

Chapter 547

(House Bill 460)

AN ACT concerning

Prescription Drug Repository Program – Disposal of Prescription Drugs and Medical Supplies

FOR the purpose of altering the purpose of the Prescription Drug Repository Program to include disposal of certain prescription drugs and medical supplies; altering the definition of “repository” to include a licensed pharmacy approved by the State Board of Pharmacy to dispose of certain prescription drugs and medical supplies; altering a certain requirement relating to disposal of prescription drugs and medical supplies by a repository; authorizing a pharmacy to accept prescription drugs and medical supplies taken to the pharmacy for disposal only under certain circumstances; prohibiting the Program from requiring a private entity to establish, operate, or fund a drop-off site or disposal program; expanding certain exemptions from criminal prosecution and liability to include disposal of medical supplies; altering certain requirements for Program regulations; authorizing the Board to take certain disciplinary action against a pharmacist or pharmacy that fails to dispense or dispose of prescription drugs or medical supplies in accordance with certain provisions of law; making a certain conforming change; and generally relating to the Prescription Drug Repository Program and disposal of prescription drugs and medical supplies.

BY repealing and reenacting, with amendments,
Article – Health – General
Section 15–601, 15–602, 15–605(b), 15–607, and 15–608
Annotated Code of Maryland
(2009 Replacement Volume and 2010 Supplement)

BY adding to
Article – Health – General
Section 15–605(f) *and (g)*
Annotated Code of Maryland
(2009 Replacement Volume and 2010 Supplement)

BY repealing and reenacting, with amendments,
Article – Health Occupations
Section 12–313(b)(30) and (31) and 12–403(b)(19) and (20)
Annotated Code of Maryland
(2009 Replacement Volume and 2010 Supplement)

BY adding to

Article – Health Occupations
Section 12–313(b)(32) and 12–403(b)(21)
Annotated Code of Maryland
(2009 Replacement Volume and 2010 Supplement)

BY repealing and reenacting, without amendments,
Article – Health Occupations
Section 12–403(g)
Annotated Code of Maryland
(2009 Replacement Volume and 2010 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health – General

15–601.

- (a) In this subtitle the following words have the meanings indicated.
- (b) “Board” means the State Board of Pharmacy.
- (c) “Drop–off site” means a pharmacy or other health care facility designated by the Board that:
 - (1) Has voluntarily agreed to accept donated prescription drugs or medical supplies; and
 - (2) Does not have a final disciplinary order issued against it by a health occupations board.
- (d) “Program” means the Prescription Drug Repository Program.
- (e) “Repository” means a licensed pharmacy that:
 - (1) Does not have a final disciplinary order issued against it by the Board of Pharmacy;
 - (2) Has voluntarily agreed to participate in the Program; and
 - (3) Has been approved by the Board to:
 - (i) Accept donated prescription drugs or medical supplies from a designated drop–off site; [and]

(ii) Dispense the donated prescription drugs or medical supplies to needy individuals; **OR**

(III) DISPOSE OF PRESCRIPTION DRUGS OR MEDICAL SUPPLIES NOT ACCEPTED FOR DISPENSING TO NEEDY INDIVIDUALS.

15-602.

(a) There is a Prescription Drug Repository Program regulated by the Board.

(b) The purpose of the Program is to [accept]:

(1) ACCEPT prescription drugs and medical supplies donated for the purpose of dispensing to needy individuals; **AND**

(2) ACCEPT PRESCRIPTION DRUGS AND MEDICAL SUPPLIES RETURNED TO A PHARMACY FOR THE PURPOSE OF PROPER DISPOSAL.

15-605.

(b) **[A] CONSISTENT WITH ITS APPROVAL BY THE BOARD,** A repository shall:

(1) Accept only donated prescription drugs and medical supplies forwarded by designated drop-off sites;

(2) Inspect all donated prescription drugs and medical supplies;

(3) Accept **FOR DISPENSING TO NEEDY INDIVIDUALS** only those donated prescription drugs and medical supplies that meet the requirements of § 15-603 of this subtitle;

(4) Dispose of donated prescription drugs and medical supplies[, in accordance with State and federal guidelines, that do not meet the requirements of § 15-603 of this subtitle] **NOT ACCEPTED FOR DISPENSING TO NEEDY INDIVIDUALS IN ACCORDANCE WITH STATE AND FEDERAL LAW;**

(5) Maintain a separate inventory of donated prescription drugs and medical supplies;

(6) Store donated prescription drugs and medical supplies in a secure location used exclusively for the Program;

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

(8) Obliterate from the labels of donated prescription drugs and medical supplies any information specific to the patient for whom the donated prescription drugs and medical supplies were originally dispensed.

(F) A PHARMACY MAY ACCEPT PRESCRIPTION DRUGS AND MEDICAL SUPPLIES TAKEN TO THE PHARMACY FOR DISPOSAL ONLY IF THE PHARMACY IS APPROVED BY THE BOARD AS A REPOSITORY FOR THIS PURPOSE.

(G) THE PROGRAM MAY NOT REQUIRE A PRIVATE ENTITY TO ESTABLISH, OPERATE, OR FUND A DROP-OFF SITE OR DISPOSAL PROGRAM.

15-607.

(a) This section applies to:

- Program;
- (1) A person that donates prescription drugs or medical supplies to the
 - (2) A drop-off site;
 - (3) A repository;
 - (4) The Board; and
 - (5) Pharmacists.

(b) For matters related to donating, accepting, **DISPOSING OF**, or dispensing **PRESCRIPTION** drugs **OR MEDICAL SUPPLIES** under the Program, a person described in subsection (a) of this section that acts in good faith may not be subject to:

- (1) Criminal prosecution; or
- (2) Liability in tort or other civil action for injury, death, or loss to person or property.

(c) A drug manufacturer acting in good faith may not be subject to criminal prosecution or liability in tort or other civil action for injury, death, or loss to person or property for matters related to the donation, acceptance, or dispensing of a drug manufactured by the drug manufacturer that is donated by any person under the Program, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug.

15-608.

(a) On or before January 1, 2007, and in consideration of the recommendations of the Task Force on the Establishment of a Prescription Drug Repository Program, the Board shall adopt regulations governing the Program.

(b) The regulations shall include:

(1) Categories of drugs that a repository will not accept, including a statement as to why the drug is ineligible for donation;

(2) A standard form each donor must sign stating that the donor is the owner of the drugs and intends to voluntarily donate them to the Program;

(3) Requirements for designation of drop-off sites to accept donated prescription drugs and medical supplies under the Program;

(4) Requirements for designation of repositories to dispense **OR DISPOSE OF** donated prescription drugs and medical supplies under the Program;

(5) Standards and procedures for accepting, safely storing, dispensing, shipping, and [if necessary,] disposing of donated prescription drugs and medical supplies;

(6) Standards and procedures for inspecting donated prescription drugs and medical supplies intended for dispensing to determine that:

(i) The original packaging is:

1. Sealed and tamper-evident; and
2. In the case of prescription drugs, in the undisturbed single unit dose packaging; and

(ii) The prescription drugs and medical supplies are unadulterated, safe, and suitable for dispensing;

(7) A standard form for health care practitioners to submit to a repository to indicate a patient's need for the Program;

(8) A standard form that an individual receiving a prescription drug or medical supply from the Program must sign before receiving the drug or supply to confirm that the individual understands that:

(i) The individual is receiving prescription drugs or medical supplies that have been donated to the Program; and

- (ii) Entities involved in the Program have certain immunity from liability;
- (9) Record keeping and reporting requirements for a repository; and
- (10) Any other standards and procedures the Board considers appropriate.

Article – Health Occupations

12–313.

(b) Subject to the hearing provisions of § 12–315 of this subtitle, the Board, on the affirmative vote of a majority of its members then serving, may deny a license to any applicant for a pharmacist’s license, reprimand any licensee, place any licensee on probation, or suspend or revoke a license of a pharmacist if the applicant or licensee:

(30) Delegates pharmacy acts to a registered pharmacy technician, pharmacy student, or a pharmacy technician trainee outside the scope of education, training, experience, and area of practice of a licensed pharmacist; **[or]**

(31) Delegates pharmacy acts that are inappropriate for a registered pharmacy technician, pharmacy student, or pharmacy technician trainee who does not have the education, training, or experience to perform the delegated pharmacy acts; **OR**

(32) FAILS TO DISPENSE OR DISPOSE OF PRESCRIPTION DRUGS OR MEDICAL SUPPLIES IN ACCORDANCE WITH TITLE 15, SUBTITLE 6 OF THE HEALTH – GENERAL ARTICLE.

12–403.

(b) Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:

(19) May not allow an unauthorized individual to represent that the individual is a pharmacist or registered pharmacy technician; **[and]**

(20) Shall provide information regarding the process for resolving incorrectly filled prescriptions in accordance with existing regulations by:

(i) Posting a sign that is conspicuously positioned and readable by consumers at the point where prescription drugs are dispensed to consumers; or

(ii) Including written information regarding the process with each prescription dispensed; AND

(21) SHALL DISPENSE OR DISPOSE OF PRESCRIPTION DRUGS OR MEDICAL SUPPLIES IN ACCORDANCE WITH TITLE 15, SUBTITLE 6 OF THE HEALTH – GENERAL ARTICLE.

(g) Subject to the hearing provisions of § 12–411 of this subtitle, if a pharmacy or a nonresident pharmacy is operated in violation of this section, the Board may suspend the applicable pharmacy permit until the pharmacy complies with this section.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2011.

Approved by the Governor, May 19, 2011.