
By: **Senator Teitelbaum**

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Assigned to: Rules

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Committee Report: Favorable with amendments

Senate action: Adopted

Read second time: March 24, 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 certain~~
 21 ~~recommendations~~ consultation with a certain Task Force, to adopt regulations
 22 that include certain items; requiring a repository to maintain certain records
 23 and submit certain reports; requiring the Board to inspect designated drop-off
 24 sites and repositories, inspect certain records, and report to the Governor and
 25 the General Assembly on the operation of the Program; defining certain terms;
 26 and generally relating to a 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 HAS VOLUNTARILY AGREED TO ACCEPT DONATED
17 PRESCRIPTION DRUGS OR MEDICAL SUPPLIES.

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

19 (E) "REPOSITORY" MEANS A LICENSED PHARMACY THAT HAS VOLUNTARILY
20 AGREED TO PARTICIPATE IN THE PROGRAM AND HAS BEEN APPROVED BY THE
21 BOARD TO:

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

24 (2) DISPENSE THE DONATED PRESCRIPTION DRUGS OR MEDICAL
25 SUPPLIES TO NEEDY INDIVIDUALS.

26 15-602.

27 (A) THERE IS A PRESCRIPTION DRUG REPOSITORY PROGRAM REGULATED BY
28 THE BOARD.

29 (B) THE PURPOSE OF THE PROGRAM IS TO ACCEPT PRESCRIPTION DRUGS AND
30 MEDICAL SUPPLIES DONATED FOR THE PURPOSE OF DISPENSING TO NEEDY
31 INDIVIDUALS.

1 15-603.

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

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

6 (2) MEDICAL SUPPLIES IN THEIR ORIGINAL UNOPENED AND SEALED
7 PACKAGING.

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

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

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

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

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

19 15-604.

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

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

24 (C) A DROP-OFF SITE SHALL:

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

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

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

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

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

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

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

4 (E) A PHARMACY OR OTHER HEALTH CARE FACILITY THAT HAS A FINAL
5 ORDER OF THE BOARD ISSUED AGAINST IT MAY NOT PARTICIPATE AS A DROP-OFF
6 SITE UNDER THE PROGRAM.

7 15-605.

8 (A) THE BOARD MAY APPROVE MEDBANK OF MARYLAND, INC., OR ANOTHER
9 LICENSED PHARMACY THAT VOLUNTARILY AGREES TO PARTICIPATE IN THE
10 PROGRAM, TO BE A REPOSITORY.

11 (B) A REPOSITORY SHALL:

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

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

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

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

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

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

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

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

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

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

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

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

4 (I) STORAGE, DISTRIBUTION, AND DISPENSING OF PRESCRIPTION
5 DRUGS; AND

6 (II) CONFIDENTIALITY OF PATIENT INFORMATION.

7 (D) A REPOSITORY MAY:

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

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

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

15 (F) A PHARMACY THAT HAS A FINAL ORDER OF THE BOARD ISSUED AGAINST
16 IT MAY NOT PARTICIPATE AS A REPOSITORY UNDER 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 THE~~
16 ~~RECOMMENDATIONS OF CONSULTATION WITH~~ 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

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

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

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

7 (8) A STANDARD FORM THAT AN INDIVIDUAL RECEIVING A
8 PRESCRIPTION DRUG OR MEDICAL SUPPLY FROM THE PROGRAM MUST SIGN BEFORE
9 RECEIVING THE DRUG OR SUPPLY TO CONFIRM THAT THE INDIVIDUAL
10 UNDERSTANDS THAT:

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

13 (II) ENTITIES INVOLVED IN THE PROGRAM HAVE CERTAIN
14 IMMUNITY FROM LIABILITY;

15 (9) RECORD KEEPING AND REPORTING REQUIREMENTS FOR A
16 REPOSITORY; AND

17 (10) ANY OTHER STANDARDS AND PROCEDURES THE BOARD CONSIDERS
18 APPROPRIATE.

19 15-609.

20 (A) A REPOSITORY SHALL:

21 (1) MAINTAIN RECORDS OF DONATED PRESCRIPTION DRUGS AND
22 MEDICAL SUPPLIES; AND

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

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

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

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

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

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

