SB 759

Department of Legislative Services

Maryland General Assembly
2019 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 759 (Senators Klausmeier and Lam)
Finance

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 identify specified prescription drug products that may cause affordability issues, may conduct a cost review of each identified drug and, if warranted, must recommend or establish an upper payment limit for the prescription drug product. The bill also establishes a Prescription Drug Affordability Fund, a stakeholder council to assist the board, and several reporting requirements. The board must be established using general funds and is then funded by an annual assessment on manufacturers. The Office of the Attorney General (OAG) may pursue any available remedy under State law when enforcing the bill.

Fiscal Summary

State Effect: Special fund revenues increase by an indeterminate but potentially significant amount beginning in FY 2021 from an assessment on manufacturers. General fund expenditures increase by *at least* $617,300 in FY 2020 to establish the board and implement the bill; future years reflect annualization and use of special funds for all costs. To the extent the bill reduces drug prices, State expenditures decrease by a potentially significant amount beginning in FY 2024 (not reflected below).

(in dollars)	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
SF Revenue	$0	-	-	-	-
GF Expenditure	$617,300	$0	$0	$0	$0
SF Expenditure	$0	$781,600	$807,400	$834,500	$862,500
Net Effect	($617,300)	($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 beginning in FY 2024. Revenues are not affected.

Small Business Effect: Meaningful.

Analysis

Bill Summary:

Prescription 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.

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. 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.

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. Members of the council must have knowledge in one or more of 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.

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. 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

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 or establish an upper payment limit after considering specified costs, methodologies, and data sources.

By December 31, 2023, the board must work with payors, purchasers, consumers, and other stakeholders to (1) refine methodologies by which to set upper payment limits for prescription drug products and (2) establish data sources for conducting analysis of the need for upper payment limits for specific drugs. The board must consider all of the information received and recommend and publicize an upper payment limit that applies to all purchases and payor reimbursements of the prescription drug product in the State.

Beginning January 1, 2024, the board must, for a prescription drug product for which the board recommended an upper payment limit, (1) consider any additional methodologies or data sources and (2) determine whether to establish an upper payment limit that applies to all purchases and payor reimbursements of the prescription drug product in the State. For any other prescription drug product that the board determines creates affordability challenges, the board must consider all of the information the board received and establish an upper payment limit that applies to all purchases and payor reimbursements of the prescription drug product in the State.

Any information submitted to the board during the process of setting upper payment limits is subject to public inspection only to the extent allowed under the Public Information Act.

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.

Manufacturer Fees and Prescription Drug Affordability Fund

The fund is a special, nonlapsing fund that may be used only to provide funding for the board, including any costs expended by any State agency to implement the bill. Any investment earnings are retained in the fund. The fund is subject to audit by the Office of Legislative Audits.

The board must be initially established using general funds, which must be repaid. The board must assess each manufacturer an annual fee based on the manufacturer's relative share of gross revenue from drug sales in the State; each manufacturer must pay the annual fee to the board. All fees collected are paid into the fund.

Reporting Requirements

By December 31 annually, 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.

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 January 1, 2023, the Health Services Cost Review Commission (HSCRC), in consultation with the Maryland Health Care Commission (MHCC), must monitor and assess the impact of upper payment limits and 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 the upper payment limits; and (3) the ability of the State to meet the requirements of the All-Payer Model Contract. HSCRC and MHCC must report their findings and recommendations to the General Assembly.

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 a minimum of $554,649 in fiscal 2020, which accounts for the bill's October 1, 2019 effective date. 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.

Prescription Drug Affordability Board Positions	5.0
Salaries and Fringe Benefits	$518,480
One-time Start-up Expenses	24,450
Ongoing Operating Expenses	11,719
Board FY 2020 General Fund Expenditures	**$554,649**

Future year expenditures reflect full salaries with annual increases and employee turnover and ongoing operating expenses. As the board must be established using general funds and then funded by an annual assessment on manufacturers, this analysis assumes that general funds are used for fiscal 2020 board costs. Once manufacturer assessments are established and collected (accruing to the Prescription Drug Affordability Board Fund), board expenditures are covered by special fund expenditures beginning in fiscal 2021.

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.

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 beginning in fiscal 2024. No savings are anticipated prior to the board establishing upper payment limits, which is required beginning January 1, 2024, under the bill. The amount of any such savings cannot be reliably estimated at this time and is, therefore, not reflected in this analysis.

The bill requires that the board be funded by an assessment on all manufacturers. General funds are to be used initially and to be repaid with the assessments. All manufacturer fees must be paid into the Prescription Drug Affordability Fund. Therefore, special fund revenues increase, likely beginning in fiscal 2021 due to the required assessment on manufacturers. Although the assessment takes effect in fiscal 2020, this analysis assumes that the board must identify manufacturers, determine the applicable assessment for each manufacturer, and collect the assessment, which takes approximately six to nine months. Thus, revenues are likely not collected until fiscal 2021. The amount of such revenues cannot be reliably estimated at this time, but the assessment is assumed to be set to match any projected expenditures for the board.

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 $62,681 in fiscal 2020, which accounts for the bill's October 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	$55,681
One-time Start-up Expenses	4,890
Ongoing Operating Expenses	2,110
OAG FY 2020 General Fund Expenditures	**$62,681**

Future year expenditures reflect a full salary with annual increases and employee turnover and ongoing operating expenses. This analysis assumes that general funds are used for fiscal 2020 OAG costs. Once manufacturer assessments are established and collected, OAG expenditures are covered by special fund expenditures beginning in fiscal 2021, as the fund is explicitly authorized to be used for any costs expended by any State agency to implement the bill.

Small Business Effect: Small business manufacturers must comply with the bill, including paying an assessment 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 a potentially significant amount beginning in fiscal 2024.

Additional Comments: The Department of Legislative Services notes that the board will not set any upper payment limits until January 1, 2024; therefore, the review required by HSCRC and MHCC on the impact of those limits could not be conducted until *after* that time, even though the bill requires that review to be *completed* a year earlier. Therefore, costs associated with the HSCRC and MHCC review have not been accounted for in this analysis. Even so, HSCRC advises that the review would cost at least $200,000 annually over multiple years.

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: First Reader - March 4, 2019
md/ljm

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