
By: **Delegate Rudolph**

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Assigned to: Rules and Executive Nominations

Re-referred to: Health and Government Operations, March 13, 2006

Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 22, 2006

CHAPTER _____

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~~ consideration of
21 certain recommendations, to adopt regulations that include certain items;
22 requiring a repository to maintain certain records and submit certain reports;
23 requiring the Board to inspect designated drop-off sites and repositories, inspect
24 certain records, and report to the Governor and the General Assembly on the
25 operation of the Program; defining certain terms; and generally relating to a
26 Prescription Drug Repository Program.

1 BY adding to
2 Article - Health - General
3 Section 15-601 through 15-609 to be under the new subtitle "Subtitle 6.
4 Prescription Drug Repository Program"
5 Annotated Code of Maryland
6 (2005 Replacement Volume and 2005 Supplement)

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

9 **Article - Health - General**

10 **SUBTITLE 6. PRESCRIPTION DRUG REPOSITORY PROGRAM.**

11 15-601.

12 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS
13 INDICATED.

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

15 (C) "DROP-OFF SITE" MEANS A PHARMACY OR OTHER HEALTH CARE FACILITY
16 DESIGNATED BY THE BOARD THAT:

17 (1) HAS VOLUNTARILY AGREED TO ACCEPT DONATED PRESCRIPTION
18 DRUGS OR MEDICAL SUPPLIES; AND

19 (2) DOES NOT HAVE A FINAL DISCIPLINARY ORDER ISSUED AGAINST IT
20 BY A HEALTH OCCUPATIONS BOARD.

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

22 (E) "REPOSITORY" MEANS A LICENSED PHARMACY THAT:

23 (1) DOES NOT HAVE A FINAL DISCIPLINARY ORDER ISSUED AGAINST IT
24 BY THE BOARD OF PHARMACY;

25 (2) HAS VOLUNTARILY AGREED TO PARTICIPATE IN THE PROGRAM; AND

26 (3) HAS BEEN APPROVED BY THE BOARD TO:

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

29 (2) DISPENSE THE DONATED PRESCRIPTION DRUGS OR MEDICAL
30 SUPPLIES TO NEEDY INDIVIDUALS.

1 15-602.

2 (A) THERE IS A PRESCRIPTION DRUG REPOSITORY PROGRAM REGULATED BY
3 THE BOARD.

4 (B) THE PURPOSE OF THE PROGRAM IS TO ACCEPT PRESCRIPTION DRUGS AND
5 MEDICAL SUPPLIES DONATED FOR THE PURPOSE OF DISPENSING TO NEEDY
6 INDIVIDUALS.

7 15-603.

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

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

12 (2) MEDICAL SUPPLIES IN THEIR ORIGINAL UNOPENED AND SEALED
13 PACKAGING.

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

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

19 (1) BEAR AN EXPIRATION DATE THAT IS LESS THAN ~~6 MONTHS~~ 90 DAYS
20 FROM THE DATE THE DRUG IS DONATED;

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

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

25 15-604.

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

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

30 (C) A DROP-OFF SITE SHALL:

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

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

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

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

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

6 (2) RESELL PRESCRIPTION DRUGS OR MEDICAL SUPPLIES DONATED TO
7 THE PROGRAM; OR

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

9 15-605.

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

12 (B) A REPOSITORY SHALL:

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

15 (2) INSPECT ALL DONATED PRESCRIPTION DRUGS AND MEDICAL
16 SUPPLIES;

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

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

22 (5) MAINTAIN A SEPARATE INVENTORY OF DONATED PRESCRIPTION
23 DRUGS AND MEDICAL SUPPLIES;

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

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

28 (8) OBLITERATE FROM THE LABELS OF DONATED PRESCRIPTION DRUGS
29 AND MEDICAL SUPPLIES ANY INFORMATION SPECIFIC TO THE PATIENT FOR WHOM
30 THE DONATED PRESCRIPTION DRUGS AND MEDICAL SUPPLIES WERE ORIGINALLY
31 DISPENSED.

32 (C) A REPOSITORY SHALL DISPENSE DONATED PRESCRIPTION DRUGS AND
33 MEDICAL SUPPLIES ONLY:

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

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

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

6 (I) STORAGE, DISTRIBUTION, AND DISPENSING OF PRESCRIPTION
7 DRUGS; AND

8 (II) CONFIDENTIALITY OF PATIENT INFORMATION.

9 (D) A REPOSITORY MAY:

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

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

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

17 15-606.

18 TO BE ELIGIBLE TO RECEIVE DONATED PRESCRIPTION DRUGS OR MEDICAL
19 SUPPLIES, AN INDIVIDUAL SHALL:

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

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

23 15-607.

24 (A) THIS SECTION APPLIES TO:

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

27 (2) A DROP-OFF SITE;

28 (3) A REPOSITORY; ~~AND~~

29 (4) THE BOARD; AND

30 (5) PHARMACISTS.

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

4 (1) CRIMINAL PROSECUTION; OR

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

7 (C) A DRUG MANUFACTURER ACTING IN GOOD FAITH MAY NOT BE SUBJECT
8 TO CRIMINAL PROSECUTION OR LIABILITY IN TORT OR OTHER CIVIL ACTION FOR
9 INJURY, DEATH, OR LOSS TO PERSON OR PROPERTY FOR MATTERS RELATED TO THE
10 DONATION, ACCEPTANCE, OR DISPENSING OF A DRUG MANUFACTURED BY THE
11 DRUG MANUFACTURER THAT IS DONATED BY ANY PERSON UNDER THE PROGRAM,
12 INCLUDING LIABILITY FOR FAILURE TO TRANSFER OR COMMUNICATE PRODUCT OR
13 CONSUMER INFORMATION OR THE EXPIRATION DATE OF THE DONATED DRUG.

14 15-608.

15 (A) ON OR BEFORE JANUARY 1, 2007, AND IN ~~ACCORDANCE WITH~~
16 CONSIDERATION OF THE RECOMMENDATIONS OF THE TASK FORCE ON THE
17 ESTABLISHMENT OF A PRESCRIPTION DRUG REPOSITORY PROGRAM, THE BOARD
18 SHALL ADOPT REGULATIONS GOVERNING THE PROGRAM.

19 (B) THE REGULATIONS SHALL INCLUDE:

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

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

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

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

29 (5) STANDARDS AND PROCEDURES FOR ACCEPTING, SAFELY STORING,
30 DISPENSING, SHIPPING, AND IF NECESSARY, DISPOSING OF DONATED PRESCRIPTION
31 DRUGS AND MEDICAL SUPPLIES;

32 (6) STANDARDS AND PROCEDURES FOR INSPECTING DONATED
33 PRESCRIPTION DRUGS AND MEDICAL SUPPLIES INTENDED FOR DISPENSING TO
34 DETERMINE THAT:

35 (I) THE ORIGINAL PACKAGING IS:

36 1. SEALED AND TAMPER-EVIDENT; AND

