HB 1143

Department of Legislative Services

Maryland General Assembly
2004 Session

FISCAL AND POLICY NOTE

House Bill 1143 (Delegate Stern)
Health and Government Operations

Prescription Drug Distribution Safety Act

This bill requires a wholesale prescription drug distributor to establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs.

Fiscal Summary

State Effect: Department of Health and Mental Hygiene (DHMH) special fund expenditures and revenues could each increase by a significant amount beginning in FY 2005 to conduct out-of-state inspections of wholesale distributors who conduct business in Maryland. The adoption of regulations and inspection of wholesalers' drug records could be handled with existing DHMH budgeted resources. Potential minimal increase in general fund revenues and expenditures due to the bill's penalty provisions.

Local Effect: Potential significant increase in revenues from the bill's monetary penalty provisions and minimal increase in expenditures due to the bill's incarceration penalty provisions.

Small Business Effect: None.

Analysis

Bill Summary: Effective July 1, 2006, a person who is engaged in the wholesale distribution of a prescription drug and who is not the manufacturer must, before each wholesale distribution of the drug, provide to the person that receives the drug a pedigree paper for the prescription drug. The pedigree paper must include at least the following

information for the prescription drug: (1) drug amount; (2) dosage form and strength; (3) lot numbers; (4) name, signature, and address of each owner; (5) shipping information; (6) certification that the recipient has authenticated the pedigree paper; and (7) name, address, telephone number, and e-mail address of each wholesale prescription drug distributor involved in the chain of custody for the drug.

A prescription drug repackager must also comply with these requirements. In addition, the bill requires a drug repackager to have a distribution permit.

The wholesaler must provide a complete audit trail from receipt to sale on prescription drugs. The records must include information on the seller or transferror, shipment, purchaser, and the drug. Inventories and records must be made available for inspection and photocopying by authorized federal, State, or local officials for three years following the disposition of the drugs or three years after the creation of the records, whichever period is longer.

A wholesaler must annually provide DHMH with a written list of all wholesale distributors and manufacturers from whom the wholesaler purchases prescription drugs. DHMH must adopt regulations specifying the form of the pedigree paper.

A selling wholesaler must indemnify a purchasing wholesaler for any loss related to the purchase of drugs that are determined to be counterfeit or to have been distributed in violation of any federal or State law governing drug distribution. A purchasing wholesaler must determine that the selling wholesaler has insurance coverage of not less than 1% of its total dollar volume of drugs sales or $500,000. The coverage need not exceed $2 million. The bill requires a wholesaler to inspect and verify other information such as permits, policies, and procedures of other wholesalers it contracts with.

DHMH must inspect each wholesale prescription drug establishment, prescription drug repackager establishment, and retail pharmacy drug establishment that is required to hold a permit to conduct business in the State. DHMH may examine, sample, seize, and stop the sale or use of prescription drugs to determine the condition of those drugs. DHMH may immediately seize and remove any drugs if it is determined the drugs are a threat to public health. DHMH may determine that a wholesaler, repackager, or pharmacy is an imminent danger to pubic health and require its immediate closure. DHMH may issue a complaint, cease and desist order, or emergency cease and desist order against a permit holder when there is a threat to public health.

The bill specifies unlawful conduct, fines, and terms of imprisonment. Prohibited acts are felonies with maximum fines ranging from $10,000 to $200,000 and prison terms ranging from three years to life.

Current Law: The Board of Pharmacy regulates prescription drugs, pharmacies, pharmacists, and drug wholesale distributors in the State. Permits are required for both in-state wholesalers and out-of-state wholesalers that ship to customers in Maryland. The board issues licenses to pharmacists, and permits to wholesalers and pharmacies, while the Division of Drug Control, also within DHMH, conducts onsite inspections of pharmacies and their drug records.

Drug wholesalers, which include repackagers, must comply with board regulations on drug storage and the maintenance of drug records. The board may suspend or revoke a wholesaler's permit for failure to maintain proper records. If the wholesaler handles controlled dangerous substances, the wholesaler must also obtain a permit from the Division of Drug Control and the federal Food and Drug Administration (FDA). A pharmacy also must comply with minimum requirements for the maintenance of drug acquisition records. These records must be kept at least two years.

The federal Prescription Drug Marketing Act of 1988 (PDMA) provides FDA with the authority to track illegal drug distribution in the U.S. PDMA requires wholesalers to keep paper records of a drug's source and distribution history to provide a pedigree for prescription products. However, FDA has not yet finalized PDMA's full implementation because wholesalers have objected to the prohibitive expense of the tracking requirements.

Background: A surge in prescription drug imports into the U.S. is raising concern with FDA and American drug manufacturers about permitting large numbers of counterfeit and unapproved medicines into the country. It is estimated that about 20 million packages containing drugs come into the U.S. each year and that 14% of these are counterfeit or unapproved drugs. FDA has increased efforts to detect and block sales of fake drugs, while manufacturers are increasing their tracking efforts and publicizing the dangers of such products.

FDA opened 22 counterfeit drug cases in 2002 and 20 cases in 2001. Most cases involve high-volume drugs such as statins, AIDS therapies, and antidepressants. FDA has found counterfeit medications with inactive, subpotent, or superpotent ingredients, or impurities that could harm patients. Some counterfeit versions of Procrit contained contaminated tap water that caused blood stream infections in some individuals. One counterfeit version of Serostim, an AIDS therapy, had no active ingredient at all. Pfizer recently warned pharmacists of a widespread distribution of unauthorized Lipitor that patients found to have a bitter taste.

One response to the influx of counterfeit and unapproved drugs is expanding federal-state initiatives. FDA is collaborating with states such as Florida, which has adopted stronger drug wholesaler licensure requirements that may provide a model approach for other states. Florida has indicted several people for marketing adulterated drugs such as diluted Epogen and illegal Viagra.

In Maryland, there are 609 wholesale drug distributors licensed to serve Maryland, of which 142 are located in the State.

State Revenues: General fund revenues could increase minimally as a result of the bill's monetary penalty provisions from cases heard in the District Court.

State Expenditures: To the extent DHMH must inspect out-of-state wholesalers, special fund expenditures and revenues could each increase by a significant amount, beginning in fiscal 2005. Of the 609 wholesalers doing business in the State, only 142 are located here. There are insufficient data at this time to reliably estimate any expenditure increase. It is assumed the Board of Pharmacy would increase distributor permit fees to cover the additional costs of conducting out-of-state inspections.

General fund expenditures could increase minimally as a result of the bill's incarceration penalties 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 $1,850 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 $350 per month. Excluding medical care, the average variable costs total $120 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 2005 are estimated to range from $14 to $58 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.

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

Local Expenditures: Expenditures could increase minimally as a result of the bill's incarceration penalties. 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 $29 to $97 per inmate in fiscal 2005.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): *Counterfeiting, Compliance, and Controls*, (September 2003), Pharmaceutical Technology; U.S. Food and Drug Administration; Department of Health and Mental Hygiene (Board of Pharmacy, Medicaid); Department of Legislative Services

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