

HOUSE BILL 460

J1, J2

(1lr1580)

ENROLLED BILL

— Health and Government Operations/Finance and Education, Health, and Environmental Affairs —

Introduced by **Delegates Murphy, Bromwell, Costa, Cullison, Donoghue, Elliott, Frank, Hammen, Hubbard, Kach, Kipke, Morhaim, Nathan-Pulliam, Oaks, Pena-Melnyk, Pendergrass, Ready, Reznik, Tarrant, ~~and V. Turner~~ V. Turner, Rudolph, and Valderrama**

Read and Examined by Proofreaders:

Proofreader.

Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this

_____ day of _____ at _____ o'clock, _____ M.

Speaker.

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;

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.

Italics indicate opposite chamber/conference committee amendments.



1 expanding certain exemptions from criminal prosecution and liability to include
2 disposal of medical supplies; altering certain requirements for Program
3 regulations; authorizing the Board to take certain disciplinary action against a
4 pharmacist or pharmacy that fails to dispense or dispose of prescription drugs
5 or medical supplies in accordance with certain provisions of law; making a
6 certain conforming change; and generally relating to the Prescription Drug
7 Repository Program and disposal of prescription drugs and medical supplies.

8 BY repealing and reenacting, with amendments,
9 Article – Health – General
10 Section 15–601, 15–602, 15–605(b), 15–607, and 15–608
11 Annotated Code of Maryland
12 (2009 Replacement Volume and 2010 Supplement)

13 BY adding to
14 Article – Health – General
15 Section 15–605(f) *and (g)*
16 Annotated Code of Maryland
17 (2009 Replacement Volume and 2010 Supplement)

18 BY repealing and reenacting, with amendments,
19 Article – Health Occupations
20 Section 12–313(b)(30) and (31) and 12–403(b)(19) and (20)
21 Annotated Code of Maryland
22 (2009 Replacement Volume and 2010 Supplement)

23 BY adding to
24 Article – Health Occupations
25 Section 12–313(b)(32) and 12–403(b)(21)
26 Annotated Code of Maryland
27 (2009 Replacement Volume and 2010 Supplement)

28 BY repealing and reenacting, without amendments,
29 Article – Health Occupations
30 Section 12–403(g)
31 Annotated Code of Maryland
32 (2009 Replacement Volume and 2010 Supplement)

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

35 **Article – Health – General**

36 15–601.

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

1 (b) "Board" means the State Board of Pharmacy.

2 (c) "Drop-off site" means a pharmacy or other health care facility designated
3 by the Board that:

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

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

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

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

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

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

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

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

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

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

20 15-602.

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

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

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

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

27 15-605.

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

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

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

6 (3) Accept **FOR DISPENSING TO NEEDY INDIVIDUALS** only those
7 donated prescription drugs and medical supplies that meet the requirements of §
8 15-603 of this subtitle;

9 (4) Dispose of donated prescription drugs and medical supplies[, in
10 accordance with State and federal guidelines, that do not meet the requirements of §
11 15-603 of this subtitle] **NOT ACCEPTED FOR DISPENSING TO NEEDY INDIVIDUALS**
12 **IN ACCORDANCE WITH STATE AND FEDERAL LAW;**

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

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

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

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

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

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

27 15-607.

28 (a) This section applies to:

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

31 (2) A drop-off site;

1 (3) A repository;

2 (4) The Board; and

3 (5) Pharmacists.

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

7 (1) Criminal prosecution; or

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

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

16 15-608.

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

20 (b) The regulations shall include:

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

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

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

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

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

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

3 (i) The original packaging is:

4 1. Sealed and tamper-evident; and

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

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

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

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

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

16 (ii) Entities involved in the Program have certain immunity
17 from liability;

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

19 (10) Any other standards and procedures the Board considers
20 appropriate.

21 Article – Health Occupations

22 12–313.

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

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

31 (31) Delegates pharmacy acts that are inappropriate for a registered
32 pharmacy technician, pharmacy student, or pharmacy technician trainee who does not

1 have the education, training, or experience to perform the delegated pharmacy acts;
2 **OR**

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

6 12–403.

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

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

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

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

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

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

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

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