

Department of Legislative Services
Maryland General Assembly
2010 Session

FISCAL AND POLICY NOTE

House Bill 649

(Delegate Barnes, *et al.*)

Environmental Matters

Environment - Pharmaceutical Disposal Act

This bill prohibits a health care facility, as well as an employee, owner, contractor, or other individual acting on behalf of or under the direction or supervision of a health care facility, from discharging, disposing of, flushing, pouring, or emptying an “unused medication” into a wastewater system. The Maryland Department of the Environment (MDE) is responsible for enforcement. However, the Department of Health and Mental Hygiene (DHMH) and the Maryland Department of Agriculture (MDA) have to assist MDE by notifying the department of any health care facility that has violated the bill and providing access to any relevant records. MDE may adopt regulations to enforce the bill or specify acceptable methods for disposing of unused medication. Violators are subject to a \$500 fine for each violation, which must be deposited into the Bay Restoration Fund.

Fiscal Summary

State Effect: The bill’s requirements can be handled with existing resources given the mandated assistance required of DHMH and MDA. Minimal increase in special fund revenues beginning in FY 2011 due to the bill’s penalty provision.

Local Effect: None.

Small Business Effect: Potential minimal impact on small businesses if regulations developed by MDE require additional equipment for the disposal of unused medication.

Analysis

Bill Summary: The bill does not apply to the disposal of a controlled medication by a home health agency, home-based hospice care program, or hospice facility unless the federal Drug Enforcement Administration adopts regulations to dispose of controlled medication consistent with the bill's disposal requirements.

An "unused medication" is an unopened, expired, or excess medication in solid form that has been dispensed for patient or resident use. This includes pills, tablets, capsules, and caplets but does not include medications contained in intravenous fluids, syringes, or transdermal patches.

A "controlled medication" is a substance prescribed and dispensed to an individual and designated as a Schedule II controlled substance in federal regulations. Eighteen "facilities" are considered "health care facilities" for purposes of the bill, which includes a wholesale distributor, pharmacy, and veterinary hospital.

A "wastewater system" is a system used to collect, store, pump, treat, or discharge any liquid or waterborne waste and includes an on-site sewage disposal system or any other system that collects wastewater or discharges wastewater into State waters.

Current Law: 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 Bay Restoration Fund (Chapter 428 of 2004) was created to address the significant decline in Chesapeake Bay water quality due to over-enrichment of nutrients such as phosphorus and nitrogen. This dedicated fund, financed in large part by wastewater treatment plant users, is used to upgrade Maryland's 67 major publicly owned wastewater treatment plants with enhanced nutrient removal technology.

DHMH's Office of Health Care Quality licenses, certifies, and inspects facilities that provide health care treatment and services, including adult day care, assisted living programs, developmental disabilities programs, freestanding ambulatory care centers, home health agencies, hospices, hospitals, nursing homes, and residential child care programs. The State Board of Pharmacy inspects pharmacies and wholesalers, and the State Board of Veterinary Medical Examiners within MDA licenses and inspects veterinary hospitals.

A substance is listed in Schedule II if the substance includes a material, compound, mixture, or preparation that contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system: amphetamine, its salts, optical isomers, and salts of its optical isomers; phenmetrazine and its salts; a substance that contains any methamphetamine, including salts, optical isomers, and salts of its optical isomers, in combination with one or more active nonnarcotic ingredients in recognized therapeutic amounts; methylphenidate; and methamphetamine, its salts, optical isomers, and salts of optical isomers.

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: Although MDE is responsible for enforcement, the bill requires DHMH and MDA to assist MDE by notifying the department of any health care facility that has violated the bill and providing access to any records relevant to the violation. Together, DHMH and MDA already inspect all facilities included the bill.

Therefore, with the assistance of MDA and DHMH, Legislative Services advises that MDE can handle enforcement within existing resources. However, to the extent that additional inspections are required, expenditures increase for MDE to hire additional inspectors. MDE can develop regulations with existing resources.

Minimal increase in special fund revenues beginning in fiscal 2011 due to the bill's penalty provision that collected penalties be deposited into the Bay Restoration Fund.

Small Business Effect: While MDE has not indicated that, through regulations, it will require any additional equipment for the disposal of unused medication under the bill, expenditures may increase for small health care providers to the extent that any regulations developed by MDE do include such a requirement. However, Legislative Services estimates that any impact will be minimal.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Maryland Department of Agriculture; 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

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