

Department of Legislative Services
 Maryland General Assembly
 2006 Session

FISCAL AND POLICY NOTE

House Bill 1190 (Delegate Stern, *et al.*)
 Health and Government Operations

Prescription Drug Safety Act

This bill repeals provisions related to distribution permits issued by the State Board of Pharmacy and instead requires the board to license wholesale distributors before the distributors engage in wholesale distribution of prescription drugs in Maryland. The board also must license a manufacturer located in Maryland before the manufacturer invoices or ships its own prescription drugs. A nonresident wholesale distributor must be licensed in the state in which it is located and in each state in which the distributor ships prescription drugs before the distributor can distribute prescription drugs in Maryland. A nonresident manufacturer must be licensed by the board before the nonresident manufacturer invoices or ships prescription drugs into Maryland.

Fiscal Summary

State Effect: Board special fund revenues could decrease by \$211,000 in FY 2007 assuming only 300 wholesale distributors and manufacturers that currently have a board permit become licensed under the more restrictive requirements. It is assumed that the other distributors would either not be subject to licensure under the bill or would discontinue operations in Maryland. Board special fund expenditures could increase by \$93,000 in FY 2007 for staffing costs. Potential significant increase in general fund revenues and expenditures due to the bill’s penalty provision.

(in dollars)	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
SF Revenue	(\$211,000)	(\$211,000)	(\$232,100)	(\$256,800)	(\$256,800)
SF Expenditure	93,000	114,100	119,100	126,000	133,400
Net Effect	(\$304,000)	(\$325,100)	(\$351,200)	(\$382,800)	(\$390,200)

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

Local Effect: Potential significant increase in revenues and expenditures due to the bill’s penalty provision.

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

Analysis

Bill Summary:

Wholesale Distributor Licenses

An applicant for licensure must submit an application to the board, pay the application fee, receive an inspection certificate from or approved by the board for each facility operated, and post the required bond. Each license is valid for one year and can be renewed for an additional year.

Each designated representative of the applicant must, at a minimum: ● be at least 21; ● have been employed full time for at least three years in a pharmacy or with a wholesale distributor in a capacity related to dispensing and distribution of, and record keeping related to, prescription drugs; ● be employed by the applicant full time in a managerial level position; ● be actively involved in and aware of the daily operation of the wholesale distributor; ● be physically present at the applicant's facility during regular business hours, except for authorized absences; ● serve in the capacity of a designated representative for only one applicant at a time; ● not have any convictions under federal, state, or local laws relating to wholesale or retail prescription drug distribution of controlled substances; and ● not have any felony convictions under federal, state, or local laws.

The application fee must include the cost of processing any criminal history records check or financial background check conducted by or through the board. The bill further specifies what must be in the application, including: ● indications of whether the applicant has been the subject of any proceeding for the revocation of any license or any criminal violation; ● whether a court of competent jurisdiction has restricted the applicant's ability to possess, control, or distribute prescription drugs; and ● whether the applicant, as an adult, has been found guilty of a misdemeanor or criminal offense.

To receive an inspection certificate, the applicant must pass a physical inspection of each facility conducted by the board or a nationally recognized accreditation program designated by the board to conduct inspections on the board's behalf. The inspection certificate must be valid for no more than three years. The board must adopt regulations specifying the times and manner inspections are conducted. As part of the inspection, the

board may require prescription drugs to be analyzed to verify their authenticity. The board or the accreditation program may charge and collect fees for inspections.

The board must require each wholesale distributor applying for a license to submit a bond of at least \$100,000, or other equivalent means of security acceptable to the board, payable to an account established by the board. The bond will secure payment of any board-imposed fines or penalties on a licensee that the licensee fails to pay within 30 days after the fines, penalties, or costs become final. The bond must cover all facilities licensed by the applicant in Maryland. The board may waive this requirement if the wholesale distributor has a comparable bond or other equivalent means of security in place in another state in which the wholesale distributor possesses a license in good standing. The board must waive the bond requirement if the wholesale distributor is under common ownership or control with an entity that has been licensed by the board. The State may make a claim against the bond or security until one year after the license ceases to be valid. The board must establish a separate account to receive the bond or security funds.

The board must apply to the central repository for a State and national criminal history records check for each designated representative of a license applicant. The board also may conduct a financial background check on an applicant's designated representative.

If the board denies a license, it must give the applicant written notice of the reasons for the denial.

A wholesale distributor must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. A wholesale distributor of a prescription drug, including a repackager, but excluding the original manufacturer of the finished form of the prescription drug, that is in possession of a pedigree for a prescription drug, must affirmatively verify before any distribution occurs that each transaction listed on the pedigree occurred. The bill further specifies what information must be included on the pedigree. Each pedigree must be maintained by the purchaser and the wholesale distributor for three years from the date of transfer and be available for inspection.

The board must adopt regulations defining an emergency situation that would permit an immediate transfer, without pedigree information, of prescription drugs between board-licensed entities.

A wholesale distributor may supply prescription drugs only to a board-licensed recipient and must contact the board to verify the licensee's authenticity.

A “wholesale distributor” or “wholesaler” is defined as a person engaged in the wholesale distribution of prescription drugs including repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, independent wholesale drug traders, retail pharmacies that conduct wholesale distribution, and chain pharmacy warehouses that conduct wholesale distribution.

The board must exempt a Food and Drug Administration licensed drug manufacturer including its affiliates, subsidiaries, agents, and other entities under common ownership and control with the manufacturer from the bill’s licensing requirements under specified conditions.

Manufacturer Licenses

To obtain a license, a manufacturer must submit an application and application fee to the board. The license is valid for one year and may be renewed for an additional year. Information required to be submitted in an application must be certified by a notary public.

Disciplinary Actions, Penalties

Subject to a hearing, the board may fine, censure, reprimand, place on probation, or suspend or revoke the license of a wholesale distributor that violates any provision of the bill.

The bill prohibits a person from performing or causing the performance of or aiding and abetting specified acts including failing to obtain or operating without a valid license; and obtaining or attempting to obtain a prescription drug by fraud, deceit, misrepresentation, or engaging in misrepresentation or fraud in the wholesale distribution of a prescription drug.

A person who violates any provision of this bill is guilty of a felony and on conviction is subject to a maximum \$500,000 fine and/or a maximum of 25 years imprisonment.

Board Study

The board must study electronic pedigrees and other advanced technology for tracking prescription drugs. Based on the study, the board may mandate electronic pedigrees or other advanced tracking technology. However, the board may not mandate implementation for this technology before December 31, 2007. The board must report its findings and recommendations to the Governor and the General Assembly by January 1, 2007.

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.

A person who violates any provision related to distribution permits is guilty of a misdemeanor and on conviction is subject to a fine of up to \$11,000 or imprisonment for up to one year, 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: (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: There are 722 distributors who have permits issued by the board. The board anticipates the number who will become licensed will decrease by 141% to 300 wholesale distributors and manufacturers licensed in fiscal 2007 as a result of the increased licensure requirements. The number of licensees in future years is expected to remain at 300 in fiscal 2008, increase to 330 in fiscal 2009, and increase again to 360 in fiscal 2010 and 2011. The board currently charges \$500 for an initial distributor permit and a renewal permit.

The bill requires licensees to submit to a criminal history records check. In Maryland, the total maximum cost of each criminal history records check is \$52, which includes State and national background checks plus fingerprinting. The Criminal Justice Information System (CJIS) Central Repository in the Department of Public Safety and Correctional Services (DPSCS) is authorized by law to collect an \$18 fee established for Maryland criminal history checks. This fee represents cost recovery for processing and administration and is revenue/cost neutral. The FBI charges a fee of \$24 for a national

criminal history records check. There is also normally a \$10 fee for two fingerprint cards (\$5 for the State card; \$5 for the separate FBI card). The CJIS Central Repository must collect the fees from the applicant, or other payer, and reimburse the FBI through that agency's monthly billing.

State Revenues: The board currently collects \$361,000 in special fund revenues from permit fees paid by persons who hold a distribution permit to distribute prescription drugs or devices. It is expected that the increased requirements under licensure are expected to result in only 300 of those distributors becoming licensed in Maryland in fiscal 2007, which would result in board special fund revenues decreasing by \$211,000 in fiscal 2007. Future year special fund revenue decreases assume 300 licensees in fiscal 2008 (\$211,000 reduction in revenues); 330 licensees in fiscal 2009 (\$232,100 reduction in revenues); and 360 licensees in fiscal 2010 and 2011 (\$256,810 reduction in revenues each year). This assumption includes the expectation that the number of distributors would otherwise be stable from fiscal 2007 to 2008 (722), increase by 10% in fiscal 2009 (794) and again in fiscal 2010 (874), and remain stable at that number in fiscal 2011 (874) if the bill were not implemented.

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 instead.

This estimate assumes that the current fee of \$500 for a distributor permit would remain in place for both new licenses.

General fund revenues could increase significantly as a result of the bill's monetary penalty provision from cases heard in the District Court.

State Expenditures: Special fund expenditures would increase by an estimated \$93,007 in fiscal 2007, which accounts for the bill's October 1, 2006 effective date. This estimate reflects the cost of hiring one administrative specialist to administer the more extensive licensing program and one pharmacist to conduct the on-site inspections. It includes salaries, fringe benefits, travel costs, one-time start-up costs, and ongoing operating expenses.

Salaries and Fringe Benefits	\$77,637
Operating Expenses	<u>15,370</u>
Total FY 2007 State Expenditures	\$93,007

Future year expenditures reflect: (1) full salaries with 4.6% annual increases and 3% employee turnover; and (2) 1% annual increases in ongoing operating expenses.

General fund expenditures could increase minimally as a result of the bill's incarceration penalty due to more people being committed to Division of Correction (DOC) facilities and increased payments to counties for reimbursement of inmate costs. The number of people convicted of this proposed crime is expected to be minimal.

Persons serving a sentence longer than 18 months are incarcerated in DOC facilities. Currently, the average total cost per inmate, including overhead, is estimated at \$1,974 per month. This bill alone, however, should not create the need for additional beds, personnel, or facilities. Excluding overhead, the average cost of housing a new DOC inmate (including medical care and variable costs) is \$341 per month. Excluding medical care, the average variable costs total \$134 per month.

Persons serving a sentence of one year or less in a jurisdiction other than Baltimore City are sentenced to local detention facilities. For persons sentenced to a term of between 12 and 18 months, the sentencing judge has the discretion to order that the sentence be served at a local facility or DOC. The State reimburses counties for part of their incarceration costs, on a per diem basis, after a person has served 90 days. State per diem reimbursements for fiscal 2007 are estimated to range from \$17 to \$65 per inmate depending upon the jurisdiction. Persons sentenced to such a term in Baltimore City are generally incarcerated in DOC facilities. The Baltimore City Detention Center, a State-operated facility, is used primarily for pretrial detentions.

DPSCS and the Department of State Police could absorb the additional criminal history records checks within existing budgeted resources.

Local Revenues: Revenues could increase significantly as a result of the bill's monetary penalty provision from cases heard in the circuit courts.

Local Expenditures: Expenditures could increase minimally as a result of the bill's incarceration penalty. Counties pay the full cost of incarceration for people in their facilities for the first 90 days of the sentence, plus part of the per diem cost after 90 days. Per diem operating costs of local detention facilities are expected to range from \$33 to \$119 per inmate in fiscal 2007.

Additional Information

Prior Introductions: HB 835 of 2005, that would have required the board to license wholesale distributors of prescription drugs and devices working in Maryland, received an unfavorable report from the House Health and Government Operations Committee.

Cross File: None.

Information Source(s): Department of Health and Mental Hygiene, Maryland Insurance Administration, Department of Budget and Management, Department of Legislative Services

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