Department of Legislative Services

Maryland General Assembly
2013 Session

FISCAL AND POLICY NOTE
Revised

House Bill 591 (Delegate Morhaim)
Health and Government Operations Education, Health, and Environmental Affairs

State Board of Pharmacy - Wholesale Distribution - Pharmacies

This bill limits the ability of a pharmacy permit holder to engage in wholesale distribution. The definition of "intracompany sales" is altered to exempt certain transactions or transfers of prescription drugs if the transaction or transfer is from a pharmacy to a wholesale distributor. The definition of "wholesale distributor" is also altered to specify that *all* pharmacies are limited to wholesale distribution of no more than 5% of the pharmacy's annual sales.

Fiscal Summary

State Effect: The bill does not materially affect State finances.

Local Effect: None.

Small Business Effect: Potential minimal.

Analysis

Bill Summary: A pharmacy permit holder may conduct wholesale distribution if (1) the wholesale distribution does not exceed 5% of annual sales and (2) the permit holder maintains records of wholesale distribution separately from other records and makes such records available to the State Board of Pharmacy for inspection.

A pharmacy permit holder that obtains a waiver from the board (commonly known as a "waiver pharmacy") may conduct wholesale distribution only with another pharmacy permit holder. A retail pharmacy may conduct wholesale distribution with another pharmacy permit holder and, under specified circumstances, with a wholesale distributor. To conduct wholesale distribution with a wholesale distributor, a retail pharmacy must

report the activity to the board, maintain separate records of wholesale distribution with wholesale distributors, and make such records available for inspection by the board.

The bill also exempts from the definition of "wholesale distribution" the sale or transfer from *any* pharmacy or pharmacy warehouse of expired, damaged, returned or recalled prescription drugs to *the original wholesale distributor*, in addition to the original manufacturer or a third-party returns processor.

Current Law: A pharmacy permit authorizes the holder to establish and operate a pharmacy. Subject to hearing provisions, the board may suspend or revoke any pharmacy permit, if the pharmacy is conducted so as to endanger the public health or safety, violates any specified standards, or otherwise is not conducted in accordance with the law. A pharmacy permit authorizes a pharmacy to distribute drugs and devices. A retail pharmacy is limited in this distribution. A retail pharmacy may conduct wholesale distribution without the requirement to obtain a wholesale distributor permit only if the wholesale distribution business accounts for no more than 5% of the retail pharmacy's annual sales.

Wholesale distributors – which may include manufacturers, warehouses, and some retail pharmacies – must be issued a permit by the board before engaging in the wholesale distribution of prescription drugs or prescription devices into, out of, or within the State. As a part of the initial application process, both a representative from the applicant's place of business and the representative's immediate supervisor must submit fingerprints for the purposes of a criminal history records check (CHRC). Within 30 days after the board receives a completed application, including the results of all required CHRCs, the board must notify the applicant of the board's acceptance or rejection of the application.

To obtain a permit, a wholesale distributor must also obtain either a surety bond (made payable to the board) of $100,000 or other equivalent means of security acceptable to the State (*e.g.*, an irrevocable letter of credit or a deposit in a trust account or financial institution). If the applicant's annual gross receipts for the previous tax year total less than $10 million, the requisite surety bond amount is reduced to $50,000. The purpose of the surety bond is to secure the payment of any fines or penalties imposed by the board and any fees and costs incurred by the State relating to the permit.

"Intracompany sales" means the (1) transaction or transfer of prescription drugs between a division, subsidiary, parent, or affiliated or related company under common ownership and control of a corporate entity or (2) transaction or transfer of a co-licensed product between co-licensed partners.

"Wholesale distribution" means the distribution of prescription drugs or devices to persons other than a consumer or patient. "Wholesale distribution" does not include intracompany sales. The following transactions are also exempt from the definition of "wholesale distribution":

- the sale, purchase, distribution, trade, or transfer of a prescription drug for emergency medical reasons;
- the sale, purchase, distribution, trade, or transfer of a prescription drug or prescription device by the Department of Health and Mental Hygiene for public health purposes;
- the distribution of samples by a manufacturer's representative;
- prescription drug returns conducted by a hospital, health care entity, or charitable institution;
- the sale of minimal quantities of prescription drugs by retail pharmacies to licensed health care practitioners for office use;
- the sale, purchase, or trade of a prescription drug, in accordance with a prescription;
- the sale, transfer, merger, or consolidation of all or part of the business of a pharmacy to or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets;
- the sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record under specified circumstances;
- the delivery of, or offer to deliver, a prescription drug by a common carrier in the common carrier's usual course of business of transporting prescription drugs; or
- the sale or transfer from a retail pharmacy or pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer or to a third-party returns processor.

Under § 12-403(c) of the Health Occupations Article, the board may waive specified pharmacy permit requirements for certain pharmacies, including the University of Maryland School of Pharmacy (and for nuclear and dental pharmacy experimental and teaching programs), pharmacies engaged in pharmaceutical specialties recognized by the board, and certain long-term care and clinic pharmacies to which the public does not have access. These pharmacies are known as "waiver pharmacies." Waiver pharmacies are authorized to purchase drugs at a reduced rate for the specific populations that they service, not to resell those medications to other pharmacies or wholesale distributors for a profit.

Background: According to the board, this bill is intended to close existing loopholes in Maryland law to prevent pharmacies from acting as wholesale distributors for the purpose

of inflating prescription drug prices. Limiting rather than prohibiting retail pharmacies from engaging in wholesale distribution with a wholesale distributor will allow pharmacies to respond to requests from hospitals or other medical facilities when a particular drug is in shortage and the pharmacy may have the drug in stock. Under the bill, the pharmacy would be required to report to the board that it is conducting wholesale distribution with a wholesale distributor, thereby alerting the board to check for compliance with the 5% limit on wholesale distribution at the pharmacy's next inspection.

A 2012 congressional investigation, *Shining Light on the "Gray Market": An Examination of Why Hospitals Are Forced To Pay Exorbitant Prices for Prescription Drugs Facing Critical Shortages*, examined a group of companies that buy and sell prescription drugs that hospitals and other health care providers urgently need to treat their patients. Operating outside of authorized distribution networks, these "gray market" companies take advantage of drug shortages to charge exorbitant prices for drugs used to treat cancer and other life-threatening conditions. The congressional investigation found that these drugs "leak" into gray market distribution networks, in which a number of different companies – some doing business as pharmacies and some as distributors – buy and resell the drugs to each other before one of them finally sells the drugs to a hospital or other health care facility.

In more than two-thirds (69%) of the 300 drug distribution chains reviewed in the investigation, prescription drugs leaked into the gray market through pharmacies. Instead of dispensing the drugs in accordance with state laws, these pharmacies resold the drugs, usually at significant markups, to gray market wholesalers. The report noted that, in September 2011, a Maryland pharmacy (no longer in business in the State) sold 25 vials of a chemotherapy drug to a New Jersey distributor. In total, eight different companies in four different states took ownership of the drugs before a gray market distributor sold them to a hospital in California. The hospital paid $600 per vial for the drug, whereas the pharmacy had paid only $7 per vial.

Additional Information

Prior Introductions: None.

Cross File: SB 595 (Senators Montgomery and Benson) - Education, Health, and Environmental Affairs.

Information Source(s): Department of Health and Mental Hygiene, Department of Legislative Services

Fiscal Note History: First Reader - February 19, 2013
mc/ljm Revised - House Third Reader - March 23, 2013

Analysis by: Jennifer B. Chasse

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