

Department of Legislative Services
Maryland General Assembly
2010 Session

FISCAL AND POLICY NOTE

House Bill 1387 (Delegate Bobo, *et al.*)
Health and Government Operations

Health Occupations - Pharmacists - Disposal of Unused Prescription Drugs
("Operation Take-back")

This bill requires that each container of a prescription drug dispensed to a retail consumer be labeled to advise the retail consumer of the proper disposal of any unused prescription drugs in the container as well as any other information required by law. A prescription drug dispensed to an inpatient in a hospital or related institution is exempt from this provision. Each pharmacy must develop a program for the disposal of unused prescription drugs that includes the provision of a secure container into which the consumer may deposit unused drugs for disposal by the pharmacy.

Fiscal Summary

State Effect: Special fund expenditures for the State Board of Pharmacy are unaffected. Potential minimal increase in general fund revenues due to the application of existing penalty provisions.

Local Effect: None.

Small Business Effect: Meaningful impact on small pharmacies that are required to purchase additional equipment for the disposal of unused medication and comply with additional labeling requirements.

Analysis

Bill Summary: A pharmacist must include with each prescription drug an information sheet that provides the current federal Food and Drug Administration (FDA) guidelines for drug disposal that are available from the FDA web site. If a drug is on the FDA's list

of unused drugs that should be flushed down the toilet, the notice on the label must reflect this. If a drug is not on this list, the prescription label must indicate that directions for proper disposal are included.

A pharmacy must dispose of secure containers containing unused prescription drugs as recommended by the FDA, and post a notice explaining the prescription drug disposal program and the positive effect on water quality derived from the proper disposal of unused prescription drugs.

Current Law: Except for a drug or device dispensed to an inpatient in a hospital or related institution, each container of a drug or device must be labeled to include specific information, including the date the prescription is filled, an expiration date of the drugs or devices, any appropriate special handling instruction regarding proper storage of the drugs or devices, and the name and strength of the drugs or devices. The name of the drug or device must also be on the label.

Chapter 287 of 2006 established a prescription drug repository program regulated by the State 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.

The State Board of Pharmacy inspects pharmacies annually and upon opening and closing. Subject to hearing requirements, the board may seek disciplinary action against a pharmacist or pharmacy permit holder who violates any provision within the Maryland Pharmacy Act. Violators are subject to civil fines up to \$10,000. In addition, the board may seek disciplinary action against a pharmacy technician that violates any provision under the Maryland Pharmacy Act. Violators are subject to civil penalties up to \$2,500.

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.
- FDA 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.

Small Business Effect: There are 1,143 pharmacies that operate in the State that will be impacted under this bill. An additional 384 out-of-state mail-order pharmacies will also be impacted by the bill's new labeling requirements. It is unknown how many of these pharmacies are considered small businesses.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Department of Natural Resources; Maryland Department of the Environment; Department of Health and Mental Hygiene; National Resources Defense Council; *Human Use Pharmaceuticals in the Estuarine Environment: A Survey of the Chesapeake Bay, Biscayne Bay and Gulf of the Farallones*; Department of Legislative Services

Fiscal Note History: First Reader - March 17, 2010
ncs/mcr

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