HB 648

Department of Legislative Services

Maryland General Assembly
2010 Session

FISCAL AND POLICY NOTE

House Bill 648 (Delegate Barnes, *et al.*)
Environmental Matters

Environment - Drug Stewardship Program

This bill creates a Drug Stewardship Program to collect, transport, and dispose of unwanted prescription and over-the-counter drugs, including veterinary drugs, from residential sources, including hospice facilities, nursing homes, assisted living facilities, residential child care programs, and residential treatment centers. Drug manufacturers, either independently or jointly, must operate and pay all administrative and operational costs of the program, which must be overseen by the Maryland Department of the Environment (MDE). The bill also creates a Drug Stewardship Fund within MDE to cover the cost of carrying out program oversight.

Fiscal Summary

State Effect: General fund expenditures increase by at least $55,500 in FY 2011 to hire one full-time regulatory and compliance engineer to develop regulations and begin reviewing program proposals. No special fund revenues are collected in FY 2011 since fees are not collected until FY 2012. Future year expenditures, which are paid with special funds, reflect annualization and inflation. Future year special fund revenues reflect fee revenue sufficient to cover program costs.

(in dollars)	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015
SF Revenue	$0	$69,400	$72,700	$76,300	$80,000
GF Expenditure	$55,500	$0	$0	$0	$0
SF Expenditure	$0	$69,400	$72,700	$76,300	$80,000
Net Effect	($55,500)	$0	$0	$0	$0

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

Local Effect: Expenditures may decrease for local governments that are able to cease the collection of unused medications in conjunction with their household hazardous waste collection events.

Small Business Effect: None.

Analysis

Bill Summary: A "manufacturer" is a person or entity that manufactures a covered drug or has legal ownership of the brand, brand name, or co-brand under which a covered drug is sold; imports a covered drug manufactured by a person or entity that has no physical presence in the United States; or sells at wholesale or retail a covered drug and does not have legal ownership of the brand or brand name but elects to fulfill the manufacturer's responsibilities for that covered drug.

A drug included in a manufacturer's program is considered a "covered drug." A drug does not include vitamins or herbal-based remedies.

Beginning January 1, 2012, a manufacturer must obtain MDE's approval of its proposed program before selling or offering a drug for sale in the State or operating the program in the State. The bill specifies information that must be included in a manufacturer's proposed program, including a description of its public education effort and communications strategy for the program. MDE must review proposed programs and must notify a manufacturer of whether it has approved or rejected the program within 90 days of the proposal's receipt. If MDE rejects a proposed program, it must include its reasons in the notification, and a manufacturer may then submit a revised program or appeal.

With some exceptions, the bill prohibits a manufacturer from making substantive changes to an approved program without MDE's written approval. A manufacturer must update its program and submit the program to MDE for approval at least every four years. MDE must establish mandated performance standards, including recovery rates, for the fourth and subsequent years of a manufacturer's program by January 1, 2014. MDE may require a manufacturer that does not meet the standards to modify its program and must approve the modifications before they are implemented.

The bill prohibits a manufacturer from charging a fee during the sale of a covered drug or at the time unwanted drugs are delivered or collected for disposal. A manufacturer's program must accept covered drugs from any manufacturer.

The bill requires a manufacturer's program to dispose of all unwanted drugs at a controlled hazardous substance facility unless a manufacturer obtains MDE's approval to use a superior alternate disposal technology.

A manufacturer must promote the use of a program and the proper disposal of unwanted drugs so that collection options are widely understood by customers, pharmacists, retailers, and health care practioners. A manufacturer also must establish a toll-free telephone number and publicly accessible web site that provide information about collection options. The bill also requires a manufacturer to provide interested parties specified information and prepaid mailing envelopes for drug collection at no cost.

The bill requires a manufacturer that operates an approved program to submit an annual report to MDE beginning February 1, 2013. The bill specifies information that must be included in the report.

Beginning on January 1, 2012, MDE must send a written warning to a manufacturer without an approved program that sells or offers for sale a drug in the State. If a manufacturer without an approved program continues to sell or offer for sale a drug in the State 60 or more days after receiving the warning, MDE must assess a $10,000 penalty for each day that the violation continues. In addition, if MDE finds a manufacturer noncompliant with the bill, it must send the manufacturer a written warning that allows a 30-day correction period, after which it must assess a $5,000 penalty for the first violation and a $10,000 for the second and each subsequent 30-day period of noncompliance. All imposed penalties must be deposited into the Drug Stewardship Fund established by the bill and discussed in more detail below.

MDE may immediately amend, suspend, or cancel an approved program without written warning if it determines that it is necessary to protect the public from imminent danger. A manufacturer may appeal any penalty or action imposed under the bill.

The Drug Stewardship Fund is a special, nonlapsing fund within MDE to cover the cost of carrying out program oversight. The fund consists of any fees MDE establishes and collects from manufacturers to cover the cost of program oversight; penalty revenue; money appropriated in the State budget; investment earnings; and any other money from any other source accepted for the benefit of the fund. The fund may only be used for MDE's cost in carrying out its responsibilities under the bill, and may be made only in accordance with the State budget.

MDE must adopt regulations to implement the bill, and must report to the Governor, the Senate Education, Health, and Environmental Affairs Committee, and the House Environmental Matters Committee on the implementation of the bill by January 1, 2012, and annually thereafter.

Current Law: Chapter 287 of 2006 established a prescription drug repository program regulated by the Board of Pharmacy. The program accepts donated prescription drugs for

the purpose of dispensing them to needy patients in the State. However, prescription drugs can only be donated if they are in unopened, sealed, and tamper-evident unit dose packaging and have an expiration date at least 90 days from the date the drug is donated.

Although MDE administers numerous programs for improving and protecting Maryland's water quality, it is not currently involved with the collection, transportation, or disposal of unwanted drugs.

Background: In 2002, the U.S. Geological Survey reported that it found traces of 82 different organic contaminants – fertilizers and flame retardants as well as pharmaceuticals – in surface waters across the nation. These drugs included natural and synthetic hormones, antibiotics, antihypertensives, painkillers, and antidepressants.

To assess the level of pharmaceuticals in the Chesapeake Bay, a team of researchers collected water samples from 14 sites near selected wastewater treatment facilities in the bay to assess the presence of human-use pharmaceuticals and related compounds. The results published in 2006 showed that 13 of 24 compounds tested were identified, including antibiotics, antidepressants, blood pressure medications and analgesics, caffeine, and a nicotine metabolite.

Recently, federal government regulators have taken the following steps to control pharmaceuticals in the environment:

- the U.S. Environmental Protection Agency has listed some pharmaceuticals as candidates for regulation in drinking water. The agency also has launched a survey to check for scores of drugs at water treatment plants across the nation.
- the U.S. Food and Drug Administration updated its list of waste drugs that should be flushed down the toilet, but the agency has also declared a goal of working toward the return of all unused medicines.
- the National Toxicology Program is conducting research to clarify how human health may be harmed by drugs at low environmental levels.

The SMARxT Disposal Campaign, a public-private partnership between the U.S. Fish and Wildlife Service, the American Pharmacists Association, and the Pharmaceutical Research and Manufacturers of America, was designed to encourage people to dispose of unused medication in their household trash, rather than flushing it down the toilet or pouring it down a sink or drain. Specific suggestions regarding medication disposal include sealing it in a plastic bag with other substances such as coffee grounds or sawdust to make it unappealing for animals or children to eat.

State Fiscal Effect: Absent any actual experience under the bill, it is impossible to determine the number of program proposals that will be submitted to MDE by manufacturers. MDE advises that there are 151 drug manufacturers and 82 pharmaceutical companies nationwide. However, some smaller manufacturers may not sell drugs in the State, and other manufacturers will likely choose to operate a joint program thereby reducing the number of proposed programs submitted to MDE and over which MDE has oversight. Although MDE believes it needs four new positions to implement the bill, Legislative Services advises that to establish a minimum viable program, one full-time person is needed to conduct oversight under the bill. If MDE's workload exceeds the capacity of one-full time staff person, or MDE chooses to conduct a robust inspection plan (which is not required under the bill), additional staff may be requested through the annual budget process. In addition, while Legislative Services assumes that most manufacturers will conduct joint programs, minimizing the number of proposals that MDE must review, additional contractual staff may be necessary to review proposals (and again four years later), if the number of program proposals is high.

General fund expenditures increase by at least $55,469 in fiscal 2011, as special funds from fees assessed to manufacturers are not collected or available until fiscal 2012. This estimate also reflects the bill's October 1, 2010 effective date. The estimate includes the hiring of one full-time regulatory and compliance engineer to develop regulations and begin reviewing manufacturer program proposals in anticipation of the January 1, 2012 deadline for manufacturers to operate programs under the bill. This estimate includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Position	1
Salary and Fringe Benefits	$49,888
One-time Start-up Costs	4,298
Ongoing Operating Expenses	1,283
Total FY 2011 Expenditures	**$55,469**

Future year expenditures reflect annualization, a full salary with 4.4% annual increases, 3% employee turnover, and 1% annual increases in ongoing operating expenses.

Although the bill authorizes MDE to assess fees on manufacturers and establishes a special fund to cover the costs of the program, no fees are collected in fiscal 2011, since manufacturers are not authorized to operate programs before January 1, 2012. Since the purpose of the special fund is to cover MDE's cost for bill implementation, Legislative Services advises that MDE will set fees accordingly. Thus, special fund revenues from fees increase by $69,408 in fiscal 2012. For example, if 35 program proposals are submitted by manufacturers or groups of manufacturers, an annual fee of $2,000 per program will cover implementation costs in fiscal 2012. MDE will likely have to adjust

the fees in future years to approximate implementation costs, which increase due to inflation. Based on estimated expenditures, fee revenues will need to total nearly $80,000 in fiscal 2015.

Penalty revenue will also be deposited into the fund, but any penalties assessed cannot be predicted.

Local Effect: MDE advises that approximately one quarter of Maryland's counties collect unused medications in conjunction with their household hazardous waste collection events, which are held periodically throughout the year. Expenditures may decrease for these local governments as they would no longer have to collect unused medication under the bill.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Maryland Department of the Environment, Department of Health and Mental Hygiene, Department of Legislative Services

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