HB 768

Department of Legislative Services

Maryland General Assembly
2019 Session

FISCAL AND POLICY NOTE
Enrolled - Revised

House Bill 768 (Delegate Pena-Melnyk, *et al.*)
Health and Government Operations Finance

Health - Prescription Drug Affordability Board

This bill establishes a 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 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 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, but the implementation of upper payment limits and certain other provisions are contingent upon specified approval.**

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 enactment of Senate Bill 759/House Bill 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 decrease by a potentially significant amount (not reflected below). Revenues are not 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 decrease by a potentially significant amount. Revenues are not 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.

Generally, the board must meet in open session at least once every six weeks. 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. Materials containing trade secrets or confidential and proprietary data or information not otherwise available to the public may not be made available to the public. 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, wholesale distributors, 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.

Pharmaceutical Distribution and Payment System and Policy Options in Other States

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 counties 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.

Identification and Collection of Available Information

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 (HMOs), managed care organizations (MCOs), wholesale distributors, and PBMs; (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.

Prescription Drug Products – Identification and Cost Review

The board must use the information collected and data obtained from other states to 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 wholesale distributor, PBM, health insurance carrier, HMO, or MCO with relevant information on setting the cost of the 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.

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 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.

Implementation of Upper Payment Limits if Plan of Action Approved

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:

- 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;

- 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

- 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.

Confidentiality of Information

All information and data obtained by the board that is not otherwise publicly available is considered to be a trade secret and confidential and proprietary information and is not subject to disclosure under the Public Information Act. Only board members and staff may access such information and data, and the provisions of the Maryland Uniform Trade Secrets Act apply to such information and data.

Appeals

A person aggrieved by a board decision may request an appeal within 30 days after the finding. 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. These provisions are contingent on the board receiving approval of the plan of action for implementing a process for setting upper payment limits; if approval is not received by January 1, 2023, these provisions are null and void.

Additional 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, 2020, 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 (3) any recommendations for legislation to make prescription drug products more affordable in the State.

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 (including upper payment limits, if applicable) 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 (including upper payment limits, if applicable); 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.

By December 1, 2023, the board, in consultation with the 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 the board to set upper payment limits to all purchases and payor reimbursements of prescription drug products in the State. This reporting requirement is contingent on the board receiving approval of the plan of action for implementing a process for setting upper payment limits; if approval is not received by January 1, 2023, this reporting requirement is null and void.

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 PBMs 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 enactment 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	18,621
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 (a combination of general, special, and federal funds for Medicaid, the State Employee and Retiree Health and Welfare Benefits Program, and other State health care programs) decline by a potentially significant amount. The amount and 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	2,813
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 and other entities 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 and other entities subject to the bill is unknown. To the extent the bill reduces drug prices, small business health care expenditures decrease by a potentially significant 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: SB 759 (Senators Klausmeier and Lam) - Finance.

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

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Analysis by: Jennifer B. Chasse

Direct Inquiries to:
(410) 946-5510
(301) 970-5510