

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.	Revenue (R+/R-)	Magnitude
	Expenditure (E+/E-)	
A. On issuing agency:	NONE	
B. On other State agencies:	NONE	
C. On local governments:	NONE	
	Benefit (+)	Magnitude
	Cost (-)	
D. On regulated industries or trade groups:	(+)	Undeterminable
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	(+)	Undeterminable

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@dhhmh.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