

**Department of Legislative Services**  
 Maryland General Assembly  
 2017 Session

**FISCAL AND POLICY NOTE**  
**Enrolled - Revised**

House Bill 631 (The Speaker, *et al.*) (By Request - Office of the Attorney General)

Health and Government Operations and Economic Matters Finance

**Public Health - Essential Off-Patent or Generic Drugs - Price Gouging - Prohibition**

This bill 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 the Attorney General when specified price increases occur. On request of the Attorney General, the manufacturer of an essential off-patent or generic drug must submit a specified statement. The Attorney General 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 the Attorney General, 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.

**Fiscal Summary**

**State Effect:** Medicaid expenditures increase by \$110,800 (75% federal funds, 25% general funds) in FY 2018 to hire one pharmacist to monitor essential off-patent or generic drug prices to the extent Medicaid elects to notify the Attorney General of specified price increases as authorized under the bill. Federal fund revenues increase accordingly. The Office of the Attorney General (OAG) can handle the bill’s requirements within existing budgeted resources. To the extent actions under the bill reduce prescription drug spending, expenditures may decrease for Medicaid and the State Employee Health and Welfare Benefits Program (State Plan), which is not reflected below. Future years reflect annualization.

(in dollars)	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
FF Revenue	\$83,100	\$106,900	\$111,200	\$115,700	\$120,500
GF Expenditure	\$27,700	\$35,600	\$37,100	\$38,600	\$40,200
FF Expenditure	\$83,100	\$106,900	\$111,200	\$115,700	\$120,500
Net Effect	(\$27,700)	(\$35,600)	(\$37,100)	(\$38,600)	(\$40,200)

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

**Local Effect:** Revenues may increase under the bill’s civil penalty provision for orders issued by a circuit court. To the extent actions under the bill reduce prescription drug spending, local government health care expenditures may decrease.

**Small Business Effect:** Minimal.

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## Analysis

**Bill Summary:** “Essential off-patent or generic drug” means any prescription drug (1) for which all exclusive marketing rights, if any, granted under the federal Food, Drug, and Cosmetic Act (FDCA), § 351 of the federal Public Health Service Act, and federal patent law have expired; (2) that appears on the Model List of Essential Medicines most recently adopted by the World Health Organization *or* that has been designated by the Secretary of Health and Mental Hygiene as an essential medicine; (3) that is actively manufactured and marketed for sale in the United States by three or fewer manufacturers; and (4) that is made available for sale in the State. “Essential off-patent or generic drug” includes any drug-device combination product used for the delivery of a drug for which all exclusive marketing rights, if any, granted under FDCA, § 351 of the federal Public Health Service Act, and federal patent law have expired.

“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.

The bill specifies that it is not a violation of the prohibition against price gouging for a wholesale distributor to increase the price of an essential off-patent or generic drug if the price increase is directly attributable to additional costs for the drug imposed on the wholesale distributor by the manufacturer of the drug.

Medicaid may notify the Attorney General 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 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 label for the drug approved under FDCA, would cost more than \$80 at the drug's wholesale acquisition cost;
- a full course of treatment with the drug, according to the label for the drug approved under FDCA, would cost more than \$80 at the drug's wholesale acquisition cost; 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 wholesale acquisition cost to obtain a 30-day supply or a full course of treatment.

On request of the Attorney General, the manufacturer of an essential off-patent or generic drug identified in a notice sent by Medicaid to the Attorney General, within 45 days after the request, must submit a statement to the Attorney General 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.

The Attorney General 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 the Attorney General, 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 the Attorney General; (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 Plan for a period of up to one year at the price at which the drug was made available to participants in the State Plan immediately prior to the manufacturer's violation; and (5) imposing a civil penalty of up to \$10,000 for each violation. The Attorney General may not bring an action for specified remedies unless the manufacturer or wholesale

distributor is given an opportunity to meet with the Attorney General 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 the Attorney General under specified sections of the bill must be considered confidential commercial information unless the confidentiality of the information is waived by the manufacturer or wholesale distributor.

In any action brought by the Attorney General, a person who is alleged to have violated a requirement of the bill may not assert as a defense that the person did not deal directly with a consumer residing in the State.

**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.

OAG'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, including some significant price increases for generic drugs, have prompted calls for action to lower prescription drug costs.

At the federal level, the EpiPen controversy 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.

The U.S. Government Accountability Office (GAO) was asked to examine price trends for generic drugs and the factors that affect prices for prescription drugs used by the Medicare Part D program. GAO's August 2016 report found that more than 300 of the 1,441 established generic drugs analyzed had at least one extraordinary price increase of 100% or more between 2010 and 2015 and that the extraordinary price increases generally persisted for at least one year with no downward movement after the extraordinary price increase. Manufacturers reported that competition, determined by the price and availability of the same drug from other manufacturers, is the primary driver of generic drug prices, as less competition could drive prices higher. Stakeholders noted that the level of competition in the generic drug market is influenced by a variety of factors, including raw material shortages, production difficulties, consolidation among manufacturers, and a backlog of new generic drug applications awaiting federal review.

At the state level, in 2016, Vermont became the first state to enact drug transparency legislation. Under Vermont's Act 65, the state must identify up to 15 prescription drugs on which the state spends significant health care dollars and where wholesale acquisition costs 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.

Twenty states' attorneys general (including Maryland's) filed a civil complaint against six pharmaceutical companies in December 2016 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:** To the extent Medicaid elects to notify the Attorney General of specified price increases, Medicaid expenditures increase by \$110,824 (75% federal funds, 25% 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 21 pharmacist to monitor off-patent and generic drug prices (which are published weekly and may undergo price changes several times per year). It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Position	1
Salary and Fringe Benefits	\$105,715
One-time Start-up Expenses	4,640
Ongoing Operating Expenses	<u>469</u>
<b>Total FY 2018 State Expenditures</b>	<b>\$110,824</b>

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

To the extent actions under the bill reduce prescription drug spending, expenditures for Medicaid and the State Plan may decrease. For Medicaid (and other third-party payors), a circuit court may issue an order restoring any money acquired as a result of a price increase for an essential off-patent or generic drug that violates the prohibition against price gouging. For the State Plan, a circuit court may issue an order specifically 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 Plan for a period of up to one year at the price at which the drug was made available to participants in the State Plan immediately prior to the manufacturer's violation. The amount and timing of any such impact cannot be reliably estimated and is, therefore, not reflected in this analysis.

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### Additional Information

**Prior Introductions:** None.

**Cross File:** SB 415 (The President, *et al.*) (By Request - Office of the Attorney General) - Finance.

**Information Source(s):** *Generic Drug Prices Under Medicare: Part D Generic Prices Declined Overall, but Some Had Extraordinary Price Increases*, U.S. Government Accountability Office, August 12, 2016; *The New York Times*; Judiciary (Administrative Office of the Courts); Department of Health and Mental Hygiene; Office of the Attorney General; Department of Legislative Services

**Fiscal Note History:**  
mm/ljm

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