HB 835

Department of Legislative Services

Maryland General Assembly
2005 Session

FISCAL AND POLICY NOTE

House Bill 835 (Delegate Stern, *et al.*)
Health and Government Operations

Wholesale Prescription Drug and Device Distribution Protection and Licensing Act of 2005

This bill requires the State Board of Pharmacy to license wholesale distributors of prescription drugs and devices working in Maryland beginning January 1, 2007. A license is valid for one year and expires on the December 31 after its effective date unless it is renewed for another year. The bill also establishes a unique electronic product identification tracking system for drugs or devices and a Prescription Drug and Device Wholesaler Advisory Council. It repeals the existing requirement for a person to hold a board-issued distribution permit to distribute prescription drugs or devices as a distributor, jobber, manufacturer, or wholesaler.

Fiscal Summary

State Effect: Special fund expenditures would increase by $134,400 in FY 2006 for the board to hire two permanent employees and one contractual employee. Special fund expenditures could increase significantly more in FY 2006 and out-years to establish a unique electronic product identification tracking system for drugs or devices. Existing special fund revenues of $300,000 annually in permit fees would continue as license fees. Revenues could increase significantly as license fees are raised to recoup the cost of establishing the electronic tracking system.

(in dollars)	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
SF Revenue	-	-	-	-	-
SF Expenditure	134,400	160,100	116,400	123,400	130,800
Net Effect	($134,400)	($160,100)	($116,400)	($123,400)	($130,800)

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

Local Effect: None.

Small Business Effect: Meaningful to the extent that any wholesale distributors of prescription drugs and devices are considered small businesses.

Analysis

Bill Summary: Subject to any other restriction under law, a person may not purchase or obtain prescription drugs or devices unless the prescription drug or device is obtained from the wholesale distributor licensee, a licensed pharmacist, a licensed pharmacy, a chain pharmacy warehouse, or an authorized prescriber.

A wholesale distributor means any person engaged in wholesale distribution of prescription drugs or devices, including: manufacturers, repackers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, independent wholesale drug traders, and retail pharmacies or chain pharmacy warehouses that conduct wholesale distributions.

Specified actions are not considered wholesale distribution including: (1) intracompany sales; (2) the purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug or device for its own use from the organization or from other hospitals or health care entities that are organization members; or (3) the sale or offer to sell, purchase, or trade a drug or device by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise authorized by law.

A prescription drug or device manufacturer that sells drugs or devices in Maryland must: (1) file a written list with the board of all of the manufacturer's authorized distributors of record; and (2) notify the board of any change to the list within 10 days. The board must publish a list of all authorized distributors of record on its web site and update the list at least monthly.

Fees

The board must set reasonable fees for issuing and renewing the license. The fees charged must be set to produce funds that approximate the cost of the licensing, inspection, and enforcement requirements set under the bill. Licensing fees must also cover the expenses of the new Prescription Drug and Device Wholesaler Advisory Council.

Prelicensure Criminal and Financial Background Checks, Inspections, and Surety Bond Requirements

Before the board issues a license, and periodically afterward on a schedule the board determines, the board must conduct a criminal and financial background check of each wholesale distributor applicant.

The background check must include:

- a criminal background and criminal and civil litigation check of all company officers, key management, principals, and owners with 10% or greater interest in the company;
- a driver's license and Social Security verification of all company officers, key management, principals, and owners;
- a credit history of the company and its key officers maintained by an independent third-party credit evaluation organization;
- a check to determine if any civil or criminal litigation exists against the company; and
- verification, as applicable, of the date of incorporation, years in business, place of incorporation, and business form of the applicant.

Background check information provided to the board is proprietary and confidential commercial information and may not be disclosed, except as otherwise required by law.

The board must physically inspect each in-State facility or warehouse of the applicant before issuing a license. At least every three years after the initial inspection, the board must conduct a physical reinspection. The board must use a qualified inspector, one who is specifically trained to inspect wholesale distributors.

An applicant must submit to the board a surety bond of $100,000 or evidence of other equivalent means of security acceptable to the board, such as insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution. A separate surety bond or other equivalent means of security is not required for each of a company's separate locations or for affiliated companies or groups. The board can make a claim against a surety bond or other equivalent means of security under specified conditions.

The board may waive the surety bond requirement if the wholesale distributor previously obtained a comparable surety bond or other equivalent means of security for licensure in another state where the wholesale distributor possesses a valid license in good standing.

The board may accept a surety bond of $25,000 if the wholesale distributor's annual gross tax receipts for the previous tax year are $10 million or less.

Product Tracking System

By December 31, 2010, the board must establish an effective, unique electronic product identification tracking system for drugs or devices to be implemented by manufacturers, repackagers, pharmacies, and wholesale distributors. The system must be designed to: (1) deter and detect counterfeiting and provide a means for prescription drug and device manufacturers, repackagers, distributors, and pharmacies to authenticate the drugs and devices; and (2) be part of a standardized system capable of being used across the health care industry, including manufacturers, wholesale distributors, and pharmacies.

By January 1, 2007 and by January 1 every year afterward, the board must report to the Governor and the General Assembly on its progress in establishing the electronic product identification tracking system required under the bill.

Advisory Council

The new advisory council must provide input to the board regarding proposed regulations that would affect the distribution of prescription drugs or devices. It also must make recommendations to the board regarding measures or procedures to improve the integrity of the prescription drug and device distribution system and protect public health.

Penalties

For any violation of this bill or any regulation adopted to implement this bill, the board may deny a license, reprimand a licensee, place a licensee on probation, or suspend or revoke a license. A person aggrieved by a final action by the board may not appeal to the Secretary of Health and Mental Hygiene or the board but may appeal as provided under the Administrative Procedures Act for contested cases. The board must notify a wholesale distributor of the action taken against the license within three working days of the action and make such actions publicly available on the board's web site within five working days of the action. Existing criminal and civil penalties for violations of the Maryland Food, Drug, and Cosmetics Act would apply to distributors under this bill.

Current Law: A person must hold a board-issued distribution permit to distribute prescription drugs or devices as a distributor, jobber, manufacturer, or wholesaler. A permit holder may distribute prescription drugs or devices only to an authorized prescriber, a pharmacy permit holder, a distribution permit holder, or any other person approved by the board; and in compliance with any rules or regulations. The applicant

must pay a fee set by the board. A permit is valid for one year and expires on the December 31 after its effective date unless it is renewed for another year.

Any person who violates any provision of the Maryland Food, Drug, and Cosmetics Act, except for an illegible prescription, or any related regulation is guilty of a misdemeanor and subject, on conviction, of: (1) a fine of up to $10,000 or imprisonment for up to one year, or both; or (2) if the person was convicted once of a violation, a fine of up to $25,000 or imprisonment for up to three years, or both. In addition to any criminal penalties, a violator is subject to a civil penalty of up to $5,000 in any action in District Court and may be enjoined from continuing the violation. Each day a violation occurs is a separate violation.

Background: This bill is based on model legislation developed by the Healthcare Distribution Management Association. There are an estimated 600 distributors who have permits issued by the board. The board did not disclose the exact number of permit holders. Legislative Services expects existing permit holders to become licensed under this bill. The board currently charges $500 for an initial distributor permit and a renewal permit.

State Revenues: It is estimated the board annually collects $300,000 in special fund revenues from permit fees paid by persons who hold a distribution permit to distribute prescription drugs or devices. Legislative Services assumes all of these individuals would be licensed by the board under the bill. However, because the bill requires the board to recoup all of the costs of implementing the bill through the license fee, special fund revenues could increase significantly more.

State Expenditures: The board did not provide an estimate of how much of its existing special fund revenues from distributor permit fees are used to pay for any salaries and operating expenditures to issue the existing permits. The board further did not provide information upon which an estimate could be made of the costs associated with establishing a unique electronic product identification tracking system for drugs or devices, other than advising that $2,000 annually in consultation fees would be required which is not expected to cover a major implementation.

While Legislative Services cannot reliably estimate the cost of developing an electronic product identification tracking system at this time, the cost could be significant and would be passed on to licensees in the form of much higher license fees during the period it took a consultant to design and implement the system. It is assumed that the cost could exceed the special fund revenues collected under the existing permit system.

Further, special fund expenditures would increase by an estimated $134,432 in fiscal 2006, which accounts for the bill's October 1, 2005 effective date. This estimate reflects the cost of hiring one administrative specialist to administer the licensing program and staff the advisory council and one pharmacist to conduct the onsite inspections and *assist* the contractor with developing the electronic product identification tracking system. It also includes the cost of the board hiring one contractual attorney to conduct the extensive background checks. It includes salaries, fringe benefits, travel costs, one-time start-up costs, and ongoing operating expenses. It does not include the cost of developing the electronic tracking system itself, which cannot be reliably determined at this time.

Salaries and Fringe Benefits	$112,981
Operating Expenses	21,451
Total FY 2006 State Expenditures	**$134,432**

Future year expenditures reflect: (1) full salaries with 4.6% annual increases and 3% employee turnover for the two permanent positions; (2) a full salary with 4.6% annual increases and 6.8% employee turnover for the contractual position; (3) the contractual position terminating at the end of fiscal 2007; and (4) 1% annual increases in ongoing operating expenses. The cost of establishing an electronic product identification tracking system by December 31, 2010 cannot be reliably determined at this time. However, special fund expenditures are expected to increase significantly to do so.

Additional Comments: Under the bill, there would be a period of time when distributors would not be required to hold a permit or a license. The bill repeals the requirement for a permit, which takes effect October 1, 2005, and requires licensure of distributors by January 1, 2007. However, Legislative Services assumes for the purpose of this analysis that there would not be a time when distributors would not be required to hold a permit or a license.

Additional Information

Prior Introductions: None.

Cross File: None.

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

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