

**Department of Legislative Services**  
Maryland General Assembly  
2014 Session

**FISCAL AND POLICY NOTE**  
**Revised**

House Bill 596

(Delegates Morhaim and Elliott)

Health and Government Operations

Education, Health, and Environmental Affairs

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**State Board of Pharmacy - Wholesale Distributors - Notification to Pharmacy**

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This bill requires a wholesale distributor to notify a pharmacy at least 30 days before the wholesale distributor imposes a limit on the quantity of a prescription drug or prescription device distributed to the pharmacy. While a limit is in effect, a wholesale distributor must provide a pharmacy with an update, at least weekly, on the quantity of a prescription drug or prescription device available to the pharmacy. The bill also specifies the circumstances under which notification and updates are not required.

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**Fiscal Summary**

**State Effect:** Any additional workload on the State Board of Pharmacy to enforce the bill can be handled within existing board resources. No effect on revenues.

**Local Effect:** None.

**Small Business Effect:** None.

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**Analysis**

**Bill Summary:** A notification is not required if (1) due to circumstances beyond the control of the wholesale distributor, the wholesale distributor is not aware of the quantity limit at least 30 days before a limit is imposed on the pharmacy or a limit is imposed on the pharmacy due to suspected illegal activity and (2) the wholesale distributor provides appropriate documentation during any inspection by the board.

Updates are not required if (1) due to circumstances beyond the control of the wholesale distributor, the wholesale distributor is not aware of the quantity of a prescription drug or

device available to a pharmacy or a limit is imposed on the pharmacy due to suspected illegal activity and (2) the wholesale distributor provides appropriate documentation during any inspection by the board.

**Current Law:** 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. A wholesale distributor may supply prescription drugs only to a person authorized by law to dispense or receive prescription drugs.

A wholesale distributor may deliver prescription drugs only to the premises listed on the recipient's license or permit or an authorized person or an agent of an authorized person at the premises of the wholesale distributor. Prescription drugs may be supplied to a hospital pharmacy receiving area if a pharmacist or authorized receiving personnel of the hospital pharmacy signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug received. Any discrepancy between the type and quantity of the prescription drug indicated on the receipt and the type and quantity of the prescription drug received must be reported to the delivering wholesale distributor by the next business day after the delivery to the hospital pharmacy receiving area and may be reported to the State Board of Pharmacy for investigation.

A wholesale distributor must receive prescription drug returns or exchanges from a pharmacy or pharmacy warehouse according to the terms and conditions of the agreement between the two parties. Returns of expired, damaged, recalled, or otherwise nonsaleable prescription drugs must be distributed by the receiving wholesale distributor only to either the original manufacturer or a third-party returns processor. Wholesale distributors and pharmacies must be accountable for administering their returns process and ensuring that the process is secure.

**Background:** According to the State Board of Pharmacy, as of January 2014, there were 978 wholesale distributors permitted by the board and 2,025 pharmacies. Notification of quantity limitations could assist pharmacies in preparing for how much supply they may need to keep for established patients and how much could be dispensed to new patients.

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### **Additional Information**

**Prior Introductions:** None.

**Cross File:** None.

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

**Fiscal Note History:** First Reader - February 18, 2014  
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