HB 1030

Department of Legislative Services

Maryland General Assembly
2007 Session

FISCAL AND POLICY NOTE
Revised

House Bill 1030 (Delegate Montgomery, *et al.*)
Health and Government Operations Education, Health, and Environmental Affairs

Wholesale Distributor Permitting and Prescription Drug Integrity Act

This bill expands the requirements for a wholesale distributor of prescription drugs or devices to obtain a State Board of Pharmacy permit, repealing the existing statutory requirements. Permits are valid for two years, instead of the current one year, and may be renewed for an additional two years. The bill also requires prescription drugs distributed outside the "normal distribution channel" to have a pedigree that records each distribution. Any person knowingly violating any provision of the bill may be subject to a board-imposed fine of up to $500,000. The board has to adopt regulations to implement the bill by January 1, 2008.

The bill takes effect July 1, 2007.

Fiscal Summary

State Effect: Board special fund expenditures could increase by $109,600 in FY 2008 to conduct the initial inspections. Future year expenditures reflect annualization and inflation. Board special fund revenues could increase beginning in FY 2008 to the extent that the board imposes any fines. Special fund revenues would increase by $325,700 in FY 2008 and decrease by $419,500 in FY 2009 due to permit renewal; future year revenues reflect a biennial permit process.

(in dollars)	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
SF Revenue	$325,700	($419,500)	$325,700	($419,500)	$325,700
SF Expenditure	109,600	103,100	108,400	114,000	120,000
Net Effect	$216,100	($522,600)	$217,300	($533,500)	$205,700

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

Local Effect: None.

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

Analysis

Bill Summary: Permits are required for a wholesale distributor and a manufacturer engaged in the wholesale distribution of prescription drugs or prescription devices into, out of, or within Maryland. A wholesale distributor includes a manufacturer, a repackager, an own-label distributor, a private-label distributor, a jobber, a broker, a warehouse, a manufacturer's exclusive distributor or an authorized distributor of record, a drug wholesaler or distributor, an independent wholesale drug trader, a third-party logistics provider, a retail pharmacy that conducts wholesale distribution under certain conditions, and a pharmacy warehouse that conducts wholesale distribution.

Before issuing a permit, the board or its designee must ● inspect the applicant's place of business; ● find that board requirements are met; and ● determine that the applicant's designated representative and the representative's supervisor meet specified requirements.

The board must notify the applicant of the board's acceptance or rejection of the application within 30 days of receiving the complete application, including the criminal history records check results. Permits expire on the December 31 after the effective date unless renewed for an additional two-year term.

The board must adopt regulations requiring routine inspections of wholesale distributor facilities. The board may adopt regulations establishing minimum requirements for the receipt, storage, and handling of prescription drugs or prescription devices; security precautions; quality control; record keeping; and personnel procedures, policy, and responsibilities. Additionally, the board may adopt regulations establishing personnel education and experience requirements.

Criminal History Records Check Required

Permit applications must include fingerprints necessary to conduct the criminal history records check for the designated representative and the representative's immediate supervisor. The board must submit those fingerprints to the central repository for a State and national criminal history records check. The bill does not require the applicant to include the criminal history records check fee with an application, although it does require a permit application fee.

The central repository must forward the criminal history record to the board and the applicant. Information obtained from the central repository must be confidential, may not be redisseminated, and must be used only for permitting purposes. The subject of a criminal history records check may contest the contents of the printed statement issued by the central repository.

Surety Bond Required for Permit Applicants

A warehouse distributor permit applicant must submit a surety bond of at least $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 an account established by the State. The surety bond will be used 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 that are authorized under State law and are not paid by the permit holder within 30 days after the fines, penalties, fees, or costs become final.

The State may make a claim against a surety bond or other security until two years after the permit holder's permit ceases to be valid. A single surety bond covers all facilities operated by the applicant in the State.

Permits by Accreditation and Reciprocity

The board may accept the accreditation of a wholesale distributor by an accreditation organization as evidence that the wholesale distributor has met State permit requirements and grant the distributor deemed status if the board determines the organization's standards are equal to or more stringent than State requirements.

The board may 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.

The board, or its designee, may inspect a wholesale distributor that receives a permit through accreditation or reciprocity to determine compliance with any permit requirement or investigate a complaint.

Pedigree

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.

Fine and Disciplinary Action

Before the board may impose a fine upon a person violating any provision of the bill, the board must consider the appropriateness of the fine in relation to the wholesale distributor's size, the gravity of the violation, the wholesale distributor's good faith effort, and any previous violations by the wholesale distributor.

In addition to the fine, the board may also take disciplinary action against a permit holder who is convicted of or pleads guilty or *nolo contendere* to a violation of State, federal, or local drug laws.

Report and Workgroup Requirements

By January 1, 2008, and by January 1 of each subsequent year, the board must report to the Governor and the General Assembly on the bill's implementation.

The Secretary of Health and Mental Hygiene, in conjunction with the board, must convene a workgroup of manufacturers, distributors, and pharmacies that sell and distribute prescription drugs in Maryland to recommend to the board a target date for implementing electronic track and trace pedigree technology. The workgroup must survey the availability of such technology, determine when such technology will be universally available, and make recommendations to the board for a target implementation date, which can be no sooner than July 1, 2010.

Taking the workgroup's recommendation into consideration, the board must establish a target implementation date for such technology, which again cannot be earlier than July 1, 2010.

The board must submit to specified legislative committees ● by January 1, 2009, a report with workgroup recommendations; and ● by July 1, 2009, the target implementation date for the electronic track and trace pedigree technology.

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. The permit holder must comply with any board rules or regulations. An applicant for a distribution permit 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.

A person who violates any provision related to distribution permits is guilty of a misdemeanor and on conviction is subject to a fine up to $1,000, one year imprisonment, or both.

Under the Maryland Food, Drug, and Cosmetic Act, the Department of Health and Mental Hygiene may impound drugs or prescription records of a board pharmacy, manufacturer, or distributor permit holder or an authorized prescriber for specified reasons, including if a permit holder's or authorized prescriber's license has expired or has been revoked or suspended or an application for a permit or license has been denied.

Any person who violates any provision of the Maryland Food, Drug, and Cosmetic Act, except for an illegible prescription, or any related regulation is guilty of a misdemeanor and on conviction is subject to a fine up to $10,000, one year imprisonment, or both. The penalties increase for repeat offenders to a fine up to $25,000, three years imprisonment, or both. In addition to any criminal penalties, a violator is subject to a maximum $5,000 civil penalty in any action in District Court and may be enjoined from continuing the violation. Each day a violation occurs is a separate violation.

Background: There are 839 distributors issued permits by the board, up from 722 distributors in 2006. The board advises that approximately 200 of these distributors are located in Maryland. Distributors currently pay a $500 annual permit fee to the board.

Other states have enacted pedigree requirements for wholesale distributors of prescription drugs. Florida requires each person engaged in the wholesale distribution of a prescription drug who is not the drug manufacturer to provide a pedigree paper to the person receiving the drug. The pedigree is a document or electronic form that records each distribution of a given drug. There are two types of forms: one for prescription drugs on the board's list of specified drugs and one for prescription drugs that are not on the list.

California will prohibit a wholesaler or pharmacy from selling, trading, or transferring a dangerous drug without providing a pedigree, beginning January 1, 2009, with certain exceptions. Likewise, with certain exceptions, a wholesaler or pharmacy will be prohibited from acquiring a dangerous drug without receiving a pedigree beginning January 1, 2009. A pedigree is defined as an electronic record containing information regarding each transaction resulting in a change of ownership of a given dangerous drug. Compliance with the pedigree requirements may be extended until January 1, 2011, if additional time is necessary to implement electronic technologies to track the distribution of dangerous drugs within the state.

The National Association of Boards of Pharmacy (NABP) operates a Verified-Accredited Wholesale Distributors program to assure a wholesale distribution facility operates legitimately, is licensed and in good standing, and is employing security and best practices for safely distributing prescription drugs from manufacturers to pharmacies and other institutions.

In Maryland, the total maximum cost of each criminal history records check is $62, which includes State and national background checks plus fingerprinting.

State Revenues: Any decrease in the number of distributors applying for or renewing a permit as a result of the bill's more stringent requirements would reduce special fund revenues. Absent the bill, it is assumed that the number of permits issued would continue to grow as in prior years. However, the board expects a 26% reduction in renewal permits issued and no new permits. As a result, a total of 621 permit holders would renew their permits; since permits expire December 31, this reduction would occur in fiscal 2008. As the board advises that it would charge a biennial permit fee of $1,200, this estimate assumes the $1,200 permit fee would be enacted in fiscal 2008. The $1,200 biennial permit fee is more than double the current annual permit fee of $500 to compensate for the loss of permits as a result of the more stringent requirements and biennial renewal. As a result, board special fund revenues would increase by $325,700 in fiscal 2008 but decrease by $419,500 in fiscal 2009. Thus, on a biennial basis board revenues could drop by $93,800. Future years reflect the biennial permit process and no new permit applicants.

Board special fund revenues could increase beginning in fiscal 2008 to the extent that the board imposes any fines on violators of the bill's provisions. The frequency with which the board would impose fines and the amount of the fines cannot be reliably estimated at this time.

State Expenditures: Distributors must be inspected prior to receiving a permit and must be inspected routinely as required under board regulations. Further, distributors receiving a permit as a result of accreditation or by reciprocity may be inspected to determine compliance with permit requirements or to investigate a complaint. The board advises that it would determine during the regulatory process whether inspections would be required annually or biennially, but the board is likely to inspect distributors biennially after requiring the initial inspection. For out-of-state distributors, the board advises that it would require accreditation through NABP's Verified-Accredited Wholesale Distributors program instead of requiring board staff to conduct the inspection. Distributors would pay for the accreditation.

Special fund expenditures could increase by an estimated $109,569 in fiscal 2008 to conduct the initial on-site inspections of an estimated 200 Maryland distributors that currently hold a permit. This estimate reflects the cost of hiring two full-time health investigators. The number of in-state distributors required to be inspected by board staff could be reduced if the board accepts national accreditation through NABP's Verified-Accredited Wholesale Distributors program instead of requiring board staff to conduct the inspection. The estimate includes salaries, fringe benefits, one-time start-up costs, travel costs, and ongoing operating expenses

Positions	2
Salaries and Fringe Benefits	$91,619
Travel Costs and Operating Expenses	17,950
Total FY 2008 State Expenditures	**$109,569**

It is assumed the two full-time investigators could conduct additional inspections of out-of-state distributors after a permit is awarded to determine compliance with permit requirements or to respond to a complaint. To the extent the inspection workload is greater than anticipated, special fund expenditures could increase further for additional contractual or regular staff.

Future year expenditures reflect ● full salaries for the full-time health investigators with 4.5% annual increases and 3% employee turnover; and ● 1% annual increases in travel costs and ongoing operating expenses.

Existing board staff could write the required regulations, process the permit applications, and issue the required annual report. DHMH could convene the required workgroup and issue the required reports using existing budgeted resources.

Additional Information

Prior Introductions: None.

Cross File: SB 759 (Senator Dyson, *et al.*) – Education, Health, and Environmental Affairs.

Information Source(s): Department of Health and Mental Hygiene, National Association of Boards of Pharmacy, Florida Department of Health, Department of Legislative Services

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