

HOUSE BILL 1310

J1

(5lr2600)

ENROLLED BILL

— Health and Government Operations/Finance —

Introduced by **Delegate Bhandari**

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 **Prescription Drug Repository Program – ~~Out of State Pharmacies~~ Revisions**

3 FOR the purpose of ~~defining “licensed pharmacy” for the purpose of allowing pharmacies~~
4 ~~licensed in another state to be designated by the State Board of Pharmacy as a~~
5 ~~repository under the Prescription Drug Repository Program~~ altering the Prescription
6 Drug Repository Program, including by allowing certain entities located in another
7 state to participate in the Program as drop-off sites and repositories, including
8 over-the-counter drugs under the Program, and altering the individuals who are
9 eligible to receive drugs or medical supplies under the Program; altering the persons
10 for whom and the activities with respect to which certain immunity is provided under
11 the Program; and generally relating to the Prescription Drug Repository Program.

12 BY repealing and reenacting, with amendments,

13 Article – Health – General

14 Section 15–601 through 15–609

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.

Italics indicate opposite chamber/conference committee amendments.



Annotated Code of Maryland
(2023 Replacement Volume and 2024 Supplement)

~~BY repealing and reenacting, without amendments,
Article – Health – General
Section 15–605, 15–607, and 15–609
Annotated Code of Maryland
(2023 Replacement Volume and 2024 Supplement)~~

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

Article – Health – General

15–601.

(a) In this subtitle the following words have the meanings indicated.

(b) “Board” means the State Board of Pharmacy.

(c) **“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) “Drop–off site” means a pharmacy or, other health care facility, OR OTHER
ENTITY PARTICIPATING IN A DRUG DONATION OR REPOSITORY PROGRAM AND
designated by the Board that:**

**(1) Has voluntarily agreed to accept donated prescription drugs,
OVER–THE–COUNTER DRUGS, or medical supplies; and**

(2) IS LOCATED WITHIN THE STATE OR IN ANOTHER STATE; AND

**(3) Does not have a final disciplinary order issued against it by a health
occupations board.**

~~**(D) “LICENSED PHARMACY” MEANS A PHARMACY LICENSED BY THE BOARD
OR A PHARMACY LICENSED IN ANOTHER STATE.**~~

**[(d)] (E) “ELIGIBLE PATIENT” MEANS AN INDIVIDUAL WHO, THROUGH
SELF–ATTESTATION, IS INDIGENT, UNINSURED, UNDERINSURED, OR ENROLLED IN A
PUBLIC HEALTH BENEFITS PROGRAM.**

(F) “Program” means the Prescription Drug Repository Program.

[(e)] ~~(F)~~ (G) “Repository” means a licensed pharmacy that:

(1) ~~Does~~ IF THE LICENSED PHARMACY IS LOCATED IN THE STATE, DOES not have a final disciplinary order issued against it by the Board of Pharmacy ~~OR, FOR AN OUT OF STATE LICENSED PHARMACY, THE APPLICABLE REGULATORY AUTHORITY;~~

(2) Has voluntarily agreed to participate in the Program; ~~and~~

(3) IS LOCATED IN THE STATE OR IN ANOTHER STATE; AND

(4) Has been approved by the Board to:

(i) Accept donated prescription drugs, OVER-THE-COUNTER DRUGS, or medical supplies from a designated drop-off site;

(ii) Dispense the donated prescription drugs, OVER-THE-COUNTER DRUGS, or medical supplies to ~~needy individuals~~ ELIGIBLE PATIENTS; or

(iii) Dispose of prescription drugs, OVER-THE-COUNTER DRUGS, or medical supplies not accepted for dispensing to ~~needy individuals~~ ELIGIBLE PATIENTS.

(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.

1 15-602.

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

3 (b) The purpose of the Program is to:

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

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

9 15-603.

10 (a) Except as provided in subsection (b) of this section, the Program may accept for
11 the purpose of dispensing only:

12 (1) Prescription drugs ~~AND OVER-THE-COUNTER DRUGS~~ in their
13 original unopened, sealed, and tamper-evident [unit dose] packaging, **INCLUDING DRUGS**
14 **THAT HAVE BEEN PACKAGED BY A MANUFACTURER OR HAVE BEEN REPACKAGED BY**
15 **AN ENTITY AUTHORIZED TO REPACKAGE DRUGS IN THE STATE IN WHICH THE ENTITY**
16 **IS LOCATED; and**

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

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

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

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

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

28 [(3)] (III) Belong to a category of unacceptable drugs established under §
29 15-608(b)(1) of this subtitle.

30 (2) (I) **THE PROGRAM MAY ACCEPT PRESCRIPTION DRUGS AND**
31 **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:

(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.

15-605.

(a) The Board may approve ~~Medbank of Maryland, Inc., or another~~ A licensed pharmacy, to be a repository.

(b) Consistent with its approval by the Board, a repository LOCATED IN THE STATE shall:

(1) Accept only donated prescription drugs, OVER-THE-COUNTER DRUGS, and medical supplies forwarded by designated drop-off sites;

(2) Inspect all donated prescription drugs, OVER-THE-COUNTER DRUGS, and medical supplies;

(3) Accept for dispensing to ~~needy individuals~~ ELIGIBLE PATIENTS only those donated prescription drugs, OVER-THE-COUNTER DRUGS, and medical supplies that meet the requirements of § 15-603 of this subtitle;

(4) Dispose of donated prescription drugs, OVER-THE-COUNTER DRUGS, and medical supplies not accepted for dispensing to ~~needy individuals~~ ELIGIBLE PATIENTS in accordance with State and federal law;

(5) Maintain a separate inventory of donated prescription drugs, OVER-THE-COUNTER DRUGS, and medical supplies;

(6) Store donated prescription drugs, OVER-THE-COUNTER DRUGS, and medical supplies in a secure location used exclusively for the Program;

(7) Maintain separate prescription files for patients receiving donated prescription drugs and medical supplies; and

(8) Obliterate from the labels of donated prescription drugs and medical supplies any information specific to the patient for whom the donated prescription drugs, OVER-THE-COUNTER DRUGS, and medical supplies were originally dispensed OR OTHERWISE PROVIDED TO THE PATIENT.

(c) A repository LOCATED IN THE STATE shall dispense donated prescription drugs, OVER-THE-COUNTER DRUGS, and medical supplies only:

(1) To an individual who meets the requirements of ~~§ 15-606~~ **§ 15-606(A)** of this subtitle;

(2) On a new prescription, in the case of a prescription drug or medical supply that requires a prescription; and

(3) In accordance with State and federal laws pertaining to:

(i) Storage, distribution, and dispensing of prescription drugs; and

(ii) Confidentiality of patient information.

(d) A repository **LOCATED IN THE STATE** may:

(1) Charge a fee, not to exceed \$10, for each prescription drug, **OVER-THE-COUNTER DRUG**, or medical supply dispensed; and

(2) Dispense a donated prescription drug, **OVER-THE-COUNTER DRUG**, or medical supply by mail, ~~provided that the repository informs the patient that a delay may be entailed.~~

(e) A repository may not establish or maintain a waiting list for any prescription drug, **OVER-THE-COUNTER DRUG**, or medical supply dispensed by the Program.

(f) A pharmacy may accept prescription drugs, **OVER-THE-COUNTER DRUGS**, and medical supplies taken to the pharmacy for disposal only if the pharmacy is approved by the Board as a repository for this purpose.

(g) **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) The Program may not require a private entity to establish, operate, or fund a drop-off site or disposal program.

~~(H)~~ (I) The Department shall develop a process for providing information about the availability of the State's earned income tax credit established under § 10-704 of the Tax – General Article to each individual receiving donated prescription drugs and medical supplies from ~~the~~ A repository.

(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 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.**

15-607.

(a) This section applies to:

**(1) A person that donates prescription drugs, OVER-THE-COUNTER
DRUGS, or medical supplies to the Program;**

(2) A drop-off site;

(3) A repository;

(4) The Board; ~~and~~

(5) Pharmacists;

(6) PHARMACY TECHNICIANS; AND

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

**(b) For matters related to donating, accepting, TRANSFERRING, disposing of, or
dispensing prescription drugs, OVER-THE-COUNTER DRUGS, or medical supplies under
the Program, OR FACILITATING THE DONATION, ACCEPTANCE, TRANSFER,
DISPOSITION OF, OR DISPENSING, a person described in subsection (a) of this section
that acts in good faith may not be subject to:**

(1) Criminal prosecution; or

(2) Liability in tort or other civil action for injury, death, or loss to person or property.

(c) A drug manufacturer acting in good faith may not be subject to criminal prosecution or liability in tort or other civil action for injury, death, or loss to person or property for matters related to the donation, acceptance, or dispensing of a drug manufactured by the drug manufacturer that is donated by any person under the Program, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug.

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

1 2. *In the case of prescription drugs, in the undisturbed single*
2 *unit dose packaging; and* **PRESCRIPTION DRUGS AND OVER-THE-COUNTER DRUGS**
3 **ARE IN ORIGINAL UNOPENED, SEALED, AND TAMPER-EVIDENT PACKAGING, WHICH**
4 **MAY INCLUDE PACKAGING PLACED BY THE MANUFACTURER AND PACKAGING PLACED**
5 **BY AN ENTITY AUTHORIZED TO REPACKAGE DRUGS IN THE STATE IN WHICH THE**
6 **ENTITY IS LOCATED;**

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

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

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

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

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

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

22 [(9)] (8) *Record keeping and reporting requirements for a repository*
23 **LOCATED IN THE STATE; and**

24 [(10)] (9) *Any other standards and procedures the Board considers*
25 *appropriate* **FOR DROP-OFF SITES AND REPOSITORIES LOCATED IN THE STATE.**

26 15-609.

27 (a) A repository **LOCATED IN THE STATE** shall:

28 (1) Maintain **WRITTEN OR ELECTRONIC** records of donated prescription
29 **drugs, OVER-THE-COUNTER DRUGS,** and medical supplies; and

30 (2) 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 LOCATED IN THE STATE;

(2) Inspect records of donated prescription drugs, ~~OVER-THE-COUNTER DRUGS~~, and medical supplies maintained by ~~the repository~~ REPOSITORIES LOCATED IN THE STATE; and

(3) Beginning January 1, 2007, and each January 1 thereafter, report to the Governor and, in accordance with § 2-1257 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 October 1, 2025.

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.