

Department of Legislative Services
Maryland General Assembly
2012 Session

FISCAL AND POLICY NOTE
Revised

House Bill 316

(Delegate Costa, *et al.*)

Health and Government Operations

Education, Health, and Environmental Affairs

State Board of Pharmacy - Wholesale Distributor Permits - Permit and
Application Requirements

This bill alters the application process for wholesale distributor permits issued by the State Board of Pharmacy by (1) creating separate requirements for criminal history records checks for applicants located in versus outside the State; and (2) exempting applicants who do not hold prescription drugs or devices (virtual manufacturers) from the requirement to be inspected prior to issuance of a permit. The bill also exempts a manufacturer that distributes its own prescription devices that are approved or authorized by the U.S. Food and Drug Administration (FDA) from specified wholesale distributor permit requirements.

Fiscal Summary

State Effect: Although the board's proposed FY 2013 budget does not account for the cost of wholesale distributor permit inspections of virtual manufacturers, special fund expenditures decrease in FY 2013, since the board will no longer need to conduct such inspections. Revenues are not affected.

Local Effect: None.

Small Business Effect: None.

Analysis

Bill Summary: The bill clarifies that wholesale distributor permit applicants located in Maryland must submit two sets of fingerprints to the Criminal Justice Information System (CJIS) for both State and national criminal history records checks rather than submit the fingerprints to the board. Applicants located outside of Maryland must submit

to a national criminal history records check and a criminal history records check for *their* state of residence rather than submitting to a Maryland criminal history records check. The designated representative of the wholesale distributor and the designated representative's immediate supervisor must request that the results of their respective state criminal history records checks be forwarded to the board and the applicant.

Current Law: A wholesale distributor is a person that is engaged in the wholesale distribution of prescription drugs or prescription devices. Wholesale distributors include manufacturers, warehouses, and some retail pharmacies. A wholesale distributor permit is issued by the board to distribute prescription drugs or prescription devices into, out of, or within the State. A manufacturer that distributes its own prescription drugs approved by FDA is exempt from specified permit requirements.

Although the board has regulated wholesale distributors of prescription drugs since 1987, its regulation of distributors has tightened in recent years in an effort to enhance patient safety and secure the State's prescription drug supply chain. Chapters 352 and 353 of 2007 imposed additional permitting requirements for wholesale prescription drug distributors. As part of the application process, the applicant must submit an application and pay a fee to the board. A representative from the wholesale distributor and the representative's immediate supervisor must submit fingerprints to the board for a criminal history records check. Within 30 days after the board receives a completed application, including the results of all criminal history records checks, the board must notify the applicant of the board's acceptance or rejection of the application.

The board may not issue a wholesale distributor permit to an applicant unless the board or its designee conducts a physical inspection of the applicant's place of business, including any facility; finds that the place of business and facility meet specified requirements; and determines that the applicant meets specified qualifications. Wholesale distributors with "deemed status" (national accreditation) or a reciprocal permit issued by another state are exempt from the inspection requirement.

Background: In fiscal 2011, the board issued 759 wholesale distributor permits. According to the board, the bill is intended to improve three issues with the wholesale distributor permit application process.

First, Maryland law requires applicants for a wholesale distributor permit to submit to a *Maryland* (and a national) criminal history records check. However, applicants who are located outside the State typically have no criminal history in the State, through they may in their state of residence. By requiring applicants to instead submit to a criminal history records check *in their own state*, the board should receive more accurate information about applicants. The bill also removes the board from its intermediary role in the process by having in-state applicants submit their fingerprints directly to CJIS rather than to the board.

Second, the board is currently required to inspect all applicants before issuing a permit. While many wholesale distributors are exempt from the inspection requirement, the board (or an entity acting on the board's behalf) is still responsible for inspecting all in-state wholesale distributors (which comprise fewer than one-fourth of all permit-holding distributors) and out-of-state wholesale distributors that are virtual manufacturers (those that do not hold prescription drugs or devices) or distributors of prescription gases, since there are no existing accreditation organizations for these entities. The board has contracted with the National Association of Boards of Pharmacy to perform inspections on its behalf, saving the board time and money as well as allowing its inspection staff to focus on other priorities. The bill would further reduce the inspection workload by exempting virtual manufacturers from the inspection requirement.

Finally, the bill extends access to the "short application" for a wholesale distributor permit to manufacturers who make their own FDA-approved prescription devices (*i.e.*, medical devices). This will simplify the application process and reduce the cost for these manufacturers, as they will no longer have to obtain a surety bond as part of the permit process.

State Fiscal Effect: Special fund expenditures decrease by a potentially significant amount for the board beginning in fiscal 2013 due to a reduction in the number of inspections required to be conducted by the board (for in-state virtual manufacturers) and a reduction in contractual services for inspection of out-of-state virtual manufacturers. As no funds are budgeted for these purposes in fiscal 2013, no actual savings will occur, though expenditures will be averted.

Additional Information

Prior Introductions: None.

Cross File: SB 133 (Senator Conway) - Education, Health, and Environmental Affairs.

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

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Analysis by: Jennifer B. Chasse

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