

MARYLAND REGISTER

## Proposed Action on Regulations

### Comparison to Federal Standards Submission and Response

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In accordance with Executive Order 01.01.1996.03 and memo dated July 26, 1996, the attached document is submitted to the Department of Business and Economic Development for review.

The Proposed Action is not more restrictive or stringent than corresponding federal standards.

**COMAR Codification:** 10.34.33.01-.07

**Corresponding Federal Standard:**

The Secure and Responsible Drug Disposal Act of 2010, 21 U.S.C. 822 (as amended)

**Discussion/Justification:**

The Board wanted the disposal of prescription drugs and medical supplies, pursuant to federal law, to compliment the Prescription Drug Repository Program with no additional restrictive requirements.

**TO BE COMPLETED BY DBED**

- Agree

-Disagree

**Comments:**

Commerce does not have the subject matter expertise in this matter. However,

we believe DHMH does and we trust their assertion that the regulation is not more restrictive/stringent than corresponding federal standards.

Name: Sandy Popp

Date: 11/6/2015

\_ -Submit to Governor's Office  
**Governor's Office Response**

**Comments:**

|  |                                       |   |
|--|---------------------------------------|---|
| <b>Transmittal Sheet</b><br><br><b>PROPOSED OR REPROPOSED</b><br><br><b>Actions on Regulations</b> | <b>Date Filed with AELR Committee</b> | <b>TO BE COMPLETED BY DSD</b>               |
|  | 11/06/2015                            | Date Filed with Division of State Documents |
|  |                                       | Document Number                             |
|  |                                       | Date of Publication in MD Register          |

**1. Desired date of publication in Maryland Register: 12/11/2015**

**2. COMAR Codification**

|              |                 |                |                   |
|--------------|-----------------|----------------|-------------------|
| <b>Title</b> | <b>Subtitle</b> | <b>Chapter</b> | <b>Regulation</b> |
| 10           | 34              | 33             | 01-.07            |

**3. Name of Promulgating Authority**

Department of Health and Mental Hygiene

## Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

### Subtitle 34 BOARD OF PHARMACY

#### 10.34.33 Prescription Drug Repository Program

Authority: Health-General Article, §§15-601—15-609, Annotated Code of Maryland

#### Notice of Proposed Action

□

The Secretary of Health and Mental Hygiene proposes to amend Regulations .01—.06, adopt new Regulations .01-1 and .06-1, repeal and adopt new Regulation .07, and repeal Regulations .08—.12 under COMAR 10.34.33 Prescription Drug Repository Program.

This action was considered by the Board of Pharmacy at a public meeting held October 21, 2015 notice of which was given by publication on the Board of Pharmacy website,

<http://dhmh.maryland.gov/pharmacy/SitePages/Home.aspx>, from September 21, 2015 — October 21, 2015, pursuant to the State Government Article, §10-506(c), Annotated Code of Maryland.

**4. Name of Regulations Coordinator**  
Michele Phinney

**Telephone Number**  
410-767-5623

**Mailing Address**

201 W. Preston Street

**City** Baltimore      **State** MD      **Zip Code** 21201

**Email**  
michele.phinney@maryland.gov

**5. Name of Person to Call About this Document**  
Anna Jeffers

**Telephone No.**  
410-764-3833

**Email Address**  
anna.jeffers@maryland.gov

**6. Check applicable items:**

- New Regulations
- Amendments to Existing Regulations
  - Date when existing text was downloaded from COMAR online: October 20, 2015.
- Repeal of Existing Regulations
  - Recodification
  - Incorporation by Reference of Documents Requiring DSD Approval
  - Reproposal of Substantively Different Text:

:                      Md.  
                              R

(vol.) (issue)      (page (date)  
                              nos)

Under Maryland Register docket no.: --P.

**7. Is there emergency text which is identical to this proposal:**  
 Yes  No

**Statement of Purpose**

The purpose of this action is to amend COMAR 10.34.33 Prescription Drug Repository Program to allow for the disposal of prescription drugs and medical supplies, including controlled dangerous substance as allowed by the Secure and Responsible Drug Disposal Act of 2010, 21 U.S.C. 822 (as amended).

**Comparison to Federal Standards**

There is a corresponding federal standard to this proposed action, but the proposed action is not more restrictive or stringent.

**Estimate of Economic Impact**

**I. Summary of Economic Impact.**

The Prescription Drug Repository Program is a voluntary program. Those pharmacies that volunteer to participate may incur minimal costs depending on whether or not those pharmacies 1) collect prescription drugs and medical supplies for disposal; and/or 2) collect donated prescription drugs and medical supplies for redispensing to the needy. The Board would not incur additional expenses now that participants in the program may collect controlled dangerous substances for disposal. Pharmacies that participate would be inspected annually as a matter of course.

**II. Types of Economic Impact.**

Revenue  
(R+/R-)

Expenditure      Magnitude  
(E+/E-)

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- A. On issuing agency: NONE
- B. On other State agencies: NONE

**8. Incorporation by Reference**

\_ Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

**9. Public Body - Open Meeting**

X- OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to State Government Article, §10-506(c), Annotated Code of Maryland.

\_ OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

**10. Children's Environmental Health and Protection**

\_ Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

**11. Certificate of Authorized Officer**

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Linda M. Bethman, Assistant Attorney General, (telephone #410-767-6906) on October 27, 2015. A written copy of the approval is on file at this agency.

**Name of Authorized Officer**

Van T. Mitchell

**Title**                      **Telephone No.**

Secretary                      410-767-6500

**Date**

C. On local governments: NONE

Benefit (+)      Magnitude  
Cost (-)

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D. On regulated industries or trade groups: (-)      Indeterminable

E. On other industries or trade groups: NONE

F. Direct and indirect effects (+)      Indeterminable on public:

**III. Assumptions.** (Identified by Impact Letter and Number from Section II.)

D. Pharmacies that volunteer to participate may incur minimal costs depending on whether or not those pharmacies 1) collect prescription drugs and medical supplies for disposal; and/or 2) collect donated prescription drugs and medical supplies for redispensing to the needy.

F. The public would benefit by having a means to dispose of controlled dangerous substance prescriptions that may be expired or unwanted in their homes. This will reduce accidental overdoses, ingestion by household pets, or theft by family members.

**Economic Impact on Small Businesses**

The proposed action has minimal or no economic impact on small businesses.

**Impact on Individuals with Disabilities**

The proposed action has no impact on individuals with disabilities.

**Opportunity for Public Comment**

November 2, 2015

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to [dhmh.regs@maryland.gov](mailto:dhmh.regs@maryland.gov), or fax to 410-767-6483. Comments will be accepted through January 11, 2016. A public hearing has not been scheduled.

### **Economic Impact Statement Part C**

A. Fiscal Year in which regulations will become effective: FY 2016

B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

The Board is not required to obtain information concerning which licensees operate small businesses, although some pharmacy permit holders may also be small businesses.

G. Small Business Worksheet:

# Title 10

## DEPARTMENT OF HEALTH AND MENTAL HYGIENE

### Subtitle 34 BOARD OF PHARMACY

#### 10.34.33 Prescription Drug Repository Program

Authority: Health-General Article, §§15-601—15-609, Annotated Code of Maryland

10.34.33.01 (October 20, 2015)

**.01 Definitions.**

A. (text unchanged)

B. Terms Defined.

(1) (text unchanged)

(1-1) *“Donation program” means pharmacies that voluntarily participate as a drop-off site or repository, or both, to accept donated drugs or medical supplies for purposes of re-dispensing those donated drugs or medical supplies to needy individuals.*

(1-2) *“Disposal program” means pharmacies that voluntarily participate as repositories to collect returned drugs and medical supplies for purposes of safe disposal.*

(2) *“Drop-off site” means a pharmacy or other health care facility designated by the Board for the purpose of receiving donated prescription drugs or medical supplies as part of the donation program and forwarding the drugs or medical supplies to a repository.*

(3)—(7) (text unchanged)

(8) *“Repository” means a pharmacy that applies to and is designated by the Board for the purpose of:*

(a) *Accepting, inspecting, and dispensing donated prescription drugs or medical supplies received from a drop-off site as part of the donation program; and*

*[(b) Inspecting donated prescription drugs or medical supplies; and*

*(c) Dispensing donated prescription drugs or medical supplies for use by needy individuals.]*

*(b) Collecting prescription drugs or medical supplies for disposal as part of the disposal program.*

**.01-1 Incorporation by Reference.**

*In this chapter, the Secure and Responsible Drug Disposal Act of 2010, 21 U.S.C. 822 (as amended), has been incorporated by reference.*

**.02 Donation Program - Eligible Drugs.**

A. — B. (text unchanged)

**.03 Donation Program - Ineligible Drugs.**

A. — B. (text unchanged)

**.04 Donation Program - Donor Form.**

A. — B. (text unchanged)

**.05 Donation Program - Drop-Off Sites Requirements.**

A. — C. (text unchanged)

D. Procedures for Handling of Donated Prescription Drugs or Medical Supplies.

(1) (text unchanged)

(2) A drop-off site may not:

(a)—(b) (text unchanged)

(c) Charge a fee for accepting a donation; [or]

(d) Accept donated prescription drugs or medical supplies until the drop-off site applicant has been approved by the Board; *or*

(e) Accept prescription drugs for disposal.

**.06 Repositories – General Requirements.**

A. In order to become a repository, a pharmacy:

(1) (text unchanged)

(1-1) Shall indicate on the application to the Board if the applicant intends to:

(a) Participate in the Donation Program;

(b) Participate in the Disposal Program by collecting only non-controlled dangerous substances and medical supplies for safe disposal; or

(c) Participate in the Disposal Program by collecting controlled dangerous substances, non-controlled dangerous substances, and medical supplies for safe disposal;

(2)—(4) (text unchanged)

[B. Designated Pharmacist. A repository shall designate a pharmacist who shall:

(1) Accept donated prescription drugs or medical supplies forwarded by:

(a) A drop-off site; or

(b) A manufacturer regulated by the U.S. Food and Drug Administration;

(2) Inspect donated prescription drugs or medical supplies;

(3) Accept donated prescription drugs or medical supplies that meet the requirements of Regulations .02 and .03 of this chapter; and

(4) Obliterate from the labels of donated prescription drugs or medical supplies patient specific information for which the donated prescription drugs or medical supplies were originally dispensed when it is placed in inventory.

C. Record Requirements. A repository shall:

(1) Maintain a separate inventory of donated prescription drugs or medical supplies;

(2) Maintain separate prescription files for patients receiving donated prescription drugs or medical supplies; and

(3) Submit an annual report on its activities to the Board that includes at least information on the:

(a) Number of recipients by county;

(b) Approximate market value of the prescription drugs or medical supplies dispensed;

(c) 50 prescription drugs or medical supplies most frequently dispensed; and

(d) Total number of donations to the Program.

D. Procedures for Handling of Donated Prescription Drugs or Medical Supplies.

(1) A repository shall store donated prescription drugs or medical supplies in a secure location separate from other inventory in accordance with State and federal laws and regulations.

(2) A repository may not:

(a) Resell prescription drugs or medical supplies donated to the Program; or

(b) Establish or maintain a waiting list for prescription drugs or medical supplies dispensed by the Program.

(3) A repository may charge a fee of not more than \$10 for each prescription drug or medical supply dispensed under the Program.

E. Limitations. A repository is under no obligation to obtain a prescription drug or medical supply that is not in inventory at the time of the request.]

**.06-1 Repositories Participating in the Donation Program.**

A. Designated Pharmacist. A repository in the donation program shall designate a pharmacist who shall:

(1) Accept donated prescription drugs or medical supplies forwarded by:

(a) A drop-off site; or

(b) A manufacturer regulated by the U.S. Food and Drug Administration;

(2) Inspect donated prescription drugs or medical supplies;

(3) Accept donated prescription drugs or medical supplies that meet the requirements of Regulations .02 and .03 of this chapter; and

(4) Obliterate from the labels of donated prescription drugs or medical supplies patient specific information for which the donated prescription drugs or medical supplies were originally dispensed when it is placed in inventory.

B. Record Requirements. A repository in the Donation Program shall:

(1) Maintain a separate inventory of donated prescription drugs or medical supplies for a minimum of 5 years;

(2) Maintain separate prescription files for patients receiving donated prescription drugs or medical supplies for a minimum of 5 years; and

(3) Submit an annual report on its activities to the Board that includes at least information on the:

(a) Number of recipients by county;

(b) Approximate market value of the prescription drugs or medical supplies dispensed;

(c) 50 prescription drugs or medical supplies most frequently dispensed; and

(d) Total number of donations to the Program.

C. Procedures for Handling of Donated Prescription Drugs or Medical Supplies.

(1) A repository in the Donation Program shall store donated prescription drugs or medical supplies in a secure location separate from other inventory in accordance with State and federal laws and regulations.

(2) A repository may not:

- (a) Resell prescription drugs or medical supplies donated to the Program; or
      - (b) Establish or maintain a waiting list for prescription drugs or medical supplies dispensed by the Program.
    - (3) A repository may charge a fee of not more than \$10 for each prescription drug or medical supply dispensed under the Program.
  - D. *Limitations.* A repository in the Donation Program is under no obligation to obtain a prescription drug or medical supply that is not in inventory at the time of the request.
  - E. *Procedure for Dispensing Donated Prescription Drugs or Medical Supplies.* A repository in the Donation Program shall dispense donated prescription drugs or medical supplies in compliance with applicable federal and State laws and regulations for dispensing prescription drugs or medical supplies.
  - F. *Procedure for Shipping Donated Prescription Drugs or Medical Supplies.* A repository in the Donation Program shall comply with COMAR 10.34.25 when shipping donated prescription drugs or medical supplies to recipients of this Program.
  - G. *Procedures for Disposing of Donated Prescription Drugs or Medical Supplies.*
    - (1) A repository in the Donation Program shall dispose of donated prescription drugs or medical supplies that do not meet the eligibility requirements of Regulation .02 of this chapter.
    - (2) A repository in the Donation Program shall dispose of donated prescription drugs or medical supplies in compliance with applicable State and federal laws and regulations for disposing of prescription drugs or medical supplies.
    - (3) A repository shall maintain records of disposal of donated prescription drugs or medical supplies.
  - H. *Determination of Patient Eligibility for the Donation Program.*
    - (1) A recipient of the Donation Program shall be a resident of the State.
    - (2) A health care practitioner with prescribing authority shall:
      - (a) Determine, at the health care practitioner's discretion, the financial need of a patient to participate in the Donation Program; and
      - (b) Indicate on the patient's prescription eligibility for the Donation Program.
  - I. *Recipient Form.* Recipients of a donated prescription drug or medical supply under the Donation Program shall sign a Board approved form before receiving the prescription drug or medical supply to confirm that the recipient understands that:
    - (1) The recipient is receiving prescription drugs or medical supplies that have been donated as part of the Donation Program; and
    - (2) Entities involved in the Donation Program have immunity from liability in accordance with Health-General Article, §15-607, Annotated Code of Maryland.

**.07 Disposal Program – Requirements.**

- A. Pharmacies that collect returned prescription drugs or medical supplies for proper disposal shall be approved by the Board as repositories.
- B. Repositories that collect only non-controlled dangerous substances for proper disposal shall:
  - (1) Dispose of prescription drugs or medical supplies collected for disposal in compliance with applicable State and federal laws and regulations;
  - (2) Have policies and procedures regarding the safe and secure handling and disposal of prescription drugs and medical supplies, to include specific guidelines for prescription drugs requiring special disposal or care;
  - (3) Dispose of collected prescription drugs and medical 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.
- C. A pharmacist may not delegate to a pharmacy technician the collection of prescription drugs or medical supplies under §B of this regulation.
- D. Repositories that collect controlled dangerous substances for disposal:
  - (1) Shall comply with the requirements of the Secure and Responsible Drug Disposal Act of 2010;
  - (2) May collect non-controlled dangerous substances and medical supplies in the same manner; and
  - (3) May commingle the collection of controlled and non-controlled dangerous substances and medical supplies in accordance with the Secure and Responsible Drug Disposal Act of 2010.

**VAN T. MITCHELL**

**Secretary of Health and Mental Hygiene**