescription drug products and (2) initiate a process of entering into memoranda of understanding (MOU) with the states to aid in the collection of transparency data for prescription drug products.

Before obtaining or using any information obtained through an MOU with another state, the board must verify that the state providing the information has obtained specified consent from the owner of the information. Only board members and staff may access information obtained through an MOU with another state. The board's unauthorized access, use, or sharing of any such information must (1) give rise to a cause of action and be subject to all applicable remedies, including civil and criminal penalties and (2) result in the immediate termination of the MOU.

If the board willfully shares or discloses specified unauthorized information, the board must provide for statutory damages to the owner of the information in the amount of \$200,000 per violation, in addition to any other penalties under applicable federal and State law.

Based on the board's determinations and the data obtained from other states, the board, in consultation with the stakeholder council, must adopt regulations to (1) establish methods for collecting 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.

Prescription Drug Products – Identification and Cost Review

The board must identify prescription drug products that are (1) brand name drugs or biologics that, as adjusted for inflation, have a specified launch wholesale acquisition cost (WAC) or a specified WAC increase over a specified period; (2) biosimilar drugs that have a specified launch WAC; (3) generic drugs that, as adjusted for inflation, have a specified WAC or a specified WAC increase over a specified period; and (4) other prescription drug products that may create affordability challenges, in consultation with the stakeholder council.

Once identified, the board must determine whether to conduct a cost review for each identified prescription drug product by seeking stakeholder council input about the product and considering the average cost share of the product. If there is no publicly available information to conduct a cost review, the board must request specified information from the manufacturer and, as appropriate, a PBM, health insurance carrier, health maintenance organization, or managed care organization with relevant information on setting the cost of a prescription drug in the State.

A cost review must determine whether use of the prescription drug product (that is fully consistent with approved labeling or standard medical practice) has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients by considering multiple specified factors and alternate factors.

Affordability Challenge

If the board finds that the spending on a prescription drug product has led or will lead to an affordability challenge, the board must recommend a strategy for making the drug more affordable in the State.

Confidentiality of Information

All information and data collected by the board during a review is considered to be confidential and proprietary information and is not subject to disclosure under the Public Information Act.

Appeals

A person aggrieved by a board decision may request an appeal within 30 days after the finding. Any person aggrieved by a final decision of the board may petition for judicial review under the Administrative Procedure Act.

Reporting Requirements

By June 1, 2020, 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 study questions and report its findings to the General Assembly.

By December 1, 2020, the State-designated health information exchange (HIE) and the board must jointly study how the HIE can provide de-identified provider and patient data to the board and report their findings and recommendations to the General Assembly.

By December 31, 2020, the board must report to specified committees of the General Assembly with a recommendation on legislation necessary to establish a funding source for the board.

By December 31, 2021, and annually thereafter, the board 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 the number and disposition of appeals and judicial reviews of board decisions; and (3) any recommendations for legislation to make prescription drug products more affordable in the State, including to expand the authority of the board.

By January 1, 2023, the board, in consultation with the stakeholder council, the Health Services Cost Review Commission, and the Maryland Health Care Commission, must monitor and assess the impact of policy actions by the board on (1) prescription drug affordability and access to hospital services in the State; (2) the ability of hospitals and other providers to obtain drugs from manufacturers and suppliers at costs consistent with policy actions by the board; and (3) the ability of the State to meet the requirements of the All-Payer Model Contract. Findings and recommendations must be reported to the General Assembly by that date as well.

Current Law/Background: Growth in spending on prescription drugs is expected to outpace the average growth in total health spending from 2017 through 2022. Prescription drug expenditures are expected to exceed \$462 billion in 2022. In an effort to make prescription drugs more affordable, the federal government, Maryland, and other states have taken action to increase transparency in drug pricing and provide other mechanisms to reduce prescription drug prices.

Actions in Maryland

Maryland was one of the first states to take action to prevent increasing drug prices. Concerned that manufacturers of generic drugs may be engaging in price gouging, particularly for drugs that serve a small market of consumers and have a small number of manufacturers, Chapter 818 of 2017 prohibited manufacturers and wholesale distributors from engaging in price gouging in the sale of essential off-patent or generic drugs that are made available for sale in the State. The legislation authorized the Attorney General to petition a circuit court to issue specified orders, including compelling a manufacturer or wholesale distributor to provide certain statements or records, restraining or enjoining a violation, requiring restitution, or imposing a civil penalty of up to \$10,000 for each violation.

The legislation defined price gouging as an “unconscionable” increase in the price of a prescription drug, meaning that it is “excessive” and not tied to the costs of producing the drug, among other criteria. The Association for Accessible Medicines (AAM), representing manufacturers and distributors of generic and biosimilar medicines, filed a lawsuit in federal court for declaratory and injunctive relief, contending that the law violates the U.S. Constitution by regulating interstate commerce in a manner that violates the Commerce Clause and defining price gouging in a manner that is impermissibly vague. In September 2017, the U.S. District Court for the District of Maryland denied AAM’s request for an injunction and dismissed AAM’s Commerce Clause challenge but allowed AAM’s lawsuit to continue on its vagueness contention. The legislation went into effect on October 1, 2017; however, in April 2018, the U.S. Court of Appeals for the Fourth Circuit found the legislation unconstitutional. In July 2018, a federal appeals court refused a request from the Attorney General to reconsider the lawsuit and, in October 2018, the Attorney General petitioned the U.S. Supreme Court to consider the constitutionality of the legislation. In February 2019, the U.S. Supreme Court declined to hear the appeal, which allows the lower court ruling to stand.

Actions in Other States

Under Vermont’s Act 65, enacted in June 2016, the state must identify up to 15 prescription drugs on which the state spends significant health care dollars and where WACs have increased by 50% or more over the past five years or by 15% or more over the past 12 months. Vermont’s Attorney General must require the manufacturers to provide justification for all factors that have contributed to a price increase and the role of each factor in contributing to the increase. Manufacturers that do not comply are subject to a civil penalty of up to \$10,000. The information provided is submitted as a report to the state legislature and posted online. The information cannot be released in a manner that allows identification of an individual drug or manufacturer.

California enacted legislation that requires manufacturers of prescription drugs to notify the state and health insurers at least 60 days before the price of a drug is expected to increase by 16% or more. Nevada enacted a law requiring manufacturers of diabetes drugs that have increased significantly in price within the past two years to submit a report to the state concerning the reasons for the price increase. The law also requires pharmacy benefits managers to report the rebates negotiated with manufacturers of these drugs. Other state legislation proposals under consideration include the establishment of drug price review boards to review, approve, or adjust launch prices for newly approved prescription drugs or drugs with list prices above certain dollar thresholds.

State Fiscal Effect:

Establishment of the Prescription Drug Affordability Board

General fund expenditures increase by \$750,000 in fiscal 2020, which reflects monies provided for the board in the fiscal 2020 operating budget. Specifically, the Medicaid budget restricts \$750,000 in general funds otherwise intended for provider reimbursements to be used only for the implementation and operation of the board; this funding is contingent on passage of Senate Bill 759 or House Bill 768 of 2019.

Initial funding needed for the board, accounting for the bill’s July 1, 2019 effective date, is estimated to be at least \$731,379. This estimate reflects the cost of hiring five full-time staff to initially establish the board, including an executive director, general counsel, pharmacist, and two executive assistants. It includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses. This estimate *does not* reflect the cost of per diems or expense reimbursements for board members or stakeholder council members, nor any additional staff or contractual services that may be necessary to fully staff the board or to complete any related reports or studies under the bill. However, the residual funding available due to the funding restricted in the budget is likely sufficient to cover certain such costs in the first year of implementation.

Prescription Drug Affordability Board Positions	5.0
Salaries and Fringe Benefits	\$691,304
One-time Start-up Expenses	24,450
Ongoing Operating Expenses	15,625
Residual Funding Available for Other Purposes	<u>18,621</u>
Board FY 2020 General Fund Expenditures	\$750,000

Future year expenditures reflect annual salary increases and employee turnover and ongoing operating expenses. As the board must be established using general funds, this analysis assumes that general funds are used. The bill requires the board to determine and recommend to the General Assembly a funding source by December 31, 2020. Therefore, the source of out-year funding may change, likely no sooner than fiscal 2022, and any such change may require legislation.

To the extent the board reduces the cost of prescription drugs in the State, State expenditures may decline. The amount or timing of any such savings cannot be reliably estimated at this time and is, therefore, not reflected in this analysis.

Office of the Attorney General

OAG is authorized to pursue any available remedy under State law when enforcing the bill. Thus, general fund expenditures increase by \$81,945 in fiscal 2020, which accounts for the bill's July 1, 2019 effective date. This estimate reflects the cost of hiring one part-time (50%) assistant Attorney General to handle enforcement of the bill. It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

OAG Position	0.5
Salary and Fringe Benefits	\$74,242
One-time Start-up Expenses	4,890
Ongoing Operating Expenses	<u>2,813</u>
OAG FY 2020 General Fund Expenditures	\$81,945

Future year expenditures reflect annual salary increases and employee turnover and ongoing operating expenses. This analysis assumes that general funds are used for OAG costs.

Small Business Effect: Small business manufacturers must comply with the bill, which may include, subject to a required report and potentially legislation, paying a fee to fund the board. The number of small business manufacturers subject to the bill is unknown. To the extent the bill reduces drug prices, small business health care expenditures decrease by an unknown amount.

Additional Information

Prior Introductions: HB 1194 of 2018, a similar bill, passed the House with amendments and received a favorable report from the Senate Finance Committee, but no further action was taken. Its cross file, SB 1023, received a hearing in the Senate Finance Committee, but no further action was taken.

Cross File: HB 768 (Delegate Pena-Melnyk, *et al.*) - Health and Government Operations.

Information Source(s): Office of the Attorney General; Department of Budget and Management; Maryland Department of Health; Office of Administrative Hearings; Maryland Health Benefit Exchange; Maryland Insurance Administration; Department of Legislative Services

Fiscal Note History:
mag/ljm

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