

HB1310/543122/1

BY: Finance Committee

AMENDMENTS TO HOUSE BILL 1310  
(Third Reading File Bill)

AMENDMENT NO. 1

On page 1, in line 2, strike “~~Out-of-State Pharmacies~~” and substitute “Revisions”; strike beginning with “defining” in line 3 down through “Program” in line 5 and substitute “altering the Prescription Drug Repository Program, including by allowing certain entities located in another state to participate in the Program as drop-off sites and repositories, including over-the-counter drugs under the Program, and altering the individuals who are eligible to receive drugs or medical supplies under the Program; altering the persons for whom and the activities with respect to which certain immunity is provided under the Program”; in line 9, after “15-601” insert “through 15-609”; and strike in their entirety lines 12 through 16, inclusive.

AMENDMENT NO. 2

On page 2, in line 3, after “(c)” insert ““DISPENSE” MEANS TO PROVIDE:

**(1) A PRESCRIPTION DRUG OR MEDICAL SUPPLY IN ACCORDANCE WITH A PRESCRIPTION; OR**

**(2) AN OVER-THE-COUNTER DRUG OR MEDICAL SUPPLY.**

**(D)**”;

in the same line, strike “or” and substitute a comma; in the same line, after “facility” insert “, OR OTHER ENTITY PARTICIPATING IN A DRUG DONATION OR REPOSITORY PROGRAM AND”; in line 5, after “drugs” insert “, OVER-THE-COUNTER DRUGS,”; in line 6, strike “and”; in line 7, after “(2)” insert “IS LOCATED WITHIN THE STATE OR IN ANOTHER STATE; AND

**(3)**;

strike in their entirety lines 9 and 10; in line 11, after “(E)” insert “**“ELIGIBLE PATIENT” MEANS AN INDIVIDUAL WHO, THROUGH SELF-ATTESTATION, IS INDIGENT, UNINSURED, UNDERINSURED, OR ENROLLED IN A PUBLIC HEALTH BENEFITS PROGRAM.**”

**(F)**;

in line 12, strike “(F)” and substitute “(G)”; in line 13, strike “Does” and substitute “**“IF THE LICENSED PHARMACY IS LOCATED IN THE STATE, DOES”**”; strike beginning with “OR,” in line 14 down through “AUTHORITY” in line 15; in line 16, strike “and”; in line 17, after “(3)” insert “**“IS LOCATED IN THE STATE OR IN ANOTHER STATE; AND**”

**(4)**;

in lines 18, 20, and 22, in each instance, after “drugs” insert “**“, OVER-THE-COUNTER DRUGS,”**”; in lines 21 and 23, in each instance, strike “needy individuals” and substitute “**“ELIGIBLE PATIENTS”**”; after line 23, insert:

**“(H) “TAMPER-EVIDENT PACKAGING” MEANS A PACKAGING SYSTEM THAT:**

**(1) MAY INVOLVE AN IMMEDIATE-CONTAINER AND CLOSURE SYSTEM, SECONDARY-CONTAINER OR CARTON SYSTEM, TERTIARY-CONTAINER SYSTEM, OR OTHER COMBINATION OF SYSTEMS INTENDED TO PROVIDE A VISUAL INDICATION OF PACKAGE INTEGRITY;**

**(2) MAY CONTAIN UNIT-DOSE OR MULTI-DOSE CONTENTS; AND**

**(3) HAS ONE OR MORE INDICATORS OR BARRIERS TO ENTRY THAT:**

**(I) IF BREACHED OR MISSING, CAN REASONABLY BE EXPECTED TO PROVIDE VISIBLE EVIDENCE TO CONSUMERS THAT TAMPERING HAS OCCURRED; AND**

**(II) IF HANDLED IN A REASONABLE MANNER DURING MANUFACTURE, DISTRIBUTION, OR RETAIL DISPLAY, IS DESIGNED TO REMAIN INTACT.**

15-602.

(a) There is a Prescription Drug Repository Program regulated by the Board.

(b) The purpose of the Program is to:

(1) Accept prescription drugs, OVER-THE-COUNTER DRUGS, and medical supplies donated for the purpose of dispensing to [needy individuals] ELIGIBLE PATIENTS; and

(2) Accept prescription drugs, OVER-THE-COUNTER DRUGS, and medical supplies returned to a pharmacy for the purpose of proper disposal.

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 AND OVER-THE-COUNTER DRUGS in their original unopened, sealed, and tamper-evident [unit dose] packaging, INCLUDING

(Over)

DRUGS THAT HAVE BEEN PACKAGED BY A MANUFACTURER OR HAVE BEEN REPACKAGED BY AN ENTITY AUTHORIZED TO REPACKAGE DRUGS IN THE STATE IN WHICH THE ENTITY IS LOCATED; and

(2) Medical supplies in their original unopened and sealed packaging.

(b) The Program may accept and dispense prescription drugs AND OVER-THE-COUNTER DRUGS packaged in single unit doses when the outside packaging is opened if the single unit dose packaging is undisturbed.

(c) (1) The Program may not accept prescription drugs, OVER-THE-COUNTER DRUGS, or medical supplies for dispensing that:

[1] (I) [Bear] EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION, BEAR an expiration date that is less than 90 days from the date the drug is donated;

[2] (II) May be adulterated, according to the standards of § 21-216 of this article; or

[3] (III) Belong to a category of unacceptable drugs established under § 15-608(b)(1) of this subtitle.

(2) (I) THE PROGRAM MAY ACCEPT PRESCRIPTION DRUGS AND OVER-THE-COUNTER DRUGS THAT BEAR AN EXPIRATION DATE THAT IS LESS THAN 90 DAYS FROM THE DATE THE DRUG IS DONATED IF THE PRESCRIPTION DRUG OR OVER-THE-COUNTER DRUG IS IN HIGH DEMAND.

(II) IF THE PROGRAM ACCEPTS A PRESCRIPTION DRUG OR OVER-THE-COUNTER DRUG UNDER SUBPARAGRAPH (I) OF THIS PARAGRAPH,

THE PROGRAM MAY NOT DISPENSE THE PRESCRIPTION DRUG OR OVER-THE-COUNTER DRUG IF THE EXPIRATION DATE OCCURS DURING THE TIME PERIOD FOR WHICH THE PRESCRIPTION DRUG OR OVER-THE-COUNTER DRUG IS PRESCRIBED.

15-604.

(a) (1) Any person may donate prescription drugs, OVER-THE-COUNTER DRUGS, or medical supplies to the Program.

(2) THE PROGRAM MAY RECEIVE DONATED PRESCRIPTION DRUGS, OVER-THE-COUNTER DRUGS, OR MEDICAL SUPPLIES FROM ANY PERSON.

(b) Prescription drugs, OVER-THE-COUNTER DRUGS, or medical supplies may be donated only [at] TO a drop-off site designated for that purpose by the Board.

(c) A drop-off site LOCATED IN THE STATE shall:

(1) Require a donor to complete and sign a donor form releasing the prescription drugs, OVER-THE-COUNTER DRUGS, or medical supplies to the Program;

(2) Store donated prescription drugs, OVER-THE-COUNTER 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, OVER-THE-COUNTER DRUGS, and medical supplies to a [central] repository.

(d) A drop-off site LOCATED IN THE STATE may not:

(Over)

(1) Dispense donated prescription drugs, ~~OVER-THE-COUNTER DRUGS~~, or medical supplies;

(2) Resell prescription drugs, ~~OVER-THE-COUNTER DRUGS~~, or medical supplies donated to the Program; or

(3) Charge a fee for accepting a donation.

**(E) CONSISTENT WITH ITS APPROVAL BY THE BOARD, AN ENTITY LOCATED IN ANOTHER STATE:**

**(1) MAY PARTICIPATE IN THE PROGRAM AS A DROP-OFF SITE; AND**

**(2) MAY ACCEPT DONATED PRESCRIPTION DRUGS, ~~OVER-THE-COUNTER DRUGS~~, AND MEDICAL SUPPLIES FROM A PERSON, UNLESS OTHERWISE PROHIBITED BY FEDERAL LAW OR THE LAWS OF THE STATE IN WHICH THE ENTITY IS LOCATED.**”;

in line 25, strike “Medbank of Maryland, Inc., or another” and substitute “A”; in line 26, strike the comma; and in line 27, after “repository” insert “LOCATED IN THE STATE”.

On page 3, in lines 1 and 3, in each instance, after “drugs” insert “, ~~OVER-THE-COUNTER DRUGS~~”; in lines 4 and 8, in each instance, strike “needy individuals” and substitute “ELIGIBLE PATIENTS”; in lines 5, 7, 9, 11, 16, and 18, in each instance, after “drugs” insert “, ~~OVER-THE-COUNTER DRUGS~~,”; in line 17, after “dispensed” insert “OR OTHERWISE PROVIDED TO THE PATIENT”; in lines 18 and 27, in each instance, after “repository” insert “LOCATED IN THE STATE”; in line 20, strike “§ 15-606” and substitute “§ 15-606(A)”; in lines 28 and 30, in each instance, after “drug” insert “, ~~OVER-THE-COUNTER DRUG~~,”; and strike beginning with the third comma in line 30 down through “entailed” in line 31.

On page 4, in line 2, after “drug” insert “, OVER-THE-COUNTER DRUG,”; in line 3, after “drugs” insert “, OVER-THE-COUNTER DRUGS,”; in line 6, after “(g)” insert “CONSISTENT WITH ITS APPROVAL BY THE BOARD, AN ENTITY LOCATED IN ANOTHER STATE:”

(1) MAY PARTICIPATE IN THE PROGRAM AS A REPOSITORY; AND

(2) SHALL DISPENSE DONATED PRESCRIPTION DRUGS, OVER-THE-COUNTER DRUGS, AND MEDICAL SUPPLIES TO RESIDENTS OF THE STATE ONLY IN ACCORDANCE WITH:

(i) FEDERAL LAW;

(ii) LAWS OF THE STATE IN WHICH THE ENTITY IS LOCATED PERTAINING TO STORAGE AND DISTRIBUTION OF PRESCRIPTION DRUGS, OVER-THE-COUNTER DRUGS, AND MEDICAL SUPPLIES; AND

(iii) STATE LAWS PERTAINING TO NONRESIDENT PHARMACIES.

(H)”;

in line 8, strike “(h)” and substitute “(I)”; in line 11, strike “the” and substitute “A”; after line 11, insert:

“(J) A PERSON DONATING, TRANSFERRING, OR RECEIVING PRESCRIPTION DRUGS, OVER-THE-COUNTER DRUGS, AND MEDICAL SUPPLIES, OR FACILITATING THE DONATION, TRANSFER, OR RECEIPT, IN ACCORDANCE

(Over)

WITH THIS SUBTITLE MAY NOT BE REQUIRED TO HOLD A WHOLESALE DISTRIBUTION LICENSE.

(K) A REPOSITORY LOCATED IN ANOTHER STATE OPERATING PRIMARILY FOR THE PURPOSE OF PARTICIPATING IN A DRUG DONATION OR REPOSITORY PROGRAM MAY NOT BE REQUIRED TO POSSESS A COMPREHENSIVE OR MINIMUM SUPPLY OF PRESCRIPTION DRUGS, OVER-THE-COUNTER DRUGS, OR MEDICAL SUPPLIES.

(L) A REPOSITORY LOCATED IN THE STATE MAY TRANSFER DONATED PRESCRIPTION DRUGS, OVER-THE-COUNTER DRUGS, AND MEDICAL SUPPLIES TO:

(1) ANOTHER REPOSITORY LOCATED IN THE STATE; OR

(2) A DROP-OFF SITE LOCATED IN ANOTHER STATE, A REPOSITORY LOCATED IN ANOTHER STATE, OR ANOTHER ENTITY LOCATED IN ANOTHER STATE THAT PARTICIPATES IN A DRUG DONATION OR REPOSITORY PROGRAM IN ACCORDANCE WITH THE LAWS OF THE STATE IN WHICH THE ENTITY IS LOCATED ONLY IF THERE IS NO NEED FOR THE DONATED PRESCRIPTION DRUGS, OVER-THE-COUNTER DRUGS, OR MEDICAL SUPPLIES FOR USE BY ELIGIBLE PATIENTS IN THE STATE, AS DETERMINED BY THE TRANSFERRING REPOSITORY.

(M) UNLESS OTHERWISE PROHIBITED BY FEDERAL LAW OR THE LAWS OF THE STATE IN WHICH IT IS LOCATED, A DROP-OFF SITE OR REPOSITORY LOCATED IN ANOTHER STATE MAY PERFORM AND RECEIVE:



**(1) INTRACOMPANY TRANSFERS OF DONATED PRESCRIPTION DRUGS, OVER-THE-COUNTER DRUGS, AND MEDICAL SUPPLIES; AND**

**(2) TRANSFERS OF DONATED PRESCRIPTION DRUGS, OVER-THE-COUNTER DRUGS, AND MEDICAL SUPPLIES FROM DROP-OFF SITES LOCATED IN ANOTHER STATE, REPOSITORIES LOCATED IN ANOTHER STATE, OR OTHER ENTITIES PARTICIPATING IN A DRUG DONATION OR REPOSITORY PROGRAM IN ACCORDANCE WITH THE LAWS OF THE STATE IN WHICH THE ENTITY IS LOCATED.**

15-606.

**(A) To be eligible to receive donated prescription drugs, OVER-THE-COUNTER DRUGS, or medical supplies FROM A REPOSITORY LOCATED IN THE STATE, an individual [shall] MUST:**

**(1) Be a resident of the State; and**

**(2) Be [a needy] AN ELIGIBLE patient[, as indicated by the individual's health care practitioner].**

**(B) TO BE ELIGIBLE TO RECEIVE DONATED PRESCRIPTION DRUGS, OVER-THE-COUNTER DRUGS, OR MEDICAL SUPPLIES FROM A REPOSITORY LOCATED IN ANOTHER STATE, AN INDIVIDUAL MUST BE AN ELIGIBLE PATIENT.”;**

in lines 14 and 21, in each instance, after “drugs” insert “, OVER-THE-COUNTER DRUGS,”; in line 18, strike “and”; in line 19, after “Pharmacists” insert “;

**(6) PHARMACY TECHNICIANS; AND**

(Over)

**(7) STAFF EMPLOYED BY OR VOLUNTEERING FOR AN ENTITY PARTICIPATING IN THE PROGRAM**;

in line 20, after “accepting,” insert “**TRANSFERRING,**”; in line 21, after “Program,” insert “**OR FACILITATING THE DONATION, ACCEPTANCE, TRANSFER, DISPOSITION OF, OR DISPENSING,**”; and after line 31, insert:

“15-608.

(a) On or before January 1, 2007, and in consideration of the recommendations of the Task Force on the Establishment of a Prescription Drug Repository Program, the Board shall adopt regulations governing the Program.

(b) The regulations shall include:

(1) Categories of drugs that a repository will not accept, including a statement as to why the drug is ineligible for donation;

(2) A standard form each donor **DONATING TO A DROP-OFF SITE LOCATED IN THE STATE** must sign stating that the donor is the owner of the drugs and intends to voluntarily donate them to the Program;

(3) Requirements for designation of drop-off sites to accept donated prescription drugs, **OVER-THE-COUNTER DRUGS**, and medical supplies under the Program;

(4) Requirements for designation of repositories to dispense or dispose of donated prescription drugs, **OVER-THE-COUNTER DRUGS**, and medical supplies under the Program;

(5) Standards and procedures for DROP-OFF SITES AND REPOSITORIES LOCATED IN THE STATE RELATED TO accepting, safely storing, dispensing, shipping, and disposing of donated prescription drugs, OVER-THE-COUNTER DRUGS, and medical supplies;

(6) Standards and procedures for REPOSITORIES LOCATED IN THE STATE RELATED TO inspecting donated prescription drugs, OVER-THE-COUNTER 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] PRESCRIPTION DRUGS AND OVER-THE-COUNTER DRUGS ARE IN ORIGINAL UNOPENED, SEALED, AND TAMPER-EVIDENT PACKAGING, WHICH MAY INCLUDE PACKAGING PLACED BY THE MANUFACTURER AND PACKAGING PLACED BY AN ENTITY AUTHORIZED TO REPACKAGE DRUGS IN THE STATE IN WHICH THE ENTITY IS LOCATED;

(ii) The MEDICAL SUPPLIES ARE IN THEIR ORIGINAL UNOPENED AND SEALED PACKAGING; AND

(iii) THE prescription drugs, OVER-THE-COUNTER DRUGS, and medical supplies are unadulterated, safe, and suitable for dispensing;

(7) [A standard form for health care practitioners to submit to a repository to indicate a patient's need for the Program;

(Over)

~~(8)~~ A standard form that an individual receiving a prescription drug, OVER-THE-COUNTER DRUG, or medical supply from [the Program] A REPOSITORY LOCATED IN THE STATE must sign before receiving the drug or supply to confirm that the individual understands that:

(i) The individual is receiving prescription drugs, OVER-THE-COUNTER DRUGS, or medical supplies that have been donated to the Program; and

(ii) Entities involved in the Program have certain immunity from liability;

[(9) (8) Record keeping and reporting requirements for a repository LOCATED IN THE STATE; and

[(10) (9) Any other standards and procedures the Board considers appropriate FOR DROP-OFF SITES AND REPOSITORIES LOCATED IN THE STATE.”.

On page 5, in line 2, after “repository” insert “LOCATED IN THE STATE”; in line 3, after “Maintain” insert “WRITTEN OR ELECTRONIC”; in lines 3 and 9, in each instance, after “drugs” insert “, OVER-THE-COUNTER DRUGS,”; in line 8, after “repositories” insert “LOCATED IN THE STATE”; and in line 10, strike “the repository” and substitute “REPOSITORIES LOCATED IN THE STATE”.