



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

December 14, 2007

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 second annual report on the operation of 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 Board promulgated the Code of Maryland Regulations (COMAR) 10.34.33 Prescription Drug Repository Program, effective January 29, 2007. Four applications have been received for participation in the Program since January 29, 2007.

The Honorable Martin O'Malley
The Honorable Thomas V. Mike Miller, Jr.
The Honorable Michael Erin Busch
Page Two
December 14, 2007

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

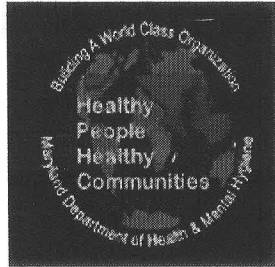
Respectfully,



LaVerne G. Naesea
Executive Director

Enclosure

cc: The Honorable Donald B. Elliott
The Honorable David D. Rudolph
Dave Chason, Chair, Practice Committee, Maryland Board of Pharmacy
Anne Hubbard, Director, Office of Governmental Affairs
Anna D. Jeffers, Legislation and Regulations Manager, Maryland Board of Pharmacy
Donald Taylor, President, Maryland Board of Pharmacy



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

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

January 1, 2008

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

ANNUAL REPORT

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Alland Leandre

Board of Pharmacy Staff

LaVerne G. Naesea, Executive Director

Anna D. Jeffers, Legislation and Regulations Manager

EXECUTIVE SUMMARY

This is the second 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. A Task Force of stakeholders, listed in Appendix I, worked during the fall of 2005 and the winter of 2006 to provide recommendations to the Maryland General Assembly via the Maryland Board of Pharmacy (the "Board"). Subsequently, 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. 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. COMAR 10.34.33 Prescription Drug Repository Program became effective on January 29, 2007. Four applications have been received for participation in this Program since January 29, 2007. The applications are still pending approval by the Board.¹

INTRODUCTION

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. Senate Bill 441 – Task Force on the Establishment of a Prescription Drug Repository Program - was passed to study and make recommendations regarding the establishment of a Prescription Drug Repository Program in Maryland. The Board chaired and staffed the Task Force for the Department of Health and Mental Hygiene (the "Department"). The Task Force submitted a First Interim Report January 1, 2006 to comply with SB 441.

The Task Force submitted a Second Interim Report on February 28, 2006 that included recommendations that could be considered for use in related proposals for legislation during the 2006 Legislative Session. The Second Interim Report was used as a basis for HB 1689 and SB 1059 - Prescription Drug Repository Program. Both bills passed, and SB 1059 was signed into law on May 6, 2006 as Chapter 287.

The Task Force submitted a Final Report, including recommendations for proposed regulations on July 1, 2006. The proposed regulations were approved by the Board on June 21, 2006 and were published in the Maryland Register on September 29, 2006. They became effective on January 29, 2007. The final regulations are incorporated into this Report and are attached as Appendix II.

The Board submitted the first Prescription Drug Repository Program Annual Report to the Governor and the General Assembly on January 1, 2007.

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.

¹ The four applications received were incomplete when submitted. The Licensing Unit has contacted the applicants and requested the information required to complete the applications and submit to the Board for approval.

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. The Prescription Drug Repository Program Application for Approval is attached as Appendix III. Once the application and necessary documentation is 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.

All Program Forms and related information are available on the Board's website at www.mdbop.org.

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. See Appendix IV for a sample Recipient Form. 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. See Appendix V for a sample Repository Program Donor Form.

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 available on the website so that the Program could begin. The Board of Pharmacy 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. The Board and Program sponsors determined that the Program should be more widely promoted than through the Board's website, a postcard mailing to permit holders and Newsletter announcements.

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.

Of the four applications received, one has applied to become a drop-off site, one has applied to become a repository and two plan to act as both a drop-off site and repository. In an attempt to assure a successful launch of the Program, the Board has approved \$25,000 funding to ensure that repositories have sufficient resources for start up. The Board anticipates that additional pharmacies and health care facilities will apply as drop-off sites because of the availability of repositories to process drugs donated to the drop-off sites.

The Board plans to provide technical and other support to all of the Program applicants and subsequent approved sites according to results of inspections by Board personnel.

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. The success of this Program depends on the number of pharmacies and health care facilities that apply to be drop-off sites and repositories. This Program is entirely voluntary on the part of pharmacies and health care facilities.

Various non-profit organizations have expressed interest in privately funding certain aspects of the Program. Pharmacies could also offer their participation in the Program as a repository or drop-off site as an additional service to their customers and their communities. Without further incentives, however, pharmacies and health care facilities may not be able to participate in this Program without expending their own resources.

The implementation of a Prescription Drug Repository Program is a national trend, and Maryland can be proud that it is among the states that have tackled this important issue. Maryland's Program, however, is not a panacea for connecting unused prescription medications with needy patients. Many unused prescription medications are not eligible for donation into this Program. If a bottle of medication has been opened, no matter how expensive or medically valuable to those in need, it is ineligible for the Program. In addition, controlled drugs are federally prohibited from being donated and medications requiring refrigeration can not be accepted.

Many patients and family members of patients have expressed an interest in donating their unused prescription medications and medical supplies. Many indigent and needy patients are looking for affordable or free prescription medications or medical supplies. The Board feels that the Program will be successful once the initial voluntary drop-off sites and repositories have developed successful operational models for use by other pharmacies and health care facilities. Maryland patients and their family members are ready and willing to participate in the State's Prescription Drug Repository Program.

APPENDIX I

TASK FORCE PARTICIPANTS

American Cancer Society

Arnold L. Amass, Pharm. D.

Pharmacy Representative

Lynette R. Bradley-Baker, R.Ph., Ph.D.

Nursing Home Representative

Elizabeth R. Bowerman

Community Health Center

Howard C. Cohen

House of Delegates

Delegate Donald B. Elliott

Delegate David D. Rudolph

Maryland Board of Pharmacy

Donald W. Taylor, Chairman of the Task Force and Board of Pharmacy Member

Pharmaceutical Industry

Philip D. Noguchi, M.D.

Office of Health Care Quality

William Vaughan

University of Maryland, School of Pharmacy

Francis Palumbo, Esquire, Ph.D.

Maryland Medical Assistance Program

Frank Tetkoski

Board of Pharmacy Staff

LaVerne G. Naesea, Executive Director

Anna D. Jeffers, Legislation and Regulations Manager

APPENDIX II

**Title 10 DEPARTMENT OF HEALTH AND
MENTAL HYGIENE**

Subtitle 34 BOARD OF PHARMACY

Chapter 33 Prescription Drug Repository Program

Authority: Health-General Article, §§15-601—15-609, Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Board" means the State Board of Pharmacy.

(2) "Drop-off site" means a pharmacy or other health care facility designated by the Board for the purpose of receiving donated prescription drugs or medical supplies.

(3) Health Care Facility.

(a) "Health care facility" means:

(i) A hospital, as defined in Health-General Article, §19-301(g), Annotated Code of Maryland;

(ii) A limited service hospital, as defined in Health-General Article, §19-301(e), Annotated Code of Maryland;

(iii) A related institution, as defined in Health-General Article, §19-301(o), Annotated Code of Maryland;

(iv) An ambulatory surgical facility;

(v) A rehabilitation facility;

(vi) A home health agency, as defined in Health-General Article, §19-401(b), Annotated Code of Maryland;

(vii) A hospice, as defined in Health-General Article, §19-901, Annotated Code of Maryland;

(viii) A kidney disease treatment facility, or the kidney disease treatment stations and services provided by or on behalf of a hospital, if the facility or the services do not include kidney transplant services or programs;

(ix) The office of one or more individuals licensed to practice dentistry under Health Occupations Article, Title 4, Annotated Code of Maryland, for the purposes of practicing dentistry;

(x) A comprehensive care facility located in Maryland; or

(xi) Other health institutions, services, or programs that may be specified as requiring a Certificate of Need under State law.

(b) "Health care facility" does not mean a hospital or related institution operated, or listed and certified, by the First Church of Christ Scientist, Boston, Massachusetts.

(4) "Health care practitioner" means an individual who is licensed, certified, or otherwise authorized under the Health Occupations Article, Annotated Code of Maryland, to provide health care services in the ordinary course of business or practice of a profession and has prescribing authority in this State.

(5) "Pharmacist" means an individual who practices pharmacy regardless of the location where the activities of practice are performed.

(6) "Pharmacy" means an establishment holding a permit under Health Occupations Article, §12-401, Annotated Code of Maryland.

(7) "Program" means the Prescription Drug Repository Program.

(8) "Repository" means a pharmacy that applies to and is designated by the Board for the purpose of:

- (a) Accepting donated prescription drugs or medical supplies from a drop-off site;
- (b) Inspecting donated prescription drugs or medical supplies; and
- (c) Dispensing donated prescription drugs or medical supplies for use by needy individuals.

.02 Eligible Drugs.

A. Prescription drugs or medical supplies may be donated at a drop-off site.

B. Prescription drugs or medical supplies may be accepted for dispensing if the prescription drugs and medical supplies are:

- (1) In their original unopened and sealed packaging; or
- (2) Packaged in single unit doses when the outside packaging is opened if the single unit dose packaging is undisturbed.

.03 Ineligible Drugs.

A. Prescription drugs or medical supplies may not be accepted for dispensing if the prescription drugs or medical supplies:

- (1) Bear an expiration date that is less than 90 days from the date the drug is donated to ensure the potency and quality of the prescription drugs or medical supplies;
- (2) Have been adulterated, according to the standards of Health-General Article, §21-216, Annotated Code of Maryland, because adulterated prescription drugs or medical supplies have been determined to be a threat to public health;
- (3) Are designated controlled dangerous substances by the U.S. Drug Enforcement Administration which has determined that controlled dangerous substances may not be donated under a repository program;
- (4) Require refrigeration because the potency and quality may not be guaranteed; or
- (5) Have been previously compounded because compounded prescription drugs are patient specific.

B. The repository shall dispose of donated prescription drugs or medical supplies if they are not accepted into the Program for the purpose of dispensing.

.04 Donor Form.

A. A donor of a prescription drug or medical supply shall sign a form containing the following statements:

- (1) That the donor is the owner or the owner's representative of the prescription drug or medical supply; and
- (2) That the donor intends to voluntarily donate the prescription drug or medical supply to the Program.

B. The drop-off site shall:

- (1) Require that the donor form contain:
 - (a) The signature of the donor or the donor's representative;
 - (b) Contact information of the donor or the donor's representative; and
 - (c) The date of donation;
- (2) Require that the donor form be completed before any donation;
- (3) Provide a copy of the donor form to the donor or the donor's representative; and
- (4) Maintain a copy of the donor form for 5 years.

.05 Drop-Off Sites.

A. In order to become a drop-off site, a pharmacy or other health care facility:

- (1) Shall submit an application to the Board to be designated as a voluntary drop-off site;
- (2) Shall be in good standing with the Board or the Office of Health Care Quality;
- (3) May not have a final disciplinary order issued against it by a health occupations board;
- (4) May not be owned or operated by a health care practitioner who has not fulfilled the requirements of a final disciplinary order that may have been issued against the owner or operator by a health occupations boards;
- (5) Shall maintain records of donated prescription drugs or medical supplies; and
- (6) Shall assign a pharmacist or other health care practitioner the responsibility to accept donated prescription drugs or medical supplies at the drop-off site.

B. Assigned Pharmacist or Other Health Care Practitioner's Responsibility. A pharmacist or health care practitioner accepting donated prescription drugs or medical supplies at a drop-off site as set forth in §A(6) of this regulation:

- (1) May not delegate acceptance of donated prescription drugs or medical supplies;
- (2) May refuse to accept hazardous prescription drugs or medical supplies for donation if the decision is based on professional judgment, experience, knowledge, or available reference materials;
- (3) Shall be in good standing with the pharmacist's or health care practitioner's respective health occupations board; and

(4) Shall have fulfilled the requirements of a final disciplinary order that may have been issued against the pharmacist or health care practitioner by a health occupations board.

C. Record Requirements. A drop-off site shall:

- (1) Obtain a signed donor form releasing the prescription drug or medical supplies to the Program;
- (2) Provide a copy of the signed donor form to the donor; and
- (3) Maintain records of signed donor forms for 5 years.

D. Procedures for Handling of Donated Prescription Drugs or Medical Supplies.

(1) A drop-off site shall:

- (a) Place the donated prescription drug or medical supply and the donor form in a sealed bag;
- (b) Store the bag containing the donated prescription drugs or medical supplies in an area accessible only to those pharmacists or health care practitioners who have been assigned the responsibility to accept the donated prescription drugs or medical supplies; and
- (c) Forward the sealed bags of donated prescription drugs or medical supplies to the repository at least every 2 weeks.

(2) A drop-off site may not:

- (a) Dispense donated prescription drugs or medical supplies;
- (b) Resell prescription drugs or medical supplies donated to the Program;
- (c) Charge a fee for accepting a donation; or
- (d) Accept donated prescription drugs or medical supplies until the drop-off site applicant has been approved by the Board.

.06 Repositories.

A. In order to become a repository, a pharmacy:

- (1) Shall submit an application to the Board to be designated as a repository;
- (2) Shall be in good standing with the Board;
- (3) May not have a final disciplinary order issued against it by the Board; and
- (4) May not be owned or operated by a health care practitioner who has not fulfilled the requirements of a final disciplinary order that may have been issued against the owner or operator by a health occupations boards.

B. Designated Pharmacist. A repository shall designate a pharmacist who shall:

- (1) Accept donated prescription drugs or medical supplies forwarded by:
 - (a) A drop-off site; or
 - (b) A manufacturer regulated by the U.S. Food and Drug Administration.

(2) Inspect donated prescription drugs or medical supplies;

(3) Accept donated prescription drugs or medical supplies that meet the requirements of Regulations .02 and .03 of this chapter; and

(4) Obliterate from the labels of donated prescription drugs or medical supplies patient specific information for which the donated prescription drugs or medical supplies were originally dispensed when it is placed in inventory.

C. Record Requirements. A repository shall:

(1) Maintain a separate inventory of donated prescription drugs or medical supplies;

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

(3) Submit an annual report on its activities to the Board that includes at least information on the:

(a) Number of recipients by county;

(b) Approximate market value of the prescription drugs or medical supplies dispensed;

(c) 50 prescription drugs or medical supplies most frequently dispensed; and

(d) Total number of donations to the Program.

D. Procedures for Handling of Donated Prescription Drugs or Medical Supplies.

(1) A repository shall store donated prescription drugs or medical supplies in a secure location separate from other inventory in accordance with State and federal laws and regulations.

(2) A repository may not:

(a) Resell prescription drugs or medical supplies donated to the Program; or

(b) Establish or maintain a waiting list for prescription drugs or medical supplies dispensed by the Program.

(3) A repository may charge a fee of not more than \$10 for each prescription drug or medical supply dispensed under the Program.

E. Limitations. A repository is under no obligation to obtain a prescription drug or medical supply that is not in inventory at the time of the request.

07 Procedure for Dispensing Donated Prescription Drugs or Medical Supplies.

A repository shall dispense donated prescription drugs or medical supplies in compliance with applicable federal and State laws and regulations for dispensing prescription drugs or medical supplies.

.08 Procedure for Shipping Donated Prescription Drugs or Medical Supplies.

A repository shall comply with COMAR 10.34.25 when shipping donated prescription drugs or medical supplies to recipients of this Program.

.09 Procedures for Disposing of Donated Prescription Drugs or Medical Supplies.

- A. A repository shall dispose of donated prescription drugs or medical supplies that do not meet the requirements of Regulation .02 of this chapter.
- B. A repository shall dispose of donated prescription drugs or medical supplies in compliance with applicable State and federal laws and regulations for disposing of prescription drugs or medical supplies.
- C. A repository shall maintain records of disposal of donated prescription drugs or medical supplies.

.10 Determination of Patient Eligibility.

- A. A recipient of this program shall be a resident of the State.
- B. A health care practitioner with prescribing authority shall:
 - (1) Determine, at the health care practitioner's discretion, the financial need of a patient to participate in the Program; and
 - (2) Indicate on the patient's prescription eligibility for this Program.

.11 Recipient Form.

Recipients of a donated prescription drug or medical supply under this Program shall sign a Board approved form before receiving the prescription drug or medical supply to confirm that the recipient understands that:

- A. The recipient is receiving prescription drugs or medical supplies that have been donated to the Program; and
- B. Entities involved in the program have immunity from liability in accordance with Health-General Article, §15-607, Annotated Code of Maryland.

.12 Record Keeping Requirements.

- A. Drop-off sites and repositories shall maintain records required by this Program separately from other prescription records.
- B. Drop-off sites and repositories shall maintain the following records for a minimum of 5 years:
 - (1) Inventory;
 - (2) Donor forms; and
 - (3) Prescription records.

Effective January 29, 2007.

APPENDIX III

PRESCRIPTION DRUG REPOSITORY PROGRAM APPLICATION (HG 15-601 - 609)

The Maryland Prescription Drug Repository Program (the "Program") was established to allow Maryland Board of Pharmacy (the "Board")- approved repositories and/or drop-off sites to accept donated prescription drugs and medical supplies for the purpose of dispensing the donated drugs to needy individuals.

An Application Must Be Filed:

- To become a repository that accepts and dispenses donated prescription drugs or medical supplies;
- To become a Board-approved drop-off site that accepts donated prescription drugs or medical supplies for transfer to a repository; and/or
- To notify the Board of a change in location or ownership of a pharmacy/health care facility previously approved to be a repository or a drop-off site under the Program.

Eligible Applicants:

- **Repository:**

The Board will approve an applicant that:

- Is a Maryland licensed pharmacy in good standing with the Board;
- Does not have a final disciplinary order issued against it by the Board; and
- Is not owned or operated by a health care practitioner who has not fulfilled the requirements of a final disciplinary order that may have been issued against the owner or operator by a health occupations board.

- **Drop-off Site:**

The Board will approve an applicant that:

- Is a Maryland licensed pharmacy, or health care facility as defined in COMAR 10.34.33.01B(3), that is in good standing with the Board and or the Maryland Office of Health Care Quality (OHCQ);
- Does not have a final disciplinary order issued against it by a health occupations board;
- Is not owned or operated by a health care practitioner who has not fulfilled the requirements of a final disciplinary order that may have been issued against the owner or operator by a health occupations board; and
- Assigns a pharmacist or other health care practitioner the responsibility to accept donated prescription drugs or medical supplies at the drop-off site.

PRESCRIPTION DRUG REPOSITORY APPLICATION INSTRUCTIONS

Please review all Program requirements under Health General §15-601 – 609, Annotated Code of Maryland and related regulations before completing the Prescription Drug Repository Application. All questions must be thoroughly answered. A response or explanation must be provided for all questions. An approval may be delayed if appropriate responses to all questions are not provided.

I. Applicant Information

- A. Application Type – Please indicate the services the applicant is seeking to provide in the state. Select one option only.
- B. Please provide all requested information about the pharmacy or health care facility where the service will be provided.
- C. The legal applicant is the individual that is authorized to respond to questions and make any decision regarding the operation of the pharmacy or health care facility. This individual may or may not be the same person that completes the application.

II. Ownership Description - Attach a list of the owners and corporate officers, for all levels of ownership. Include the following on the attachment: Name, Title, Percent ownership, Business address, Telephone Number, and Fax Number.

- A. Indicate the date that the pharmacy/facility initially opened.
- B. Indicate the date of the most recent inspection by the Board, Division of Drug Control, Office of Health Care Quality, and/or other health care facility licensing body in Maryland.
- C. Attach a detailed explanation about any violations (federal, state or local convictions) as requested.
- D. Indicate the type of ownership (select only one). If a corporation, list principal owners, indicate the corporate name, charter state and date of charter, and indicate whether it is a Public or Non-Public corporation.

III. BUSINESS OPERATIONS

- A. Indicate all applicable descriptions of the pharmacy.
- B. Indicate all applicable descriptions of the health care facility services.
- C. If the pharmacy/health care facility conducts business on the internet, describe the services and web site business name(s).
- D. Indicate the hours of operation for each day of the week.
- E. Personnel - List employees' names who will be accepting and dispensing donated prescription drugs or medical supplies, in addition to their scheduled hours and license/permit numbers and expiration dates. The Board must be notified in 30 days of any changes in pharmacists/health care practitioners employment.

IV. CERTIFICATION – Each item must be read and initialed by the legal applicant.

V. LEGAL SIGNATURE – The statement must be read and signed by the legal applicant.

Revised 11/17/06

MARYLAND BOARD OF PHARMACY
4201 PATTERSON AVENUE, BALTIMORE, MARYLAND 21215
410-764-4756 800-542-4964 FAX 410-358-6207
Web site: www.mdbop.org

APPLICATION FOR PRESCRIPTION DRUG REPOSITORY (HG 15-601 - 609)

BOARD USE ONLY

Date Received: _____ Date Approved: _____
Number: _____ Initials: _____

Please refer to instruction for completing the Application. Approval may be delayed if appropriate responses to all questions are not provided.

I. APPLICANT INFORMATION: DATE: _____

A. APPLICATION TYPE:

- _____ Repository
- _____ Drop-off Site
- _____ Repository and Drop-Off Site

B. APPLICANT FACILITY INFORMATION:

1. _____
PHARMACY/HEALTH CARE FACILITY NAME - DOING BUSINESS AS (DBA) OR TRADE NAME

2. _____
CURRENT PERMIT/LICENSE NUMBER

3. _____
STREET ADDRESS

CITY STATE ZIP CODE

4. _____
BUSINESS TELEPHONE NUMBER BUSINESS FAX NUMBER

5. _____
WEB SITE ADDRESS EMAIL ADDRESS FEDERAL TAX ID NO.

C. PHARMACY/HEALTH CARE FACILITY CONTACT INFORMATION:

1. Legal Representative:

Name Title Telephone Fax

2. Person Completing Application:

Name Title Telephone Fax

APPLICATION FOR PRESCRIPTION DRUG REPOSITORY (HG 15-601 - 609)

Page 2

II. Ownership Description:

A. Date Established: _____

B. Date of Last State Inspection: _____

C. Has the corporation or any officers thereof, or any partners, or the individual owner ever been convicted of violations of any federal, State, or local laws or regulations dealing with drug products or alcohol?

___ No ___ Yes, (If yes, attach a detailed explanation)

D. Ownership Information is attached: Yes ___ No ___

- ___ Individual Ownership
___ Partnership
___ Corporation

Corporate Name: _____

Principal Owner(s): _____

Charter State/Date: ___ / ___ Non-Public ___ Public ___

III. BUSINESS OPERATIONS

A. TYPE OF PHARMACY SERVICES:

- Community (less than 10), Hospital, Chain (10 + stores), Long Term Care, Intravenous Therapy, Mail Order/Internet/USA, Veterinary, Clinic, Managed Care, Nuclear, Correctional Institution, Home Health, Independent, Pharmacy Service Center, Research, Mail Order/Internet Intl, Nursing Home, HMO, Consultant, Medbank of Maryland, Inc., Other (specify below)

B. TYPE OF HEALTH CARE FACILITY SERVICES:

- Hospital, Nursing Home, HMO, Clinic, Long Term Care, Day Care, Free Clinic, Managed Care, Home Health, Other (specify below)

C. Services Provided Through the Internet? ___ No ___ Yes

- 1. Specify Services: _____
2. Website Business Name(s): _____

APPLICATION FOR PRESCRIPTION DRUG REPOSITORY (HG 15-601 – 609)

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D. Hours of Operation:

Sunday _____ Thursday _____
Monday _____ Friday _____
Tuesday _____ Saturday _____
Wednesday _____

PERSONNEL - Personnel accepting and dispensing donated prescription drugs or medical supplies:

Table with 4 columns: Name, Employment (Full-time, Part-Time), Maryland License/Registration #, and Expiration Date. Includes multiple blank rows for data entry.

IV. CERTIFICATION: (please initial)

- a. I hereby certify that the pharmacy/health care facility is equipped with sanitary appliances such as toilets, plumbing, running water, lighting, etc. in order to maintain the premises in a clean and orderly manner.
b. I hereby certify that the pharmacy/health care facility meets the requirements of the attached Code of Maryland Regulations regarding the Prescription Drug Repository Program (10.34.33).
c. I hereby certify that the pharmacy/health care facility does not have a final disciplinary order issued against it by a health occupations board.
d. I hereby certify that the owner or operator of the pharmacy/health care facility has fulfilled any requirements of a final disciplinary order that may have been issued against the owner or operator by a health occupations board.

V. LEGAL SIGNATURE: I understand that obtaining approval to be a repository or a drop-off site by making false representations may result in the revocation of approval to operate a repository or drop-off site in Maryland. By signing this application, I solemnly affirm under the penalties of perjury that the contents of this application are true to the best of my knowledge, information, and belief.

Signature of Legal Applicant Business Telephone Number Business Fax Number

Typed Name and Title Email Address

Revised 11/17/06

APPENDIX IV
PRESCRIPTION DRUG REPOSITORY PROGRAM
RECIPIENT FORM

Date: _____

Name of recipient: _____

Address: _____

Phone Number: _____

Email address (optional): _____

List of prescription drugs or medical supplies received: _____

The recipient understands that:

The recipient is receiving prescription drugs or medical supplies that have been donated to the program,
and

Entities involved in the program have immunity from liability in accordance with Health-General
Article, §15-607, Annotated Code of Maryland.

Signature of Recipient

APPENDIX V

PRESCRIPTION DRUG REPOSITORY PROGRAM

DONOR FORM

Date of Donation: _____

Name of donor: _____

Address: _____

Phone Number: _____

Email address (optional): _____

List of donated prescription drugs or medical supplies: _____

I hereby certify that I am the owner, or the owner's representative, of the prescription drug(s) or medical supply(s) donated today. My donation of the prescription drug(s) or medical supply(s) to the program is voluntary.

Signature of donor