

**Maryland General Assembly
Department of Legislative Services**

**Proposed Regulation
Department of Health and Mental Hygiene
(DLS Control No. 15-342)**

Overview and Legal and Fiscal Impact

The regulations allow for the collection and disposal of prescription drugs and medical supplies by approved pharmacies.

The regulations present no legal issues of concern.

There is no fiscal impact on State or local agencies.

Regulations of COMAR Affected

Department of Health and Mental Hygiene:

Board of Pharmacy: Prescription Drug Repository Program: COMAR 10.34.33.01-.07

Legal Analysis

Background

The federal Secure and Responsible Disposal Act of 2010 allows for the collection and disposal of prescription drugs and medical supplies by approved pharmacies. Chapters 546 and 547 of 2011 updated State law to reflect this; however, the related regulations were never updated.

Summary of Regulations

The regulations allow for the collection and disposal of prescription drugs and medical supplies by approved pharmacies.

Regulation .01 defines “donation program” and “disposal program” and changes the definitions of “drop-off site” and “repository” to make a distinction between pharmacies that accept prescription drugs or medical supplies that will be redispensed to needy individuals and pharmacies that accept prescription drugs or medical supplies for disposal.

Regulation .01-1 incorporates by reference the federal Secure and Responsible Drug Disposal Act of 2010.

Regulations .02 through .04 specify that they govern the donation program only.

Regulation .05 specifies that it only governs drop-off site requirements for the donation program only and prohibits a drop-off site in the donation program from accepting prescription drugs and medical supplies for disposal.

Provisions from Regulation .05 that apply only to repositories participating in the donation program are being moved to Regulation .06-1. Regulation .06-1 also requires that a repository maintain the required inventories and prescription files for a minimum of five years. Additionally, Regulation .06-1 requires a repository to (1) dispense donated prescription drugs and medical supplies in compliance with applicable federal and State law and regulations; (2) comply with COMAR 10.34.25 when shipping drugs and supplies to recipients; (3) dispose of donated prescription drugs and medical supplies that do not meet eligibility requirements in compliance with applicable federal and State laws and regulations; and (4) maintain records of disposal. Finally, the regulation provides that (1) a recipient must be a resident of the State; (2) a health care practitioner with prescribing authority must determine the financial need of a patient to participate in the program and indicate the patient's eligibility; and (3) recipients must sign a board approved form before receiving the prescription drug or medical supply.

Regulation .07 requires that pharmacies be approved by the State Board of Pharmacy as repositories to collect returned prescription drugs and medical supplies for proper disposal. The regulation also requires that repositories that collect only noncontrolled dangerous substances for proper disposal to (1) dispose of the drugs or supplies in compliance with applicable State and federal laws and regulations; (2) have policies and procedures regarding the safe and secure handling and disposal of the drugs and supplies, including specific guidelines for drugs requiring special disposal or care; (3) dispose of the drugs and supplies through a third party processor or a reverse distributor as appropriate; and (4) maintain a separate secure container behind the prescription counter that is clearly marked for the disposal program. The regulation prohibits a pharmacist from delegating to a pharmacy technician the collection of the drugs and supplies. Finally, the regulation requires that repositories that collect controlled dangerous substances for disposal comply with the requirements of the federal Secure and Responsible Drug and Disposal Act of 2010 and authorizes those repositories to collect noncontrolled dangerous substances and medical supplies in the same manner and commingle the collection in accordance with the federal law.

Legal Issues

The regulations present no legal issues of concern.

Statutory Authority and Legislative Intent

The Department of Health and Mental Hygiene cites §§ 15-601 through 15-609 of the Health – General Article as statutory authority for the regulations. More specifically, § 15-608 requires the board to adopt regulations governing the Prescription Drug Repository Program. The regulations must include requirements for designation of repositories to dispose of donated prescription drugs and medical supplies and standards and procedures for disposing of donated prescription drugs and medical supplies, and any other standards and procedures the board considers appropriate. The remaining cited authority is not relevant to these regulations.

The relevant cited authority is correct and complete. The regulations comply with the legislative intent of the law.

Technical Corrections and Special Notes

In response to a suggestion from the Department of Legislative Services, staff for the board agreed to add language to Regulation .05D(2)(e) to prohibit donation program drop-off sites from accepting medical supplies for disposal. This change is reflected in the discussion of the regulations above.

Fiscal Analysis

There is no fiscal impact on State or local agencies.

Agency Estimate of Projected Fiscal Impact

The regulations alter the Prescription Drug Repository Program to allow for the disposal of prescription drugs and medical supplies, including controlled dangerous substances, as authorized under federal law and Chapters 546 and 547 of 2011 (Senate Bill 770 and House Bill 460). As the changes do not impact the workload of the State Board of Pharmacy, the department advises that the regulations have no impact on State or local governments. The Department of Legislative Services concurs.

Impact on Budget

There is no impact on the State operating or capital budget.

Agency Estimate of Projected Small Business Impact

While participating pharmacies may incur minimal additional costs, the program is already voluntary; thus, the department advises that the regulations have minimal or no economic impact on small businesses in the State. The Department of Legislative Services concurs.

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