



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

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

January 1, 2012

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

SIXTH ANNUAL REPORT

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Executive Summary

This is the sixth 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 five years. Ten pharmacies have been approved to be repositories and eleven pharmacies have been approved to be drop-off sites. Thirteen pharmacies are in the application process. 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 phone 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. Callers have also expressed environmental concerns regarding disposal of prescription drugs and are reluctant to flush, throw in the trash, or crunch up the medications in coffee grounds. Many pharmacies, to accommodate their customers’ requests, have begun participating in various private disposal programs. The Board applauded these pharmacies, but had concerns because Maryland law, prior to the 2011 Legislative Session, did not specifically address record keeping and accountability for disposal of returned prescription drugs.

Since repositories are required to dispose of medications that are not eligible for re-dispensing through the Program, it was a natural transition to expand the purpose of the program to also accept prescription drugs and medical supplies for proper disposal. Thus, the Board recommended legislation in 2011 that would expand the purpose of the Program to include disposal. SB 770/HB 460 Prescription Drug Repository Program – Disposal of Prescription Drugs and Medical Supplies, passed and became effective on October 1, 2011. 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. The Attorney General’s Office approached the Board during the 2011 Legislative Session with its interest in the proper disposal of prescription drugs through drop boxes and is working with the Board to implement regulations.

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. 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 as a repository for that purpose. 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 five Prescription Drug Repository Program Annual Reports to the Governor and the General Assembly on January 1, 2007, 2008, 2009, 2010, and 2011. The forms, the regulations, and prior Annual Reports are available on the Board's website at <http://dhmh.maryland.gov/pharmacyboard/legislation/index.htm#R>.

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. 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. 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 phone calls from patients and their families inquiring about where to donate unused drugs or where to dispose of 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 has attributed 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.

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.

EXPANSION OF THE PROGRAM TO INCLUDE DISPOSAL

In December of 2010, President Obama signed into law the Secure and Responsible Drug Disposal Act of 2010. On October 1, 2011, Maryland SB 770/HB 460 Prescription Drug Repository Program – Disposal of Prescription Drugs and Medical Supplies became effective, requiring all disposing

pharmacies in Maryland to register with the Board as a drop-off site/repository. The Board is aware that federal regulations implementing the Secure and Responsible Drug Disposal Act of 2010 will be forthcoming in the fall of 2011. In order to accommodate the federal regulations, the Board is waiting for the publication of the proposed federal regulations before revising the existing COMAR 10.34.33 Prescription Drug Repository Program. The Maryland Attorney General's Office had expressed an interest in disposing of unused drugs based on its involvement in an initiative sponsored by the National Association of State Attorneys General. The Attorney General's office asked the Board to include in the proposed regulations an allowance for drop boxes at pharmacy counters for consumers to use to dispose of prescription drugs. The pharmacy would then contract with a reverse distributor or disposal company to collect the drugs for disposal. The Attorney General's office has indicated that start up funding may be available to pharmacies interested in such a drop off box. The Board's forthcoming revisions to COMAR 10.34.33 will accommodate both the proposed federal regulations and the request of the Attorney General's office.

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 past 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 both donating and disposing 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's recommendation to expand the Program by including donation for disposal was realized with the passage of SB 770/HB 460. 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.