

ENROLLED BILL
-- Finance/Health and Government Operations --

Introduced by **Senator Teitelbaum**

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.

President.

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

1 donated drugs; prohibiting certain persons that act in good faith from being
 2 subject to certain prosecution or liability for certain matters; requiring the
 3 Board, on or before a certain date and in ~~accordance with certain~~
 4 ~~recommendations consultation with a certain Task Force~~ *consideration of*
 5 *certain recommendations*, to adopt regulations that include certain items;
 6 requiring a repository to maintain certain records and submit certain reports;
 7 requiring the Board to inspect designated drop-off sites and repositories, inspect
 8 certain records, and report to the Governor and the General Assembly on the
 9 operation of the Program; defining certain terms; and generally relating to a
 10 Prescription Drug Repository Program.

11 BY adding to

12 Article - Health - General
 13 Section 15-601 through 15-609 to be under the new subtitle "Subtitle 6.
 14 Prescription Drug Repository Program"
 15 Annotated Code of Maryland
 16 (2005 Replacement Volume and 2005 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 **SUBTITLE 6. PRESCRIPTION DRUG REPOSITORY PROGRAM.**

21 15-601.

22 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS
 23 INDICATED.

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

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

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

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

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

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

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

35 (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
3 SUPPLIES FROM A DESIGNATED DROP-OFF SITE; AND

4 (2) (II) DISPENSE THE DONATED PRESCRIPTION DRUGS OR MEDICAL
5 SUPPLIES TO NEEDY INDIVIDUALS.

6 15-602.

7 (A) THERE IS A PRESCRIPTION DRUG REPOSITORY PROGRAM REGULATED BY
8 THE BOARD.

9 (B) THE PURPOSE OF THE PROGRAM IS TO ACCEPT PRESCRIPTION DRUGS AND
10 MEDICAL SUPPLIES DONATED FOR THE PURPOSE OF DISPENSING TO NEEDY
11 INDIVIDUALS.

12 15-603.

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

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

17 (2) MEDICAL SUPPLIES IN THEIR ORIGINAL UNOPENED AND SEALED
18 PACKAGING.

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

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

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

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

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

30 15-604.

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

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

1 (C) A DROP-OFF SITE SHALL:

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

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

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

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

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

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

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

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

17 15-605.

18 (A) THE BOARD MAY APPROVE MEDBANK OF MARYLAND, INC., OR ANOTHER
19 LICENSED PHARMACY ~~THAT VOLUNTARILY AGREES TO PARTICIPATE IN THE~~
20 ~~PROGRAM~~, TO BE A REPOSITORY.

21 (B) A REPOSITORY SHALL:

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

24 (2) INSPECT ALL DONATED PRESCRIPTION DRUGS AND MEDICAL
25 SUPPLIES;

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

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

31 (5) MAINTAIN A SEPARATE INVENTORY OF DONATED PRESCRIPTION
32 DRUGS AND MEDICAL SUPPLIES;

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

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

3 (8) OBLITERATE FROM THE LABELS OF DONATED PRESCRIPTION DRUGS
4 AND MEDICAL SUPPLIES ANY INFORMATION SPECIFIC TO THE PATIENT FOR WHOM
5 THE DONATED PRESCRIPTION DRUGS AND MEDICAL SUPPLIES WERE ORIGINALLY
6 DISPENSED.

7 (C) A REPOSITORY SHALL DISPENSE DONATED PRESCRIPTION DRUGS AND
8 MEDICAL SUPPLIES ONLY:

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

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

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

14 (I) STORAGE, DISTRIBUTION, AND DISPENSING OF PRESCRIPTION
15 DRUGS; AND

16 (II) CONFIDENTIALITY OF PATIENT INFORMATION.

17 (D) A REPOSITORY MAY:

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

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

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

25 ~~(F) A PHARMACY THAT HAS A FINAL ORDER OF THE BOARD ISSUED AGAINST~~
26 ~~IT MAY NOT PARTICIPATE AS A REPOSITORY UNDER THE PROGRAM.~~

27 15-606.

28 TO BE ELIGIBLE TO RECEIVE DONATED PRESCRIPTION DRUGS OR MEDICAL
29 SUPPLIES, AN INDIVIDUAL SHALL:

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

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

1 15-607.

2 (A) THIS SECTION APPLIES TO:

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

5 (2) A DROP-OFF SITE;

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

7 (4) THE BOARD; AND

8 (5) PHARMACISTS.

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

12 (1) CRIMINAL PROSECUTION; OR

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

15 (C) A DRUG MANUFACTURER ACTING IN GOOD FAITH MAY NOT BE SUBJECT
16 TO CRIMINAL PROSECUTION OR LIABILITY IN TORT OR OTHER CIVIL ACTION FOR
17 INJURY, DEATH, OR LOSS TO PERSON OR PROPERTY FOR MATTERS RELATED TO THE
18 DONATION, ACCEPTANCE, OR DISPENSING OF A DRUG MANUFACTURED BY THE
19 DRUG MANUFACTURER THAT IS DONATED BY ANY PERSON UNDER THE PROGRAM,
20 INCLUDING LIABILITY FOR FAILURE TO TRANSFER OR COMMUNICATE PRODUCT OR
21 CONSUMER INFORMATION OR THE EXPIRATION DATE OF THE DONATED DRUG.

22 15-608.

23 (A) ON OR BEFORE JANUARY 1, 2007, AND IN ~~ACCORDANCE WITH THE~~
24 ~~RECOMMENDATIONS OF CONSULTATION WITH CONSIDERATION OF THE~~
25 RECOMMENDATIONS OF THE TASK FORCE ON THE ESTABLISHMENT OF A
26 PRESCRIPTION DRUG REPOSITORY PROGRAM, THE BOARD SHALL ADOPT
27 REGULATIONS GOVERNING THE PROGRAM.

28 (B) THE REGULATIONS SHALL INCLUDE:

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

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

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

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

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

6 (6) STANDARDS AND PROCEDURES FOR INSPECTING DONATED
7 PRESCRIPTION DRUGS AND MEDICAL SUPPLIES INTENDED FOR DISPENSING TO
8 DETERMINE THAT:

9 (I) THE ORIGINAL PACKAGING IS:

10 1. SEALED AND TAMPER-EVIDENT; AND

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

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

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

17 (8) A STANDARD FORM THAT AN INDIVIDUAL RECEIVING A
18 PRESCRIPTION DRUG OR MEDICAL SUPPLY FROM THE PROGRAM MUST SIGN BEFORE
19 RECEIVING THE DRUG OR SUPPLY TO CONFIRM THAT THE INDIVIDUAL
20 UNDERSTANDS THAT:

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

23 (II) ENTITIES INVOLVED IN THE PROGRAM HAVE CERTAIN
24 IMMUNITY FROM LIABILITY;

25 (9) RECORD KEEPING AND REPORTING REQUIREMENTS FOR A
26 REPOSITORY; AND

27 (10) ANY OTHER STANDARDS AND PROCEDURES THE BOARD CONSIDERS
28 APPROPRIATE.

29 15-609.

30 (A) A REPOSITORY SHALL:

31 (1) MAINTAIN RECORDS OF DONATED PRESCRIPTION DRUGS AND
32 MEDICAL SUPPLIES; AND

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

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

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

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

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

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