Department of Legislative Services

Maryland General Assembly
2024 Session

FISCAL AND POLICY NOTE
Third Reader - Revised

Senate Bill 986 (Senator Lam)
Finance Rules and Executive Nominations

State Board of Pharmacy - Prohibition on Discrimination Against 340B Drug Distribution

This bill prohibits a "340B manufacturer" from directly or indirectly denying, restricting, prohibiting, discriminating against, or limiting the acquisition or delivery of a "340B drug" to a pharmacy on behalf of a "covered entity," with specified exceptions. A violation is an unfair, abusive, or deceptive trade practice under the Maryland Consumer Protection Act (MCPA) and is subject to specified enforcement actions and penalties. An alleged violation must be investigated by the Consumer Protection Division of the Office of the Attorney General (OAG) or, as applicable, the State Board of Pharmacy (MBOP). The bill may not be construed to be (1) less restrictive than any federal law that is applicable to a person regulated under the bill or (2) in conflict with applicable federal and State laws and regulations. By July 1, 2026, the Prescription Drug Affordability Board (PDAB) must study the 340B Program, as specified, and report its findings and recommendations to specified committees of the General Assembly. **The bill takes effect July 1, 2024.**

Fiscal Summary

State Effect: MBOP special fund expenditures increase by $39,600 in FY 2025 for staff; future years reflect annualization and elimination of one-time costs. PDAB general fund expenditures increase by $7,500 in FY 2025 and 2026 only for contractual expenses. OAG can likely absorb any additional workload under the bill with existing budgeted resources. The imposition of penalty provisions does not materially impact State finances.

(in dollars)	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
Revenues	$0	$0	$0	$0	$0
GF Expenditure	7,500	7,500	0	0	0
SF Expenditure	39,600	41,900	43,700	45,600	47,600
Net Effect	($47,100)	($49,400)	($43,700)	($45,600)	($47,600)

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

Local Effect: The bill's imposition of existing penalty provisions does not have a material impact on local government finances or operations.

Small Business Effect: Minimal.

Analysis

Bill Summary:

Definitions

A "340B drug" means a drug that (1) is a covered outpatient drug under federal law; (2) has been subject to an offer for reduced prices by a 340B manufacturer; and (3) is purchased by a covered entity. A 340B drug includes a drug that would have been purchased but for the purchase being prohibited by the U.S. Department of Health and Human Services (HHS).

"340B manufacturer" means a manufacturer, as defined under federal law, of covered outpatient drugs that has a signed a pharmaceutical pricing agreement under federal law.

"Covered entity" has the meaning stated in 42 U.S.C. § 256(B)(4). Generally, covered entities include federally qualified health centers, Ryan White HIV/AIDS Program grantees, certain hospitals, and specialized clinics.

"Package" means the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product.

Exceptions to the Prohibition

A 340B manufacturer may deny, restrict, prohibit, discriminate against, or limit the acquisition or delivery of a 340B drug to a pharmacy on behalf of a covered entity if the receipt of 340B drugs is prohibited by HHS. Additionally, a 340B manufacturer may limit the distribution of a 340B drug if the limitation is required under a federal risk evaluation and mitigation strategy, as specified under federal law.

Violations – Investigations and Penalties

A violation by a 340B manufacturer is an unfair, abusive, or deceptive trade practice under MCPA. In general, an alleged violation must be investigated by OAG's Consumer Protection Division; however, for an alleged violation committed by a person who is

licensed or permitted by MBOP, the investigation may be conducted by MBOP. As part of an investigation, MBOP or the Consumer Protection Division may investigate an affiliate or a contractor of the 340B manufacturer, including a wholesaler or third-party logistics provider.

A violator is subject to specified enforcement actions and penalties under MCPA. In addition to these penalties, a civil fine of up to $5,000 per violation may be assessed. Each package of 340B drugs subject to a violation constitutes a separate violation. If a violation is committed by a person licensed or permitted by MBOP, the board may impose discipline, suspension, or revocation of the person's license or permit. A violation does not create a private right of action under MCPA.

Study and Report on 340B Program

Uncodified language requires PDAB, in consultation with the Maryland Department of Health (MDH), to conduct a study on (1) the current implementation and scope of the 340B Program in the State; (2) the bill's implementation and the impact of its implementation; and (3) the finances of the program in the State, including how covered entities reinvest savings realized from the program. PDAB is authorized to require covered entities and 340B manufacturers to provide information as necessary to complete the study.

By July 1, 2026, PDAB must report its findings and recommendations from the study to the Senate Finance Committee and the House Health and Government Operations Committee.

Current Law: The federal 340B Drug Pricing Program was established to enable health care providers that serve low-income and uninsured patients to purchase drugs at lower costs. The program requires pharmaceutical manufacturers to sell outpatient drugs to covered entities at reduced prices in order to have their drugs covered under Medicaid.

The 340B statute specifies that the Secretary of HHS must enter into purchase price agreements (PPAs) with pharmaceutical manufacturers that participate in Medicaid. Under a PPA, a manufacturer must sell certain covered outpatient drugs at a "ceiling price," which is calculated based on a specified statutory formula. Manufacturers may not charge covered entities more than the ceiling price if they sell the drug to any other entity at any price. Providers may pass the drug discounts on to patients, but the statute does not require them to do so.

Maryland Consumer Protection Act

An unfair, abusive, or deceptive trade practice under MCPA 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, abusive, 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 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 $10,000 for each violation and up to $25,000 for each repetition of the same 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.

Maryland Board of Pharmacy

MBOP regulates the practice of pharmacy by licensing pharmacists, registering pharmacy technicians, issuing permits to individuals to establish or operate pharmacies in the State, setting pharmacy practice standards, and developing and enforcing laws and regulations to protect the public. MBOP also regulates manufacturers and virtual manufacturers distributing their own prescription drugs or devices and wholesale distributors.

State Expenditures:

State Board of Pharmacy

MBOP advises that the board does not currently investigate trade practices and, as such, needs to hire a part-time (50%) contractual investigator with an appropriate skill set to investigate violations by 340B manufacturers (including a wholesaler or third-party logistics provider). Accordingly, MBOP special fund expenditures increase by $39,561 in fiscal 2025, which assumes a 90-day start-up delay from the bill's July 1, 2024, effective date. The estimate includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Contractual Position	0.5
Salary and Fringe Benefits	$32,709
Operating Expenses	6,852
Total FY 2025 State Expenditures	**$39,561**

This estimate does not include any health insurance costs that could be incurred for specified contractual employees under the State's implementation of the federal Patient Protection and Affordable Care Act.

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

Office of the Attorney General

OAG advises that, as long as it receives fewer than 50 complaints annually as a result of the bill, the Consumer Protection Division can absorb the increased workload using existing budgeted resources. To the extent that a higher volume of complaints is received, OAG would likely need to hire an additional staff member to assist with reviewing and investigating complaints. OAG advises that the annual cost of hiring such an employee would be approximately $150,000.

Prescription Drug Affordability Board

According to PDAB, it does not have the internal staff capacity to comply with the bill's study and reporting requirements without adversely impacting its other required work. Therefore, PDAB advises that it must hire contractual support, at a total cost of $15,000, to adequately study and report on the implementation and scope of the 340B Program in the State, as well as the bill's implementation and its impact. Given that PDAB's report to the General Assembly is due by July 1, 2026, this analysis assumes that the $15,000 in contractual expenses is incurred evenly between fiscal 2025 and 2026, at a cost of $7,500 in each year.

Maryland Department of Health

MDH advises that it can assist PDAB with fulfilling the bill's study and reporting requirements using existing budgeted resources.

Additional Comments: The Health Resources and Services Administration within HHS estimates that 340B sales constitute about 7.2% of the overall U.S. drug market. In 2021, total 340B sales reached approximately $44 billion.

Additional Information

Recent Prior Introductions: Similar legislation has not been introduced within the last three years.

Designated Cross File: HB 1056 (Delegate Guzzone, *et al.*) - Health and Government Operations.

Information Source(s): Congressional Research Service; Office of the Attorney General (Consumer Protection Division); Maryland Department of Health; Prescription Drug Affordability Board; Department of Legislative Services

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