Department of Legislative Services
Maryland General Assembly
2006 Session

FISCAL AND POLICY NOTE
Revised

Senate Bill 1059 (Senator Teitelbaum)
Finance Health and Government Operations

Prescription Drug Repository Program

This bill establishes a prescription drug repository program regulated by the Board of Pharmacy. The purpose of the program is to accept donated prescription drugs for the purpose of dispensing the drugs to eligible individuals.

The bill takes effect July 1, 2006.

Fiscal Summary

State Effect: Regulatory oversight of the repository program could be handled with existing Board of Pharmacy budgeted resources. No effect on revenues.

Local Effect: None.

Small Business Effect: None.

Analysis

Bill Summary: The program may only accept and dispense drugs in their original unopened, sealed, and tamper-evident unit dose packaging, and with an expiration date at least 90 days from the date the drug is donated. Any person, including an individual, drug manufacturer, or health care facility, may donate prescription drugs. Drugs may only be donated at a drop-off site designated by the Board of Pharmacy. A drop-off site must: (1) require a donor to complete and sign a donor form releasing the drugs or medical supplies to the program; (2) store donated prescription drugs and supplies in a secure location used exclusively for the program; and (3) forward, at the cost of the designated drop-off site, all prescription drugs and supplies to a central repository.

A "drop-off site" is a pharmacy or other health care facility designated by the Board of Pharmacy that has voluntarily agreed to accept donated drugs and does not have a final disciplinary order issued against it by a health occupations board. A "repository" is a licensed pharmacy that does not have a final disciplinary order issued against it by the board, has voluntarily agreed to participate in the program, and has been approved by the board to accept and dispense donated drugs.

The Board of Pharmacy may approve Medbank of Maryland, Inc. or another licensed pharmacy, to be a repository. A repository must follow specified requirements that ensure the safety of the prescription drugs and supplies. A repository may dispense the drugs and charge a fee not exceeding $10.

To be eligible to receive donated drugs or supplies, a person must be a State resident and a needy patient as indicated by the individual's health care practitioner.

A donor, drop-off site, repository, pharmacist, or the Board of Pharmacy acting in good faith may not be subject to criminal prosecution or civil liability for injury, death, or loss to person or property for matters related to the donation, acceptance, or dispensing of a drug made by the manufacturer. A drug manufacturer acting in good faith may not be subject to criminal prosecution or liability in tort or other civil action for injury, death, or loss to person or property for matters related to donation, acceptance, or dispensing a drug manufactured by the drug manufacturer that is donated by any person under the program, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug.

The board must adopt regulations governing the program by January 1, 2007, specifically regarding safety, inspection, and record-keeping requirements.

Beginning January 1, 2007 and annually thereafter, a repository must report to the Governor and the General Assembly on the operation of the program.

Current Law: A pharmacist may accept the return of a properly labeled and properly sealed manufacturer's package or an individual unit dose of a drug or a device that the pharmacist determines to have been handled in a manner which preserves the strength, quality, purity, and identity of the drug or device during an interim period between the sale of the drug or device and its return to the pharmacy.

A pharmacist may not: (1) return to the pharmacy's stock or offer for sale a prescribed drug or device that has been previously sold and has left the pharmacy's possession except as provided above; or (2) sell, give away, or otherwise dispose of a drug, drug

accessory, chemical, or device if the pharmacist knows or should know that the drug, drug accessory, chemical, or device is to be used in an illegal activity.

Background: Chapter 310 of 2005 established the Task Force on the Establishment of a Prescription Drug Repository Program. The task force's initial meeting took place on December 15, 2005, and it submitted a *First Interim Report* on January 1, 2006. The task force made several recommendations that have been incorporated in this bill. The task force also recommended that it continue to work through June 2006 and submit a final report on July 1, 2006 that would provide recommendations for regulations that maybe used to support implementation of a prescription drug repository program in the State.

State Fiscal Effect: The Board of Pharmacy assumes there would be a small number of regionally-located repositories that would provide the services required by the bill. Accordingly, the board could handle regulatory oversight of the program with existing budgeted resources.

The repository program is not expected to have any fiscal impact on the Medicaid program. Medicaid recipients have comprehensive drug coverage with lower copayments than what is expected under the new program.

Additional Information

Prior Introductions: Similar bills, HB 317 and SB 441 of 2005 (as introduced) would have established a similar repository program. The bills were amended to establish a task force to study the issue. SB 441, as amended, was signed into law (Chapter 310 of 2005). HB 317 was vetoed as duplicative.

Cross File: HB 1689 (Delegate Rudolph) – Health and Government Operations.

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

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