
By: **Delegate Rudolph**

Introduced and read first time: March 6, 2006

Assigned to: Rules and Executive Nominations

A BILL ENTITLED

1 AN ACT concerning

2 **Prescription Drug Repository Program**

3 FOR the purpose of establishing a Prescription Drug Repository Program regulated
4 by the State Board of Pharmacy; providing for the purpose of the Program;
5 authorizing the Program to accept, for the purpose of dispensing, only certain
6 prescription drugs and medical supplies under certain conditions; prohibiting
7 the Program from accepting, for dispensing purposes, certain prescription drugs
8 or medical supplies; providing that any person may donate prescription drugs or
9 medical supplies to the Program at certain drop-off sites; requiring a designated
10 drop-off site to meet certain requirements; prohibiting a designated drop-off
11 site from taking certain actions; authorizing the Board to approve certain
12 pharmacies to be repositories; requiring a repository to meet certain
13 requirements; authorizing a repository to charge a fee, not to exceed a certain
14 amount, for each prescription drug or medical supply dispensed, and, subject to
15 a certain requirement, to dispense a prescription drug or medical supply by
16 mail; prohibiting a repository from establishing or maintaining a certain
17 waiting list; establishing eligibility requirements for individuals to receive
18 donated drugs; prohibiting certain persons that act in good faith from being
19 subject to certain prosecution or liability for certain matters; requiring the
20 Board, on or before a certain date and in accordance with certain
21 recommendations, to adopt regulations that include certain items; requiring a
22 repository to maintain certain records and submit certain reports; requiring the
23 Board to inspect designated drop-off sites and repositories, inspect certain
24 records, and report to the Governor and the General Assembly on the operation
25 of the Program; defining certain terms; and generally relating to a Prescription
26 Drug Repository Program.

27 BY adding to
28 Article - Health - General
29 Section 15-601 through 15-609 to be under the new subtitle "Subtitle 6.
30 Prescription Drug Repository Program"
31 Annotated Code of Maryland
32 (2005 Replacement Volume and 2005 Supplement)

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

3 **Article - Health - General**

4 SUBTITLE 6. PRESCRIPTION DRUG REPOSITORY PROGRAM.

5 15-601.

6 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS
7 INDICATED.

8 (B) "BOARD" MEANS THE STATE BOARD OF PHARMACY.

9 (C) "DROP-OFF SITE" MEANS A PHARMACY OR OTHER HEALTH CARE FACILITY
10 DESIGNATED BY THE BOARD TO ACCEPT DONATED PRESCRIPTION DRUGS OR
11 MEDICAL SUPPLIES.

12 (D) "PROGRAM" MEANS THE PRESCRIPTION DRUG REPOSITORY PROGRAM.

13 (E) "REPOSITORY" MEANS A LICENSED PHARMACY APPROVED BY THE BOARD
14 TO:

15 (1) ACCEPT DONATED PRESCRIPTION DRUGS OR MEDICAL SUPPLIES
16 FROM A DESIGNATED DROP-OFF SITE; AND

17 (2) DISPENSE THE DONATED PRESCRIPTION DRUGS OR MEDICAL
18 SUPPLIES TO NEEDY INDIVIDUALS.

19 15-602.

20 (A) THERE IS A PRESCRIPTION DRUG REPOSITORY PROGRAM REGULATED BY
21 THE BOARD.

22 (B) THE PURPOSE OF THE PROGRAM IS TO ACCEPT PRESCRIPTION DRUGS AND
23 MEDICAL SUPPLIES DONATED FOR THE PURPOSE OF DISPENSING TO NEEDY
24 INDIVIDUALS.

25 15-603.

26 (A) EXCEPT AS PROVIDED IN SUBSECTION (B) OF THIS SECTION, THE
27 PROGRAM MAY ACCEPT FOR THE PURPOSE OF DISPENSING ONLY:

28 (1) PRESCRIPTION DRUGS IN THEIR ORIGINAL UNOPENED, SEALED, AND
29 TAMPER-EVIDENT UNIT DOSE PACKAGING; AND

30 (2) MEDICAL SUPPLIES IN THEIR ORIGINAL UNOPENED AND SEALED
31 PACKAGING.

1 (B) THE PROGRAM MAY ACCEPT AND DISPENSE PRESCRIPTION DRUGS
2 PACKAGED IN SINGLE UNIT DOSES WHEN THE OUTSIDE PACKAGING IS OPENED IF
3 THE SINGLE UNIT DOSE PACKAGING IS UNDISTURBED.

4 (C) THE PROGRAM MAY NOT ACCEPT PRESCRIPTION DRUGS OR MEDICAL
5 SUPPLIES FOR DISPENSING THAT:

6 (1) BEAR AN EXPIRATION DATE THAT IS LESS THAN 6 MONTHS FROM
7 THE DATE THE DRUG IS DONATED;

8 (2) MAY BE ADULTERATED, ACCORDING TO THE STANDARDS OF § 21-216
9 OF THIS ARTICLE; OR

10 (3) BELONG TO A CATEGORY OF UNACCEPTABLE DRUGS ESTABLISHED
11 UNDER § 15-608(B)(1) OF THIS SUBTITLE.

12 15-604.

13 (A) ANY PERSON MAY DONATE PRESCRIPTION DRUGS OR MEDICAL SUPPLIES
14 TO THE PROGRAM.

15 (B) PRESCRIPTION DRUGS OR MEDICAL SUPPLIES MAY BE DONATED ONLY AT
16 A DROP-OFF SITE DESIGNATED FOR THAT PURPOSE BY THE BOARD.

17 (C) A DROP-OFF SITE SHALL:

18 (1) REQUIRE A DONOR TO COMPLETE AND SIGN A DONOR FORM
19 RELEASING THE PRESCRIPTION DRUGS OR MEDICAL SUPPLIES TO THE PROGRAM;

20 (2) STORE DONATED PRESCRIPTION DRUGS AND MEDICAL SUPPLIES IN
21 A SECURE LOCATION USED EXCLUSIVELY FOR THE PROGRAM; AND

22 (3) FORWARD, AT THE COST OF THE DESIGNATED DROP-OFF SITE, ALL
23 DONATED PRESCRIPTION DRUGS AND MEDICAL SUPPLIES TO A CENTRAL
24 REPOSITORY.

25 (D) A DROP-OFF SITE MAY NOT:

26 (1) DISPENSE DONATED PRESCRIPTION DRUGS OR MEDICAL SUPPLIES;

27 (2) RESELL PRESCRIPTION DRUGS OR MEDICAL SUPPLIES DONATED TO
28 THE PROGRAM; OR

29 (3) CHARGE A FEE FOR ACCEPTING A DONATION.

30 15-605.

31 (A) THE BOARD MAY APPROVE MEDBANK OF MARYLAND, INC., OR ANOTHER
32 LICENSED PHARMACY, TO BE A REPOSITORY.

33 (B) A REPOSITORY SHALL:

1 (1) ACCEPT ONLY DONATED PRESCRIPTION DRUGS AND MEDICAL
2 SUPPLIES FORWARDED BY DESIGNATED DROP-OFF SITES;

3 (2) INSPECT ALL DONATED PRESCRIPTION DRUGS AND MEDICAL
4 SUPPLIES;

5 (3) ACCEPT ONLY THOSE DONATED PRESCRIPTION DRUGS AND
6 MEDICAL SUPPLIES THAT MEET THE REQUIREMENTS OF § 15-603 OF THIS SUBTITLE;

7 (4) DISPOSE OF DONATED PRESCRIPTION DRUGS AND MEDICAL
8 SUPPLIES, IN ACCORDANCE WITH STATE AND FEDERAL GUIDELINES, THAT DO NOT
9 MEET THE REQUIREMENTS OF § 15-603 OF THIS SUBTITLE;

10 (5) MAINTAIN A SEPARATE INVENTORY OF DONATED PRESCRIPTION
11 DRUGS AND MEDICAL SUPPLIES;

12 (6) STORE DONATED PRESCRIPTION DRUGS AND MEDICAL SUPPLIES IN
13 A SECURE LOCATION USED EXCLUSIVELY FOR THE PROGRAM;

14 (7) MAINTAIN SEPARATE PRESCRIPTION FILES FOR PATIENTS
15 RECEIVING DONATED PRESCRIPTION DRUGS AND MEDICAL SUPPLIES; AND

16 (8) OBLITERATE FROM THE LABELS OF DONATED PRESCRIPTION DRUGS
17 AND MEDICAL SUPPLIES ANY INFORMATION SPECIFIC TO THE PATIENT FOR WHOM
18 THE DONATED PRESCRIPTION DRUGS AND MEDICAL SUPPLIES WERE ORIGINALLY
19 DISPENSED.

20 (C) A REPOSITORY SHALL DISPENSE DONATED PRESCRIPTION DRUGS AND
21 MEDICAL SUPPLIES ONLY:

22 (1) TO AN INDIVIDUAL WHO MEETS THE REQUIREMENTS OF § 15-606 OF
23 THIS SUBTITLE;

24 (2) ON A NEW PRESCRIPTION, IN THE CASE OF A PRESCRIPTION DRUG
25 OR MEDICAL SUPPLY THAT REQUIRES A PRESCRIPTION; AND

26 (3) IN ACCORDANCE WITH STATE AND FEDERAL LAWS PERTAINING TO:

27 (I) STORAGE, DISTRIBUTION, AND DISPENSING OF PRESCRIPTION
28 DRUGS; AND

29 (II) CONFIDENTIALITY OF PATIENT INFORMATION.

30 (D) A REPOSITORY MAY:

31 (1) CHARGE A FEE, NOT TO EXCEED \$10, FOR EACH PRESCRIPTION DRUG
32 OR MEDICAL SUPPLY DISPENSED; AND

33 (2) DISPENSE A DONATED PRESCRIPTION DRUG OR MEDICAL SUPPLY BY
34 MAIL, PROVIDED THAT THE REPOSITORY INFORMS THE PATIENT THAT A DELAY MAY
35 BE ENTAILED.

1 (E) A REPOSITORY MAY NOT ESTABLISH OR MAINTAIN A WAITING LIST FOR
2 ANY PRESCRIPTION DRUG OR MEDICAL SUPPLY DISPENSED BY THE PROGRAM.

3 15-606.

4 TO BE ELIGIBLE TO RECEIVE DONATED PRESCRIPTION DRUGS OR MEDICAL
5 SUPPLIES, AN INDIVIDUAL SHALL:

6 (1) BE A RESIDENT OF THE STATE; AND

7 (2) BE A NEEDY PATIENT, AS INDICATED BY THE INDIVIDUAL'S HEALTH
8 CARE PRACTITIONER.

9 15-607.

10 (A) THIS SECTION APPLIES TO:

11 (1) A PERSON THAT DONATES PRESCRIPTION DRUGS OR MEDICAL
12 SUPPLIES TO THE PROGRAM;

13 (2) A DROP-OFF SITE;

14 (3) A REPOSITORY; AND

15 (4) THE BOARD.

16 (B) FOR MATTERS RELATED TO DONATING, ACCEPTING, OR DISPENSING
17 DRUGS UNDER THE PROGRAM, A PERSON DESCRIBED IN SUBSECTION (A) OF THIS
18 SECTION THAT ACTS IN GOOD FAITH MAY NOT BE SUBJECT TO:

19 (1) CRIMINAL PROSECUTION; OR

20 (2) LIABILITY IN TORT OR OTHER CIVIL ACTION FOR INJURY, DEATH, OR
21 LOSS TO PERSON OR PROPERTY.

22 (C) A DRUG MANUFACTURER ACTING IN GOOD FAITH MAY NOT BE SUBJECT
23 TO CRIMINAL PROSECUTION OR LIABILITY IN TORT OR OTHER CIVIL ACTION FOR
24 INJURY, DEATH, OR LOSS TO PERSON OR PROPERTY FOR MATTERS RELATED TO THE
25 DONATION, ACCEPTANCE, OR DISPENSING OF A DRUG MANUFACTURED BY THE
26 DRUG MANUFACTURER THAT IS DONATED BY ANY PERSON UNDER THE PROGRAM,
27 INCLUDING LIABILITY FOR FAILURE TO TRANSFER OR COMMUNICATE PRODUCT OR
28 CONSUMER INFORMATION OR THE EXPIRATION DATE OF THE DONATED DRUG.

29 15-608.

30 (A) ON OR BEFORE JANUARY 1, 2007, AND IN ACCORDANCE WITH THE
31 RECOMMENDATIONS OF THE TASK FORCE ON THE ESTABLISHMENT OF A
32 PRESCRIPTION DRUG REPOSITORY PROGRAM, THE BOARD SHALL ADOPT
33 REGULATIONS GOVERNING THE PROGRAM.

34 (B) THE REGULATIONS SHALL INCLUDE:

1 (1) CATEGORIES OF DRUGS THAT A REPOSITORY WILL NOT ACCEPT,
2 INCLUDING A STATEMENT AS TO WHY THE DRUG IS INELIGIBLE FOR DONATION;

3 (2) A STANDARD FORM EACH DONOR MUST SIGN STATING THAT THE
4 DONOR IS THE OWNER OF THE DRUGS AND INTENDS TO VOLUNTARILY DONATE
5 THEM TO THE PROGRAM;

6 (3) REQUIREMENTS FOR DESIGNATION OF DROP-OFF SITES TO ACCEPT
7 DONATED PRESCRIPTION DRUGS AND MEDICAL SUPPLIES UNDER THE PROGRAM;

8 (4) REQUIREMENTS FOR DESIGNATION OF REPOSITORIES TO DISPENSE
9 DONATED PRESCRIPTION DRUGS AND MEDICAL SUPPLIES UNDER THE PROGRAM;

10 (5) STANDARDS AND PROCEDURES FOR ACCEPTING, SAFELY STORING,
11 DISPENSING, AND IF NECESSARY, DISPOSING OF DONATED PRESCRIPTION DRUGS
12 AND MEDICAL SUPPLIES;

13 (6) STANDARDS AND PROCEDURES FOR INSPECTING DONATED
14 PRESCRIPTION DRUGS AND MEDICAL SUPPLIES INTENDED FOR DISPENSING TO
15 DETERMINE THAT:

16 (I) THE ORIGINAL PACKAGING IS:

17 1. SEALED AND TAMPER-EVIDENT; AND

18 2. IN THE CASE OF PRESCRIPTION DRUGS, IN THE
19 UNDISTURBED SINGLE UNIT DOSE PACKAGING; AND

20 (II) THE PRESCRIPTION DRUGS AND MEDICAL SUPPLIES ARE
21 UNADULTERATED, SAFE, AND SUITABLE FOR DISPENSING;

22 (7) A STANDARD FORM FOR HEALTH CARE PRACTITIONERS TO SUBMIT
23 TO A REPOSITORY TO INDICATE A PATIENT'S NEED FOR THE PROGRAM;

24 (8) A STANDARD FORM THAT AN INDIVIDUAL RECEIVING A
25 PRESCRIPTION DRUG OR MEDICAL SUPPLY FROM THE PROGRAM MUST SIGN BEFORE
26 RECEIVING THE DRUG OR SUPPLY TO CONFIRM THAT THE INDIVIDUAL
27 UNDERSTANDS THAT:

28 (I) THE INDIVIDUAL IS RECEIVING PRESCRIPTION DRUGS OR
29 MEDICAL SUPPLIES THAT HAVE BEEN DONATED TO THE PROGRAM; AND

30 (II) ENTITIES INVOLVED IN THE PROGRAM HAVE CERTAIN
31 IMMUNITY FROM LIABILITY;

32 (9) RECORD KEEPING AND REPORTING REQUIREMENTS FOR A
33 REPOSITORY; AND

34 (10) ANY OTHER STANDARDS AND PROCEDURES THE BOARD CONSIDERS
35 APPROPRIATE.

1 15-609.

2 (A) A REPOSITORY SHALL:

3 (1) MAINTAIN RECORDS OF DONATED PRESCRIPTION DRUGS AND
4 MEDICAL SUPPLIES; AND

5 (2) SUBMIT PERIODIC REPORTS TO THE BOARD ON ITS ACTIVITIES.

6 (B) TO DETERMINE COMPLIANCE WITH THE REQUIREMENTS OF THIS
7 SUBTITLE, THE BOARD SHALL:

8 (1) INSPECT DESIGNATED DROP-OFF SITES AND REPOSITORIES;

9 (2) INSPECT RECORDS OF DONATED PRESCRIPTION DRUGS AND
10 MEDICAL SUPPLIES MAINTAINED BY THE REPOSITORY; AND

11 (3) BEGINNING JANUARY 1, 2007, AND EACH JANUARY 1 THEREAFTER,
12 REPORT TO THE GOVERNOR AND, IN ACCORDANCE WITH § 2-1246 OF THE STATE
13 GOVERNMENT ARTICLE, THE GENERAL ASSEMBLY ON THE OPERATION OF THE
14 PROGRAM.

15 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
16 July 1, 2006.