



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

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

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

ANNUAL REPORT

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EXECUTIVE SUMMARY

This is the third 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. Although the Program has been established for approximately two years, only one pharmacy has been approved to be a repository and drop-off site and one application for a repository and drop-off site is pending. These pharmacies are all located in the greater Baltimore area. 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. Absent state incentives, it is unlikely that this Program will have successful impacts on those needy individuals for whom the legislation was intended, nor on the safe disposal of unused and unwanted prescription drugs.

INTRODUCTION

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 two Prescription Drug Repository Program Annual Reports to the Governor and the General Assembly on January 1, 2007 and January 1, 2008. The forms, the regulations, and prior Annual Reports are available on the Board’s website at www.mdbop.org.

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. Only four applications were received for participation in this Program between January 29, 2007 and January 1, 2008. As of the submission of this report, only two additional applications have been received for participation in the Program as both repositories and drop-off sites.

DESCRIPTION OF PROGRAM OPERATIONS

The Program consists of three key components: 1) administrative oversight by the Board of Pharmacy (regulatory agency); 2) establishment of repositories that will accept, dispense and/or dispose of drugs that do not meet the criteria for the Program; and 3) establishment of drop-off sites that may receive and will forward donated drugs to a Board approved repository. A description of each Program component follows.

Administrative Oversight Procedures

The Licensing Unit of the Board receives the applications for approval of repositories and drop-off sites. A staff member has been designated to implement the Program and is currently processing applications. The Program is completely voluntary and applications have been accepted since the effective date of the

regulations in January 2007. Once the application and necessary documentation are complete, the applications are presented to the Licensing Committee and then the full Board for approval. Since only pharmacies may be approved as repositories, the Board will monitor repositories as a part of its existing annual pharmacy inspection process. Drop-off sites may be either a pharmacy or other health care facility. If the site is a pharmacy, the Board will incorporate monitoring of the site as part of its existing inspection process. The Board is developing procedures for monitoring other health care facilities and anticipates inspecting these sites to insure Program compliance or in some cases developing memorandums of agreement with agencies that are already responsible for monitoring health care facilities to act as the Board's agent if the need arises.

Designated Repositories and Repository Acceptance, Storing and Dispensing Procedures

The basis for Board approval of a repository begins with the submission of a Prescription Drug Repository Program Application for Approval. The repository must be a pharmacy that is in good standing with the Board. Pursuant to Health-General Article, § 15-605, Annotated Code of Maryland, Medbank of Maryland, Inc. may also apply to be a repository. The repository will accept and dispense donated prescription drugs or medical supplies received from approved drop-off sites. The repository must designate a pharmacist to accept and inspect the donated prescription drugs and medical supplies. If the donated prescription drugs are ineligible drugs and/or medical supplies, then the repository will dispose of them. The designated pharmacist will also obliterate patient specific information from the labels of donated prescription drugs or medical supplies. Repositories may not resell donated prescription drugs or medical supplies. Repositories may not establish or maintain a waiting list for donated medications. A repository may charge a fee of not more than \$10 per dispensed prescription. A recipient of the donated prescription drugs or medical supplies may complete a Recipient Form at their prescriber's office or upon receiving their prescription at the repository. The standards and procedures for safely storing donated prescription drugs or medical supplies shall be in accordance with existing State and federal laws and regulations, except that donated prescription drugs or medical supplies must be stored in a secure location separate from other inventories. The standards and procedures for dispensing, shipping and disposing of donated prescription drugs or medical supplies will also be the same standards and procedures currently set forth in State and federal laws and regulations.

Designated Drop-Off Sites and Donation Procedures

The basis for Board approval of a drop-off site begins with the submission of a Prescription Drug Repository Program Application for Approval. Designated drop-off sites may be a pharmacy or other health care facility that is in good standing with its respective licensing board. Once a donor, or the donor's representative, makes the decision to donate prescription drugs or medical supplies, they may only donate at approved designated volunteer drop-off sites. At the drop-off site, the donor will complete a Repository Program Donor Form and then donate the prescription drugs or medical supplies.

A pharmacist or other health care practitioner at the drop-off site will place the donated items in a sealed bag with the signed Donor Form, label the bag with a control number and place the sealed bag in a secure box designated for prescription drugs or medical supplies donated to the Program. The drop-off site will then forward the sealed bags of donated prescription drugs or medical supplies to an approved repository at least every two weeks. The drop-off site may not dispense donated prescription drugs or devices, resell them, or charge a fee for accepting donations.

DISCUSSION OF PROGRAM OUTCOMES

Upon completion of the regulations, procedures and required forms were made available on the Board's website so that the Program could begin. The Board also mailed postcards to all permit holders and placed an article in its quarterly Newsletter announcing the start up of the Program. There have not been a large number of applications from pharmacies or health care facilities to participate in this Program.

One possible obstacle for any potential drop-off site is identifying a funding source, or mechanism, for delivering donated prescription drugs and/or medical supplies to the designated repositories. There are some existing "pony" systems (routine delivery systems between pharmacies and health care entities or facilities) available, but not for all potential drop-off site locations. Additionally, repositories will incur costs due to the required paperwork and the storage of donated medications in a secure location separate from other inventories

Of the four applications received in the first year, two applied to become drop-off sites, one applied to become a repository, and one planned to act as both a drop-off site and repository. The entity that applied to be a repository withdrew their application because of subsequent disinterest in the program. Another entity, MedBank of Maryland, Inc., did not comply with all application requirements within a year of submitting their application, left phone messages that they might be closing, and subsequently withdrew their application due to inadequate funding and a possible merger with Baltimore Medical System, a Federally Qualified Health Center; which is not interested in participating in the Program. The two entities that applied to be drop-off sites withdrew their application because of subsequent disinterest in the program. In an attempt to assure a successful launch of the Program, the Board approved \$25,000 in funding in FY 2008 to ensure that repositories have sufficient resources for start up. Since no repositories were approved in FY 2008, the money was not re-allocated in FY 2009.

During the summer of 2008 two more pharmacies located in Baltimore City applied to be both drop-off sites and repositories. One of those pharmacies, Harlem Gardens Pharmacy, has completed the application requirements and was approved by the Board on November 19, 2008 to be a repository and drop-off site. The second pharmacy is pending approval. Both facilities are located in the greater Baltimore area. There has not been interest shown for this Program in Western Maryland, the Eastern Shore or the counties surrounding Washington, D.C.

Due to the slow start up of this Program, Board staff met with Delegate Rudolph, a sponsor and advocate of the Program legislation, in October 2008 to discuss the Program and possible incentives to encourage more participation. One incentive would be to allow a tax credit for expenses incurred by entities that have been approved to be either a repository or drop-off site. Another incentive would be to make an annual amount of \$50,000 available to defray start-up cost for all approved repositories or drop-off sites to defray expenses. This money could be allocated from monies received by the General Fund from penalties imposed on disciplined pharmacists and permit holders. Delegate Rudolph has asked the Department of Legislative Services staff to research the various possible incentives for those entities that volunteer to participate in this Program.

CONCLUSION

The Prescription Drug Repository Program Task Force, the General Assembly and the Board worked together to research, develop and establish this Program over a relatively short period of time. Many patients and family members of patients have since expressed an interest in donating unused prescription medications and medical supplies. Board staff members receive weekly phone calls from Marylanders, and individuals in surrounding states, asking if Maryland has a prescription medication donation program. Many of these individuals are family members of a deceased person who left large amounts of expensive medications that were never used. Some out-of-state individuals actually call numerous states to locate a donation program. Ideally, these individuals should be directed to a drop-off site, instead of merely receiving condolences and information regarding disposal of those precious medications.

The Board initially believed that the Program would be successful after the initial voluntary drop-off sites and repositories had developed successful operational models for use by other pharmacies and health care facilities. Unfortunately, pharmacies and health care facilities have been slow to volunteer to make this a viable Program. Pharmacies could offer their participation in the Program as a repository or drop-off site as an additional public service to their customers and their communities. Without incentives, however, it appears that pharmacies and health care facilities are not able to participate in this Program because they would be required to expend company resources. The past two years have shown that most pharmacies and health care facilities are not willing to voluntarily expend their own resources to participate in this valuable community and patient support Program.

After the experience of the past two years, the Board recommends that the legislature consider providing financial or other incentives to encourage more Program volunteers and defray the costs involved with operating a repository or drop-off sites in Maryland.