

# SENATE BILL 770

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CF HB 460

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By: ~~Senators Conway and Montgomery~~, Montgomery, Muse, Astle, Garagiola, Glassman, Kittleman, Klausmeier, Mathias, Middleton, and Pugh

Introduced and read first time: February 4, 2011

Assigned to: Education, Health, and Environmental Affairs

Reassigned: Finance and Education, Health, and Environmental Affairs, February 11, 2011

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Committee Report: Favorable with amendments

Senate action: Adopted

Read second time: March 23, 2011

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## CHAPTER \_\_\_\_\_

1 AN ACT concerning

2 **Prescription Drug Repository Program – Disposal of Prescription Drugs and**  
3 **Medical Supplies**

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

20 BY repealing and reenacting, with amendments,  
21 Article – Health – General

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1 Section 15–601, 15–602, 15–605(b), 15–607, and 15–608  
2 Annotated Code of Maryland  
3 (2009 Replacement Volume and 2010 Supplement)

4 BY adding to  
5 Article – Health – General  
6 Section 15–605(f) and (g)  
7 Annotated Code of Maryland  
8 (2009 Replacement Volume and 2010 Supplement)

9 BY repealing and reenacting, with amendments,  
10 Article – Health Occupations  
11 Section 12–313(b)(30) and (31) and 12–403(b)(19) and (20)  
12 Annotated Code of Maryland  
13 (2009 Replacement Volume and 2010 Supplement)

14 BY adding to  
15 Article – Health Occupations  
16 Section 12–313(b)(32) and 12–403(b)(21)  
17 Annotated Code of Maryland  
18 (2009 Replacement Volume and 2010 Supplement)

19 BY repealing and reenacting, without amendments,  
20 Article – Health Occupations  
21 Section 12–403(g)  
22 Annotated Code of Maryland  
23 (2009 Replacement Volume and 2010 Supplement)

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

26 **Article – Health – General**

27 15–601.

28 (a) In this subtitle the following words have the meanings indicated.

29 (b) “Board” means the State Board of Pharmacy.

30 (c) “Drop-off site” means a pharmacy or other health care facility designated  
31 by the Board that:

32 (1) Has voluntarily agreed to accept donated prescription drugs or  
33 medical supplies; and

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

1 (d) "Program" means the Prescription Drug Repository Program.

2 (e) "Repository" means a licensed pharmacy that:

3 (1) Does not have a final disciplinary order issued against it by the  
4 Board of Pharmacy;

5 (2) Has voluntarily agreed to participate in the Program; and

6 (3) Has been approved by the Board to:

7 (i) Accept donated prescription drugs or medical supplies from  
8 a designated drop-off site; [and]

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

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

13 15-602.

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

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

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

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

20 15-605.

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

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

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

26 (3) Accept **FOR DISPENSING TO NEEDY INDIVIDUALS** only those  
27 donated prescription drugs and medical supplies that meet the requirements of §  
28 15-603 of this subtitle;

1 (4) Dispose of donated prescription drugs and medical supplies[, in  
2 accordance with State and federal guidelines, that do not meet the requirements of §  
3 15–603 of this subtitle] **NOT ACCEPTED FOR DISPENSING TO NEEDY INDIVIDUALS**  
4 **IN ACCORDANCE WITH STATE AND FEDERAL LAW;**

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

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

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

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

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

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

19 15–607.

20 (a) This section applies to:

21 (1) A person that donates prescription drugs or medical supplies to the  
22 Program;

23 (2) A drop-off site;

24 (3) A repository;

25 (4) The Board; and

26 (5) Pharmacists.

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

30 (1) Criminal prosecution; or

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

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

9   15–608.

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

13          (b)    The regulations shall include:

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

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

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

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

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

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

27                   (i)   The original packaging is:

28                           1.    Sealed and tamper–evident; and

29                           2.    In the case of prescription drugs, in the undisturbed  
30 single unit dose packaging; and

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

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

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

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

8 (ii) Entities involved in the Program have certain immunity  
9 from liability;

10 (9) Record keeping and reporting requirements for a repository; and

11 (10) Any other standards and procedures the Board considers  
12 appropriate.

13 **Article – Health Occupations**

14 12–313.

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

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

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

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

30 12–403.

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

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

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

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

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

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

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

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

Approved:

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Governor.

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President of the Senate.

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Speaker of the House of Delegates.