



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

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

**January 1, 2014**

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

**EIGHT ANNUAL REPORT**

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## **Executive Summary**

This is the eighth 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 seven years. Eleven (11) pharmacies have been approved to be repositories and thirty-five (35) pharmacies have been approved to be drop-off sites. The site locations have expanded from Baltimore City, Baltimore County, the Eastern Shore and Southern Maryland to include Harford, Cecil, Anne Arundel and Montgomery Counties. 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.

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, 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. It has greatly increased the number and location of drop-off/repository sites. 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 requested that the Board work with them to draft and promulgate regulations. The regulations to address disposal for those entities that choose to only dispose have been on hold waiting for promulgation of federal regulations that would allow disposal of controlled dangerous substances at the pharmacy level.

## **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](http://mlis.state.md.us/2011rs/chapters_noln/Ch_546_sb0770T.pdf). The Board has submitted seven Prescription Drug Repository Program Annual Reports to the Governor and the General Assembly from January 1, 2007 through January 1, 2013. 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>

## **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. 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. 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 drop-off/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 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. This Act allows pharmacies to collect controlled dangerous substances for disposal. 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 Program. 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.

On December 21, 2012 the DEA published a Notice of proposed rulemaking in the Federal Register, Vol. 77, Number 246. Quoting from the Federal Register, in brief, the final DEA rule:

would implement the Secure and Responsible Drug Disposal Act of 2010 (Pub. L. 111–273) by expanding the options available to collect controlled substances from ultimate users for purposes of disposal to include: Take-back events, mail-back programs, and collection receptacle locations. These proposed regulations contain specific language to continue to allow law enforcement agencies to voluntarily conduct take-back events, administer mail-back programs, and maintain collection receptacles. These regulations propose to allow authorized manufacturers, distributors, reverse distributors, and retail pharmacies to voluntarily administer mail-back programs and maintain collection receptacles. In addition, this proposed rule expands the authority of authorized retail pharmacies to voluntarily maintain collection receptacles at long term care facilities. This proposed rule also reorganizes and consolidates existing regulations on disposal, including the role of reverse distributors.

It is anticipated that these regulations would be final by the end of 2013. 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 the proposed federal regulations which include provisions for drop off boxes.

## **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 calls 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 a result, there has been a threefold increase in the number of participants in the Program. Once the federal regulations are in place, drop-off sites/repositories that only accept medications for disposal will then 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.