

Title 10
MARYLAND DEPARTMENT OF HEALTH
Subtitle 34 BOARD OF PHARMACY

10.34.33 Prescription Drug Repository Program

Authority: Health Occupations Article, §§15-601 – 15-609 Annotated Code of Maryland

.01-1 Incorporation by Reference.

In this chapter, the Secure and Responsible Drug Disposal Act of 2010, 21 U.S.C. 822 (as amended), has been incorporated by reference.

.01 Definitions.

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

B. Terms Defined.

(1) “Board” means the State Board of Pharmacy.

(1-1) “Dispense” means to provide:

(a) A prescription drug or medical supply in accordance with a prescription; or

(b) An over-the-counter drug or medical supply;

(1-2) “Disposal program” means pharmacies that voluntarily participate as repositories to collect returned drugs and medical supplies for purposes of safe disposal.

(1-3) “Donation program” means pharmacies that accept donated drugs or medical supplies for purposes of dispensing to eligible patients.

(2) “Drop-off site” means a pharmacy, other health care facility or other entity participating in a drug donation or repository program that:

(a) Has voluntarily agreed to accept donated prescription drugs, over-the-counter drugs, or medical supplies;

(b) Is located within the State or in another State; and

(c) Does not have a final disciplinary order issued against it by a health occupations board.

(3) “Eligible Patient” means an individual who, through self-attestation is indigent, uninsured, underinsured, or enrolled in a public health benefits program.

(4) 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;

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

(xii) *An entity licensed and regulated under the law of a state in which the entity is located and staffs health care practitioners.*

(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, or licensed, certified or otherwise authorized under the laws of the state in which the individual is practicing.

(5) “Pharmacist” means an individual who is authorized to practice 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:*

(a) *Has voluntarily agreed to participate in the Program;*

(b) *Is located in the State or in another state; and*

(c) *Has been approved by the Board to:*

(i) *Accept donated prescription drugs, over-the-counter drugs, or medical supplies from a designated drop-off site;*

(ii) *Dispense the donated prescription drugs, over-the-counter drugs, or medical supplies to eligible patients; or*

(iii) *Dispose of prescription drugs, over-the-counter drugs, or medical supplies that are not accepted for dispensing to eligible patients.*

(10) “Tamper-Evident Packaging” means *a packaging system that:*

(a) *May involve an immediate-container and closure system, secondary-container or carton system, tertiary-container system, or other combination of systems intended to provide a visual indication of package integrity;*

(b) *May contain unit-dose or multi-dose contents; and*

(c) *Has one or more indicators or barriers to entry that:*

(i) *If breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred; and*

(ii) *If handled in a reasonable manner during manufacture, distribution, or retail display, is designed to remain intact.*

.02 Donation Program — Eligible Drugs.

A. Prescription drugs, *over-the-counter-drugs*, or medical supplies, may *only* be donated at a drop-off site.

B. Prescription drugs *or over-the-counter-drugs*, may be accepted for dispensing if the prescription drugs *or over-the-counter drugs* are:

(1) In their original unopened and sealed, *tamper-evident packaging, including drugs that have been packaged by a manufacturer or have been repackaged by an entity authorized to repackage drugs in the state in which the entity is located; or*

(2) Packaged in single unit doses when the outside packaging is opened if the single unit dose packaging is undisturbed.

C. Medical supplies may be accepted for dispensing to eligible patients if the medical supplies are in their original unopened and sealed packaging.

.03 Donation Program — Ineligible Drugs.

A. Prescription drugs, *over-the-counter drugs*, or medical supplies may not be accepted for dispensing if the prescription drugs, *over-the-counter drugs*, or medical supplies:

(1) *Except as provided in .03B* 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, *over-the-counter drugs*, or medical supplies;

(2) *May be adulterated*, according to the standards of Health-General Article, §21-216, Annotated Code of Maryland, because adulterated prescription drugs, *over-the-counter 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. Prescription Drugs, over-the-counter drugs, or medical supplies with approaching expiration deadlines may be donated to the Program:

(1) *If the prescription drugs, over-the-counter drugs, or medical supplies bear an expiration date that is less than 90 days from the date of donation, the prescription drug or over-the-counter drug must be in high demand.*

(2) *If the Program accepts a prescription drug or over-the-counter drug under B(1), the Program may not dispense the prescription drug or over-the-counter drug if the expiration date occurs during the time period for which the prescription drug or over-the-counter drug is prescribed.*

C. The repository shall dispose of donated prescription drugs, over-the-counter drugs, or medical supplies if they are not accepted into the Program for the purpose of dispensing.

.04 Donation Program — In State Drop-Off Sites Requirements.

A-1. In order to become a drop-off site located in the State, a pharmacy, other health care facility, or other entity:

- (1) Shall submit an application to the Board to be designated as a drop-off site;
- (2) Shall be in good standing with the Board , Office of Health Care Quality, *or other appropriate regulatory health care oversight agency*;
- (3) May not have a final disciplinary order issued against it by a health occupations board *or other appropriate regulatory health care oversight agency*;
- (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, *over-the-counter drugs*, or medical supplies;
- (6) *For pharmacies* shall assign a pharmacist the responsibility to accept donated prescription drugs, *over-the-counter drugs*, or medical supplies at the drop-off site;
- (7) *For other healthcare facilities*, shall assign a health care practitioner the responsibility to accept donated prescription drugs, *over-the-counter 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, *over-the-counter drugs*, or medical supplies at a drop-off site as set forth in §§A(6) and (7) of this regulation:

- (1) May not delegate acceptance of donated prescription drugs, *over-the-counter drugs*, or medical supplies;
- (2) May refuse to accept hazardous prescription drugs, *over-the-counter 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 *in the State* shall:

- (1) *Before accepting any donation*, obtain a completed donor form that:
 - (a) Releases the prescription drug, *over-the-counter drug* or medical supplies to the Program;
 - (b) *Confirms that the donor is the owner or the owner's representative of the prescription drugs, over-the-counter drugs, or medical supplies*;
 - (c) *Contains the signature and contact information of the donor or donor's representative; and*
 - (d) *Contains the date of donation*;
- (2) Provide a copy of the signed donor form to the donor *or the donor's representative*; 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 *located in the State* shall:
 - (a) Place the donated prescription drug, *over-the-counter drug*, or medical supply and the donor form in a sealed bag;
 - (b) Store the bag containing the donated prescription drugs, *over-the-counter 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, *over-the-counter drugs*, or medical supplies; and

(c) Forward, *at the cost of the drop-off site*, the sealed bags of donated prescription drugs, *over-the-counter drugs*, or medical supplies to the repository at least every 2 weeks.

(2) A drop-off site *located in the State* may not:

(a) Dispense donated prescription drugs, *over-the-counter drugs*, or medical supplies;

(b) Resell prescription drugs, *over-the-counter-drugs*, or medical supplies donated to the Program;

(c) Charge a fee for accepting a donation;

(d) Accept donated prescription drugs, *over-the-counter drugs*, or medical supplies until the drop-off site applicant has been approved by the Board; or

(e) Accept prescription drugs for disposal.

.04-1 Donation Program – Out-of-State Drop-Off Sites

A. *In order to be designated as a drop-off site located in another state, a pharmacy, other health care facility, or other entity shall:*

(1) *Submit an application to the Board to be designated as a drop-off site;*

(2) *Not have a final disciplinary order or equivalent adverse regulatory action issued against it by the applicable regulatory authority in the state in which it is located;*

(3) *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 board;*

(4) *Maintain records of donated prescription drugs, over-the-counter drugs, and medical supplies; and*

(5) *For pharmacies, assign a pharmacist the responsibility to accept donated prescription drugs, over-the-counter drugs, or medical supplies at the drop-off site; and*

(6) *For health care facilities or other entities, assign a health care practitioner the responsibility to accept donated prescription drugs, over-the-counter drugs or medical supplies at the drop-off site.*

B. *An out-of-state drop-off site may accept donated prescription drugs, over-the-counter drugs, and medical supplies from any person, unless otherwise prohibited by federal law or the laws of the state in which the drop-off is located.*

C. *Unless otherwise prohibited by federal law or other laws of the state in which it is located, an out-of-state drop-off site may perform and receive:*

(1) *Intracompany transfers of donated prescription drugs, over-the-counter drugs, and medical supplies; and*

(2) *Transfers of donated prescription drugs, over-the-counter drugs, and medical supplies from drop-off sites and repositories located in another state or other entities participating in a drug donation or repository program in accordance with the law of the state in which the entity is located.*

.05 Donation Program Repositories General Requirements.

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

(1) *Shall submit an application to the Board;*

(2) *Shall indicate on the application to the Board if the applicant intends to:*

(a) *Participate in the Donation Program;*

(b) *Participate in the Disposal Program by collecting only non-controlled dangerous substances and medical supplies for safe disposal; or*

(c) Participate in the Disposal Program by collecting controlled dangerous substances, non-controlled dangerous substances, and medical supplies for safe disposal;

(3) Shall be in good standing with the Board, or applicable regulatory oversight agency in the state in which the pharmacy is located;

(4) If located in the State, may not have a final disciplinary order issued against it;

(5) 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 board; and

B. A repository in the Donation Program shall dispose of donated prescription drugs, over-the-counter drugs, or medical supplies that do not meet eligibility requirements of [Regulation .02](#) of this chapter.

C. A repository in the Donation Program shall dispose of donated prescription drugs, and over-the-counter drugs, or medical supplies in compliance with applicable State and federal laws and regulations for disposing of prescription drugs or medical supplies.

D. A repository shall maintain records of disposal of donated prescription drugs, over-the-counter drugs, or medical supplies.

E. A repository may not resell prescription drugs, over-the-counter drugs, or medical supplies donated to the Program.

F. A repository in the Donation Program shall dispense donated prescription drugs, over-the-counter drugs, or medical supplies in compliance with applicable State and federal laws and regulations for dispensing prescription drugs or medical supplies.

G. May not be required to possess a comprehensive or minimum supply of prescription drugs, over-the-counter drugs, or medical supplies.

.06-1 In State Repositories Participating in the Donation Program.

A. Designated Pharmacist. An in-state repository in the donation program shall designate a pharmacist who shall:

(1) Accept donated prescription drugs, over-the-counter drugs, or medical supplies forwarded by:

(a) A drop-off site;

(b) Another repository in the State; or

(c) A manufacturer regulated by the U.S. Food and Drug Administration;

(2) Inspect donated prescription drugs, over-the-counter drugs, or medical supplies;

(3) Accept donated prescription drugs, over-the-counter drugs, or medical supplies in accordance with Regulations .02 and .03 of this chapter; and

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

B. Record Requirements. A repository in the Donation Program shall:

(1) Maintain a separate inventory of donated prescription drugs or medical supplies for a minimum of 5 years;

(2) Maintain separate prescription files for patients receiving donated prescription drugs, over-the-counter drugs, or medical supplies for a minimum of 5 years; 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, *over-the-counter drugs*, or medical supplies dispensed;

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

(d) Total number of *prescription drugs, over-the-counter drugs or medical supplies donated* to the Program.

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

(1) *An in-State repository in the Donation Program shall store donated prescription drugs, over-the-counter drugs, or medical supplies in a secure location separate from other inventory in accordance with State and federal laws and regulations.*

(2) *An in-State repository may not:*

(a) *Establish or maintain a waiting list for prescription drugs, over-the-counter drugs, or medical supplies dispensed by the Program.*

(b) *May not charge a fee more than \$10 for each prescription drug, over-the-counter drug, or medical supply dispensed under the program.*

D. *Procedure for Shipping Donated Prescription Drugs or Medical Supplies. An in-State repository in the Donation Program shall comply with [COMAR 10.34.25](#) when shipping donated prescription drugs or medical supplies to eligible patients.*

E. Recipient Form. Recipients of a donated prescription drug, *over-the-counter drugs*, or medical supply under the Donation Program shall sign a Board approved form before receiving the prescription drug, *over-the-counter drugs*, or medical supply to confirm that the recipient understands that:

(1) The recipient is receiving prescription drugs, *over-the-counter drugs*, or medical supplies that have been donated as part of the Donation Program; and

(2) Entities involved in the Donation Program have immunity from liability in accordance with Health-General Article, §15-607, Annotated Code of Maryland.

F. *Transfer of Donated Drugs to Other Entities. An in-State repository may transfer donated prescription drugs, over-the-counter drugs, or medical supplies to:*

(1) *Another repository in the State; or*

(2) *A drop-off site, repository or other entity in another state that participates in a drug donation program or repository program in accordance with the laws of the state in which the drop-off site, repository or other entity is located only if there is no need for the donated prescription drugs, other-the-counter drugs, or medical supplies for use by eligible patients in the State.*

.06-2 Donation Program - Out-of-State Repositories

A. *To be designated as an out-of-state repository, a pharmacy shall:*

(1) *Submit an application to the Board on a form prescribed by the Board;*

(2) *Be in good standing with the applicable regulatory oversight agency in the state in which the pharmacy is located; and*

(3) *Have a non-resident pharmacy permit issued by the Board.*

B. *Authorized Activities. Consistent with its approval by the Board of Pharmacy, an out-of-state repository shall dispense donated prescription drugs, over-the-counter drugs, and medical supplies to residents of the State only in accordance with:*

(1) *Federal law;*

(2) *Laws of the state in which the repository is located pertaining to storage and distribution of prescription drugs, over-the-counter drugs, and medical supplies;*

(3) *State laws pertaining to non-resident pharmacies; and*

(4) *The eligibility requirements under. Regulation .02 and Regulation .03 of this chapter.*

C. Patient Eligibility. An out-of-state repository may dispense donated prescription drugs, over-the-counter-drugs, or medical supplies only to an eligible patient.

D. Transfers. Unless otherwise prohibited by federal law or the laws of the state in which the repository is located, an out-of-state repository may perform and receive:

(1) Intracompany transfers of donated prescription drugs, over-the-counter drugs, and medical supplies; and

(2) Transfers of donated prescription drugs, over-the-counter drugs, and medical supplies from drop-off sites located in another state, repositories located in another state, or other entities participating in a drug donation or repository program in accordance with the laws of the state in which the entity is located.

.06-3 – Donation Program – Patient Eligibility

A. In-State Repository. To be eligible to receive donated prescription drugs, over-the-counter drugs, or medical supplies from a repository located in the State, an individual must;

(1) Be a resident of the State; and

(2) Be an eligible patient.

B. Out-of-State Repository. To be eligible to receive donated prescription drugs, over-the-counter drugs, or medical supplies from a repository located in another state, an individual must be eligible patient.

C. Self-Attestation. A patient establishes eligibility by self-attestation that the patient is indigent, uninsured, underinsured, or enrolled in a public health benefits program.

.07 Disposal Program — Requirements.

A. Pharmacies that collect returned prescription drugs or medical supplies for proper disposal shall be approved by the Board as repositories.

B. Repositories that collect only non-controlled dangerous substances for proper disposal shall:

(1) Dispose of prescription drugs or medical supplies collected for disposal in compliance with applicable State and federal laws and regulations;

(2) Have policies and procedures regarding the safe and secure handling and disposal of prescription drugs and medical supplies, to include specific guidelines for prescription drugs requiring special disposal or care;

(3) Dispose of collected prescription drugs and medical supplies through a *third-party* processor or a reverse distributor, as appropriate; and

(4) Maintain a separate secure container behind the prescription counter that is clearly marked for the Disposal Program.

C. A pharmacist may not delegate to a *pharmacy technician* the collection of prescription drugs or medical supplies under [§B of this regulation](#).

D. Repositories that collect controlled dangerous substances for disposal:

(1) Shall comply with the requirements of the Secure and Responsible Drug Disposal Act of 2010;

(2) May collect non-controlled dangerous substances and medical supplies in the same manner; and

(3) May commingle the collection of controlled and non-controlled dangerous substances and medical supplies in accordance with the Secure and Responsible Drug Disposal Act of 2010.

.08 Redirecting Safe Prescription Drugs Pilot Program.

A. Definitions. In this regulation, the following terms have the meaning indicated.

(1) "DEA" means the federal Drug Enforcement Administration.

(2) "Drop-off site" means a pharmacy that has been designated by the Board as a drop-off site, a repository, and a DEA-registered collection site.

(3) "National Prescription Drug Take Back Day" means a DEA-sponsored event during which registered collection sites accept unused prescription drugs from the public for safe disposal.

(4) "Pilot Program" means the Redirecting Safe Prescription Drugs Pilot Program,

(5) "Secretary" means the Secretary of Health.

B. To administer the Pilot Program, the Secretary shall collaborate with the DEA and four repositories located in the State that are registered with the DEA to participate in a National Prescription Drug Take Back Day.

C. The purpose of the Pilot Program is to:

(1) Expand medication access for underserved populations;

(2) Reduce pharmaceutical waste; and

(3) Ensure drug safety and prevent diversion while leveraging safe medications for public good.

D. Drop-off site obligations. Each drop-off site participating in the Pilot Program shall:

(1) Coordinate with the DEA to:

(a) Separate out eligible, non-controlled, unopened prescription medications collected by the drop-off site during a National Prescription Drug Take Back Day; and

(b) Redirect collected eligible, non-controlled, unopened prescription medications to a State Repository designated by the Board for dispensing prescription drugs to eligible patients;

(2) Ensure that collected prescription medications for dispensing to eligible patients are packaged in a manner that is consistent with .02 and .03 of this chapter;

(3) Ensure that controlled dangerous substances collected by the drop-off site are provided to the DEA in accordance with the Safe and Responsible Disposal Act and underlying regulations; and

(4) Comply with all other program requirements set forth by the Secretary and the DEA.

F. This Pilot Program shall expire on June 30, 2028.

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