1 AN ACT concerning

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
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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, to adopt regulations that include certain items;
5 requiring a repository to maintain certain records and submit certain reports;
6 requiring the Board to inspect designated drop-off sites and repositories, inspect
7 certain records, and report to the Governor and the General Assembly on the
8 operation of the Program; defining certain terms; and generally relating to a
9 Prescription Drug Repository Program.

10 BY adding to
11 Article - Health - General
12 Section 15-601 through 15-609 to be under the new subtitle "Subtitle 6.
13 Prescription Drug Repository Program"
14 Annotated Code of Maryland
15 (2005 Replacement Volume and 2005 Supplement)

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

18 Article - Health - General

19 SUBTITLE 6. PRESCRIPTION DRUG REPOSITORY PROGRAM.

20 15-601.

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

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

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

26 (1) HAS VOLUNTARILY AGREED TO ACCEPT DONATED PRESCRIPTION
27 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
HAS BEEN APPROVED BY THE BOARD TO:

ACCEPT DONATED PRESCRIPTION DRUGS OR MEDICAL SUPPLIES FROM A DESIGNATED DROP-OFF SITE; AND

DISPENSE THE DONATED PRESCRIPTION DRUGS OR MEDICAL SUPPLIES TO NEEDY INDIVIDUALS.

15-602.

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

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

15-603.

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

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

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

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

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

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

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

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

15-604.

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

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

1. REQUIRE A DONOR TO COMPLETE AND SIGN A DONOR FORM RELEASING THE PRESCRIPTION DRUGS OR MEDICAL SUPPLIES TO THE PROGRAM;

2. STORE DONATED PRESCRIPTION DRUGS AND MEDICAL SUPPLIES IN A SECURE LOCATION USED EXCLUSIVELY FOR THE PROGRAM; AND

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

A DROP-OFF SITE MAY NOT:

1. DISPENSE DONATED PRESCRIPTION DRUGS OR MEDICAL SUPPLIES;

2. RESELL PRESCRIPTION DRUGS OR MEDICAL SUPPLIES DONATED TO THE PROGRAM; OR

3. CHARGE A FEE FOR ACCEPTING A DONATION.

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

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

A REPOSITORY SHALL:

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

2. INSPECT ALL DONATED PRESCRIPTION DRUGS AND MEDICAL SUPPLIES;

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

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

5. MAINTAIN A SEPARATE INVENTORY OF DONATED PRESCRIPTION DRUGS AND MEDICAL SUPPLIES;

6. STORE DONATED PRESCRIPTION DRUGS AND MEDICAL SUPPLIES IN A SECURE LOCATION USED EXCLUSIVELY FOR THE PROGRAM;
1 MAINTAIN SEPARATE PRESCRIPTION FILES FOR PATIENTS RECEIVING DONATED PRESCRIPTION DRUGS AND MEDICAL SUPPLIES; AND

2 OBLITERATE FROM THE LABELS OF DONATED PRESCRIPTION DRUGS AND MEDICAL SUPPLIES ANY INFORMATION SPECIFIC TO THE PATIENT FOR WHOM THE DONATED PRESCRIPTION DRUGS AND MEDICAL SUPPLIES WERE ORIGINALLY DISPENSED.

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

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

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

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

7 (I) STORAGE, DISTRIBUTION, AND DISPENSING OF PRESCRIPTION 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 OR MEDICAL SUPPLY DISPENSED; AND

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

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

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

14 15-606.

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

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

17 (2) BE A NEEDY PATIENT, AS INDICATED BY THE INDIVIDUAL'S HEALTH 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 STATEING 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;
REQUIREMENTS FOR DESIGNATION OF REPOSITORIES TO DISPENSE
DONATED PRESCRIPTION DRUGS AND MEDICAL SUPPLIES UNDER THE PROGRAM;

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

STANDARDS AND PROCEDURES FOR INSPECTING DONATED
PRESCRIPTION DRUGS AND MEDICAL SUPPLIES INTENDED FOR DISPENSING TO
DETERMINE THAT:

(I) THE ORIGINAL PACKAGING IS:

1. SEALED AND TAMPER-EVIDENT; AND

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

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

A STANDARD FORM FOR HEALTH CARE PRACTITIONERS TO SUBMIT
TO A REPOSITORY TO INDICATE A PATIENT’S NEED FOR THE PROGRAM;

A STANDARD FORM THAT AN INDIVIDUAL RECEIVING A
PRESCRIPTION DRUG OR MEDICAL SUPPLY FROM THE PROGRAM MUST SIGN BEFORE
RECEIVING THE DRUG OR SUPPLY TO CONFIRM THAT THE INDIVIDUAL
UNDERSTANDS THAT:

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

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

RECORD KEEPING AND REPORTING REQUIREMENTS FOR A
REPOSITORY; AND

ANY OTHER STANDARDS AND PROCEDURES THE BOARD CONSIDERS
APPROPRIATE.

A REPOSITORY SHALL:

MAINTAIN RECORDS OF DONATED PRESCRIPTION DRUGS AND
MEDICAL SUPPLIES; AND

SUBMIT PERIODIC REPORTS TO THE BOARD ON ITS ACTIVITIES.
(B) TO DETERMINE COMPLIANCE WITH THE REQUIREMENTS OF THIS
SUBTITLE, THE BOARD SHALL:

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

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

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

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