Department of Legislative Services

Maryland General Assembly
2018 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 201 (Senator Brochin)
Finance

Public Health - Prescription Drug Manufacturers - Sales to Wholesale Distributors

This bill requires a manufacturer to submit the "average sales price" of specified prescription drugs and devices to the Maryland Department of Health (MDH). MDH must then make the information available on its website. A manufacturer is prohibited from denying a wholesale distributor the right to purchase prescription drugs or devices under specified circumstances. A circuit court may issue an order requiring certain actions and imposing a civil penalty for violations of the bill. A wholesale distributor may additionally bring an action to recover specified damages and attorney's fees.

Fiscal Summary

State Effect: MDH can receive and post on the department's website quarterly pricing reports from manufacturers using existing budgeted resources. Revenues are not affected.

Local Effect: Revenues may increase under the bill's civil penalty provision for orders issued by a circuit court. Expenditures are not affected.

Small Business Effect: Potential meaningful.

Analysis

Bill Summary: "Average sales price" means the average sales price including rebates and discounts as defined in federal law and calculated according to methods stated in federal regulations. A manufacturer, within 30 days of the end of each calendar quarter, must submit to MDH the "average sales price" for the calendar quarter for each prescription drug

or device made available in the State by the manufacturer. MDH must make the information available on its website within 10 days of receipt.

A manufacturer may not deny a wholesale distributor the right to purchase a prescription drug or device from the manufacturer if the wholesale distributor agrees to pay the average sales price reported for the most recent calendar quarter.

On petition of MDH, a circuit court may issue an order to (1) impose a civil penalty of up to $10,000 for each violation of the bill's requirements; (2) require a manufacturer who denies a wholesale distributor the right to purchase to make the drug available to the wholesale distributor for up to one year at the average sales price for the quarter immediately preceding the quarter in which the violation occurred; or (3) require a manufacturer or wholesale distributor to produce specified records or documentation to determine whether a violation has occurred.

A wholesale distributor may also bring an action to recover damages for injury or loss resulting from a violation. A wholesale distributor that is awarded damages may seek reasonable attorney's fees. If an action is brought in bad faith or is of a frivolous nature, the court may order the offending party to pay reasonable attorney's fees.

Current Law: A "manufacturer" is a person licensed or approved by the U.S. Food and Drug Administration to engage in the manufacture of prescription drugs or prescription devices. A "wholesale distributor" is a person engaged in the wholesale distribution of prescription drugs or devices, including a manufacturer, repackager, own-label distributor, private-label distributor, jobber, broker, warehouse, manufacturer's exclusive distributor or an authorized distributor of record, drug wholesaler or distributor, independent wholesale drug trader, third-party logistics provider, pharmacy that conducts wholesale distribution (if the wholesale distribution business accounts for more than 5% of the pharmacy's annual sales), and pharmacy warehouse that conducts wholesale distribution. A wholesale distributor must obtain a permit from the State Board of Pharmacy to distribute prescription drugs or devices into, out of, or within the State as a wholesale distributor.

Chapter 818 of 2017 prohibits a manufacturer or wholesale distributor from engaging in price gouging (an "unconscionable" increase in price) in the sale of an essential off-patent or generic drug. Medicaid may notify the Attorney General when specified price increases occur. On petition of the Attorney General, a circuit court may issue specified orders, including (1) imposing a civil penalty of up to $10,000 for each violation; (2) requiring a manufacturer or wholesale distributor to provide certain statements or records; and (3) requiring a manufacturer that has engaged in price gouging to make the drug available to participants in the State Employee Health and Welfare Benefits Program (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.

Small Business Effect: Savings may be realized by small business wholesale distributors and may also be passed on to independent pharmacies. The magnitude of any such impact cannot be reliably estimated.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Judiciary (Administrative Office of the Courts); Maryland Department of Health; Department of Legislative Services

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