MARYLAND
BOARD OF PHARMACY PRESCRIPTION
DRUG REPOSITORY PROGRAM

ANNUAL REPORT TO THE GOVERNOR
AND
THE GENERAL ASSEMBLY

January 1, 2007
MARYLAND BOARD OF PHARMACY PRESCRIPTION DRUG REPOSITORY
PROGRAM

ANNUAL REPORT

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Members of the Maryland Board of Pharmacy

Mark Levi, President
Donald W. Taylor, Secretary
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Mayer Handelman
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Board of Pharmacy Staff

LaVerne G. Naesea, Executive Director
Anna D. Jeffers, Legislation and Regulations Manager
EXECUTIVE SUMMARY

This is the first 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 diligently during the fall of 2005 and the winter of 2006 to provide recommendations to the Maryland General Assembly and the Board of Pharmacy. The General Assembly used those recommendations to introduce and pass Senate Bill (SB) 1059 to establish the Program during the 2006 Legislative Session. The Board of Pharmacy used the Task Force's recommendations and SB 1059 to develop and promulgate regulations to implement the Program. The Board of Pharmacy utilized the statute and proposed regulations to develop the necessary donor and recipient forms, and applications for drop-off sites and/or repositories to be approved for this Program. As soon as promulgation of the regulations is completed, the Program will be fully operational and ready to accept applications for approval of drop-off sites and repositories. It is anticipated that the proposed regulations will be effective by the end of December 2006 or in early January 2007.

INTRODUCTION

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 Maryland Board of Pharmacy (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 Maryland Board of Pharmacy on June 21, 2006 and were published in the Maryland Register on September 29, 2006. The proposed regulations are incorporated into this Report and are attached as Appendix II. Only one comment was received during the official regulatory comment period and that comment requested that the regulations include that the Program is voluntary on the part of drop-off sites and repositories. Since it is clearly set forth in the law that the Program is voluntary, the Board voted that it would be redundant to repeat this in the regulations and recommended final adoption as originally proposed. The effective date of the regulations is forthcoming.
OPERATION OF THE PROGRAM

The Program will consist 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. A description of each Program component follows.

Administrative Oversight Procedures

The Licensing Unit of the Board will receive the applications for approval of repositories and drop-off sites. The Program is completely voluntary and applications may be submitted anytime after the effective date of the regulations. The Prescription Drug Repository Program Application for Approval is attached as Appendix III. Once the application and necessary documentation is complete, the applications will be 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.

When the regulations become effective, the Board will be ready to begin the operation of the Program. Forms and information will be available on the Board's website at www.mdbop.org once the regulations are effective.

Designated Repositories and Repository Acceptance, Storing and Dispensing Procedures

The basis for Board approval of a repository will begin 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 or establish or maintain a waiting list. 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 will begin 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.

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 will depend 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. The only potential repository that has been identified is Medbank of Maryland, Inc. (Medbank).

There have been no potential drop-off sites identified at this time. One obstacle for any potential drop-off site is a funding source, or mechanism, for delivering donated prescription drugs and/or medical supplies to the designated repositories. There are some existing “pony” systems available, but not for all potential drop-off site locations. Various non-profit organizations, however, 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.

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 Prescription Drug Repository 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 and medications requiring refrigeration may 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 success of the Program will depend on the interest of the pharmacies and health care communities in participating and supporting this Program. Maryland patients, and family members of patients, are ready and willing to participate.
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. Naesesa, Executive Director
Anna D. Jeffers, Legislation and Regulations Manager
APPENDIX II

Subtitle 34 BOARD OF PHARMACY

10.34.33 Prescription Drug Repository Program

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

Notice of Proposed Action

[06-281-P]

The Secretary of Health and Mental Hygiene proposes to adopt new Regulations .01—.12 under a new chapter, COMAR 10.34.33 Prescription Drug Repository Program. This action was considered by the Board of Pharmacy at a public meeting held June 21, 2006, notice of which was given by publication in the Daily Record, Legal Section: Misc. Public Notices, June 12—16, 2006, pursuant to State Government Article, §10-506(c), Annotated Code of Maryland;

Statement of Purpose

The purpose of this action is to adopt regulations for the Board of Pharmacy to govern a Prescription Drug Repository Program in Maryland. The purpose of the program is to accept donated prescription drugs and medical supplies for the purpose of dispensing to needy individuals.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact. There is a minimal economic impact on the Board staff due to receiving and reviewing drop-off site and repository applications, and issuing confirmations of designation as a drop-off site or repository to permit holders who have applied to be drop-off sites or repositories. This additional workload for the staff can be absorbed at this time. As the program develops, the Board may reassess at a later date the necessity for imposing a fee for applications for designation of drop-off sites or repositories.

II. Types of Economic Impact.

<table>
<thead>
<tr>
<th>Economic Impact</th>
<th>Revenue (R+/R–)</th>
<th>Expenditure (E+/E–)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. On issuing agency:</td>
<td>NONE</td>
<td></td>
</tr>
<tr>
<td>B. On other State agencies:</td>
<td>NONE</td>
<td></td>
</tr>
<tr>
<td>C. On local governments:</td>
<td>NONE</td>
<td></td>
</tr>
<tr>
<td>D. On regulated industries or trade groups:</td>
<td>(+)</td>
<td>Undeterminable</td>
</tr>
<tr>
<td>E. On other industries or trade groups:</td>
<td>NONE</td>
<td></td>
</tr>
<tr>
<td>F. Direct and indirect effects on public:</td>
<td>(+)</td>
<td>Undeterminable</td>
</tr>
</tbody>
</table>
III. Assumptions. (Identified by Impact Letter and Number from Section II.) D. and F. There is a positive unquantifiable economic impact on the public and the regulated industry due to the broader availability of medications for needy individuals.

**Economic Impact on Small Businesses**

The proposed action has minimal or no economic impact on small businesses.

**Impact on Individuals with Disabilities**

The proposed action has no impact on individuals with disabilities.

**Opportunity for Public Comment**

Comments may be sent to Michele Phinney, Director, Department of Health and Mental Hygiene, 201 W. Preston St. Room 512, Baltimore, Maryland 21201, or call 410-767-6499, or email to regs@dhmh.state.md.us, or fax to 410-333-7687. Comments will be accepted through October 30, 2006. A public hearing has not been scheduled.

.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.

S. ANTHONY McCANN
Secretary of Health and Mental Hygiene
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
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 ______________
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)   _____ Clinic   _____ Research
   _____ Hospital   _____ Managed Care   _____ Mail Order/Internet Intl
   _____ Chain (10 + stores)   _____ Nuclear   _____ Nursing Home
   _____ Long Term Care   _____ Correctional Institution   _____ HMO
   _____ Intravenous Therapy   _____ Home Health   _____ Consultant
   _____ Mail Order/Internet/USA   _____ Independent   _____ Medbank of Maryland, Inc.
   _____ Veterinary   _____ Pharmacy Service Center   _____ Other (specify below)

B. TYPE OF HEALTH CARE FACILITY SERVICES:

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

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)

Page 3

D. Hours of Operation:

Sunday   _________   Thursday   _________
Monday    _________   Friday     _________
Tuesday   _________   Saturday    _________
Wednesday _________

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

Name:   Employment:   Maryland License/ Registration #:   Expiration Date:

Full-time   Part-Time
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

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