SB 1023

Department of Legislative Services

Maryland General Assembly
2018 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 1023 (Senator Conway, *et al.*)
Finance

Health - Drug Cost Review Commission

This bill establishes a Drug Cost Review Commission to protect specified stakeholders from excessive costs of prescription drugs. A Drug Cost Review Advisory Board is created to assist the commission. Drug manufacturers must notify the commission of specified pricing changes or if specified drugs will be introduced to market. The commission must establish additional reporting thresholds for other specified drugs. The commission must review the cost of a prescription drug under specified circumstances and, if it determines that spending on a reviewed drug creates excess costs, the commission must establish the level of reimbursement that must be billed and paid for the drug. The commission must be initially funded with general funds, then by an assessment on the manufacturers required to provide notifications under the bill. Noncompliance must be referred to the Office of the Attorney General (OAG), which may pursue specified legal remedies.

Fiscal Summary

State Effect: General fund expenditures increase by *at least* $744,000 in FY 2019 to establish the commission and otherwise implement the bill; out-years reflect annualization. General fund revenues increase by an indeterminate but significant amount beginning in FY 2019 from the assessment. To the extent the bill reduces drug prices, State expenditures decrease by a potentially significant amount beginning in FY 2019 (not reflected below).

(in dollars)	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
GF Revenue	-	-	-	-	-
GF Expenditure	$744,000	$942,200	$971,100	$1,004,600	$1,039,400
Net Effect	(-)	(-)	(-)	(-)	(-)

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 2019. Revenues are not affected.

Small Business Effect: Meaningful.

Analysis

Bill Summary:

Drug Cost Review Commission

The chair of the commission must hire an executive director, general counsel, and staff for the commission, who must receive a salary, as provided in the budget of the commission. Members of the commission may not receive compensation but are entitled to reimbursement for expenses under standard State travel regulations, as provided in the State budget.

The commission must meet at least every six weeks in open session to review prescription drug product information submissions. Notwithstanding the Open Meetings Act, the commission may meet in closed session, but specified deliberations and decisions of the commission must be made in open session. Public notice of each commission 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 commission must provide an opportunity for the public to comment at each open meeting and to provide written comments on pending decisions of the commission.

The commission must make an annual report available to the public on prescription drug pricing trends, the number of manufacturers required to submit notifications to the commission, and the number of products that were subject to commission review.

Drug Cost Review Advisory Board

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

Recusal and Conflicts of Interest

The bill requires the commission to recuse members from specified decisions that may present a conflict of interest and requires specified procedures for disclosing potential

conflicts of interest. Members of the commission, advisory board, commission 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 commission.

Manufacturer Notifications

A manufacturer of a patent-protected, brand-name drug or biological must notify the commission if (1) the wholesale acquisition cost (WAC) of the drug is increasing by more than 10% or $10,000 during any 12-month period or (2) the manufacturer intends to introduce a brand-name drug that has a WAC of $30,000 per calendar year or per course of treatment.

A manufacturer of a generic or off-patent sole source branded product drug must notify the commission if the WAC of the drug is increasing by more than 25% or $300 during any 12-month period.

Notifications must be provided in writing at least 30 days before the planned effective date of the price increase or the introduction of the drug to market and include a justification for the proposed pricing that includes specified documents and research.

The commission must establish additional thresholds for manufacturer reporting of brand prescription drugs, including biologics and biosimilars, and generic and off-patent sole source branded prescription drugs that are not otherwise reported but that impose costs on the State health care system that create significant challenges to affordability.

To the extent feasible and practicable, the commission must access manufacturer justification information made public by other states. If such information is not available, the commission must require a manufacturer to submit specified documents and research related to pricing of the drug. The commission must inform the public about these reports.

Review of Reported Prescription Drugs

The commission must allow the public to request commission review of the cost of any prescription drug reported to the commission. The chair of the commission must review any public request and may initiate a review of the cost of a prescription drug in the absence of a public request.

If the commission conducts a review of the cost of a prescription drug, the review must determine if a utilization of the drug that is fully consistent with the U.S. Food and Drug Administration label has led, or will lead, to excess costs for health care systems in the State.

The bill specifies the factors that the commission may consider in determining cost and excess costs. If the commission is unable to determine whether a prescription drug product will produce or has produced excess costs using specified factors, the commission may consider additional specified factors.

If the commission finds that the spending on a prescription drug product reviewed by the commission creates excess costs for payors and consumers, the commission must establish the level of reimbursement that must be billed and payed among (1) payors and pharmacies or administering providers; (2) wholesalers and distributors and pharmacies or administering providers; and (3) pharmacies or administering providers and uninsured consumers or consumers in a deductible period. The commission must determine how each participant in the supply chain of the prescription drug must be remunerated.

Penalties for Noncompliance

The noncompliance of an entity to bill or pay the reimbursement rates established by the commission must be referred to OAG. Price concessions from a manufacturer that result in the insurer's net cost being lower than the rate established by the commission may not be construed as noncompliance.

If OAG finds that an entity was noncompliant with commission reimbursement requirements, OAG may pursue remedies consistent with State law or other appropriate criminal laws if there is evidence of intentional profiteering. OAG must provide guidance to stakeholders concerning activities that could be considered noncompliant that are in addition to billing and payment where drug costs exceed the rates established by the commission.

Failure of a manufacturer to submit required notifications as required under the bill must also be referred to OAG. OAG may pursue any available remedy under State law when enforcing the bill.

A person aggrieved by a decision of the commission may request an appeal within 30 days after the finding of the commission. The commission must hear the appeal and make a final decision within 60 days of the hearing. Any person aggrieved by a final decision of the commission may take a direct judicial appeal as provided in the Administrative Procedure Act.

Funding

The commission must be funded by an assessment on each manufacturer required to submit notifications under the bill. The commission must determine the amount of the assessment

required in regulations. The commission must be initially established using general funds, which are to be repaid to the State with the assessments.

Current Law: Chapter 818 of 2017 prohibits a manufacturer or wholesale distributor from engaging in "price gouging" in the sale of an "essential off-patent or generic drug." Medicaid may notify OAG when specified price increases occur. On request of OAG, the manufacturer of an essential off-patent or generic drug must submit a specified statement. OAG may require a manufacturer or wholesale distributor to produce any records or documents relevant to determining if a violation of the prohibition on price gouging has occurred. On petition of OAG, a circuit court may issue specified orders, including compelling a manufacturer or wholesale distributor to provide certain statements or records, restraining or enjoining a violation, requiring restitution, and imposing a civil penalty of up to $10,000 for each violation.

"Price gouging" means an unconscionable increase in the price of a prescription drug. "Unconscionable increase" means an increase in the price of a prescription drug that (1) is excessive and not justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug to promote public health and (2) results in consumers for whom the drug has been prescribed having no meaningful choice about whether to purchase the drug at an excessive price because of the importance of the drug to their health and insufficient competition in the market for the drug.

Medicaid may notify OAG of any increase in the price of an essential off-patent or generic drug when:

(1) the price increase, by itself or in combination with other price increases, would result in an increase of 50% or more in the:

- WAC of the drug within the preceding one-year period; or
- the price paid by Medicaid for the drug within the preceding one-year period; *and*

(2) any of the following apply:

- a 30-day supply of the maximum recommended dosage of the drug for any indication, according to the approved label for the drug, would cost more than $80 at the drug's WAC;
- a full course of treatment with the drug, according to the approved label for the drug, would cost more than $80 at the drug's WAC; or

- if the drug is made available to consumers only in quantities that do not correspond to a 30-day supply, a full course of treatment, or a single dose, it would cost more than $80 at the drug's WAC to obtain a 30-day supply or a full course of treatment.

On request of OAG, the manufacturer of an essential off-patent or generic drug identified in a notice sent by Medicaid to OAG, within 45 days after the request, must submit a statement to OAG that (1) itemizes the components of the cost of producing the drug and identifies the circumstances and timing of any increase in materials or manufacturing costs that caused any increase in the price of the drug within the one-year period preceding the date of the price increase; (2) identifies the circumstances and timing of any expenditures made by the manufacturer to expand access to the drug and explains any improvement in public health associated with those expenditures; and (3) provides any other information the manufacturer believes to be relevant to a determination of whether a violation of the prohibition against price gouging has occurred.

OAG may require a manufacturer or a wholesale distributor to produce any records or documents relevant to determining if a violation of the prohibition on price gouging has occurred.

On petition of OAG, a circuit court may issue an order (1) compelling a manufacturer or a wholesale distributor to provide the required statement *and* to produce specific records or other documents requested by OAG; (2) restraining or enjoining a violation of the prohibition against price gouging; (3) restoring to any consumer, including a third-party payor, any money acquired as a result of a price increase that violates the prohibition; (4) requiring a manufacturer that has engaged in price gouging in the sale of an essential off-patent or generic drug to make the drug available to participants in the State Employee and Retiree Health and Welfare Benefits Program for a period of up to one year at the price at which the drug was made available to participants in the program immediately prior to the manufacturer's violation; and (5) imposing a civil penalty of up to $10,000 for each violation. OAG may not bring an action for specified remedies unless the manufacturer or wholesale distributor is given an opportunity to meet with OAG to offer a justification for the increase in the price of the essential off-patent or generic drug.

Any information provided by a manufacturer or wholesale distributor to OAG under specified provisions of the law must be considered confidential commercial information unless the confidentiality of the information is waived by the manufacturer or wholesale distributor.

Background: With prescription drugs accounting for the largest component of health insurance premium expenses, at 22.1% on average, and individuals incurring significant out-of-pocket expenses for prescription drugs, prescription drug pricing and affordability continues to be an issue of interest nationwide.

According to QuintilesIMS, the United States spent $450 billion on prescription drugs in 2016, an increase of 5.8% over 2015 levels. Similarly, the U.S. Department of Health and Human Services estimates that spending on retail prescription drugs grew by 4.8% in 2016. Growth in spending on prescription drugs is expected to rise by an average of 6.4% through 2025, outpacing the average 5.6% growth in total health spending during this time period. Prescription drug spending is expected to accelerate from 5.7% in 2017 to an average of 7.0% for 2018 and 2019 as fewer brand-name drugs will be losing patent protection.

An August 2016 special communication in the *Journal of the American Medical Association* found that per capita prescription drug spending in the United States ($858 in 2013) is more than twice that of 19 advanced industrialized nations (an average of $400). The study asserted that market exclusivity of brand-name drugs allows manufacturers to set high prices and that generic drugs are slow to market, delayed by manufacturer business and legal practices.

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. Vermont released the first drug pricing report in December 2016, which noted that, of 87,248 national drug codes evaluated, 9.4% saw more than a 50% increase in the last five years and 4.6% saw more than a 15% increase in the last year.

California recently enacted a law 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.

Canada has a Patented Medicine Prices Review Board (PMPRB) to protect and inform Canadians by ensuring that prices of patented medicines sold in Canada are not excessive and by reporting on pharmaceutical trends. PMPRB monitors the prices charged for

patented drugs through price and sales information filings to ensure that prices comply with guidelines established by the board.

State Fiscal Effect:

Establishment of Drug Cost Review Commission

General fund expenditures increase by a minimum of $539,990 in fiscal 2019, which accounts for the bill's October 1, 2018 effective date. This estimate reflects the cost of hiring five full-time staff to initially establish the commission, 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.

Drug Cost Review Commission Positions	5
Salaries and Fringe Benefits	$505,101
One-time Start-up Expenses	23,170
Ongoing Operating Expenses	11,719
Commission FY 2019 General Fund Expenditures	**$539,990**

Future year expenditures reflect full salaries with annual increases and employee turnover and ongoing operating expenses.

This estimate *does not* reflect the cost of per diems or expense reimbursement for commission members or advisory board members, nor any additional staff or contractual services that may be necessary to fully staff the commission.

To the extent the commission 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 2019. The amount of any such reduction cannot be reliably estimated at this time and is, therefore, not reflected in this analysis.

The bill requires that the commission be funded by an assessment on each manufacturer required to provide notifications to the commission. General funds are to be used initially and to be repaid with the assessments. As no special fund is established for the commission, it is assumed that all funds for the commission are general funds. General fund revenues increase beginning in fiscal 2019 due to the required assessment on manufacturers. 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 commission.

Office of the Attorney General

OAG is authorized to pursue any available remedy under State law when enforcing the bill. If OAG funds that an entity was noncompliant, OAG may pursue remedies consistent with State law or other appropriate criminal laws if there is evidence of intentional profiteering. OAG must provide guidance to stakeholders concerning activities that could be considered noncompliant. Thus, general fund expenditures increase by at least $203,972 in fiscal 2019, which accounts for the bill's October 1, 2018 effective date. This estimate reflects the cost of hiring two assistant Attorneys General and one management associate to handle enforcement of the bill. It includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Office of the Attorney General Positions	3
Salaries and Fringe Benefits	$182,271
One-time Start-up Expenses	14,670
Ongoing Operating Expenses	7,031
OAG FY 2019 General Fund Expenditures	**$203,972**

Future year expenditures reflect full salaries with annual increases and employee turnover and ongoing operating expenses.

Small Business Effect: Small business manufacturers must comply with the bill; 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 2019.

Additional Comments: Senate Bill 437 of 2017, as introduced, would have required the manufacturer of an "expensive drug" sold in Maryland to file a specified annual report with the Secretary of Health and a specified notice before increasing the average wholesale price or WAC cost of the drug by more than a specified amount. The bill passed the Senate with amendments and was referred to the House Rules and Executive Nominations Committee. Its cross file, House Bill 666 of 2017, received a hearing in the House Health and Government Operations Committee, but no further action was taken.

Additional Information

Prior Introductions: None.

Cross File: HB 1194 (Delegate Pena-Melnyk, *et al.*) - Health and Government Operations.

Information Source(s): QuintilesIMS; U.S. Department of Health and Human Services; *Journal of the American Medical Association*; Patented Medicine Prices Review Board; Office of the Attorney General; Maryland Department of Health; Maryland Insurance Administration; Department of Legislative Services

Fiscal Note History: First Reader - February 27, 2018
mm/ljm

Analysis by: Jennifer B. Chasse

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