HB 1194

Department of Legislative Services

Maryland General Assembly
2018 Session

FISCAL AND POLICY NOTE
Third Reader - Revised

House Bill 1194 (Delegate Pena-Melnyk, *et al.*)
Health and Government Operations Finance

Health – Drug Cost Commission

This bill establishes a Drug Cost Commission to determine how to make prescription drugs more affordable. The commission must (1) review, evaluate, and assess the pharmaceutical distribution and payment system in the State; (2) assess and collect publicly available information from specified sources; and (3) compare the prices for prescription drugs in the United States and in other countries. The commission must create an advisory council consisting of specified stakeholders. The Department of Legislative Services (DLS), in consultation with the Office of the Attorney General (OAG), must provide staff to the commission. By January 1, 2019, and each January 1 thereafter, the commission must report to specified committees of the General Assembly on its findings and recommendations. **The bill takes effect June 1, 2018, and terminates June 30, 2021.**

Fiscal Summary

State Effect: Staffing for the commission and any expense reimbursements for commission members can be handled within existing budgeted resources. However, as technical assistance is likely necessary to complete the activities required under the bill, DLS general fund expenditures increase by an indeterminate amount for contractual services for the three years the commission is in existence. Revenues are not affected.

Local Effect: None.

Small Business Effect: None.

Analysis

Bill Summary:

Drug Cost Commission

The commission 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 commission must meet in open session except when discussing nonpublic pricing information. 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 public comment at each open meeting and for provision of written comments on pending decisions of the commission. The commission may allow expert testimony at commission meetings.

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.

Members of the commission, advisory council, 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.

Drug Pricing Information

To the extent feasible and practicable, the commission must access drug pricing justification information for brand name and generic drugs that is available to the public from manufacturers, wholesalers, pharmacy benefits managers, insurance carriers, and pharmacies, including any rebates offered on the drugs. To the extent feasible and practicable, the commission may access public and nonpublic prescription drug pricing information by entering into a memorandum of understanding with another state.

Proprietary Information

The commission may not publicly disclose proprietary information. Proprietary information obtained by the commission must be considered confidential, commercial information and may not be released by the commission in any manner that (1) allows for the identification of an individual drug, a manufacturer, or another entity from which

proprietary information was obtained or (2) is likely to compromise the financial, competitive, or proprietary nature of the information.

Reporting Requirements

By January 1, 2019, and each January 1 thereafter, the commission must report to specified committees of the General Assembly on (1) findings related to the prescription drug pricing information accessed by the commission; (2) recommendations on how entities within the prescription drug supply chain can improve access to affordable prescription drugs by State residents; and (3) findings related to the price of prescription drugs in the United States as compared to other countries and recommendations on how to make the prices of drugs in the United States comparable to the price of drugs in other countries.

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:

- wholesale acquisition cost (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.

Additional Information

Prior Introductions: None.

Cross File: SB 1023 (Senator Conway, *et al.*) - Finance.

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

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