



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

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

January 1, 2010

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

ANNUAL REPORT

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Executive Summary

This is the fourth 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 while also creating a new avenue for the disposal of unused prescription drugs. The Program has been established for approximately three years and five pharmacies have been approved to be repositories and drop-off sites. The site locations include one in Baltimore City, two on the Eastern Shore and two in Southern Maryland. One of the repositories has been opened for more than a year, while the others were recently approved by the Board of Pharmacy (the "Board") as designated sites.

The Board has received numerous calls from patients and their families inquiring about where to donate unused drugs, as well as where prescriptions may be acquired at a discount. Unfortunately, as of the Fall of 2009, prescription donations have not been received nor dispensed through the program. Using available resources, the Board of Pharmacy, along with various stakeholders, has attempted to promote the program.

Despite those efforts and the low number of pharmacies that have applied to become repositories or drop-off sites, the Board of Pharmacy feels strongly that this is an important program. In order to achieve better program success, incentives for pharmacy permit holders, health care facilities, authorized prescribers and drug donors must be created. The Board therefore encourages the legislature to consider the following recommendations:

- Allow a tax credit for expenses incurred by pharmacies and health care facilities that are approved to be repositories and/or drop-off sites;
- To help to defray start-up cost for new repository and drop-off sites, allocate up to \$50,000 annually for start-up grants to be allocated to new repositories or drop-off sites to help reduce the impact of initial costs incurred by implementing the program;
- Encourage pharmacies to become designated repositories or drop-off sites by providing information about the many patients that could benefit from this program and emphasize the free access the pharmacies would have to drug take-back programs that can appropriately dispose of unused prescription drugs and at the same time help protect the environment;
- Encourage authorized prescribers to refer needy patients to the program; and
- To stimulate donation of unused prescription medications, develop and disseminate information or brochures to patients upon discharge from hospitals (or when they leave their prescribers' offices) about where to drop off unused medications.
- Allow a tax incentive for the donation of unused medications by comprehensive care facilities and other health care facilities.

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 three Prescription Drug Repository Program Annual Reports to the Governor and the General Assembly on January 1, 2007, 2008 and 2009. 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, dispense 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 will monitor 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.

DISCUSSION OF PROGRAM CHALLENGES

The Board has received numerous calls from patients and their families inquiring about where to donate unused drugs, as well as where prescriptions may be acquired at a discount. Unfortunately, as of the Fall of 2009, prescription donations have not been dispensed through the program. Harlem Gardens Pharmacy located in Baltimore City, has been a repository for about a year, and has yet to receive a prescription indicating that a patient qualifies for the program. 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. Each challenge is discussed in this section.

Limited Program Incentives

Independent drop-off sites incur costs to deliver 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 sites. Thus, many pharmacies have no incentive for participating in the program because the space requirements, staff resources to maintain records and other related costs outweigh the perceived value of the goodwill that may be generated for the pharmacy in the community.

Additionally, a constant obstacle for any potential repository has been the costs related to the required recordkeeping and the storage of donated medications in a secure location separate from other inventories. All donated prescription drugs that will be redispensed must be stored in a location separate from other drug inventory at pharmacies designated as repositories. The records for the repository inventory and patient dispensing records must also be maintained separately at the designated pharmacy repository.

Board staff met with Delegate Rudolph, a sponsor and advocate of the Program legislation, in October 2008 to discuss the lack of incentives for pharmacies and health care facilities to enroll in the program as well as incentives that may encourage greater interest and participation. Ideas discussed will be presented later in the *Conclusion* of this report.

Limited Program Promotion

Using available resources, the Board of Pharmacy has attempted to promote the program through newsletter articles, postings on its web site, and specific solicitations sent to potential program applicants. Specifically, the Board has published two newsletter articles which may be viewed on the Board's website (See Summer 2006 and Spring 2007 newsletters). Since the articles only reached pharmacists and pharmacy establishments, the Board also sent a letter to various health care facilities in Maryland to encourage them to participate in the program as drop-off sites. A copy of that letter is attached as Appendix I. Many health care facilities are centrally located in the community and would be the perfect place for citizens to donate their unused medications. With the establishment of drop-off sites in health care facilities, it is hoped that prescribers will become more aware of, and participate in, the program. Most physicians were and still are unaware of the existence of the program. In response, the Board submitted a newsletter article to the Board of Physicians for inclusion in one of their upcoming newsletters. A copy of that article is attached as Appendix II. The Board has delayed promoting to the public of the availability of sites where unused drugs can be donated because up until the fall of 2009, there was only one drop-off site in all of Maryland where drugs could be donated (Harlem Gardens).

Without greater promotion to pharmacies and healthcare facilities to enroll as repositories and/or drop-off site; to authorized prescribers about referring needy patients to repositories to fill prescriptions; and to Maryland patients and their families about drop-off sites where unused prescription drugs may be donated, the full benefits of this program may not be fully realized for Maryland's needy individuals.

Limited Necessary Resources

Program regulations require all drugs dispensed through the program to be handled by pharmacists or health care practitioners only and to be relabeled. Also, patient records for drugs dispensed by the repository must be maintained separately from other records. Resources necessary for efficiently running a repository or drop-off site include sufficient pharmacist staff to review donated medications and supplies to ensure the safety of Maryland patients that may be receiving prescriptions from donated inventory and to perform dispensing tasks at repositories, staff to prepare prescriptions and maintain separate patient records and adequate space for storing donated drugs apart from the pharmacy's other inventory.

Also, accessible locations where unused donated drugs may be safely disposed are needed. A newly approved repository had initially contacted the Board about the possibility of participating in a drug take back and disposal program. Many of their customers had asked about the proper disposal of medications and whether the pharmacy could accept their unused medications for disposal. Although environmentally safe disposal of medications was not the impetus for this program, the program does provide a means for pharmacies to provide this service. There are several drug take-back programs that appropriately dispose of unused prescription drugs. However, Maryland laws do not allow pharmacies to accept unused medications unless the pharmacy is approved as a Repository/Drop-off site. This is a great incentive for pharmacies to become involved in the program.

Even if pharmacies initially participate in the program to assist their communities in drug take back and disposal, it is hoped that the system will develop into a true re-dispensing system for the needy.

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. 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 periodically receives 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. This year the Board can direct them to the five Repository/Drop-Off sites in Maryland. But until the prescribers in Maryland are aware of this program, the drugs donated will be disposed of and not re-dispensed. As last year, 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.

In order for the Prescription Drug Repository Program to become successful, incentives for pharmacy permit holders, health care facilities, authorize prescribers and drug donors must be created. After the experience of the past three years, the Board encourages the legislature to consider the following recommendations:

- Allow a tax credit for expenses incurred by pharmacies and health care facilities that are approved to be repositories and/ or drop-off sites;
- To help to defray start-up cost for new repository and drop-off sites, allocate up to \$50,000 annually for start-up grants to be allocated to new repositories or drop-off sites to help reduce the impact of initial costs incurred by implementing the program;
- Encourage pharmacies to become designated repositories or drop-off sites by providing information about the many patients that could benefit from this program and emphasize the free access the pharmacies would have to drug take-back programs that can appropriately dispose of unused prescription drugs and at the same time help protect the environment;
- Encourage authorized prescribers to refer needy patients to the program; and
- To stimulate donation of unused prescription medications, develop and disseminate information or brochures to patients upon discharge from hospitals (or when they leave their prescribers' offices) about where to drop off unused medications.

At the current rate of growth, it will be years before the Prescription Drug Repository Program fulfills its true purpose. The Board believes that adoption of the above recommendations would greatly increase the number of available, voluntary repositories and drop-off sites across the state, increase the number of prescription drug donations, and enhance the environment by allowing for safe disposal of unused medications. Most importantly their adoption would lead to improved treatment outcomes for Maryland's needy patients who require prescription drugs.

APPENDIX I

Director of Pharmacy
Hospital
Street Address
City, Maryland Zip

Dear Director of Pharmacy:

The Maryland Board of Pharmacy (Board) is writing to inform you about the Prescription Drug Repository Program and to request your participation in this worthwhile program. The Prescription Drug Repository Program became effective, with the passage of SB 1059, on July 1, 2006. It allows patients or their representatives to donate unused, non-controlled, prescribed medications to Board designated Drop-off Sites for re-dispensing by Board designated Drug Repositories to patients that need assistance with paying for their prescribed medications. Repositories must be pharmacies, but Drop-off Sites may be health care facilities.

If your facility has an on-site pharmacy, you are requested to consider applying for to become a Drop-off Site and Prescription Repository. If a pharmacy is not part of your operation, then you are encouraged to become a Drop-off Site and to refer your needy patients to a Repository where they may be able to have some prescriptions filled for \$10.00 or less.

The benefits of participating in the Prescription Drug Repository Program are many, including:

- Providing support to needy patients and attracting new patients from the community who may be eligible for prescriptions through your Prescription Drug Repository Program;
- Ensuring the ability of patients to purchase prescribed drugs;
- Ensuring that drug treatment plans are followed by needy patients;
- Avoiding the unnecessary waste of unopened or otherwise non-tampered with prescription drugs that are not used by the patient for whom they were originally prescribed;
- Supporting protection of the environment from the improper disposal of prescription medications; and
- Potentially attracting new patients to your pharmacy.

Health care practitioners determine whether their patients are in need of donated drug assistance and therefore eligible to receive donated prescription drugs from a Repository by simply indicating *eligible for Prescription Drug Repository Program* on the patient's prescription and directing their patient where a designated Maryland Repository. Repositories may not have all of the drugs prescribed for a patient in their inventory, but the prescription can still be filled by the pharmacy where the Repository is located.

To acquire complete information regarding this program and how your facility may become a Drop-off Site, go to the Board of Pharmacy's website at www.mdbop.org. On the homepage, scroll down to "What's New" and click on "Legislation/Regulations." Then click on "Prescription Drug Repository Program." There you will find a link to COMAR 10.34.33.01 - .12, three program forms, the Task Force Report and the Annual Reports.

The process is simple and the need is great. The more Drop-Off Sites and Repositories that are approved, the more needy Maryland patients will have access to inexpensive medications, and less medications will be flushed or disposed of improperly. Please consider participating in this program either as a Drop-Off Site or a Repository. Please also recommend to patients and their family members to donate any unused prescription drugs to one of the designated Repositories or Drop-off Sites listed on the Board's web site.

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

Sincerely,

LaVerne G. Naesea
Executive Director

cc: Anna D. Jeffers, Legislation and Regulations Manager
Board of Pharmacy

APPENDIX II

DRAFT ARTICLE SUBMITTED TO THE BOARD OF PHYSICIANS FOR THEIR NEWSETTER

Prescription Drug Repository Program May Help Needy Patients in Maryland

The Prescription Drug Repository Program became effective, with the passage of SB 1059, on July 1, 2006. It allows patients or their representatives to donate unused, non-controlled, prescribed medications for re-dispensing to needy individuals. The regulations are in place and a Repository/Drop-Off Site has opened in Baltimore City. Several applications have been received for additional Repository/Drop-Off Sites on the Eastern Shore and in Southern Maryland.

Physicians are urged to refer patients who have limited financial resources to the Prescription Repository Program. When a Physicians make the determination that a patient is needy they simply need to indicate on the patient's a prescription that they are eligible for the Prescription Drug Repository Program and direct the patient to take the prescription to an approved Maryland Repository to obtain their prescription medications for \$10.00 or less. Repositories may not have all of the drugs prescribed for a patient in the inventory, but the prescription can still be filled by the pharmacy where the Repository is located. For a list of approved Repository/Drop-Off Sites please go to:

<http://www.mdbop.org/verifications/DrugRepository.htm> . Repositories in Maryland are required to be licensed pharmacies.

Physicians are also encouraged to recommend to patients and their family members to donate any unused prescription drugs to designated Repositories or Drop-off Sites. A Drop-off Site is a designated health clinic or pharmacy that receives donated drugs. If the drugs are in unopened containers, the Drop-off Site will deliver the drugs to the Repositories. A *Prescription Drug Repository Recipient Form* must be completed by all patient recipients to confirm that they understand that the donated items have been donated and that entities involved in the program are not liable. An added benefit of the program is that unused donated medications, that are not eligible for re-dispensing, will be disposed of in an environmentally appropriate manner. Pharmacies routinely work with reverse distributors to ensure the proper disposal of expired prescription medications and will dispose of ineligible donated medications in the same fashion.

Repositories and Drop-Off Sites are HIPAA compliant and all patient-specific information is removed from prescription labels of donated items. Repositories may not resell donated items or establish or maintain a waiting list. Repositories must maintain separate inventories for donated items; store donated items in a secure location; maintain separate prescription files for patients receiving donated items; and submit annual reports on its activities to the Board.

The Prescription Drug Repository Program put the determination of eligible patients for this program in the hands of Maryland health care practitioners because they have a unique understanding of how patients' health can be affected because patients can not afford to pay for prescribed medications. To access information regarding this program on the Board of Pharmacy's website, go to: www.mdbop.org. On the homepage, scroll down to "What's New" and click on "Legislation/Regulations." Then click on "Prescription Drug Repository Program." There you will find a link to COMAR 10.34.33.01 - .12, three program forms, the Task Force Report and the Annual Reports.