

ENROLLED BILL

-- Health and Government Operations/Finance --

Introduced by ~~Delegate Hammen~~ **Delegates Hammen, Benson, Boteler, Boutin, Bromwell, Costa, Donoghue, Elliott, Frank, Hurson, Kach, Kullen, Mandel, Morhaim, Murray, Nathan-Pulliam, Oaks, Pendergrass, Rudolph, V. Turner, and Weldon**

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.

Speaker.

CHAPTER _____

1 AN ACT concerning

2 **Task Force on the Establishment of a Prescription Drug Repository**
3 **Program**

4 FOR the purpose of ~~requiring the State Board of Pharmacy to establish a Prescription~~
5 ~~Drug Repository Program to accept and dispense prescription drugs donated for~~
6 ~~the purpose of dispensing to certain individuals; providing that the Program~~
7 ~~may only accept and dispense drugs in certain unit dose packaging; providing~~
8 ~~for a certain exception; prohibiting the Program from accepting or dispensing~~
9 ~~drugs that bear a certain expiration date or may be adulterated; authorizing any~~
10 ~~person to donate prescription drugs to the Program; specifying that drugs may~~
11 ~~only be donated to certain entities that participate in the Program; requiring an~~
12 ~~entity that seeks to participate in the Program to apply to the Board in the form~~
13 ~~and manner required in regulation; specifying the persons who can receive~~
14 ~~drugs donated through the Program; requiring a drug donated through the~~

1 Program to be dispensed through a prescription issued by an authorized
 2 prescriber; requiring an entity that accepts donated drugs to comply with
 3 certain laws and conduct a certain inspection; authorizing an entity to charge a
 4 handling fee to individuals receiving donated drugs; prohibiting drugs donated
 5 to the Program from being resold; prohibiting for certain matters a certain
 6 person who acts in good faith from being subject to certain prosecution, liability,
 7 or disciplinary action; requiring the Board to adopt certain regulations on or
 8 before a certain date; requiring the regulations to establish certain items;
 9 defining certain terms; and generally relating to a Prescription Drug Repository
 10 Program in the State Board of Pharmacy establishing a Task Force on the
 11 Establishment of a Prescription Drug Repository Program; providing for the
 12 composition, chair, staffing, and duties of the Task Force; requiring the Task
 13 Force to submit a report to the Governor and the General Assembly on or before
 14 a certain date; providing for the termination of this Act; and generally relating
 15 to a Task Force on the Establishment of a Prescription Drug Repository
 16 Program.

17 ~~BY adding to~~
 18 ~~Article Health Occupations~~
 19 ~~Section 12-6B-01 through 12-6B-07 to be under the new subtitle "Subtitle 6B-~~
 20 ~~Prescription Drug Repository Program"~~
 21 ~~Annotated Code of Maryland~~
 22 ~~(2000 Replacement Volume and 2004 Supplement)~~

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

25 **~~Article Health Occupations~~**

26 **~~SUBTITLE 6B. PRESCRIPTION DRUG REPOSITORY PROGRAM.~~**

27 ~~12-6B-01.~~

28 (A) ~~IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS~~
 29 ~~INDICATED.~~

30 (B) ~~"HEALTH CARE FACILITY" MEANS:~~

31 (1) ~~A HOSPITAL;~~

32 (2) ~~A HOSPICE CARE PROGRAM;~~

33 (3) ~~A NURSING HOME;~~

34 (4) ~~A HOME HEALTH AGENCY;~~

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

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

3 (7) AN ASSISTED LIVING PROGRAM.

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

6 (D) "NONPROFIT CLINIC" MEANS A PUBLIC OR PRIVATE NONPROFIT
7 ORGANIZATION THAT PROVIDES PRIMARY OR SPECIALTY OUTPATIENT HEALTH CARE
8 SERVICES TO INDIGENT AND UNINSURED INDIVIDUALS FOR FREE OR AT REDUCED
9 COST.

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

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

13 ~~12-6B-02.~~

14 THE BOARD SHALL ESTABLISH A PRESCRIPTION DRUG REPOSITORY PROGRAM
15 TO ACCEPT AND DISPENSE PRESCRIPTION DRUGS DONATED FOR THE PURPOSE OF
16 DISPENSING TO INDIVIDUALS WHO ARE RESIDENTS OF THE STATE AND MEET
17 ELIGIBILITY REQUIREMENTS ESTABLISHED BY THE BOARD.

18 ~~12-6B-03.~~

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

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

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

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

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

30 ~~12-6B-04.~~

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

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

1 ~~12-6B-05.~~

2 (A) ~~A PHARMACY, HOSPITAL, OR NONPROFIT CLINIC SEEKING TO~~
3 ~~PARTICIPATE IN THE PROGRAM SHALL APPLY TO THE BOARD IN THE FORM AND~~
4 ~~MANNER REQUIRED BY THE BOARD IN REGULATION.~~

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

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

11 (D) ~~A PHARMACY, HOSPITAL, OR NONPROFIT CLINIC THAT ACCEPTS DONATED~~
12 ~~DRUGS SHALL:~~

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

15 (2) ~~INSPECT ALL DRUGS BEFORE DISPENSING TO DETERMINE THAT THE~~
16 ~~DRUGS ARE NOT ADULTERATED.~~

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

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

21 ~~12-6B-06.~~

22 (A) ~~THIS SECTION APPLIES TO:~~

23 (1) ~~THE BOARD;~~

24 (2) ~~THE SECRETARY OF HEALTH AND MENTAL HYGIENE;~~

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

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

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

31 (1) ~~CRIMINAL PROSECUTION;~~

32 (2) ~~LIABILITY IN TORT OR OTHER CIVIL ACTION FOR INJURY, DEATH, OR~~
33 ~~LOSS TO PERSON OR PROPERTY; OR~~

1 (3) ~~DISCIPLINARY ACTION BY A PROFESSIONAL LICENSING BOARD.~~

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

9 ~~42-6B-07.~~

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

12 (B) ~~THE REGULATIONS SHALL ESTABLISH:~~

13 (1) ~~PARTICIPATION REQUIREMENTS FOR PHARMACIES, HOSPITALS, AND~~
14 ~~NONPROFIT CLINICS TO ACCEPT AND DISPENSE DONATED DRUGS UNDER THE~~
15 ~~PROGRAM;~~

16 (2) ~~STANDARDS AND PROCEDURES FOR ACCEPTING, SAFELY STORING,~~
17 ~~AND DISPENSING DONATED DRUGS;~~

18 (3) ~~STANDARDS AND PROCEDURES FOR INSPECTING DONATED DRUGS~~
19 ~~TO DETERMINE THAT:~~

20 (I) ~~THE ORIGINAL UNIT DOSE PACKAGING IS SEALED AND~~
21 ~~TAMPER EVIDENT; AND~~

22 (II) ~~THE DRUGS ARE UNADULTERATED, SAFE, AND SUITABLE FOR~~
23 ~~DISPENSING;~~

24 (4) ~~ELIGIBILITY STANDARDS BASED ON ECONOMIC NEED FOR~~
25 ~~INDIVIDUALS TO RECEIVE DRUGS;~~

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

30 (6) ~~A FORM THAT AN INDIVIDUAL RECEIVING A DRUG FROM THE~~
31 ~~PROGRAM MUST SIGN BEFORE RECEIVING THE DRUG TO CONFIRM THAT THE~~
32 ~~INDIVIDUAL UNDERSTANDS THE IMMUNITY PROVISIONS OF THE PROGRAM;~~

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

36 (8) (4) ~~A LIST OF DRUGS THAT THE REPOSITORY WILL ACCEPT;~~

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

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

6 (9) ANY OTHER STANDARDS AND PROCEDURES THE BOARD CONSIDERS
7 APPROPRIATE.

8 (a) There is a Task Force on the Establishment of a Prescription Drug
9 Repository Program.

10 (b) The Task Force consists of the following members:

11 (1) two members of the Senate of Maryland, appointed by the President
12 of the Senate;

13 (2) two members of the House of Delegates, appointed by the Speaker of
14 the House;

15 (3) the Secretary of Health and Mental Hygiene, or the Secretary's
16 designee;

17 (4) the Executive Director of the State Board of Pharmacy, or the
18 Executive Director's designee;

19 (5) the Executive Director of the Maryland Health Insurance Plan, or the
20 Executive Director's designee; and one representative of the Board of Directors for the
21 Maryland Health Insurance Plan, as determined by the Chairman of the Board of
22 Directors;

23 (4) one representative of the State Board of Pharmacy, as determined by
24 the President of the State Board of Pharmacy;

25 (5) the following two members, appointed by the Secretary of Health and
26 Mental Hygiene:

27 (i) one representative of the Maryland Medical Assistance Program
28 in the Department of Health and Mental Hygiene; and

29 (ii) one representative of the Office of Health Care Quality in the
30 Department of Health and Mental Hygiene; and

31 (6) the following ~~six~~ eight members, appointed by the Governor:

32 (i) one representative of the American Cancer Society;

33 (ii) one hospital representative;

34 (iii) one nursing home representative;

- 1 (iv) one representative of a community health center;
 2 (v) one pharmacy representative; ~~and~~
 3 (vi) one representative of the Medbank Program;
 4 (vii) one representative of the pharmaceutical industry; and
 5 (viii) one representative of the University of Maryland School of
 6 Pharmacy.

7 (c) The members shall elect a chair from among the members.

8 (d) The Department of Health and Mental Hygiene shall provide staff for the
 9 Task Force.

10 (e) A member of the Task Force may not receive compensation.

11 (f) The Task Force shall:

12 (1) study and make recommendations regarding the establishment of a
 13 Prescription Drug Repository Program in the State, including:

- 14 (i) types of drugs that may be donated to the Program;
 15 (ii) types of drugs that may not be donated to the Program;
 16 (iii) who may donate drugs to the Program;
 17 (iv) entities that may receive drugs for distribution;
 18 (v) standards and procedures for accepting, storing, and dispensing
 19 donated drugs;
 20 (vi) eligibility requirements for individuals wishing to receive
 21 donated drugs;
 22 (vii) standards and procedures for inspecting donated drugs;
 23 (viii) the appropriate entity to operate the Program;
 24 (ix) liability issues;
 25 (x) fees; and
 26 (xi) any other matter relating to the establishment of a Prescription
 27 Drug Repository Program; and

28 (2) report its findings and recommendations to the Governor and, in
 29 accordance with § 2-1246 of the State Government Article, the General Assembly, on
 30 or before January 1, 2006.

1 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take
2 effect ~~October~~ July 1, 2005. It shall remain effective for a period of 1 year and, at the
3 end of June 30, 2006, with no further action required by the General Assembly, this
4 Act shall be abrogated and of no further force and effect.