HB 666

Department of Legislative Services

Maryland General Assembly
2017 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 666 (Delegate Bromwell, *et al.*)
Health and Government Operations

Public Health - Expensive Drugs - Manufacturer Reporting and Drug Price Transparency Advisory Committee

This bill requires the manufacturer of an "expensive drug" sold in Maryland to file (1) by March 31 of each year, a specified annual report with the Secretary of Health and Mental Hygiene and (2) a specified notice with the Secretary before increasing the average wholesale price or wholesale acquisition cost of the expensive drug by more than a specified amount. Both documents must be posted online. Electronic notice of the filing of a price increase must be sent to specified entities. By December 31, 2018, and annually thereafter, the Secretary must publish a summary report of the annual reports and provide a copy to the Governor and the General Assembly. A newly established Drug Price Transparency Advisory Committee must advise the Secretary on the annual report process. If a manufacturer fails to file an annual report or notice of a price increase, the Secretary must impose a civil penalty of up to $10,000 for each day the violation continues. The Attorney General may seek a court order requiring a manufacturer to file an annual report.

Fiscal Summary

State Effect: General fund revenues increase as a result of the bill's civil penalty provisions. Medicaid expenditures increase by $65,600 (50% federal funds, 50% general funds) in FY 2018 to hire one health policy analyst to staff the advisory committee and perform related duties. Federal fund revenues increase accordingly. Future years reflect annualization.

(in dollars)	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
GF Revenue	-	-	-	-	-
FF Revenue	$32,800	$41,400	$43,200	$45,200	$47,200
GF Expenditure	$32,800	$41,400	$43,200	$45,200	$47,200
FF Expenditure	$32,800	$41,400	$43,200	$45,200	$47,200
Net Effect	($32,800)	($41,400)	($43,200)	($45,200)	($47,200)

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

Local Effect: None.

Small Business Effect: Meaningful as small business manufacturers of expensive drugs must comply with the bill's requirements. However, the number of small business manufacturers of expensive drugs in Maryland is unknown.

Analysis

Bill Summary: "Expensive drug" means a prescription drug that a manufacturer makes available in the State that has a wholesale acquisition cost of $2,500 or more annually or per course of treatment. "Wholesale acquisition cost" (WAC) is defined in 42 USC § 1395W-3A as the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data. In other words, WAC is the manufacturer's reported list price to a wholesaler or direct purchaser without discounts.

Annual Reports by Manufacturers of Expensive Drugs

The annual report must include specified information regarding the expensive drug, including (1) research and development costs; (2) intellectual property rights, approvals, and associated regulatory costs; (3) manufacturing, production, marketing, and advertising costs; (4) prices of the expensive drug and returns from sales; (5) the manufacturer's federal, State, and local income tax rates, governmental benefits, and credits; (6) financial assistance provided to patients; (7) the comparative effectiveness of the expensive drug; and (8) any other category of information required to be included under regulations adopted by the Secretary.

The manufacturer must (1) separately identify by line item the information included in the annual report to the maximum extent possible to promote public transparency and understanding of the information; (2) provide documentation for the information included in the annual report; (3) have the information in the annual report audited by an independent third-party auditor before the report is filed with the Secretary; and (4) include information for the immediately preceding calendar year, unless another reporting period is required.

An annual report constitutes public information. A custodian may not deny inspection under the Public Information Act of an annual report or any part of the report.

If a manufacturer fails to file an annual report or files an inaccurate report, the Secretary must impose a civil penalty of up to $10,000 for each day the violation continues. In addition, the Attorney General may seek a court order in a court of competent jurisdiction requiring the manufacturer to file the required report. The Attorney General must serve notice on the manufacturer of the intent to seek such an order at least seven days before seeking the order. If the Attorney General is granted an order requiring the manufacturer to file a required report, the Attorney General is entitled to recover reasonable attorney's fees and costs.

The Secretary, in consultation with the Drug Price Transparency Advisory Committee, must adopt regulations to implement the annual reporting requirement for manufacturers. The regulations must facilitate public transparency, identify any additional information that the manufacturer must include in an annual report, and include a uniform reporting form that the manufacturer must use.

Drug Price Transparency Advisory Committee

The advisory committee must advise the Secretary on the development of regulations regarding annual reports required to be submitted by manufacturers, review of the annual reports filed, and the preparation of summary reports. The advisory committee consists of the Secretary (or the Secretary's designee) and eight additional members, appointed by the Secretary. A member of the advisory committee may not be affiliated with a manufacturer or have any other conflict of interest relating to the duties of the advisory committee. The Secretary (or the Secretary's designee) must chair the advisory committee. The Secretary must adopt regulations regarding the advisory committee, including the minimum number of times the advisory committee must meet each year, any compensation for and reimbursement of expenses incurred by advisory committee members, and the terms of members.

Manufacturer Notice of Certain Price Increases for Expensive Drugs

A manufacturer of an expensive drug that is sold or offered for sale in Maryland must file a notice with the Secretary before increasing the average wholesale price or WAC of the expensive drug by more than (1) 10% or $2,500, whichever is less, during a 12-month period or (2) 15% cumulatively during any 24-month period.

The notice must be filed in writing at least 60 days before the increase takes effect and must state (1) the justification for the price increase; (2) the marketing budget for the expensive drug in the immediately preceding calendar year; (3) if the expensive drug was not developed by the manufacturer, the date the expensive drug was acquired by the manufacturer and the price of the acquisition; and (4) the history of all price increases for the expensive drug that took effect during the immediately preceding five calendar years.

Within 15 days after a notice is filed, the Secretary must post the notice on the Department of Health and Mental Hygiene website and send electronic notice of the filing to purchasers that have requested to receive notification and the State Board of Pharmacy. A custodian may not deny inspection under the Public Information Act of a notice, or any part of a notice. The Secretary must establish a process through which a purchaser may request to receive notice of filings.

If a manufacturer fails to file a notice or files an inaccurate notice, the Secretary must impose a civil penalty of up to $10,000 for each day the violation continues.

Current Law: Under the Maryland Consumer Protection Act (MCPA), an unfair or deceptive trade practice includes, among other acts, any false, falsely disparaging, or misleading oral or written statement, visual description, or other representation of any kind, which has the capacity, tendency, or effect of deceiving or misleading consumers. The prohibition against engaging in any unfair or deceptive trade practice encompasses the offer for or actual sale, lease, rental, loan, or bailment of any consumer goods, consumer realty, or consumer services; the extension of consumer credit; the collection of consumer debt; or the offer for or actual purchase of consumer goods or consumer realty from a consumer by a merchant whose business includes paying off consumer debt in connection with the purchase of any consumer goods or consumer realty from a consumer.

The Office of the Attorney General's Consumer Protection Division is responsible for enforcing MCPA and investigating the complaints of aggrieved consumers. The division may attempt to conciliate the matter, issue a cease and desist order, or file a civil action in court. A merchant who violates MCPA is subject to a fine of up to $1,000 for the first violation and up to $5,000 for each subsequent violation. In addition to any civil penalties that may be imposed, any person who violates MCPA is guilty of a misdemeanor and, on conviction, is subject to a fine of up to $1,000 and/or imprisonment for up to one year.

Background: Concerns about the high cost of prescription drugs have prompted calls for action to lower prescription drug costs. At the federal level, the EpiPen controversy has prompted calls for approval of more generic versions of common drugs, and the U.S. Food and Drug Administration is under pressure to reduce a backlog of more than 4,000 generic drug applications. There are proposals to limit secondary patents for trivial changes of a patented molecule and to lower the exclusivity period for biologic drugs, as well as calls for more aggressive policing of anticompetitive business practices.

Vermont is the only state to enact drug transparency legislation to date. 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 who 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.

In December 2016, 20 states' attorneys general (including Maryland's) filed a civil complaint against six pharmaceutical companies alleging price fixing schemes to artificially inflate prices on generic drugs. Federal prosecutors have made similar claims against several former pharmaceutical executives.

State Fiscal Effect: Medicaid expenditures increase by $65,582 (50% federal funds, 50% general funds) in fiscal 2018, which accounts for the bill's October 1, 2017 effective date. Federal fund revenues increase accordingly. This estimate reflects the cost of hiring one full-time grade 18 health policy analyst to staff the advisory committee, prepare regulations, receive and track annual reports and notices of price increases from manufacturers of expensive drugs, assist the Secretary in preparing the annual summary report, post specified reports and notices online, and transmit notice of price increases to specified purchasers and the State Board of Pharmacy. It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Position	1
Salary and Fringe Benefits	$60,473
One-time Start-up Expenses	4,640
Ongoing Operating Expenses	469
Total FY 2018 State Expenditures	**$65,582**

This estimate does not reflect the cost of any compensation or reimbursement of advisory committee members, which may be adopted in regulations as authorized under the bill. To the extent compensation or reimbursement is provided, general fund expenditures increase, likely by a minimal amount.

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

Any impact on the Office of the Attorney General to implement the bill is not reflected in this analysis as a response was not provided to the Department of Legislative Services.

Additional Information

Prior Introductions: None.

Cross File: SB 437 (Senator Conway, *et al.*) - Finance.

Information Source(s): Judiciary (Administrative Office of the Courts); Department of Health and Mental Hygiene; Maryland Insurance Administration; *The New York Times*; Department of Legislative Services

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Analysis by: Jennifer B. Chasse

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