



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

Lawrence J. Hogan, Jr., Governor – Boyd K. Rutherford, Lt. Governor – Van T. Mitchell, Secretary

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue • Baltimore, Maryland 21215-2299

Mitra Gavgani, Board President – Richard A. Proctor, Acting Executive Director

January 1, 2016

The Honorable Larry Hogan
Office of the Governor
State House
Annapolis, Maryland 21401-1925

The Honorable Thomas V. Mike Miller, Jr.
President of Senate
State House, H-107
Annapolis, MD 21401 – 1991

The Honorable Michael Erin Busch
Speaker of House of Delegates
State House, H-101
Annapolis, MD 21401 – 1991

Re: Tenth Annual Report on the Operation of the Prescription Drug Repository Program,
Health-General Article, § 15-609(b)(3), Annotated Code of Maryland

Dear Governor Hogan, President Miller and Speaker Busch:

In accordance with Health-General Article, § 15-609(b)(3), Annotated Code of Maryland, the Maryland Board of Pharmacy (the "Board") respectfully submits the enclosed Prescription Drug Repository Program Annual Report.

This is the tenth annual report on the operation of the Prescription Drug Repository Program (the "Program") as required by Health-General Article, § 15-609(b)(3), Annotated Code of Maryland. The Program is intended to provide a mechanism for the acceptance of prescription drugs and medical supplies donated by individuals and entities for the purpose of dispensing to needy individuals or for the purpose of disposal. The Program has been established for approximately nine years. A total of 47 pharmacies have been approved to be repositories and/or drop-off sites. The site locations have expanded from Baltimore City, Baltimore County, the Eastern Shore and Southern Maryland to also include Harford, Cecil, Anne Arundel and Montgomery Counties. There has been a small, steady increase in participants since 2006. Participation in the Program has expanded significantly since the program now requires pharmacies that only dispose of customer's unwanted or expired prescription drugs to register with the program.

The Honorable Larry Hogan
The Honorable Thomas V. Mike Miller, Jr.
The Honorable Michael Erin Busch
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With the promulgation of federal regulations to implement the Secure and Responsible Drug Disposal Act of 2010, the Board is in the process of revising COMAR 10.34.33 to allow for the collection of medications, including controlled dangerous substances, for disposal. The proposed regulations were published in the Maryland Register on December 28, 2015. Allowing pharmacies participating in the Program to collect controlled dangerous substances will provide a convenient place for consumers to dispose of controlled dangerous substances, keeping them out of the community at large.

Should you have questions or additional concerns, please feel free to contact Anna D. Jeffers, Legislation and Regulations Manager, at (410) 764-4794.

Respectfully,



Richard A. Proctor
Acting Executive Director

Enclosure

cc: The Honorable Joan Carter Conway
The Honorable Peter A. Hammen
Sarah Albert, Department of Legislative Services, MSAR#5841
Linda Bethman, Board Counsel, Maryland Board of Pharmacy
Shawn Cain, Chief of Staff, DHMH
Mitra Gavgani, President, Maryland Board of Pharmacy
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David H. Jones, Chair, Practice Committee, Maryland Board of Pharmacy
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Katie Wunderlich, Governor's Legislative Office



**MARYLAND
BOARD OF PHARMACY PRESCRIPTION
DRUG REPOSITORY PROGRAM**

**TENTH ANNUAL REPORT TO THE
GOVERNOR
AND
THE GENERAL ASSEMBLY**



January 1, 2016

**MARYLAND BOARD OF PHARMACY PRESCRIPTION DRUG
REPOSITORY PROGRAM**

TENTH ANNUAL REPORT

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Executive Summary

This is the tenth annual report on the operation of the Prescription Drug Repository Program (the “Program”) as required by Health-General Article, § 15-609(b)(3), Annotated Code of Maryland. The Program is intended to provide a mechanism for the acceptance of prescription drugs and medical supplies donated by individuals and entities for the purpose of dispensing to needy individuals or for the purpose of disposal. The Program has been expanded to include collection of prescription drugs for disposal. The Program has been established for approximately nine years.

Thirteen (13) pharmacies have been approved to be repositories and thirty-four (34) pharmacies have been approved to be drop-off sites. The site locations are in Baltimore City, Anne Arundel County, Baltimore County, Cecil County, Harford County, Montgomery County, counties on the Eastern Shore, and Southern Maryland. There has been a small, steady increase in participants since 2006. The program has expanded significantly as it now requires pharmacies that only dispose of customer’s unwanted or expired prescription drugs to register with the program as repositories.

In December of 2010, President Obama signed into law the Secure and Responsible Drug Disposal Act of 2010. This Act allows pharmacies to collect controlled dangerous substances for disposal. As a result of this legislation, in 2011 the Maryland Board of Pharmacy (the “Board”) expanded the purpose of the Program to include disposal: SB 770/HB 460 Prescription Drug Repository Program – Disposal of Prescription Drugs and Medical Supplies, Chapters 546 and 547. This expansion ensures accountability by pharmacies who take back drugs and increases awareness among consumers that unused or unwanted prescription medications may be donated to pharmacies for disposal or redispensing if the medications are eligible for redispensing. It increased the number and location of drop-off sites and repository sites.

The Board voted at the November 19, 2014 Public Board Meeting to continue to allow repositories to collect non-controlled dangerous substances under the current repository standards and to continue the program. The Board voted to incorporate by reference into COMAR 10.34.33 the federal regulations for disposal of controlled substances to be located in 21 CFR PARTS 1300, 1301, 1304, 1305, 1307, and 1317. The federal regulations were finalized in the fall of 2014. The Board approved proposed revisions to COMAR 10.34.33 to accommodate the federal law and regulations on October 21, 2015 and the proposed regulations were published in the Maryland Register on December 28, 2015.

BACKGROUND

In the Fall of 2005 and Winter of 2006, a task force of stakeholders (listed in prior annual reports), provided recommendations for a prescription medication donation program to the Maryland General Assembly via the Maryland Board of Pharmacy. As a result of those recommendations, SB 1059 Prescription Drug Repository Program (Chapter 287) was passed during the 2006 legislative session requiring establishment of the Program. The Board used the task force's recommendations and SB 1059 to develop and promulgate regulations to implement the Program. COMAR 10.34.33 Prescription Drug Repository Program became effective on

January 29, 2007. The Board utilized the statute and proposed regulations to develop the necessary donor and recipient forms, and applications for drop-off sites and/or repositories for the Program. During the 2011 legislative session, SB 770/HB 460 Prescription Drug Repository Program – Disposal of Prescription Drugs and Medical Supplies, Chapters 546 and 547, introduced at the request of the Board, made it a requirement that a pharmacy may accept prescription drugs and medical supplies taken to the pharmacy for disposal only if the pharmacy is approved by the Board under the Program. This legislation provides accountability for pharmacies and it is hoped will increase awareness among consumers that unused or unwanted prescription medications may be donated to pharmacies for disposal or redispensing if the medications are eligible for redispensing. For Chapter 546 see:

http://mlis.state.md.us/2011rs/chapters_noln/Ch_546_sb0770T.pdf. The Board has submitted nine Prescription Drug Repository Program Annual Reports to the Governor and the General Assembly from January 1, 2007 through January 1, 2015. The forms, the regulations, and prior annual reports are available on the Board's website at:

<http://dhmh.maryland.gov/pharmacy/SitePages/laws-regulation-legislation-reports.aspx#pr>

In December of 2010, President Obama signed into law the Secure and Responsible Drug Disposal Act of 2010. This Act allows pharmacies to collect controlled dangerous substances for disposal. The Board has delayed promulgating regulations to specifically address disposal while the U.S. Drug Enforcement Administration (DEA) promulgated federal regulations to implement the Secure and Responsible Drug Disposal Act of 2010. The federal regulations were final in September 2014. The Board's revisions to COMAR 10.34.33 will accommodate the proposed federal regulations and are attached in the Appendix.

PROGRAM DESCRIPTION

A description of the program operations was included in the January 1, 2009 report. In brief, the Board has administrative oversight of the Program by receiving and approving the applications for repositories and drop-off sites. Applications may be for the establishment of a repository that will accept dispensed medications to identified Maryland patients and/or dispose of drugs that do not meet the criteria for the Program. Applications may also be approved for drop-off sites that may receive and forward all donated drugs to a Board approved repository. Only a pharmacy may be a repository. Drop-off sites may be in either a pharmacy or a health care facility. The Board monitors repositories as a part of its existing annual pharmacy inspection process. With the passage of SB 770/HB 460, the Board also inspects pharmacies that only dispose of prescription medications during the same annual pharmacy inspection process. A pharmacy must be registered as a repository to collect medications for disposal. The Board will develop procedures for monitoring health care facilities, or develop memorandums of agreement with those agencies that are already responsible for monitoring health care facilities to act as the Board's agent, if any health care facilities enroll in the program. No health care facility has ever applied to participate.

PROGRAM CHALLENGES

The increase in participation in this Program has given Maryland citizens more options for disposal of prescription drugs. Although there has been an increase in repositories for disposal,

there still are not enough repositories to accommodate those in need of free prescription drugs. The Board has attributed the possible causes for the lack of participation in the program to three primary, possibly overlapping, challenges: 1) limited incentives to participate; 2) limited program promotion to healthcare providers and patients; and 3) limited staff, storage, disposal and other necessary resources for efficiently operating a drop-off or repository site. The Board made a number of recommendations in the January 1, 2010 Report that would have established tax incentives for participation in the Program or funding for startup costs. In the current economic climate, those recommendations may not be possible.

Now that the Program includes pharmacies that solely wish to dispose of customer's medications, the Program serves a dual purpose. More and more consumers are asking their pharmacists if they can dispose of their unwanted medications at the pharmacy, which may become an incentive for more pharmacies to participate. The challenge will be whether or not customers take the next step and begin to ask the pharmacies to accept medications for proper re-dispensing to the needy as well.

CONCLUSION

As noted in prior reports, the low interest in becoming a repository or drop-off site appears to be due to the costs and liabilities related to the perceived increase in workload, including documentation of transactions, and separate storage requirements for repositories and drop-off sites. It was believed that absent State incentives and extensive promotion, it is unlikely that this Program will have a successful impact on those needy individuals for whom the legislation was intended.

The Board's recommendation to expand the Program by including donation for disposal was realized with the passage of SB 770/HB 460. As a result, there has been an increase in the number of participants in the Program. With the federal regulations in place, repositories that only accept medications for disposal will now be able to accept controlled dangerous substances, which would remove these medications from the population at large.

As more consumers bring in their medications for disposal, it may very well increase the public's knowledge of the Program. The natural next question when disposing of prescription medications is whether or not some of the prescription medications might be used to help those less fortunate. Donation of medications for disposal may very well be the best way to promote the original purpose of the Program, dispensing to needy individuals.

APPENDIX

Maryland Register

Issue Date: December 28, 2015

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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

[15-400-P]

The Secretary of Health and Mental Hygiene proposes to amend Regulations **.01—.06**, adopt new Regulations **.01-1** and **.06-1**, repeal existing Regulation **.07** and adopt new Regulation **.07**, and repeal existing 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 General Provisions Article, §3-302(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is 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-)	Magnitude
	Expenditure (E+/E-)	
A. On issuing agency:	NONE	
B. On other State agencies:	NONE	
C. On local governments:	NONE	
	Benefit (+)	Magnitude
	Cost (-)	
D. On regulated industries or trade groups:	(-)	Indeterminable
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	(+)	Indeterminable
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

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, or fax to 410-767-6483. Comments will be accepted through January 27, 2016. A public hearing has not been scheduled.

.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