
By: **Delegates Rudolph, Bromwell, Conway, and Donoghue**

Introduced and read first time: February 11, 2005

Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

2 **Cancer Drug Repository Program**

3 FOR the purpose of requiring the State Board of Pharmacy to establish a Cancer
 4 Drug Repository Program under which any person may donate a cancer drug
 5 and certain supplies for use by 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 Cancer 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 Cancer 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:

1

Article - Health Occupations

2

SUBTITLE 6B. CANCER DRUG REPOSITORY PROGRAM.

3 12-6B-01.

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

6 (B) "CANCER DRUG" MEANS A PRESCRIPTION DRUG THAT IS USED TO TREAT:

7 (1) CANCER;

8 (2) THE SIDE EFFECTS OF CANCER; OR

9 (3) THE SIDE EFFECTS OF ANY PRESCRIPTION DRUG THAT IS USED TO
10 TREAT CANCER OR THE SIDE EFFECTS OF CANCER.

11 (C) "HEALTH CARE FACILITY" MEANS:

12 (1) A HOSPITAL;

13 (2) A HOSPICE CARE PROGRAM;

14 (3) A NURSING HOME; OR

15 (4) A HOME HEALTH AGENCY.

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

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

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

24 (G) "PROGRAM" MEANS THE CANCER DRUG REPOSITORY PROGRAM.

25 12-6B-02.

26 THE BOARD SHALL ESTABLISH A CANCER DRUG REPOSITORY PROGRAM UNDER
27 WHICH ANY PERSON MAY DONATE A CANCER DRUG OR SUPPLIES NEEDED TO
28 ADMINISTER A CANCER DRUG FOR USE BY AN INDIVIDUAL WHO IS A RESIDENT OF
29 THE STATE AND MEETS ELIGIBILITY REQUIREMENTS ESTABLISHED BY THE BOARD.

1 12-6B-03.

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

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

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

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

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

13 12-6B-04.

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

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

18 12-6B-05.

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

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

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

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

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

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

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

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

5 12-6B-06.

6 (A) THIS SECTION APPLIES TO:

7 (1) THE BOARD;

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

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

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

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

15 (1) CRIMINAL PROSECUTION;

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

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

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

26 12-6B-07.

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

29 (B) THE REGULATIONS SHALL ESTABLISH:

30 (1) PARTICIPATION REQUIREMENTS FOR PHARMACIES, HOSPITALS, AND
31 NONPROFIT CLINICS TO ACCEPT AND DISPENSE DONATED DRUGS UNDER THE
32 PROGRAM;

33 (2) STANDARDS AND PROCEDURES FOR ACCEPTING, SAFELY STORING,
34 AND DISPENSING DONATED DRUGS;

1 (3) STANDARDS AND PROCEDURES FOR INSPECTING DONATED DRUGS
2 TO DETERMINE THAT:

3 (I) THE ORIGINAL UNIT DOSE PACKAGING IS SEALED AND
4 TAMPER-EVIDENT; AND

5 (II) THE DRUGS ARE UNADULTERATED, SAFE, AND SUITABLE FOR
6 DISPENSING;

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

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

13 (6) A FORM THAT AN INDIVIDUAL RECEIVING A DRUG FROM THE
14 PROGRAM MUST SIGN BEFORE RECEIVING THE DRUG TO CONFIRM THAT THE
15 INDIVIDUAL UNDERSTANDS THE IMMUNITY PROVISIONS OF THE PROGRAM;

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

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

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

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

25 (9) ANY OTHER STANDARDS AND PROCEDURES THE BOARD CONSIDERS
26 APPROPRIATE.

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