

**First Regular Session
Seventy-fifth General Assembly
STATE OF COLORADO**

REREVISED

*This Version Includes All Amendments
Adopted in the Second House*

LLS NO. 25-1042.01 Brita Darling x2241

SENATE BILL 25-289

SENATE SPONSORSHIP

Cutter, Catlin, Frizell, Hinrichsen, Jodeh, Kipp, Michaelson Jenet, Sullivan, Wallace, Winter F.

HOUSE SPONSORSHIP

Brown and Sirota, Bird, Boesenecker, Clifford, Duran, Feret, Garcia, Hamrick, Joseph, Lieder, Lindsay, Mabrey, McCluskie, Paschal, Rutinel, Rydin, Smith, Stewart K., Story, Titone, Willford

Senate Committees
Health & Human Services

House Committees
Health & Human Services

A BILL FOR AN ACT

101 **CONCERNING THE CREATION OF A DRUG DONATION PROGRAM.**

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 amends statutory provisions relating to unused medication in facilities, including correctional facilities, nursing care facilities, assisted living residences, hospice, and other facilities, to change the defined term "medication" to "medicine" and to expand the types of unused medicines that may be redispensed to patients or donated to a nonprofit entity.

The bill creates the Colorado drug donation program (donation program). The donation program allows a person legally authorized to

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

HOUSE
3rd Reading Unamended
May 2, 2025

HOUSE
Amended 2nd Reading
May 1, 2025

SENATE
Amended 3rd Reading
April 29, 2025

SENATE
Amended 2nd Reading
April 28, 2025

possess medicine, including an individual member of the public, a pharmacy, a long-term care facility, a surgical center, a prescriber or other health-care professional or facility, or others (donor) to donate unused medicine (donated medicine).

A donor may donate unused medicine to a donation recipient (donation recipient) that is authorized to possess medicine and that has a credential in good standing in the state in which the donation recipient is located. A donation recipient may include a wholesaler, distributor, third-party logistics provider, repackager, hospital, pharmacy, clinic, health-care provider, or prescriber's office.

The bill requires the donation recipient to:

- Keep a record of the donated medicine;
- Keep donated medicine separate from regular stock; and
- Have donated medicine inspected by a licensed pharmacist.

The donation recipient may transfer the donated medicine to another donation recipient or entity, repackage the donated medicine, or, if the donation recipient is a prescription drug outlet, replenish medicine.

The bill requires donated medicine to first be dispensed to an eligible patient who is an individual who is indigent, uninsured, underinsured, or enrolled in a public health benefits program. Donated medicine must not be resold; except that a donation recipient may charge a handling or dispensing fee for the donated medicine.

When acting in good faith, the participants in the donation program are not subject to criminal liability or professional disciplinary action.

1 *Be it enacted by the General Assembly of the State of Colorado:*

2 **SECTION 1.** In Colorado Revised Statutes, 12-280-135, **amend**
3 (1)(e), (2)(a), (2)(b) introductory portion, (2)(b)(II), (2)(b)(III), (2)(c)
4 introductory portion, (2)(c)(I), (2)(c)(III), (2)(c)(V), (3), (4), and (6);
5 **repeal** (2)(c)(IV) and (5); and **add** (2)(b)(IV), (2)(c)(VI), (2)(c)(VII), and
6 (2)(c)(VIII) as follows:

7 **12-280-135. Unused medicine - licensed facilities - correctional**
8 **facilities - reuse - definitions - rules.** (1) As used in this section, unless
9 the context otherwise requires:

10 (e) (I) ~~"Medication" means a prescription that is not a controlled~~
11 ~~substance~~ "MEDICINE" MEANS PRESCRIPTION DRUGS. _____

1 (II) "MEDICINE" INCLUDES:

2 (A) A PRESCRIPTION DRUG THAT REQUIRES REFRIGERATION,
3 FREEZING, OR SPECIAL STORAGE IF THE PRESCRIPTION DRUG HAS BEEN
4 CONTINUALLY MAINTAINED BY A DONOR PURSUANT TO THE
5 MANUFACTURER'S STORAGE REQUIREMENTS, SO LONG AS THE COLD CHAIN
6 CAN BE VERIFIED; AND

7 (B) PRESCRIPTION SUPPLIES AND DEVICES.

8 (III) "MEDICINE" DOES NOT INCLUDE:

9 (A) COMPOUNDED DRUGS;

10 (B) PRESCRIPTION DRUGS DISPENSED BY PHARMACIES OUTSIDE OF
11 THE UNITED STATES;

12 (C) PRESCRIPTION DRUGS THAT ARE SUBJECT TO RISK EVALUATION
13 AND MITIGATION STRATEGIES (REMS) UNDER 21 U.S.C. SEC. 355-1 (f)(3)
14 UNLESS ALL OF THE REQUIRED GUIDELINES FOR THE MEDICINE ARE
15 FOLLOWED OR REMS DRUGS THAT WERE INITIALLY DISPENSED BY A
16 PHARMACY PURSUANT TO A RESTRICTED REMS DISTRIBUTION CHANNEL;
17 OR

18 (D) CONTROLLED SUBSTANCES.

19 (2) (a) (I) If donated by the patient, the resident, or the patient's or
20 resident's next of kin, a licensed facility may return unused ~~medications~~
21 MEDICINE or medical supplies and used or unused medical devices to a
22 pharmacist within the licensed facility or a prescription drug outlet in
23 order for the materials to be redispensed to another patient or donated to
24 a nonprofit entity that has the legal authority to possess the materials or
25 to a practitioner authorized by law to dispense the materials.

26 (II) (A) A licensed facility or a prescription drug outlet may
27 donate materials to a nonprofit AN entity that has legal authority to

1 possess the materials or to a person legally authorized to dispense the
2 materials. A licensed pharmacist shall review the process of donating the
3 unused ~~medications~~ MEDICINE to the nonprofit entity.

4 (B) Nothing in this subsection (2)(a)(II) creates or abrogates any
5 liability on behalf of a prescription drug manufacturer for the storage,
6 donation, acceptance, or dispensing of ~~a medication~~ MEDICINE or A
7 product or creates any civil cause of action against a prescription drug
8 manufacturer in addition to that which is available under applicable law.

9 (C) A person or entity is not subject to civil or criminal liability
10 or professional disciplinary action for donating, accepting, dispensing, or
11 facilitating the donation of materials in good faith, without negligence OR
12 WILLFUL OR WANTON MISCONDUCT, and in compliance with this section.

13 (III) A correctional facility may return unused ~~medications~~
14 MEDICINE or medical supplies and used or unused medical devices to the
15 pharmacist within the correctional facility or a prescription drug outlet in
16 order for the ~~medication~~ MEDICINE to be redispensed to another patient or
17 donated to a nonprofit AN entity that has the legal authority to possess the
18 materials or to a practitioner authorized by law to prescribe the materials.

19 (b) ~~Medications are~~ MEDICINE IS only available to be dispensed to
20 another person or donated to a nonprofit AN entity under this section if the
21 ~~medications are~~ MEDICINE IS:

22 (II) Individually packaged and the packaging has not been
23 damaged; ~~or~~

24 (III) In ~~the original~~, unopened, ~~sealed~~, and tamper-evident ~~unit~~
25 ~~dose~~ packaging; OR

26 (IV) FOR MEDICINE THAT REQUIRES REFRIGERATION, FREEZING, OR
27 SPECIAL STORAGE, CONTINUALLY MAINTAINED BY THE DONOR PURSUANT

1 TO THE MANUFACTURER'S STORAGE REQUIREMENTS, SO LONG AS THE COLD
2 CHAIN CAN BE VERIFIED.

3 (c) The following ~~medications may not be donated~~ MEDICINE IS
4 NOT ACCEPTABLE FOR DONATION:

5 (I) ~~Medications~~ MEDICINE THAT IS NOT packaged in A traditional
6 ~~brown or amber pill bottles~~ DISPENSING SYSTEM, AS DEFINED BY THE
7 BOARD BY RULE;

8 (III) ~~Medications~~ EXCEPT AS PROVIDED IN SUBSECTION (2)(b)(IV)
9 OF THIS SECTION, MEDICINE that ~~require~~ REQUIRES refrigeration, freezing,
10 or special storage;

11 (IV) ~~Medications that require special registration with the~~
12 ~~manufacturer; or~~

13 (V) ~~Medications~~ MEDICINE that ~~are~~ IS adulterated or misbranded,
14 as determined by a person legally authorized to dispense the ~~medications~~
15 MEDICINE on behalf of the nonprofit entity OR A PERSON LEGALLY
16 AUTHORIZED TO DISPENSE THE MEDICINE;

17 (VI) COMPOUNDED MEDICINE;

18 (VII) MEDICINE DISPENSED BY PHARMACIES OUTSIDE OF THE
19 UNITED STATES; OR

20 (VIII) MEDICINE THAT IS SUBJECT TO RISK EVALUATION AND
21 MITIGATION STRATEGIES (REMS) UNDER 21 U.S.C. SEC. 355-1 (f)(3)
22 UNLESS ALL OF THE REQUIRED GUIDELINES FOR THE MEDICINE ARE
23 FOLLOWED OR REMS DRUGS THAT WERE INITIALLY DISPENSED BY A
24 PHARMACY PURSUANT TO A RESTRICTED REMS DISTRIBUTION CHANNEL.

25 (3) ~~Medication~~ MEDICINE dispensed or donated pursuant to this
26 section must not be expired. A ~~medication shall not be dispensed~~
27 PRESCRIBING PRACTITIONER SHALL NOT DISPENSE MEDICINE that will

1 expire before the use by the patient based on the prescribing practitioner's
2 directions for use.

3 (4) ~~Medication~~ MEDICINE, medical supplies, and medical devices
4 donated pursuant to this section may SHALL not be resold for profit. The
5 entity that receives the donated materials may charge the end user a
6 handling fee, which fee shall not exceed the amount specified by rule of
7 the board AND ARE CONSIDERED NONSALEABLE; EXCEPT THAT HANDLING,
8 DISPENSING, OR USUAL AND CUSTOMARY CHARGES TO AN ELIGIBLE
9 PATIENT, HEALTH PLAN, PHARMACY BENEFIT MANAGER, PHARMACY
10 SERVICE, ADMINISTRATIVE ORGANIZATION, GOVERNMENT AGENCY, OR
11 OTHER ENTITY IS NOT CONSIDERED RESELLING. IF THE DONATION
12 RECIPIENT IS A FOR-PROFIT ENTITY, THESE CHARGES MUST NOT EXCEED
13 THE DONATION RECIPIENT'S COST OF PROVIDING THE MEDICINE, INCLUDING
14 THE CURRENT AND ANTICIPATED COSTS OF EDUCATING ELIGIBLE DONORS
15 AND INDIVIDUAL DONORS, PROVIDING TECHNICAL SUPPORT TO
16 PARTICIPATING DONORS AND INDIVIDUAL DONORS, SHIPPING AND
17 HANDLING, LABOR, STORAGE, LICENSING, UTILITIES, ADVERTISING,
18 TECHNOLOGY, SUPPLIES, AND EQUIPMENT. EXCEPT AS DESCRIBED IN THIS
19 SUBSECTION (4), THE AMOUNT OF THESE CHARGES IS NOT SUBJECT TO
20 ADDITIONAL LIMITATIONS. ____

21 (5) ~~The board shall adopt rules that allow a pharmacist to~~
22 ~~redispense medication pursuant to this section and section 25.5-5-502 and~~
23 ~~to donate medication pursuant to this section.~~

24 (6) (a) EXCEPT AS PROVIDED IN SUBSECTION (6)(b) OF THIS
25 SECTION, nothing in this section or section 25.5-5-502 creates or
26 abrogates any liability on behalf of a prescription drug manufacturer for
27 the storage, donation, acceptance, or dispensing of ~~an~~ unused donated

1 ~~medication~~ MEDICINE or creates any civil cause of action against a
2 prescription drug manufacturer in addition to that which is available
3 under applicable law.

4 (b) A MANUFACTURER OF A PRESCRIPTION DRUG THAT IS SUBJECT
5 TO RISK EVALUATION AND MITIGATION STRATEGIES (REMS) IS NOT
6 SUBJECT TO CRIMINAL PROSECUTION OR LIABILITY IN TORT OR OTHER CIVIL
7 ACTION FOR INJURY, DEATH, OR LOSS TO PERSON OR PROPERTY FOR
8 MATTERS RELATED TO THE DONATION, ACCEPTANCE, OR DISPENSING OF A
9 REMS DRUG MANUFACTURED BY THE DRUG MANUFACTURER THAT IS
10 DONATED BY ANY PERSON PURSUANT TO THE PROGRAM, INCLUDING
11 LIABILITY FOR FAILURE TO TRANSFER OR COMMUNICATE PRODUCT OR
12 CONSUMER INFORMATION OR THE EXPIRATION DATE OF THE DONATED
13 PRESCRIPTION DRUG.

14 **SECTION 2.** In Colorado Revised Statutes, **add** 12-280-135.5 as
15 follows:

16 **12-280-135.5. Colorado drug donation program - created -**
17 **rules - records - definitions.** (1) AS USED IN THIS SECTION, UNLESS THE
18 CONTEXT OTHERWISE REQUIRES:

19 (a) "COLORADO DRUG DONATION PROGRAM" OR "PROGRAM"
20 MEANS THE COLORADO DRUG DONATION PROGRAM CREATED IN THIS
21 SECTION.

22 (b) "CONTROLLED SUBSTANCE" HAS THE MEANING SET FORTH IN
23 SECTION 18-18-102.

24 (c) (I) "DONATION RECIPIENT" MEANS AN ENTITY THAT:

25 (A) IS LEGALLY AUTHORIZED TO POSSESS MEDICINE;

26 (B) HAS A LICENSE OR REGISTRATION IN GOOD STANDING IN THE
27 STATE IN WHICH THE ENTITY IS LOCATED; AND

1 (C) RECEIVES A DONATION OF MEDICINE.

2 (II) "DONATION RECIPIENT" INCLUDES _____ A HOSPITAL, A
3 PHARMACY, A CLINIC, A HEALTH-CARE PROVIDER, OR A PRESCRIBER
4 OFFICE.

5 (III) "DONATION RECIPIENT" ALSO INCLUDES A WHOLESALER, A
6 DISTRIBUTOR, A THIRD-PARTY LOGISTICS PROVIDER, A REVERSE
7 DISTRIBUTOR, OR A REPACKAGER IF THE ENTITY IS A NONPROFIT ENTITY OR
8 IS DIRECTLY OR INDIRECTLY OWNED, CONTROLLED, OR COULD BE
9 CONTROLLED BY A NONPROFIT ENTITY.

10 (d) (I) "DONOR" MEANS ANY ENTITY LEGALLY AUTHORIZED TO
11 POSSESS MEDICINE, INCLUDING _____ A WHOLESALER, A DISTRIBUTOR, A
12 THIRD-PARTY LOGISTICS PROVIDER, A PHARMACY, A DISPENSER, A CLINIC,
13 A SURGICAL OR HEALTH CENTER, A REHABILITATION CENTER, A DETENTION
14 CENTER, A JAIL, A PRISON, A LABORATORY, A PRESCRIBER OR OTHER
15 HEALTH-CARE PROFESSIONAL, _____ A LONG-TERM CARE FACILITY OR
16 HEALTH-CARE FACILITY, AND ANY OTHER ENTITY REGULATED BY THE
17 BOARD THAT DONATES MEDICINE.

18 (II) "DONOR" INCLUDES GOVERNMENT AGENCIES AND ENTITIES
19 THAT ARE FEDERALLY AUTHORIZED TO POSSESS MEDICINE, INCLUDING
20 MANUFACTURERS, REPACKAGERS, RELABELERS, OUTSOURCING FACILITIES,
21 VETERANS AFFAIRS HOSPITALS, FDA-AUTHORIZED IMPORTERS SUCH AS
22 THOSE DESCRIBED UNDER THE FEDERAL "FOOD, DRUG, AND COSMETIC
23 ACT", 21 U.S.C. SECS. 801 AND 804, AS AMENDED, OR SIMILAR
24 PROVISIONS, AND FEDERAL PRISONS.

25 (e) (I) "ELIGIBLE PATIENT" MEANS AN INDIVIDUAL WITH A NEED
26 FOR DONATED MEDICINE WHO IS INDIGENT, UNINSURED, OR
27 UNDERINSURED. _____

1 (II) "ELIGIBLE PATIENT" INCLUDES OTHER INDIVIDUALS IF A NEED
2 FOR DONATED MEDICINE IS NOT IDENTIFIED AMONG INDIVIDUALS WHO ARE
3 INDIGENT, UNINSURED, OR UNDERINSURED.

4 (f) "HEALTH-CARE PROFESSIONAL" MEANS AN INDIVIDUAL WHO IS
5 LICENSED TO PRACTICE AS A PHYSICIAN, REGISTERED NURSE, ADVANCED
6 PRACTICE REGISTERED NURSE, PRACTICAL NURSE, OPTOMETRIST, OR
7 PHARMACIST; A CERTIFIED MIDWIFE WITH PRESCRIPTIVE AUTHORITY
8 PURSUANT TO SECTION 12-255-112; OR ANY OTHER PRACTITIONER
9 AUTHORIZED TO DISPENSE OR ADMINISTER MEDICINE.

10 (g) "INDIVIDUAL DONOR" MEANS A NONLICENSED INDIVIDUAL
11 MEMBER OF THE PUBLIC.

12 (h) (I) "MEDICINE" MEANS PRESCRIPTION DRUGS.

13 (II) "MEDICINE" INCLUDES:

14 (A) A PRESCRIPTION DRUG THAT REQUIRES REFRIGERATION,
15 FREEZING, OR SPECIAL STORAGE IF THE MEDICINE HAS BEEN CONTINUALLY
16 MAINTAINED BY THE DONOR PURSUANT TO THE MANUFACTURER'S
17 STORAGE REQUIREMENTS, SO LONG AS THE COLD CHAIN CAN BE VERIFIED;
18 AND

19 (B) PRESCRIPTION SUPPLIES AND DEVICES.

20 (III) "MEDICINE" DOES NOT INCLUDE:

21 (A) COMPOUNDED DRUGS;

22 (B) PRESCRIPTION DRUGS DISPENSED BY PHARMACIES OUTSIDE OF
23 THE UNITED STATES;

24 (C) PRESCRIPTION DRUGS THAT ARE SUBJECT TO RISK EVALUATION
25 AND MITIGATION STRATEGIES (REMS) UNDER 21 U.S.C. SEC. 355-1 (f)(3)
26 UNLESS ALL OF THE REQUIRED GUIDELINES FOR THE MEDICINE ARE
27 FOLLOWED OR REMS DRUGS THAT WERE INITIALLY DISPENSED BY A

1 PHARMACY PURSUANT TO A RESTRICTED REMS DISTRIBUTION CHANNEL;

2 OR

3 (D) CONTROLLED SUBSTANCES.

4 (i) "PRESCRIBER" HAS THE MEANING SET FORTH IN SECTION
5 12-280-125.7 (1)(f).

6 (j) "RETURNS PROCESSOR" HAS THE MEANING SET FORTH IN 21
7 U.S.C. SEC. 360eee (18) AND INCLUDES A REVERSE DISTRIBUTOR.

8 (k) (I) "UNOPENED, TAMPER-EVIDENT PACKAGING" MEANS AN
9 INTACT PACKAGING SYSTEM THAT RENDERS MEDICINE INACCESSIBLE
10 WITHOUT OBVIOUS DESTRUCTION OF THE SEAL OR SOME PORTION OF THE
11 PACKAGING SYSTEM.

12 (II) "UNOPENED, TAMPER-EVIDENT PACKAGING" MAY INCLUDE
13 UNOPENED UNIT-DOSE, MULTIPLE-DOSE, IMMEDIATE, SECONDARY, OR
14 TERTIARY PACKAGING.

15 (2) THERE IS CREATED THE COLORADO DRUG DONATION PROGRAM
16 TO FACILITATE THE SAFE DONATION AND REDISPENSING OF UNUSED
17 MEDICINE TO COLORADANS IN NEED OF THE MEDICINE. PARTICIPATION IN
18 THE PROGRAM IS VOLUNTARY.

19 (3) (a) NOTWITHSTANDING ANY OTHER LAW OR RULE TO THE
20 CONTRARY, A DONOR OR AN INDIVIDUAL DONOR MAY DONATE MEDICINE
21 TO A DONATION RECIPIENT. A DONATION RECIPIENT MAY RECEIVE
22 DONATED MEDICINE FROM A DONOR OR AN INDIVIDUAL DONOR.

23 (b) PRIOR TO THE FIRST DONATION FROM A PERSON, A DONATION
24 RECIPIENT SHALL RECORD THE PERSON'S NAME, ADDRESS, PHONE NUMBER,
25 AND LICENSE NUMBER, IF APPLICABLE, AND SHALL:

26 (I) VERIFY THAT THE PERSON MEETS THE DEFINITION PROVIDED IN
27 SUBSECTION (1)(d) OF THIS SECTION;

1 (II) CONFIRM THAT THE PERSON AGREES TO MAKE DONATIONS OF
2 MEDICINE ONLY IN ACCORDANCE WITH THIS SECTION AND RULES ADOPTED
3 BY THE BOARD RELATING TO DONATED MEDICINE; AND

4 (III) IF APPLICABLE, CONFIRM THAT THE PERSON AGREES TO
5 REMOVE OR REDACT ANY PATIENT NAMES AND PRESCRIPTION NUMBERS ON
6 DONATED MEDICINE OR TO OTHERWISE MAINTAIN PATIENT
7 CONFIDENTIALITY BY EXECUTING A CONFIDENTIALITY AGREEMENT WITH
8 THE AUTHORIZED DONATION RECIPIENT.

9 (c) NO OTHER INFORMATION OR RECORDS ARE REQUIRED PRIOR TO
10 THE FIRST DONATION FROM A NEW DONOR OR A NEW INDIVIDUAL DONOR
11 OTHER THAN AS DESCRIBED IN SUBSECTION (3)(b) OF THIS SECTION.

12 (4) A DONATION RECIPIENT SHALL MAINTAIN A WRITTEN OR AN
13 ELECTRONIC RECORD OF DONATED MEDICINE CONSISTING OF THE NAME,
14 STRENGTH, QUANTITY, AND LOT NUMBER, IF KNOWN, OF EACH ACCEPTED
15 OR TRANSFERRED DRUG AND THE NAME, ADDRESS, AND PHONE NUMBER OF
16 THE DONOR, INDIVIDUAL DONOR, OR TRANSFERRING ENTITY. NO OTHER
17 RECORD OF DONATION IS REQUIRED.

18 (5) A DONATION RECIPIENT SHALL ENSURE THAT DONATED
19 MEDICINE IS IDENTIFIED PHYSICALLY OR ELECTRONICALLY AS SEPARATE
20 FROM REGULAR STOCK.

21 (6) NOTWITHSTANDING ANY OTHER LAW TO THE CONTRARY, A
22 DONATION RECIPIENT MAY:

23 (a) TRANSFER DONATED MEDICINE TO ANOTHER DONATION
24 RECIPIENT OR TO AN ENTITY PARTICIPATING IN A DRUG DONATION
25 PROGRAM OPERATED BY ANOTHER STATE;

26 (b) REPACKAGE DONATED MEDICINE IN ACCORDANCE WITH
27 SUBSECTION (8) OF THIS SECTION AS NECESSARY FOR STORAGE,

1 DISPENSING, ADMINISTRATION, OR TRANSFER; OR

2 (c) IF THE DONATION RECIPIENT IS A PRESCRIPTION DRUG OUTLET
3 OR OTHER OUTLET, REPLACE MEDICINE OF THE SAME DRUG NAME AND
4 STRENGTH PREVIOUSLY DISPENSED OR ADMINISTERED TO ELIGIBLE
5 PATIENTS IN ACCORDANCE WITH 42 U.S.C. SEC. 256b, AS AMENDED.

6 (7) (a) DONATED MEDICINE THAT DOES NOT MEET THE
7 REQUIREMENTS SPECIFIED IN THIS SECTION AND THE RULES ADOPTED BY
8 THE BOARD MUST BE DISPOSED OF BY:

9 (I) RETURNING THE DONATED MEDICINE TO THE DONOR;

10 (II) DESTROYING THE DONATED MEDICINE THROUGH AN
11 INCINERATOR, A MEDICAL WASTE HAULER, A REVERSE DISTRIBUTOR, OR
12 OTHER LAWFUL METHOD; OR

13 (III) TRANSFERRING THE DONATED MEDICINE TO A RETURNS
14 PROCESSOR.

15 (b) A DONATION RECIPIENT SHALL MAINTAIN A WRITTEN OR AN
16 ELECTRONIC RECORD OF DISPOSED MEDICINE CONSISTING OF THE DISPOSAL
17 METHOD, AS DESCRIBED IN SUBSECTION (7)(a) OF THIS SECTION; THE DATE
18 OF DISPOSAL; AND THE NAME, STRENGTH, AND QUANTITY OF EACH
19 DISPOSED DRUG. NO OTHER RECORD OF DISPOSAL IS REQUIRED.

20 (8) REPACKAGED MEDICINE MUST BE LABELED WITH THE DRUG
21 NAME, STRENGTH, AND EXPIRATION DATE, IF THE EXPIRATION DATE IS
22 KNOWN, AND IDENTIFIED SEPARATELY FROM REGULAR STOCK UNTIL
23 INSPECTED AND INITIALED BY A LICENSED PHARMACIST. IF MULTIPLE
24 PACKAGED, DONATED MEDICINES WITH VARIED EXPIRATION DATES ARE
25 REPACKAGED TOGETHER, THE EARLIEST EXPIRATION DATE MUST BE USED.
26 PRESCRIPTION DRUGS SPECIFIED BY NDC NUMBER IN A RECALL NOTICE
27 MUST BE CONSIDERED RECALLED UNLESS THE PRESCRIPTION DRUG HAS AN

1 AFFIXED LOT NUMBER THAT EXCLUDES IT FROM THE RECALL.

2 (9) A DONATION RECIPIENT SHALL ONLY ADMINISTER OR
3 REDISPENSE MEDICINE THAT:

4 (a) IS IN UNOPENED, TAMPER-EVIDENT PACKAGING OR HAS BEEN
5 REPACKAGED UNDER THIS PROGRAM;

6 (b) MEETS THE REQUIREMENTS SET FORTH IN THIS SECTION BASED
7 ON AN INSPECTION BY A LICENSED PHARMACIST;

8 (c) IF DISPENSED TO AN ELIGIBLE PATIENT, IS REPACKAGED BY A
9 LICENSED PHARMACIST INTO A NEW CONTAINER OR, IF KEPT IN THE
10 DONATED CONTAINER, IS IN A CONTAINER THAT HAS ALL PREVIOUS
11 PATIENT INFORMATION REDACTED OR REMOVED;

12 (d) IS PROPERLY LABELED IN ACCORDANCE WITH THE RULES
13 ADOPTED BY THE BOARD;

14 (e) HAS AN EXPIRATION OR BEYOND-USE DATE THAT WILL NOT
15 EXPIRE BEFORE THE MEDICINE IS USED BY THE ELIGIBLE PATIENT BASED ON
16 THE PRESCRIBER'S DIRECTIONS FOR USE; AND

17 (f) IF THE MEDICINE REQUIRES REFRIGERATION, FREEZING, OR
18 SPECIAL STORAGE, HAS BEEN CONTINUALLY MAINTAINED BY THE DONOR
19 PURSUANT TO THE MANUFACTURER'S STORAGE REQUIREMENTS, SO LONG
20 AS THE COLD CHAIN CAN BE VERIFIED.

21 (10) A DONATION RECIPIENT:

22 (a) MAY DISPENSE OR ADMINISTER PRESCRIPTION DRUGS TO AN
23 ELIGIBLE PATIENT PURSUANT TO THIS SECTION ONLY IF OTHERWISE
24 PERMITTED BY LAW PURSUANT TO A VALID PRESCRIPTION OR PRESCRIPTION
25 DRUG ORDER; AND

26 (b) SHALL MAINTAIN ELIGIBLE PATIENT-SPECIFIC WRITTEN OR
27 ELECTRONIC RECORDS IN ACCORDANCE WITH RULES ADOPTED BY THE

1 BOARD.

2 (11) A MANUFACTURER, PRESCRIPTION DRUG OUTLET,
3 REPACKAGER, DISPENSER, OR WHOLESALER, OTHER THAN A RETURNS
4 PROCESSOR, PARTICIPATING IN THE PROGRAM SHALL COMPLY WITH THE
5 REQUIREMENTS OF 21 U.S.C. SECS. 360eee-1 TO 360eee-4 RELATING TO
6 DRUG SUPPLY CHAIN SECURITY.

7 (12) THE DONATION, TRANSFER, OR RECEIPT OF MEDICINE OR THE
8 FACILITATION OF A DONATION, TRANSFER, OR RECEIPT OF MEDICINE
9 PURSUANT TO THIS SECTION IS NOT WHOLESALE DISTRIBUTION AND DOES
10 NOT REQUIRE LICENSING AS A WHOLESALE DISTRIBUTOR.

11 (13) MEDICINE DONATED TO THE PROGRAM MUST NOT BE RESOLD
12 AND IS CONSIDERED NONSALEABLE; EXCEPT THAT HANDLING, DISPENSING,
13 OR USUAL AND CUSTOMARY CHARGES TO AN ELIGIBLE PATIENT, HEALTH
14 PLAN, PHARMACY BENEFIT MANAGER, PHARMACY SERVICES
15 ADMINISTRATIVE ORGANIZATION, GOVERNMENT AGENCY, OR OTHER
16 ENTITY IS NOT CONSIDERED RESELLING. IF THE DONATION RECIPIENT IS A
17 FOR-PROFIT ENTITY, THESE CHARGES MUST NOT EXCEED THE DONATION
18 RECIPIENT'S COST OF PROVIDING THE MEDICINE, INCLUDING THE CURRENT
19 AND ANTICIPATED COSTS OF EDUCATING ELIGIBLE DONORS AND
20 INDIVIDUAL DONORS, PROVIDING TECHNICAL SUPPORT TO PARTICIPATING
21 DONORS AND INDIVIDUAL DONORS, SHIPPING AND HANDLING, LABOR,
22 STORAGE, LICENSING, UTILITIES, ADVERTISING, TECHNOLOGY, SUPPLIES,
23 AND EQUIPMENT. EXCEPT AS DESCRIBED IN THIS SUBSECTION (13), THE
24 AMOUNT OF THESE CHARGES IS NOT SUBJECT TO ANY ADDITIONAL
25 LIMITATIONS.

26 (14) WHEN PERFORMING ANY ACTION ASSOCIATED WITH THE
27 PROGRAM OR OTHERWISE PROCESSING DONATED MEDICINE FOR TAX, A

1 MANUFACTURER CREDIT, OR OTHER CREDIT, A DONATION RECIPIENT IS
2 CONSIDERED TO BE ACTING AS A RETURNS PROCESSOR AND SHALL COMPLY
3 WITH ALL RECORD-KEEPING REQUIREMENTS UNDER FEDERAL LAW FOR
4 NONSALEABLE RETURNS.

5 (15) ALL REQUIRED RECORDS MUST BE RETAINED IN PHYSICAL OR
6 ELECTRONIC FORMAT, ON OR OFF THE DONATION RECIPIENT'S PREMISES,
7 FOR A PERIOD OF TWO YEARS. DONORS OR DONATION RECIPIENTS MAY
8 CONTRACT WITH ONE ANOTHER OR WITH A THIRD PARTY TO CREATE OR
9 MAINTAIN RECORDS. AN IDENTIFIER, SUCH AS A SERIAL NUMBER OR BAR
10 CODE, MAY BE USED IN PLACE OF INFORMATION IF IT ALLOWS FOR THE
11 INFORMATION TO BE READILY RETRIEVABLE. UPON REQUEST BY A STATE
12 OR FEDERAL REGULATOR, THE IDENTIFIER USED FOR A REQUESTED RECORD
13 MUST BE REPLACED WITH THE ORIGINAL INFORMATION. AN IDENTIFIER
14 MUST NOT BE USED ON LABELS WHEN DISPENSING OR ADMINISTERING A
15 DRUG TO AN ELIGIBLE PATIENT.

16 (16) A DONATION OR OTHER TRANSFER OF POSSESSION OR
17 CONTROL IS NOT A CHANGE OF OWNERSHIP UNLESS IT IS SPECIFIED AS SUCH
18 BY THE DONATION RECIPIENT. IF A RECORD OF THE DONATION'S
19 TRANSACTION INFORMATION OR HISTORY IS REQUIRED, THE HISTORY MUST
20 BEGIN WITH THE DONOR OR INDIVIDUAL DONOR, MUST INCLUDE ALL PRIOR
21 DONATIONS, AND, IF THE MEDICINE WAS PREVIOUSLY DISPENSED, MUST
22 INCLUDE ONLY DRUG INFORMATION THAT IS REQUIRED TO BE ON THE
23 PATIENT LABEL IN ACCORDANCE WITH RULES ADOPTED BY THE BOARD.

24 (17) AN ENTITY PARTICIPATING IN A DRUG DONATION OR
25 REPOSITORY PROGRAM OPERATED BY ANOTHER STATE MAY PARTICIPATE
26 IN THE PROGRAM AND, IF THE REGISTERED ENTITY IS A PRESCRIPTION DRUG
27 OUTLET, MAY DISPENSE DONATED DRUGS TO ELIGIBLE PATIENTS OF THIS

1 STATE. THE REGISTERED ENTITY IS REQUIRED TO COMPLY WITH ALL
2 STATUTES AND RULES IN THIS STATE UNLESS THE STATUTES OR RULES
3 DIFFER FROM OR CONFLICT WITH THE STATUTES OR RULES OF THE STATE
4 IN WHICH THE ENTITY IS LOCATED.

5 (18) THE BOARD SHALL ADOPT ANY RULES NECESSARY TO
6 IMPLEMENT THIS SECTION. THE RULES MUST REQUIRE THE LEAST AMOUNT
7 OF RECORD KEEPING NECESSARY TO ENSURE PATIENT SAFETY AND MUST
8 ALLOW FLEXIBILITY IN THE FORMAT FOR RECORD KEEPING.

9 (19) NOTWITHSTANDING ANY LAW TO THE CONTRARY, THIS
10 SECTION CONTROLS ALL ACTIVITIES UNDER THE PROGRAM AND
11 SUPERSEDES ANY INCONSISTENT LAW OR RULE.

12 (20) WHEN ACTING IN GOOD FAITH, WITHOUT NEGLIGENCE OR
13 WILLFUL OR WANTON MISCONDUCT, THE FOLLOWING INDIVIDUALS OR
14 ENTITIES ARE NOT SUBJECT TO CIVIL OR CRIMINAL LIABILITY OR
15 PROFESSIONAL DISCIPLINARY ACTION:

16 (a) AN INDIVIDUAL OR ENTITY INVOLVED IN THE SUPPLY CHAIN OF
17 DONATED MEDICINE, INCLUDING THE DONOR, THE INDIVIDUAL DONOR, THE
18 DONATION RECIPIENT, THE MANUFACTURER, THE REPACKAGER, THE
19 PRESCRIPTION DRUG OUTLET OR OTHER ENTITY REGULATED BY THE
20 BOARD, AND THE ELIGIBLE PATIENT;

21 (b) AN INDIVIDUAL OR ENTITY, INCLUDING AN EMPLOYEE, AN
22 OFFICER, A VOLUNTEER, AN OWNER, A PARTNER, A MEMBER, A DIRECTOR,
23 A CONTRACTOR, OR OTHER INDIVIDUAL OR ENTITY ASSOCIATED WITH THE
24 INDIVIDUAL OR ENTITY THAT, IN COMPLIANCE WITH THIS SECTION,
25 PRESCRIBES, DONATES, RECEIVES DONATIONS OF, DISPENSES,
26 ADMINISTERS, TRANSFERS, REPLACES, OR REPACKAGES MEDICINE OR
27 FACILITATES ANY OF THE ACTIONS DESCRIBED IN THIS SECTION; AND

1 (c) THE BOARD.

2 (21) NOTWITHSTANDING SUBSECTION (20) OF THIS SECTION, A
3 MANUFACTURER OF A PRESCRIPTION DRUG THAT IS SUBJECT TO RISK
4 EVALUATION AND MITIGATION STRATEGIES (REMS) IS NOT SUBJECT TO
5 CRIMINAL PROSECUTION OR LIABILITY IN TORT OR OTHER CIVIL ACTION FOR
6 INJURY, DEATH, OR LOSS TO PERSON OR PROPERTY FOR MATTERS RELATED
7 TO THE DONATION, ACCEPTANCE, OR DISPENSING OF A REMS DRUG
8 MANUFACTURED BY THE DRUG MANUFACTURER THAT IS DONATED BY ANY
9 PERSON PURSUANT TO THE PROGRAM, INCLUDING LIABILITY FOR FAILURE
10 TO TRANSFER OR COMMUNICATE PRODUCT OR CONSUMER INFORMATION
11 OR THE EXPIRATION DATE OF THE DONATED PRESCRIPTION DRUG.

12 (22) A DONATION RECIPIENT OPERATING PRIMARILY FOR THE
13 PURPOSE OF PARTICIPATING IN THIS PROGRAM SHALL NOT BE REQUIRED TO
14 POSSESS A COMPREHENSIVE OR MINIMUM SUPPLY OF MEDICINE.

15 **SECTION 3.** In Colorado Revised Statutes, 25-15-328, **amend**
16 (6)(a) as follows:

17 **25-15-328. Household medication take-back program -**
18 **creation - collection and disposal of medication injection devices -**
19 **liability - definitions - cash fund - rules.** (6) Nothing in this section:

20 (a) Affects the authority to collect and reuse ~~medications~~
21 MEDICINE pursuant to section 12-280-135 OR 12-280-135.5; or

22 

23 **SECTION 4. Act subject to petition - effective date.** This act
24 takes effect at 12:01 a.m. on the day following the expiration of the
25 ninety-day period after final adjournment of the general assembly; except
26 that, if a referendum petition is filed pursuant to section 1 (3) of article V
27 of the state constitution against this act or an item, section, or part of this

1 act within such period, then the act, item, section, or part will not take
2 effect unless approved by the people at the general election to be held in
3 November 2026 and, in such case, will take effect on the date of the
4 official declaration of the vote thereon by the governor.