HB 1085

Department of Legislative Services

Maryland General Assembly
2019 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 1085 (Delegate K. Young)
Health and Government Operations

Drug Manufacturers - Drug Take-Back Programs

This bill requires each manufacturer of a "covered drug" sold or distributed in the State to (1) operate a drug take-back program approved by the Maryland Department of Health (MDH); (2) enter into an agreement with a "drug take-back organization" to operate such a program; or (3) enter into an agreement with MDH to operate such a program on behalf of the manufacturer. By January 1, 2020, each manufacturer and drug take-back organization must submit to MDH a proposal for a drug take-back program that meets specified requirements. MDH must provide, and update annually on its website, a list of all manufacturers participating in an approved drug take-back program. A person in violation of the bill's provisions is subject to a civil penalty of up to $1,000. The State may recover from the manufacturer the State's actual costs related to administration and enforcement.

Fiscal Summary

State Effect: General fund expenditures increase by at least $183,000 in FY 2020 for staff. Future years reflect annualization. General fund revenues increase equivalent to expenditures from cost recoveries from manufacturers and may increase from civil penalties beginning in FY 2020.

(in dollars)	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
GF Revenue	-	-	-	-	-
GF Expenditure	$183,000	$224,500	$232,000	$239,900	$248,100
Net Effect	(-)	-	-	-	-

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

Local Effect: None.

Small Business Effect: Potential meaningful.

Analysis

Bill Summary:

Definitions

"Authorized collector" means (1) a person that is registered with the U.S. Drug Enforcement Administration (DEA) to collect controlled substances for the purposes of safe disposal and destruction; (2) a State or local law enforcement agency; or (3) a person authorized by MDH to provide alternative collection methods for covered drugs that are not controlled substances.

"Covered drug" means any substance recognized as a drug under federal law that is sold, offered for sale, or dispensed in the State, whether directly or through a wholesaler, in any form, including prescription and nonprescription drugs, drugs in medical devices and combination products, brand and generic drugs, and drugs for veterinary use.

"Drug take-back organization" means an organization designated by a manufacturer or a group of manufacturers to operate and implement a drug take-back program as authorized by the bill.

Program Proposals

Each manufacturer and drug take-back organization that has a contract with a manufacturer must submit to MDH a proposal for a drug take-back program that, at a minimum:

- certifies that the program will accept all covered drugs regardless of the producer;
- provides contact information for the person submitting the proposal;
- details a collection system that is geographically distributed to ensure access in rural and underserved areas to provide convenient, ongoing collection services to all persons seeking to dispose of covered drugs;
- describes other collection methods through which covered drugs will be collected by an authorized collector;
- explains how covered drugs will be safely and securely tracked and handled and the policies that will be implemented to ensure security and compliance with all applicable laws and regulations;
- describes the public education and outreach activities that will be performed and how the effectiveness of such activities will be evaluated;
- details how the costs of an authorized collector will be reimbursed and, if more than one manufacturer will be involved, details a plan for allocating costs among the participants, including retroactive costs; and
- provides any further information considered appropriate by MDH.

Within 60 days after receipt of a proposal, MDH must determine whether a proposed program complies with specified requirements and notify the applicant of the department's decision. MDH may conduct a public hearing before approving a proposed program.

If a program is approved, MDH must notify the applicant in writing. If a program is not approved, MDH must notify the applicant in writing and the applicant must submit a revised proposal within 30 days. If MDH rejects the revised proposal, the manufacturer is considered out of compliance with the bill's requirements and subject to a civil penalty.

At least every three years, each manufacturer and drug take-back organization must update their program and submit an updated proposal to MDH.

A manufacturer who begins to offer a covered drug in the State after October 1, 2019, must provide evidence of joining an approved drug take-back program or submit a proposal for a program within 90 days following the initial offer for sale of a covered drug in the State.

Drug Take-back Program Requirements

Each manufacturer must pay all administrative and operational fees associated with the program, as well as the actual costs incurred by the State in the administration and enforcement of the manufacturer's program.

A manufacturer may not charge a point-of-sale or other fee to a consumer, or a fee that could be passed on to a consumer, to recoup the cost of the manufacturer's program.

Reporting Requirements

Each approved drug take-back program must report to MDH at a date and manner established by the department.

By October 1 each year, MDH must submit a report to the Governor, the Secretary of Health, and the General Assembly a report on all drug take-back program activities, the weight of covered drugs collected by each program, a description of collection activities, the name and location of all collection sites, public education and outreach activities, an evaluation of the efficacy of the program and of each collection method, and any manufacturer out of compliance or subject to a penalty under the bill.

Current Law/Background: Chapter 287 of 2006 established a prescription drug repository program regulated by the State Board of Pharmacy. Chapters 546 and 547 of 2011 expanded the scope of the program to allow the acceptance of prescription drugs and medical supplies returned to a pharmacy for proper disposal. Each pharmacy for which a pharmacy permit has been issued must dispose of returned prescription drugs or medical

supplies in accordance with program policies. However, this program is voluntary and, according to the State Board of Pharmacy, there are currently fewer than 10 participating pharmacies.

Safe disposal of prescription drugs preserves patient safety, reduces abuse or unintended ingestion of prescription drugs, and limits the impact of unused medications on the environment. DEA-registered collectors safely and securely collect and dispose of pharmaceutical controlled substances and other prescription drugs. Authorized collection sites may be retail pharmacies, hospital or clinic pharmacies, and law enforcement locations. Some pharmacies may also offer mail-back envelopes to assist consumers in safely disposing of their unused medicines through the U.S. mail. Many independent community pharmacies, including 37 in Maryland, participate in DisposeMyMeds.org, a website that directs consumers to local medication disposal programs. Sharps Compliance, Inc. offers the TakeAway Environmental Return System for unused consumer prescription drugs in which returned drugs are mailed to the company, processed by law enforcement officials, and destroyed. Additionally, several jurisdictions have implemented drug take-back programs that allow individuals to safely dispose of unwanted prescription medication. All Department of State Police barracks in Maryland serve as around-the-clock, drop-off locations for unused prescription medications.

In July 2018, New York enacted legislation that requires certain manufacturers to operate a drug take-back program and be responsible for the collection, transport, and destruction of unused or unwanted prescription drugs. This bill is based on the New York law.

State Fiscal Effect: General fund expenditures increase by *at least* $183,024 in fiscal 2020, which accounts for the bill's October 1, 2019 effective date. This estimate reflects the cost of hiring three full-time staff to receive and review proposals for drug take-back programs, approve or deny such proposals, notify applicants in writing of program approval or the need for revisions, receive and approve any changes to existing drug take-back programs (including updates required at least every three years), ensure manufacturers are complying with the bill's requirements, publish and update a list of drug take-back programs on the MDH website, receive and analyze reports from drug take-back programs, evaluate the efficacy of the program and each collection method, compile and issue annual reports, calculate actual costs to administer and enforce drug take-back programs, and recover such costs from manufacturers. It includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Positions	3.0
Salaries and Fringe Benefits	$166,948
Operating Expenses	16,076
Total FY 2020 State Expenditures	**$183,024**

Future year expenditures reflect full salaries with annual increases and employee turnover and ongoing operating expenses. To the extent many manufacturers jointly conduct drug take-back programs, expenditures may be reduced due to fewer programs to review and oversee.

The bill requires each manufacturer to pay costs incurred by the State to administer and enforce the bill and authorizes the State to recover actual costs from manufacturers. Thus, this analysis assumes that general fund revenues increase in an amount equal to actual expenditures from cost recoveries from manufacturers. However, the receipt of such revenues will occur after State costs are incurred, likely in the following fiscal year.

Small Business Effect: Any small business manufacturers of covered drugs must comply with the bill and pay any costs incurred by the State to administer or enforce the manufacturer's drug take-back program.

Additional Comments: Although the bill permits a manufacturer to enter into an agreement with MDH to operate a drug take-back program on behalf of the manufacturer, the bill does not specify how such agreements would function.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Maryland Association of Counties; Maryland Municipal League; Maryland Department of Health; Department of State Police; Department of Legislative Services

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Analysis by: Jennifer B. Chasse

Direct Inquiries to:
(410) 946-5510
(301) 970-5510