

HOUSE BILL 460

J1, J2

11r1580
CF 11r1858

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**
Introduced and read first time: February 7, 2011
Assigned to: Health and Government Operations

A BILL ENTITLED

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; expanding certain exemptions from criminal
12 prosecution and liability to include disposal of medical supplies; altering certain
13 requirements for Program regulations; authorizing the Board to take certain
14 disciplinary action against a pharmacist or pharmacy that fails to dispense or
15 dispose of prescription drugs or medical supplies in accordance with certain
16 provisions of law; making a certain conforming change; and generally relating to
17 the Prescription Drug Repository Program and disposal of prescription drugs
18 and medical supplies.

19 BY repealing and reenacting, with amendments,
20 Article – Health – General
21 Section 15–601, 15–602, 15–605(b), 15–607, and 15–608
22 Annotated Code of Maryland
23 (2009 Replacement Volume and 2010 Supplement)

24 BY adding to
25 Article – Health – General
26 Section 15–605(f)
27 Annotated Code of Maryland

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.
[Brackets] indicate matter deleted from existing law.



1 (2009 Replacement Volume and 2010 Supplement)

2 BY repealing and reenacting, with amendments,
3 Article – Health Occupations
4 Section 12–313(b)(30) and (31) and 12–403(b)(19) and (20)
5 Annotated Code of Maryland
6 (2009 Replacement Volume and 2010 Supplement)

7 BY adding to
8 Article – Health Occupations
9 Section 12–313(b)(32) and 12–403(b)(21)
10 Annotated Code of Maryland
11 (2009 Replacement Volume and 2010 Supplement)

12 BY repealing and reenacting, without amendments,
13 Article – Health Occupations
14 Section 12–403(g)
15 Annotated Code of Maryland
16 (2009 Replacement Volume and 2010 Supplement)

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

19 **Article – Health – General**

20 15–601.

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

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

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

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

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

29 (d) “Program” means the Prescription Drug Repository Program.

30 (e) “Repository” means a licensed pharmacy that:

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

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

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

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

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

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

8 15-602.

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

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

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

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

15 15-605.

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

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

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

21 (3) Accept **FOR DISPENSING TO NEEDY INDIVIDUALS** only those
22 donated prescription drugs and medical supplies that meet the requirements of §
23 15-603 of this subtitle;

24 (4) Dispose of donated prescription drugs and medical supplies[, in
25 accordance with State and federal guidelines, that do not meet the requirements of §
26 15-603 of this subtitle] **NOT ACCEPTED FOR DISPENSING TO NEEDY INDIVIDUALS**
27 **IN ACCORDANCE WITH STATE AND FEDERAL LAW;**

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

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

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

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

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

11 15-607.

12 (a) This section applies to:

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

15 (2) A drop-off site;

16 (3) A repository;

17 (4) The Board; and

18 (5) Pharmacists.

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

22 (1) Criminal prosecution; or

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

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

31 15-608.

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

4 (b) The regulations shall include:

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

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

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

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

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

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

18 (i) The original packaging is:

19 1. Sealed and tamper-evident; and

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

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

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

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

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

31 (ii) Entities involved in the Program have certain immunity
32 from liability;

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

2 (10) Any other standards and procedures the Board considers
3 appropriate.

4 Article – Health Occupations

5 12–313.

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

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

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

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

21 12–403.

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

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

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

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

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

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

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

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