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By: **Delegate Hammen**

Introduced and read first time: January 27, 2005

Assigned to: Health and Government Operations

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A BILL ENTITLED

1 AN ACT concerning

2 **Prescription Drug Repository Program**

3 FOR the purpose of requiring the State Board of Pharmacy to establish a Prescription  
4 Drug Repository Program to accept and dispense prescription drugs donated for  
5 the purpose of dispensing to certain individuals; providing that the Program  
6 may only accept and dispense drugs in certain unit dose packaging; providing  
7 for a certain exception; prohibiting the Program from accepting or dispensing  
8 drugs that bear a certain expiration date or may be adulterated; authorizing any  
9 person to donate prescription drugs to the Program; specifying that drugs may  
10 only be donated to certain entities that participate in the Program; requiring an  
11 entity that seeks to participate in the Program to apply to the Board in the form  
12 and manner required in regulation; specifying the persons who can receive  
13 drugs donated through the Program; requiring a drug donated through the  
14 Program to be dispensed through a prescription issued by an authorized  
15 prescriber; requiring an entity that accepts donated drugs to comply with  
16 certain laws and conduct a certain inspection; authorizing an entity to charge a  
17 handling fee to individuals receiving donated drugs; prohibiting drugs donated  
18 to the Program from being resold; prohibiting for certain matters a certain  
19 person who acts in good faith from being subject to certain prosecution, liability,  
20 or disciplinary action; requiring the Board to adopt certain regulations on or  
21 before a certain date; requiring the regulations to establish certain items;  
22 defining certain terms; and generally relating to a Prescription Drug Repository  
23 Program in the State Board of Pharmacy.

24 BY adding to

25 Article - Health Occupations

26 Section 12-6B-01 through 12-6B-07 to be under the new subtitle "Subtitle 6B.

27 Prescription Drug Repository Program"

28 Annotated Code of Maryland

29 (2000 Replacement Volume and 2004 Supplement)

30 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF

31 MARYLAND, That the Laws of Maryland read as follows:

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**Article - Health Occupations**

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## SUBTITLE 6B. PRESCRIPTION DRUG REPOSITORY PROGRAM.

3 12-6B-01.

4 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS  
5 INDICATED.

6 (B) "HEALTH CARE FACILITY" MEANS:

7 (1) A HOSPITAL;

8 (2) A HOSPICE CARE PROGRAM;

9 (3) A NURSING HOME;

10 (4) A HOME HEALTH AGENCY;

11 (5) AN INTERMEDIATE CARE FACILITY FOR THE MENTALLY RETARDED;

12 (6) A FACILITY THAT PROVIDES TREATMENT OR OTHER SERVICES FOR  
13 INDIVIDUALS WHO HAVE MENTAL DISORDERS; OR

14 (7) AN ASSISTED LIVING PROGRAM.

15 (C) "HEALTH CARE PRACTITIONER" MEANS AN INDIVIDUAL LICENSED OR  
16 CERTIFIED UNDER THIS ARTICLE TO PROVIDE HEALTH CARE.

17 (D) "NONPROFIT CLINIC" MEANS A PUBLIC OR PRIVATE NONPROFIT  
18 ORGANIZATION THAT PROVIDES PRIMARY OR SPECIALTY OUTPATIENT HEALTH CARE  
19 SERVICES TO INDIGENT AND UNINSURED INDIVIDUALS FOR FREE OR AT REDUCED  
20 COST.

21 (E) "PRESCRIPTION DRUG" HAS THE MEANING STATED IN § 21-201 OF THE  
22 HEALTH - GENERAL ARTICLE.

23 (F) "PROGRAM" MEANS THE PRESCRIPTION DRUG REPOSITORY PROGRAM.

24 12-6B-02.

25 THE BOARD SHALL ESTABLISH A PRESCRIPTION DRUG REPOSITORY PROGRAM  
26 TO ACCEPT AND DISPENSE PRESCRIPTION DRUGS DONATED FOR THE PURPOSE OF  
27 DISPENSING TO INDIVIDUALS WHO ARE RESIDENTS OF THE STATE AND MEET  
28 ELIGIBILITY REQUIREMENTS ESTABLISHED BY THE BOARD.

29 12-6B-03.

30 (A) EXCEPT AS PROVIDED IN SUBSECTION (B) OF THIS SECTION, THE  
31 PROGRAM MAY ONLY ACCEPT AND DISPENSE DRUGS IN THEIR ORIGINAL UNOPENED,  
32 SEALED, AND TAMPER-EVIDENT UNIT DOSE PACKAGING.

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

4 (C) THE PROGRAM MAY NOT ACCEPT OR DISPENSE DRUGS THAT:

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

7 (2) MAY BE ADULTERATED ACCORDING TO THE STANDARDS OF § 21-216  
8 OF THE HEALTH - GENERAL ARTICLE.

9 12-6B-04.

10 (A) ANY PERSON, INCLUDING AN INDIVIDUAL, A DRUG MANUFACTURER, OR A  
11 HEALTH CARE FACILITY, MAY DONATE PRESCRIPTION DRUGS TO THE PROGRAM.

12 (B) DRUGS MAY ONLY BE DONATED AT A PHARMACY, HOSPITAL, OR  
13 NONPROFIT CLINIC THAT PARTICIPATES IN THE PROGRAM.

14 12-6B-05.

15 (A) A PHARMACY, HOSPITAL, OR NONPROFIT CLINIC SEEKING TO  
16 PARTICIPATE IN THE PROGRAM SHALL APPLY TO THE BOARD IN THE FORM AND  
17 MANNER REQUIRED BY THE BOARD IN REGULATION.

18 (B) A PHARMACY, HOSPITAL, OR NONPROFIT CLINIC THAT PARTICIPATES IN  
19 THE PROGRAM MAY ONLY DISPENSE DRUGS DONATED THROUGH THE PROGRAM TO  
20 INDIVIDUALS WHO ARE RESIDENTS OF THE STATE AND MEET THE ELIGIBILITY  
21 STANDARDS ESTABLISHED BY THE BOARD.

22 (C) A DRUG DONATED THROUGH THE PROGRAM MAY ONLY BE DISPENSED ON  
23 A PRESCRIPTION ISSUED BY AN AUTHORIZED PRESCRIBER.

24 (D) A PHARMACY, HOSPITAL, OR NONPROFIT CLINIC THAT ACCEPTS DONATED  
25 DRUGS SHALL:

26 (1) COMPLY WITH ALL APPLICABLE FEDERAL LAWS AND LAWS OF THIS  
27 STATE PERTAINING TO STORAGE AND DISTRIBUTION OF DANGEROUS DRUGS; AND

28 (2) INSPECT ALL DRUGS BEFORE DISPENSING TO DETERMINE THAT THE  
29 DRUGS ARE NOT ADULTERATED.

30 (E) THE PHARMACY, HOSPITAL, OR NONPROFIT CLINIC MAY CHARGE  
31 INDIVIDUALS RECEIVING DONATED DRUGS A HANDLING FEE ESTABLISHED IN  
32 ACCORDANCE WITH REGULATIONS ADOPTED BY THE BOARD.

33 (F) DRUGS DONATED TO THE PROGRAM MAY NOT BE RESOLD.

1 12-6B-06.

2 (A) THIS SECTION APPLIES TO:

3 (1) THE BOARD;

4 (2) THE SECRETARY OF HEALTH AND MENTAL HYGIENE;

5 (3) ANY PERSON THAT DONATES DRUGS TO THE PROGRAM; AND

6 (4) ANY PHARMACY, HOSPITAL, NONPROFIT CLINIC, OR HEALTH CARE  
7 PRACTITIONER THAT ACCEPTS OR DISPENSES DRUGS UNDER THE PROGRAM.

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

11 (1) CRIMINAL PROSECUTION;

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

14 (3) DISCIPLINARY ACTION BY A PROFESSIONAL LICENSING BOARD.

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 12-6B-07.

23 (A) ON OR BEFORE OCTOBER 1, 2006, AND IN CONSULTATION WITH THE  
24 SECRETARY, THE BOARD SHALL ADOPT REGULATIONS GOVERNING THE PROGRAM.

25 (B) THE REGULATIONS SHALL ESTABLISH:

26 (1) PARTICIPATION REQUIREMENTS FOR PHARMACIES, HOSPITALS, AND  
27 NONPROFIT CLINICS TO ACCEPT AND DISPENSE DONATED DRUGS UNDER THE  
28 PROGRAM;

29 (2) STANDARDS AND PROCEDURES FOR ACCEPTING, SAFELY STORING,  
30 AND DISPENSING DONATED DRUGS;

31 (3) STANDARDS AND PROCEDURES FOR INSPECTING DONATED DRUGS  
32 TO DETERMINE THAT:

33 (I) THE ORIGINAL UNIT DOSE PACKAGING IS SEALED AND  
34 TAMPER-EVIDENT; AND

1 (II) THE DRUGS ARE UNADULTERATED, SAFE, AND SUITABLE FOR  
2 DISPENSING;

3 (4) ELIGIBILITY STANDARDS BASED ON ECONOMIC NEED FOR  
4 INDIVIDUALS TO RECEIVE DRUGS;

5 (5) A MEANS, SUCH AS AN IDENTIFICATION CARD, BY WHICH AN  
6 INDIVIDUAL WHO IS ELIGIBLE TO RECEIVE DONATED DRUGS MAY DEMONSTRATE  
7 ELIGIBILITY TO THE PHARMACY, HOSPITAL, OR NONPROFIT CLINIC DISPENSING THE  
8 DRUGS;

9 (6) A FORM THAT AN INDIVIDUAL RECEIVING A DRUG FROM THE  
10 PROGRAM MUST SIGN BEFORE RECEIVING THE DRUG TO CONFIRM THAT THE  
11 INDIVIDUAL UNDERSTANDS THE IMMUNITY PROVISIONS OF THE PROGRAM;

12 (7) A FORMULA TO DETERMINE THE AMOUNT OF A HANDLING FEE THAT  
13 PHARMACIES, HOSPITALS, AND NONPROFIT CLINICS MAY CHARGE TO DRUG  
14 RECIPIENTS TO COVER RESTOCKING AND DISPENSING COSTS;

15 (8) (I) A LIST OF DRUGS THAT THE REPOSITORY WILL ACCEPT;

16 (II) A LIST OF DRUGS THAT THE REPOSITORY WILL NOT ACCEPT,  
17 INCLUDING A STATEMENT AS TO WHY THE DRUG IS INELIGIBLE FOR DONATION; AND

18 (III) FOR AN INDIVIDUAL DONOR, A FORM EACH DONOR MUST SIGN  
19 STATING THAT THE DONOR IS THE OWNER OF THE DRUGS AND INTENDS TO  
20 VOLUNTARILY DONATE THEM TO THE PROGRAM; AND

21 (9) ANY OTHER STANDARDS AND PROCEDURES THE BOARD CONSIDERS  
22 APPROPRIATE.

23 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take  
24 effect October 1, 2005.