

Second Regular Session
Seventy-third General Assembly
STATE OF COLORADO

INTRODUCED

LLS NO. 22-0640.01 Brita Darling x2241

SENATE BILL 22-098

SENATE SPONSORSHIP

Rodriguez,

HOUSE SPONSORSHIP

(None),

Senate Committees
Health & Human Services

House Committees

A BILL FOR AN ACT

101 CONCERNING THE CREATION OF A PROGRAM ALLOWING FOR THE USE
102 OF DONATED UNUSED DRUGS.

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at <http://leg.colorado.gov>.)

The bill creates the Colorado drug reuse opportunity program (program). The program allows members of the public, health-care providers, pharmacies, health-care facilities, drug manufacturers, and other entities to donate prescription drugs, excluding controlled substances, and "over-the-counter" medicine (drugs) to be distributed or redispensed to Colorado residents with a prescription for such a drug or

Shading denotes HOUSE amendment. Double underlining denotes SENATE amendment.
Capital letters or bold & italic numbers indicate new material to be added to existing statute.
Dashes through the words indicate deletions from existing statute.

1 OR ANY ENTITY LEGALLY AUTHORIZED TO POSSESS DRUGS, INCLUDING A
2 WHOLESALER, A THIRD-PARTY LOGISTICS PROVIDER, A PHARMACY, AN
3 OTHER OUTLET, A PRACTITIONER, A HOSPITAL, A HOSPITAL SATELLITE
4 PHARMACY, A LICENSED FACILITY, OR A CORRECTIONAL FACILITY.

5 (b) "DONOR" INCLUDES A MANUFACTURER, A REPACKAGER, OR A
6 HEALTH-CARE FACILITY OPERATED BY THE UNITED STATES DEPARTMENT
7 OF VETERANS AFFAIRS.

8 (3) "DRUG" MEANS A PRESCRIPTION DRUG OR AN
9 OVER-THE-COUNTER MEDICATION AND SUPPLIES NEEDED TO ADMINISTER
10 A PRESCRIPTION DRUG OR OVER-THE-COUNTER MEDICATION; EXCEPT THAT
11 "DRUG" DOES NOT INCLUDE A CONTROLLED SUBSTANCE OR ANY
12 METHAMPHETAMINE PRECURSOR.

13 (4) "ELIGIBLE PATIENT" MEANS A COLORADO RESIDENT WITH A
14 PRESCRIPTION FOR A DRUG, IF A PRESCRIPTION IS REQUIRED TO DISPENSE
15 THE DRUG, OR WHO REPORTS SYMPTOMS THAT MAY BE TREATED BY AN
16 OVER-THE-COUNTER MEDICATION.

17 (5) "LICENSED FACILITY" HAS THE MEANING SET FORTH IN SECTION
18 12-280-135 (1)(b).

19 (6) "PRIORITY PATIENT" MEANS AN ELIGIBLE PATIENT WHO IS NOT
20 COVERED BY HEALTH INSURANCE, LACKS ADEQUATE HEALTH INSURANCE
21 COVERAGE, OR HAS AN INCOME THAT DOES NOT EXCEED TWO HUNDRED
22 PERCENT OF THE FEDERAL POVERTY LINE.

23 (7) "PROGRAM" MEANS THE COLORADO DRUG REUSE OPPORTUNITY
24 PROGRAM CREATED IN SECTION 12-280-703.

25 (8) "RECEIVER" MEANS ANY PERSON, INCLUDING A WHOLESALER
26 OR DISTRIBUTOR, REVERSE DISTRIBUTOR, REPACKAGER, HOSPITAL,
27 PHARMACY, OR CLINIC, THAT POSSESSES A LICENSE, REGISTRATION, OR

1 PERMIT IN THE STATE IN WHICH THE PERSON IS LOCATED, WHICH LICENSE,
2 REGISTRATION, OR PERMIT AUTHORIZES THE PERSON TO LEGALLY POSSESS
3 MEDICINE.

4 (9) "UNOPENED, TAMPER-EVIDENT PACKAGING" HAS THE MEANING
5 SET FORTH IN THE OFFICIAL COMPENDIA, CHAPTER 659, PACKAGING AND
6 STORAGE REQUIREMENTS, AND INCLUDES UNOPENED UNIT-DOSE,
7 MULTIPLE-DOSE, IMMEDIATE, SECONDARY, AND TERTIARY PACKAGING.

8 **12-280-703. Colorado drug reuse opportunity program -**
9 **creation - donated drugs - receiving, accepting, redispensing, and**
10 **administering donated drugs - eligible patients - priority patients.**

11 (1) EFFECTIVE JANUARY 1, 2023, THE COLORADO DRUG REUSE
12 OPPORTUNITY PROGRAM IS HEREBY CREATED TO PROVIDE UNUSED
13 DONATED DRUGS AT NO COST TO ELIGIBLE PATIENTS, WITH PRIORITY
14 GIVEN, TO THE EXTENT POSSIBLE, TO PRIORITY PATIENTS.

15 (2) NOTWITHSTANDING ANY LAW TO THE CONTRARY, A DONOR
16 MAY DONATE DRUGS TO A RECEIVER, AND A RECEIVER MAY RECEIVE THE
17 DONATED DRUGS. A RECEIVER MAY TAKE ONE OF THE FOLLOWING
18 ACTIONS:

19 (a) REDISPENSE OR ADMINISTER DONATED DRUGS TO ELIGIBLE
20 PATIENTS PURSUANT TO SUBSECTION (7) OF THIS SECTION;

21 (b) REPACKAGE OR REPLENISH DONATED DRUGS PURSUANT TO
22 SUBSECTION (6) OF THIS SECTION;

23 (c) FURTHER DONATE DRUGS TO ANOTHER RECEIVER PURSUANT TO
24 SUBSECTION (6) OF THIS SECTION; OR

25 (d) DISPOSE OF DONATED DRUGS PURSUANT TO SUBSECTION (5) OF
26 THIS SECTION.

27 (3) NOTHING IN THIS PART 7 REQUIRES A PHARMACY OR

1 PHARMACIST TO BE A RECEIVER UNDER THE PROGRAM.

2 (4) UPON RECEIPT OF A DRUG FROM A DONOR, A RECEIVER SHALL
3 KEEP THE DRUG IN A SEPARATE AREA DESIGNATED FOR RECEIVING
4 DONATED DRUGS UNTIL THE DRUG IS ACCEPTED INTO THE RECEIVER'S
5 INVENTORY FOR THE PROGRAM. A DONATED DRUG MAY BE ACCEPTED FOR
6 REUSE UNDER THE PROGRAM ONLY IF ALL OF THE FOLLOWING
7 REQUIREMENTS ARE MET:

8 (a) THE DRUG IS IN UNOPENED, TAMPER-EVIDENT PACKAGING OR
9 HAS BEEN REPACKAGED AS DESCRIBED IN SUBSECTION (6) OF THIS
10 SECTION;

11 (b) THE DRUG IS NOT EXPIRED;

12 (c) THE RECEIVER MAINTAINS A WRITTEN OR ELECTRONIC RECORD
13 OF THE DONATION CONSISTING OF THE NAME, STRENGTH, AND QUANTITY
14 OF EACH ACCEPTED DRUG AND THE NAME, ADDRESS, AND TELEPHONE
15 NUMBER OF THE DONOR, UNLESS A RECEIVER IS FURTHER DONATING TO A
16 RECEIVER UNDER COMMON OWNERSHIP OR COMMON CONTROL. NO OTHER
17 RECORD OF A DONATION IS REQUIRED.

18 (d) THE DONOR REMOVES OR REDACTS ANY PATIENT NAME AND
19 PRESCRIPTION NUMBER OR ANY OTHER PATIENT-IDENTIFYING
20 INFORMATION ON THE DRUG OR PACKAGING OR OTHERWISE MAINTAINS
21 CONFIDENTIALITY BY EXECUTING A CONFIDENTIALITY AGREEMENT WITH
22 THE RECEIVER ACCORDING TO APPLICABLE STATE AND FEDERAL HEALTH
23 INFORMATION PRIVACY LAWS; AND

24 (e) THE DRUG OR PACKAGING HAS A METHOD RECOGNIZED BY THE
25 OFFICIAL COMPENDIA TO DETECT IMPROPER TEMPERATURE VARIATIONS IF
26 THE DRUG REQUIRES TEMPERATURE CONTROL OTHER THAN ROOM
27 TEMPERATURE STORAGE.

1 (5) (a) IF A DONATED DRUG DOES NOT MEET THE ACCEPTANCE
2 REQUIREMENTS SET FORTH IN SUBSECTION (4) OF THIS SECTION, THE
3 RECEIVER SHALL DISPOSE OF THE DRUG BY:

4 (I) RETURNING THE DRUG TO THE DONOR; OR

5 (II) DESTROYING THE DRUG BY A LAWFUL METHOD OR BY
6 TRANSFERRING THE DRUG TO A RETURNS PROCESSOR.

7 (b) A RECEIVER SHALL MAKE A RECORD OF THE DISPOSAL OF A
8 DONATED DRUG, WHICH RECORD MUST INCLUDE THE DISPOSAL METHOD,
9 THE DATE OF DISPOSAL, AND THE NAME AND QUANTITY OF THE DISPOSED
10 DRUG. NO OTHER RECORD OF DISPOSAL IS REQUIRED.

11 (6) NOTWITHSTANDING ANY LAW TO THE CONTRARY, A RECEIVER
12 OF A DONATED DRUG THAT MEETS THE ACCEPTANCE REQUIREMENTS SET
13 FORTH IN SUBSECTION (4) OF THIS SECTION MAY:

14 (a) DONATE THE DRUG TO ANOTHER RECEIVER;

15 (b) REPACKAGE THE DRUG AS NECESSARY FOR STORAGE,
16 REDISPENSING, ADMINISTRATION, OR TRANSFER IN ACCORDANCE WITH THE
17 FOLLOWING REQUIREMENTS:

18 (I) A REPACKAGED DRUG MUST BE LABELED WITH THE DRUG'S
19 NAME, STRENGTH, AND EXPIRATION DATE AND AND KEPT IN A SEPARATE
20 DESIGNATED AREA UNTIL INSPECTED AND INITIALED BY A PHARMACIST,
21 PRACTITIONER, OR PHARMACY TECHNICIAN; AND

22 (II) IF MULTIPLE PACKAGED DONATED DRUGS WITH VARIED
23 EXPIRATION DATES ARE REPACKAGED TOGETHER, A RECEIVER SHALL ACT
24 BASED ON THE SOONEST EXPIRATION DATE ON THE NEW PACKAGING; AND

25 (c) USE THE DRUG TO REPLENISH A DRUG OF THE SAME DRUG NAME
26 AND STRENGTH PREVIOUSLY DISPENSED OR ADMINISTERED TO AN ELIGIBLE
27 PATIENT IN ACCORDANCE WITH SECTION 340B OF THE FEDERAL "PUBLIC

1 HEALTH SERVICE ACT", 42 U.S.C. SEC. 201 ET SEQ., AS AMENDED.

2 (7) (a) A RECEIVER MAY REDISPENSE OR ADMINISTER A DRUG TO
3 AN ELIGIBLE PATIENT ONLY IF:

4 (I) THE RECEIVER IS OTHERWISE AUTHORIZED BY LAW TO
5 REDISPENSE OR ADMINISTER THE DRUG;

6 (II) THE DRUG MEETS THE REQUIREMENTS OF SUBSECTION (4) OF
7 THIS SECTION FOR ACCEPTING DONATED DRUGS FOR REUSE;

8 (III) THE DRUG IS REPACKAGED PURSUANT TO SUBSECTION (6)(b)
9 OF THIS SECTION OR IS IN ITS UNOPENED, TAMPER-EVIDENT PACKAGING
10 WITH ALL PREVIOUS PATIENT INFORMATION REDACTED OR REMOVED;

11 (IV) THE DRUG IS PROPERLY LABELED IN ACCORDANCE WITH
12 SECTION 12-280-124, IF APPLICABLE, AND BOARD RULES;

13 (V) THE DONATED DRUG IS NOT EXPIRED AND WILL NOT EXPIRE,
14 BASED ON THE EXPIRATION OR BEYOND-USE DATE FOR THE DRUG, BEFORE
15 USE BY THE ELIGIBLE PATIENT, BASED ON THE PRESCRIBING
16 PRACTITIONER'S DIRECTIONS FOR USE OR, FOR A NONPRESCRIPTION DRUG,
17 BASED ON THE EXPIRATION DATE ON THE DRUG CONTAINER'S LABEL; AND

18 (VI) THE DRUG IS NOT ADULTERATED OR MISBRANDED, AS
19 DEFINED IN SECTIONS 25-5-410 AND 25-5-411 FOR THE PURPOSES OF THE
20 "COLORADO FOOD AND DRUG ACT", PART 4 OF ARTICLE 5 OF TITLE 25, AS
21 DETERMINED BY A PHARMACIST OR PRACTITIONER.

22 (b) A RECEIVER SHALL, TO THE GREATEST EXTENT PRACTICABLE,
23 REDISPENSE DRUGS RECEIVED UNDER THIS PART 7 TO PRIORITY PATIENTS.

24 (8) A PERSON, INCLUDING A RECEIVER, WHO RECEIVES DRUGS
25 DONATED FOR USE PURSUANT TO THIS PART 7 SHALL NOT SELL OR RESELL
26 OR OFFER TO SELL OR RESELL THE DONATED DRUGS. WHEN REDISPENSING
27 OR ADMINISTERING A DRUG TO AN ELIGIBLE PATIENT, A RECEIVER MUST DO

1 SO AT NO COST TO THE ELIGIBLE PATIENT; EXCEPT THAT THE RECEIVER
2 MAY CHARGE A UNIFORM, REASONABLE, END-USER HANDLING FEE FOR
3 PROCESSING AND DISPENSING THE DRUG, WHICH FEE MUST NOT EXCEED
4 THE DIRECT OR INDIRECT COST TO THE RECEIVER OF PROVIDING THE DRUG.
5 CHARGING THE FEE DESCRIBED IN THIS SUBSECTION (8) DOES NOT
6 CONSTITUTE SELLING OR RESELLING THE DRUG.

7 **12-280-704. Change of ownership - record-keeping**
8 **requirements.** (1) A DONATION OR OTHER TRANSFER OF POSSESSION OR
9 CONTROL OF A DRUG PURSUANT TO THIS PART 7 IS NOT A CHANGE OF
10 OWNERSHIP UNLESS IT IS SPECIFIED AS SUCH BY THE RECEIVER.

11 (2) WHEN PERFORMING ACTIONS PURSUANT TO THIS PART 7 OR
12 OTHERWISE PROCESSING A DONATED DRUG FOR TAX, MANUFACTURER, OR
13 OTHER CREDIT, A RECEIVER IS CONSIDERED TO BE ACTING AS A RETURNS
14 PROCESSOR AND SHALL COMPLY WITH ALL RECORD-KEEPING
15 REQUIREMENTS FOR RETURNED DRUGS THAT CANNOT BE SOLD UNDER
16 FEDERAL LAW.

17 **12-280-705. Board rules - program administration - program**
18 **application.** THE BOARD SHALL ADOPT RULES FOR THE IMPLEMENTATION
19 OF THIS PART 7, INCLUDING RULES FOR DONATING AND RECEIVING DRUGS,
20 LABELING AND REPACKAGING DRUGS, REDISPENSING OR ADMINISTERING
21 DRUGS BY PERSONS AUTHORIZED TO DISPENSE OR ADMINISTER DRUGS, AND
22 RECORD-KEEPING REQUIRED UNDER THE PROGRAM.

23 **12-280-706. Immunity from criminal and civil liability -**
24 **professional discipline - exceptions.** (1) (a) EXCEPT AS PROVIDED IN
25 SUBSECTION (1)(b) OF THIS SECTION, A MANUFACTURER, DONOR, OR
26 RECEIVER IS NOT LIABLE IN ANY CRIMINAL OR CIVIL ACTION, OR SUBJECT
27 TO PROFESSIONAL DISCIPLINE, FOR ACTS OR OMISSIONS SOLELY AND

1 DIRECTLY ATTRIBUTABLE TO DONATING, RECEIVING, REDISPENSING, OR
2 ADMINISTERING A DRUG PURSUANT TO THIS PART 7.

3 (b) THE IMMUNITY PROVIDED IN SUBSECTION (1)(a) OF THIS
4 SECTION DOES NOT APPLY:

5 (I) IF THE ACT OR OMISSION WAS GROSSLY NEGLIGENT, WILLFUL,
6 WANTON, OR RECKLESS; OR

7 (II) IF THE PERSON OR ENTITY KNEW OR SHOULD HAVE KNOWN
8 THAT THE DONATED DRUG WAS ADULTERATED OR MISBRANDED.

9 (2) NOTHING IN THIS SECTION:

10 (a) CREATES OR ABROGATES ANY LIABILITY OF A MANUFACTURER
11 FOR THE STORAGE, DONATION, ACCEPTANCE, OR REDISPENSING OF AN
12 UNUSED DONATED DRUG; OR

13 (b) CREATES ANY CIVIL CAUSE OF ACTION AGAINST A
14 MANUFACTURER IN ADDITION TO THAT WHICH IS AVAILABLE UNDER
15 APPLICABLE LAW.

16 **SECTION 2. Act subject to petition - effective date.** This act
17 takes effect at 12:01 a.m. on the day following the expiration of the
18 ninety-day period after final adjournment of the general assembly; except
19 that, if a referendum petition is filed pursuant to section 1 (3) of article V
20 of the state constitution against this act or an item, section, or part of this
21 act within such period, then the act, item, section, or part will not take
22 effect unless approved by the people at the general election to be held in
23 November 2022 and, in such case, will take effect on the date of the
24 official declaration of the vote thereon by the governor.