

Department of Legislative Services
 Maryland General Assembly
 2010 Session

FISCAL AND POLICY NOTE
 Revised

House Bill 868 (Delegate Montgomery, *et al.*)
 Health and Government Operations Education, Health, and Environmental Affairs

State Board of Pharmacy - Wholesale Distributor Permitting and Prescription
 Drug Integrity Act - Revisions

This bill clarifies the conditions under which the State Board of Pharmacy may exempt wholesale distributors under “deemed status” from initial and routine inspection requirements. The bill also authorizes the Department of Health and Mental Hygiene (DHMH) to purchase and distribute prescription drugs and devices for public health purposes. These purchases and distributions are exempt from wholesale distribution requirements. DHMH, in consultation with the State Board of Pharmacy, must adopt regulations to implement this provision.

Fiscal Summary

State Effect: DHMH and the board can adopt regulations with existing resources. Although the board’s proposed FY 2011 budget does not account for the cost of wholesale distributor inspections, special fund expenditures decrease by \$337,500 in FY 2011, since the board will no longer need to inspect wholesale distributors in other states. Out-year expenditure decreases reflect annualization, biennial permit renewal, and a constant number of permit renewals for out-of-state distributors. Revenues are not affected.

(in dollars)	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015
Revenues	\$0	\$0	\$0	\$0	\$0
SF Expenditure	(337,500)	(15,000)	(420,000)	(15,000)	(420,000)
Net Effect	\$337,500	\$15,000	\$420,000	\$15,000	\$420,000

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

Local Effect: None.

Small Business Effect: None.

Analysis

Bill Summary: Deemed status may be given to a wholesale distributor that is (1) currently accredited by an accreditation organization recognized by the board, wherever the wholesale distributor is located; or (2) located in a state that has requirements that are substantially equivalent to the requirements of Maryland and include pedigrees, routine inspections of wholesale distributors, operation of wholesale distributors in a commercial nonresidential facility, and security measures. Under the bill, wholesale distributors in states that do not qualify for reciprocity and that seek a permit in the State must be accredited by an organization approved by the board. Out-of-state wholesale distributors that receive a permit by reciprocity are subject to criminal history record checks and surety bond requirements.

Current Law: A wholesale distributor is a person that is engaged in the wholesale distribution of prescription drugs or prescription devices. Wholesale distributors include 13 different categories including 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.

The Wholesale Distributor Permitting and Prescription Drug Integrity Act (Chapters 352 and 353 of 2007) imposed additional permitting requirements for wholesale prescription drug distributors. Among other requirements, the Act requires a pedigree, or history of the distribution chain, for prescription drugs that are distributed in Maryland. A person engaged in the wholesale distribution of a prescription drug that leaves, or ever has left, the normal distribution channel must provide a pedigree to the person who receives the prescription drug before each wholesale distribution of such a drug. The pedigree must include specified identifying information.

The Act also requires the board to adopt regulations requiring routine inspections of wholesale distributor facilities, including those that operate out of state. However, the board is authorized to grant “deemed status” to wholesale distributors accredited by an accreditation organization whose standards are equal to or more stringent than State requirements, which exempts them from the inspection requirements. The board is also authorized to issue a permit by reciprocity to a wholesale distributor who holds a license or permit issued by another state if the board determines that the requirements of the other state are substantially equivalent to Maryland’s requirements. Distributors with reciprocal permits are also exempt from the inspection requirements.

As a part of the application process, a representative from the applicant’s place of business and the representative’s immediate supervisor must submit fingerprints so the board may complete a criminal history record check of the applicant. Within 30 days after the board receives a completed application, including the results of all required

criminal history record checks, the board must notify the applicant of the board's acceptance or rejection of the application.

Wholesale distributors seeking a permit in the State must obtain a surety bond of \$100,000 or other equivalent means of security acceptable to the State, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the State Board of Pharmacy. If the applicant's annual gross receipts for the previous tax year are less than \$10 million, the surety bond amount is reduced to \$50,000. The purpose of the surety bond is to secure payment of any fines or penalties imposed by the board and any fees and costs incurred by the State relating to the permit.

Background: The Wholesale Distributor Permitting and Prescription Drug Integrity Act also repealed language that permitted any other person approved by the board to purchase and distribute prescription drugs and devices. Prior to 2007, the department had purchased prescription drugs and devices under this provision, but it was inadvertently repealed by the Act. Therefore, the department began working with local health departments (LHDs) to purchase the same vaccines and antibiotics it was purchasing prior to the Act's enactment. DHMH advises that, although the State is still able to obtain the necessary vaccines and antibiotics to protect public health, purchasing prescription drugs through LHDs creates confusion at the State level because the department has to monitor 24 separate contracts (one for each LHD) to keep track of the State's prescription drug inventory. Purchasing prescription drugs at the State level eliminates such confusion and allows the department to distribute prescription drugs and devices to LHDs as necessary.

Completing inspections in most other states has proven difficult for the board, as hundreds of out-of-state facilities have been applying for permits in Maryland. Under the Act, distributors that have been accredited by an accreditation organization, such as the National Association of Boards of Pharmacy (NABP) Verified-Accredited Wholesale Distributors (VAWD) Certification process, may be granted "deemed status" and therefore be exempt from the inspection requirement. However, only three states require VAWD accreditation. A number of distributors located in other states have voluntarily obtained VAWD accreditation and are thus exempt from inspection.

To accommodate distributors located in states that do not satisfy the reciprocity standards, the board has issued permits by reciprocity in those states based on the premise that it would be impossible for a newly permitted facility to have pedigrees on file if they have not been previously required to keep them under their own state's law. In 2009, approximately 19 states fell into this category.

Even with these accommodations, numerous states still do not satisfy the "substantially equivalent" requirement. Board inspectors have to travel out of state or the board has to

subcontract with a vendor in order to inspect all wholesale distributors in nonreciprocal states prior to issuing them a permit in Maryland. According to the board, no other state board performs out-of-state inspections of wholesale distributor facilities.

To remedy this challenge the board has contracted with NABP to perform inspections on its behalf, saving the board time and money as well as allowing its inspection staff to focus on other priorities. NABP finished all renewal inspections by January 2010; however, the board received an additional four new applications for wholesale distributor permits that month. Therefore, NABP continues to do inspections on behalf of the board.

In addition, the board has delayed the deadline for permit renewals multiple times. However, effective February 1, 2010, the State Board of Pharmacy raised its fee for initial permits and biennial permit renewals from \$500 to \$1,750, in large measure to cover the anticipated cost of conducting inspections.

State Fiscal Effect: DHMH and the board can develop regulations to purchase prescription drugs and devices with existing resources. Since the department currently purchases prescription drugs through LHDs, DHMH does not anticipate an increase in expenditures under the bill.

In fiscal 2009, the board spent \$30,000 on contracts for the inspection of out-of-state wholesale distributors by NABP. Each inspection conducted by NABP is \$1,000. While the board had contracted for only 30 inspections in fiscal 2010, the board must perform a minimum of 400 out-of-state renewal inspections, and up to 100 out-of-state initial inspections in fiscal 2011, depending on the volume of new permit applicants. The increase in inspections is a result of the board's biennial permit renewal process, with fiscal 2011 being a renewal year under the delayed implementation of the law.

Although the board has not budgeted for inspections, for the purposes of this estimate, the Department of Legislative Services assumes the board must conduct 450 out-of-state initial and renewal inspections in fiscal 2011. At \$1,000 per inspection, DLS estimates that, under current law, \$450,000 is needed to contract NABP to inspect out-of-state wholesale distributors. The board already budgets \$30,000 for out-of-state inspection costs but does not have sufficient resources to conduct the inspections itself. In nonrenewal years (fiscal 2012 and 2014), the board advises there will be 15 new out-of-state applicants for wholesale distributor permits, requiring \$15,000 for inspection costs.

Under the bill, the board no longer needs to contract with NABP to perform inspections; instead, it requires out-of-state wholesale distributors seeking a permit to be accredited by an accreditation organization approved by the board, resulting in a \$337,500 decrease in projected special fund expenditures, which accounts for the bill's October 1, 2010

effective date. Although the board will no longer need to conduct expensive out-of-state inspections, the board advises that it does not plan to reduce its higher permit fees. Thus, reduce special fund revenues do *not* decline by a commensurate amount. Out-year expenditure reductions reflect annualization, biennial permit renewal, and a constant number of permit renewals.

Additional Comments: Out-of-state wholesale distributors that do not qualify for a reciprocal permit and that seek accreditation in Maryland have to pay a \$5,500 fee to an accrediting body to gain “deemed status” under this bill as well as continue to pay the higher \$1,750 permit fee. They also have to comply with surety bond and criminal history record check requirements.

Additional Information

Prior Introductions: None.

Cross File: SB 163 (Senator Conway) - Education, Health, and Environmental Affairs.

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

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