

STATE OF MARYLAND

DHMH

Department of Health and Mental Hygiene

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue • Baltimore, Maryland 21215-2299

Donald Taylor, Board President - LaVerne G. Naesea, Executive Director



January 1, 2011

The Honorable Martin O'Malley
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

Dear Governor O'Malley, 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 fifth annual report on the operation of the Prescription Drug Repository Program (the "Program"). 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. The Program consists of three key components: 1) administrative oversight by the Board of Pharmacy (regulatory agency); 2) repositories that are allowed to accept, dispense and/or dispose of drugs that do not meet the criteria for the Program; and 3) drop-off sites that are only allowed to receive and forward donated drugs to a Board approved repository. The Code of Maryland Regulations (COMAR) 10.34.33 Prescription Drug Repository Program, has been in effect since January 29, 2007. There are currently 9 Repositories and 12 Drop-Off sites in Maryland.

The Board recommends that the Program be amended through legislation to expand the Programs purpose to include the acceptance of prescription drugs and medical supplies returned to a pharmacy for proper disposal. Pharmacies are beginning to participate in various prescription

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The Honorable Martin O'Malley
The Honorable Thomas V. Mike Miller, Jr.
The Honorable Michael Erin Busch
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drug disposal programs with little or no accountability for the drugs they receive. Enrollment in the Program would assure proper handling and accountability for donated and returned prescription drugs and devices and would support pharmacies' efforts to dispose of medications. When consumers donate their medications for disposal through the Program, it will increase the public's knowledge of the Program. Donation of medications for disposal may very well be the best way to promote the original purpose of the Program, dispensing to needy individuals.

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

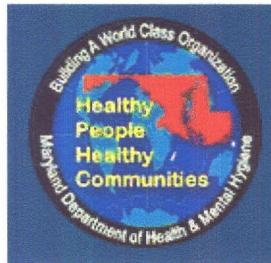
Respectfully,



LaVerne G. Naesea
Executive Director

Enclosure

cc: The Honorable Joan Carter Conway
The Honorable Donald B. Elliott
The Honorable Peter A. Hammen
The Honorable David D. Rudolph
Linda Bethman, Board Counsel, Maryland Board of Pharmacy
Harry Finke, Chair, Practice Committee, Maryland Board of Pharmacy
Wynee Hawk, Director, Office of Governmental Affairs
Anna D. Jeffers, Legislation and Regulations Manager, Maryland Board of Pharmacy
James Johnson, Deputy Secretary, DHMH
Michael N. Souranis, President, Maryland Board of Pharmacy
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Wendy Kronmiller, Chief of Staff, DHMH
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Carolyn Quattrocki, Governor's Legislative Office
Kathleen Wunderlich, Department of Legislative Services



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

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

January 1, 2011

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

ANNUAL REPORT

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LaVerne G. Naesea, Executive Director

Anna D. Jeffers, Legislation and Regulations Manager

Executive Summary

This is the fifth 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. The Program has been established for approximately four years. Nine pharmacies have been approved to be repositories and twelve pharmacies have been approved to be drop-off sites. The site locations include Baltimore City, Baltimore County, the Eastern Shore and Southern Maryland. There has been a small, steady increase in participants since 2006.

The Board continues to receive numerous calls from patients and their families inquiring where to donate unused drugs or where to dispose of drugs they have kept in their medicine cabinets. As of the Fall of 2010, there has been an increase in the prescription donations that have been received by drop off sites/repositories, but few prescription medications have subsequently been dispensed through the program.

A solution to expanding awareness of the program has emerged from consumers eager to dispose of their unused or unwanted medications in an environmentally sound manner. Recently, more and more consumers have been asking if they could return their unwanted or unused medications to the pharmacy instead of flushing, throwing in the trash, or crunching up in coffee grounds. Many pharmacies, to accommodate their customers’ requests, have begun participating in various private disposal programs. The Board applauds these pharmacies that have begun participating in disposal programs, but has concerns because Maryland law does not specifically address record keeping and accountability for returned prescription drugs.

Since repositories are required to dispose of medications that are not eligible for re-dispensing through the Program, it would be a natural transition to expand the purpose of the program to also accept prescription drugs and medical supplies for proper disposal. The Board’s recommendation is for legislation in 2011 that would expand the purpose of the Program to accept prescription drugs and medical supplies returned to a pharmacy for the purpose of proper disposal. This expansion would provide accountability for pharmacies and 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.

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 (the “Board”). As a result of those recommendations, Senate Bill (SB) 1059 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. The Board has submitted four Prescription Drug Repository Program Annual Reports to the Governor and the General Assembly on January 1, 2007, 2008, 2009 and 2010. The forms, the regulations, and prior Annual Reports are available on the Board’s website at www.mdbop.org .

PROGRAM DESCRIPTION

A description of the program operations was included in the January 1, 2009 Report. In brief, the Board of Pharmacy 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. Since only pharmacies may be approved as repositories, the Board monitors repositories as a part of its existing annual pharmacy inspection process. 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.

PROGRAM CHALLENGES

The Board receives numerous phone calls from patients and their families inquiring about where to donate unused drugs. Although there are a dozen drop-off sites, it is not nearly enough to adequately serve the entire State of Maryland. The Board attributes the possible causes for the lack of participation in the program to three primary, possibly overlapping, challenges: limited incentives to participate; limited program promotion to healthcare providers and patients; and 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 start up costs. In the current economic climate, those recommendations may not be possible.

During the past year the Board has been faced with an emerging challenge of consumers who are eager to return medications to pharmacies for disposal in an environmentally appropriate manner. Since repositories are required to dispose of donated prescription drugs or medical supplies if they are not accepted into the Program for the purpose of dispensing, it would be appropriate for the Program to now serve a dual purpose.

DISPOSAL

The Maryland Board of Pharmacy applauds the proactive effort of some pharmacies to collect unwanted, unused or expired prescription medications for disposal. These efforts accommodate customers while also protecting the environment. The Board has concerns, however; because Maryland law does not specifically address record keeping and accountability for returned prescription drugs. The integrity of our closed system of drug distribution may be compromised unless minimum standards are set to ensure proper handling of returned drugs.

The Board has encouraged pharmacies accepting returned medications for disposal to apply to become a Board approved Drop-Off Site/Repository which would expand and compliment the services that they wish to provide consumers under the various disposal programs available. Prescription drugs and medical devices that are donated to a Drop-off Site, and are not eligible for re-dispensing, are disposed of by a Repository using a disposal company. Enrollment in the Program assures proper handling and accountability for donated and returned prescription drugs and devices; provides support to customers

who may otherwise be unable to pay for certain medications; and further supports the intended environmental and safety efforts of the various disposal programs available.

EXPANSION OF THE PROGRAM TO INCLUDE DISPOSAL

The Board is aware of the compelling public safety and environmental issues relating to the disposal of unwanted medications. Many consumers have numerous unused or outdated prescriptions in their homes. Many family members are left with a bounty of unused prescription medications when loved ones die. The Board is also cognizant of the serious potential hazards to children and teenagers who may pull discarded medications from the trash, or medicine cabinets and ingest them. The Board has been in discussion with the federal EPA and others across the country regarding the environmental impact of flushing medications into the sewage system or discarding them into land fills that may affect the ground water.

The Board recommends that the Program be amended through legislation to include the acceptance of prescription drugs and medical supplies returned to a pharmacy for the purpose of disposal. A draft bill is included in the Appendix. COMAR 10.34.33 Prescription Drug Repository Program would then be revised to include requirements for those pharmacies that are solely interested in disposal of returned drugs. Enrollment in this program would assure proper handling and accountability for donated and returned prescription drugs and devices; may provide support to customers who may otherwise be unable to pay for certain medications; and further supports the pharmacies efforts to dispose of medications.

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. In the current economic climate, the tax incentives and start up funding recommended in last year's annual report are unlikely.

Yet the Board continues to receive phone call from patients, and family members of patients, expressing an interest in donating unused prescription medications and medical supplies. Oftentimes these phone calls are from citizens in surrounding states looking for a place to donate unused medications from their deceased loved ones. They are willing to bring the medications great distances so that they could benefit others. The Board also receives an increasing number of phone calls from patients expressing an interest in the proper disposal of prescription medications they no longer want in their homes.

The Board recommends expanding the Program by including donation for disposal. 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

DRAFT

A BILL ENTITLED

AN ACT concerning

Health-General – Prescription Drug Repository Program - Disposal

FOR the purpose of expanding the intent of the existing Prescription Drug Repository Program to include the disposal of unwanted or expired prescription drugs and devices returned to a pharmacy; and generally relating to the Prescription Drug Repository Program.

BY repealing and reenacting, with amendments

Article – Health-General

Section 15-601, 15-602, 15-605, 15-607, and 15-608

Annotated Code of Maryland

(2009 Replacement Volume and 2011 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article - Health - General

§15–601.

(a) In this subtitle the following words have the meanings indicated.

(b) “Board” means the State Board of Pharmacy.

(c) “Drop-off site” means a pharmacy or other health care facility designated by the Board that:

(1) Has voluntarily agreed to accept donated prescription drugs or medical supplies;

and

(2) Does not have a final disciplinary order issued against it by a health occupations

board.

(d) “Program” means the Prescription Drug Repository Program.

(e) “Repository” means a licensed pharmacy that:

(1) Does not have a final disciplinary order issued against it by the Board of Pharmacy;

(2) Has voluntarily agreed to participate in the Program; and

(3) Has been approved by the Board to:

(i) Accept donated prescription drugs or medical supplies from a designated

drop-off site; [and]

(ii) Dispense the donated prescription drugs or medical supplies to needy

individuals[.] ; AND

(III) DISPOSE OF DONATED PRESCRIPTION DRUGS OR MEDICAL

SUPPLIES.

§15-602.

(a) There is a Prescription Drug Repository Program regulated by the Board.

(b) The purpose of the Program is to [accept]:

(1) ACCEPT prescription drugs and medical supplies donated for the purpose of dispensing to needy individuals; AND

(2) ACCEPT PRESCRIPTION DRUGS AND MEDICAL SUPPLIES RETURNED TO A PHARMACY FOR THE PURPOSE OF PROPER DISPOSAL.

§15-605.

(a) The Board may approve Medbank of Maryland, Inc., or another licensed pharmacy, to be a repository.

(b) A repository shall:

(1) Accept only donated prescription drugs and medical supplies forwarded by designated drop-off sites;

(2) Inspect all donated prescription drugs and medical supplies;

(3) Accept only those donated prescription drugs and medical supplies that meet the requirements of § 15-603 of this subtitle;

(4) Dispose of donated prescription drugs and medical supplies[, in accordance with State and federal guidelines, that do not meet the requirements of § 15-603 of this subtitle] IN ACCORDANCE WITH STATE AND FEDERAL LAW;

(5) Maintain a separate inventory of donated prescription drugs and medical supplies;

(6) Store donated prescription drugs and medical supplies in a secure location used exclusively for the Program;

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

(8) Obliterate from the labels of donated prescription drugs and medical supplies any information specific to the patient for whom the donated prescription drugs and medical supplies were originally dispensed.

(c) A repository shall dispense donated prescription drugs and medical supplies only:

(1) To an individual who meets the requirements of § 15-606 of this subtitle;

(2) On a new prescription, in the case of a prescription drug or medical supply that requires a prescription; and

(3) In accordance with State and federal laws pertaining to:

(i) Storage, distribution, and dispensing of prescription drugs; and

(ii) Confidentiality of patient information.

(d) A repository may:

(1) Charge a fee, not to exceed \$10, for each prescription drug or medical supply dispensed; and

(2) Dispense a donated prescription drug or medical supply by mail, provided that the repository informs the patient that a delay may be entailed.

(e) A repository may not establish or maintain a waiting list for any prescription drug or medical supply dispensed by the Program.

§15-607.

(a) This section applies to:

- (1) A person that donates prescription drugs or medical supplies to the Program;
- (2) A drop-off site;
- (3) A repository;
- (4) The Board; and
- (5) Pharmacists.

(b) For matters related to donating, accepting, DISPOSING, or dispensing drugs under the Program, a person described in subsection (a) of this section that acts in good faith may not be subject to:

- (1) Criminal prosecution; or
- (2) Liability in tort or other civil action for injury, death, or loss to person or property.

(c) A drug manufacturer acting in good faith may not be subject to criminal prosecution or liability in tort or other civil action for injury, death, or loss to person or property for matters related to the donation, acceptance, or dispensing of a drug manufactured by the drug manufacturer that is donated by any person under the Program, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug.

§15-608.

(a) On or before January 1, 2007, and in consideration of the recommendations of the Task Force on the Establishment of a Prescription Drug Repository Program, the Board shall adopt regulations governing the Program.

(b) The regulations shall include:

(1) Categories of drugs that a repository will not accept, including a statement as to why the drug is ineligible for donation;

(2) A standard form each donor must sign stating that the donor is the owner of the drugs and intends to voluntarily donate them to the Program;

(3) Requirements for designation of drop-off sites to accept donated prescription drugs and medical supplies under the Program;

(4) Requirements for designation of repositories to dispense OR DISPOSE OF donated prescription drugs and medical supplies under the Program;

(5) Standards and procedures for accepting, safely storing, dispensing, shipping, [and if necessary,] AND disposing of donated prescription drugs and medical supplies;

(6) Standards and procedures for inspecting donated prescription drugs and medical supplies intended for dispensing to determine that:

(i) The original packaging is:

1. Sealed and tamper-evident; and
2. In the case of prescription drugs, in the undisturbed single unit dose

packaging; and

(ii) The prescription drugs and medical supplies are unadulterated, safe, and suitable for dispensing;

(7) A standard form for health care practitioners to submit to a repository to indicate a patient's need for the Program;

(8) A standard form that an individual receiving a prescription drug or medical supply from the Program must sign before receiving the drug or supply to confirm that the individual understands that:

(i) The individual is receiving prescription drugs or medical supplies that have been donated to the Program; and

(ii) Entities involved in the Program have certain immunity from liability;

(9) Record keeping and reporting requirements for a repository; and

(10) Any other standards and procedures the Board considers appropriate.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2011.