

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

PREAMENDED

*This Unofficial Version Includes Committee
Amendments Not Yet Adopted on Second Reading*

LLS NO. 25-1042.01 Brita Darling x2241

SENATE BILL 25-289

SENATE SPONSORSHIP

Cutter,

HOUSE SPONSORSHIP

Brown,

Senate Committees
Health & Human Services

House Committees

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.

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 UNDER 21 U.S.C. SEC. 355-1 (f)(3) UNLESS ALL OF THE
14 REQUIRED GUIDELINES FOR THE MEDICINE ARE FOLLOWED; OR

15 (D) CONTROLLED SUBSTANCES.

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

23 (II) (A) A licensed facility or a prescription drug outlet may
24 donate materials to ~~a nonprofit~~ AN entity that has legal authority to
25 possess the materials or to a person legally authorized to dispense the
26 materials. A licensed pharmacist shall review the process of donating the
27 unused ~~medications~~ MEDICINE to the nonprofit entity.

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

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

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

16 (b) ~~Medications are~~ MEDICINE IS only available to be dispensed to
17 another person or donated to a nonprofit entity under this section if the
18 ~~medications are~~ MEDICINE IS:

19 (II) Individually packaged and the packaging has not been
20 damaged; ~~or~~

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

23 (IV) FOR MEDICINE THAT REQUIRES REFRIGERATION, FREEZING, OR
24 SPECIAL STORAGE, CONTINUALLY MAINTAINED PURSUANT TO THE
25 MANUFACTURER'S STORAGE REQUIREMENTS, SO LONG AS THE COLD CHAIN
26 CAN BE VERIFIED.

27 (c) The following ~~medications may not be donated~~ MEDICINE IS

1 NOT ACCEPTABLE FOR DONATION:

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

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

8 (IV) ~~Medications that require special registration with the~~
9 ~~manufacturer; or~~

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

14 (VI) COMPOUNDED MEDICINE;

15 (VII) MEDICINE DISPENSED BY PHARMACIES OUTSIDE OF THE
16 UNITED STATES; OR

17 (VIII) MEDICINE THAT IS SUBJECT TO RISK EVALUATION AND
18 MITIGATION UNDER 21 U.S.C. SEC. 355-1 (f)(3) UNLESS ALL OF THE
19 REQUIRED GUIDELINES FOR THE MEDICINE ARE FOLLOWED.

20 (3) ~~Medication~~ MEDICINE dispensed or donated pursuant to this
21 section must not be expired. A ~~medication shall not be dispensed~~
22 PRESCRIBING PRACTITIONER SHALL NOT DISPENSE MEDICINE that will
23 expire before the use by the patient based on the prescribing practitioner's
24 directions for use.

25 (4) ~~Medication~~ MEDICINE, medical supplies, and medical devices
26 donated pursuant to this section may SHALL not be resold for profit. The
27 entity that receives the donated materials may charge the end user a

1 handling fee, which fee shall not exceed the amount specified by rule of
2 the board AND ARE CONSIDERED NONSALEABLE; EXCEPT THAT HANDLING,
3 DISPENSING, OR USUAL AND CUSTOMARY CHARGES TO AN ELIGIBLE
4 PATIENT, HEALTH PLAN, PHARMACY BENEFIT MANAGER, PHARMACY
5 SERVICE, ADMINISTRATIVE ORGANIZATION, GOVERNMENT AGENCY, OR
6 OTHER ENTITY IS NOT CONSIDERED RESELLING. IF THE DONATION
7 RECIPIENT IS A FOR-PROFIT ENTITY, THESE CHARGES MUST NOT EXCEED
8 THE DONATION RECIPIENT'S COST OF PROVIDING THE MEDICINE, INCLUDING
9 THE CURRENT AND ANTICIPATED COSTS OF EDUCATING ELIGIBLE DONORS
10 AND INDIVIDUAL DONORS, PROVIDING TECHNICAL SUPPORT TO
11 PARTICIPATING DONORS AND INDIVIDUAL DONORS, SHIPPING AND
12 HANDLING, LABOR, STORAGE, LICENSING, UTILITIES, ADVERTISING,
13 TECHNOLOGY, SUPPLIES, AND EQUIPMENT. EXCEPT AS DESCRIBED IN THIS
14 SUBSECTION (4), THE AMOUNT OF THESE CHARGES IS NOT SUBJECT TO
15 ADDITIONAL LIMITATIONS. ____

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

19 (6) Nothing in this section or section 25.5-5-502 creates or
20 abrogates any liability on behalf of a prescription drug manufacturer for
21 the storage, donation, acceptance, or dispensing of ~~an~~ unused donated
22 ~~medication~~ MEDICINE or creates any civil cause of action against a
23 prescription drug manufacturer in addition to that which is available
24 under applicable law.

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

27 **12-280-135.5. Colorado drug donation program - created -**

1 **rules - records - definitions.** (1) AS USED IN THIS SECTION, UNLESS THE
2 CONTEXT OTHERWISE REQUIRES:

3 (a) "COLORADO DRUG DONATION PROGRAM" OR "PROGRAM"
4 MEANS THE COLORADO DRUG DONATION PROGRAM CREATED IN THIS
5 SECTION.

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

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

9 (A) IS LEGALLY AUTHORIZED TO POSSESS MEDICINE;

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

12 (C) RECEIVES A DONATION OF MEDICINE.

13 (II) "DONATION RECIPIENT" INCLUDES A WHOLESALER, A
14 DISTRIBUTOR, A THIRD-PARTY LOGISTICS PROVIDER, A REVERSE
15 DISTRIBUTOR, A REPACKAGER, A HOSPITAL, A PHARMACY, A CLINIC, A
16 HEALTH-CARE PROVIDER, OR A PRESCRIBER OFFICE.

17 (d) (I) "DONOR" MEANS ANY ENTITY LEGALLY AUTHORIZED TO
18 POSSESS MEDICINE, INCLUDING ____ A WHOLESALER, A DISTRIBUTOR, A
19 THIRD-PARTY LOGISTICS PROVIDER, A PHARMACY, A DISPENSER, A CLINIC,
20 A SURGICAL OR HEALTH CENTER, A REHABILITATION CENTER, A DETENTION
21 CENTER, A JAIL, A PRISON, A LABORATORY, A PRESCRIBER OR OTHER
22 HEALTH-CARE PROFESSIONAL, _____ A LONG-TERM CARE FACILITY OR
23 HEALTH-CARE FACILITY, AND ANY OTHER ENTITY REGULATED BY THE
24 BOARD WHICH DONATES MEDICINE.

25 (II) "DONOR" INCLUDES GOVERNMENT AGENCIES AND ENTITIES
26 THAT ARE FEDERALLY AUTHORIZED TO POSSESS MEDICINE, INCLUDING
27 MANUFACTURERS, REPACKAGERS, RELABELERS, OUTSOURCING FACILITIES,

1 VETERANS AFFAIRS HOSPITALS, FDA-AUTHORIZED IMPORTERS SUCH AS
2 THOSE DESCRIBED UNDER THE FEDERAL "FOOD, DRUG, AND COSMETIC
3 ACT", 21 U.S.C. SECS. 801 AND 804, AS AMENDED, OR SIMILAR
4 PROVISIONS, AND FEDERAL PRISONS.

5 (e) (I) "ELIGIBLE PATIENT" MEANS AN INDIVIDUAL WITH A NEED
6 FOR DONATED MEDICINE WHO IS INDIGENT, UNINSURED, OR
7 UNDERINSURED.

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

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

17 (g) "INDIVIDUAL DONOR" MEANS A NONLICENSED INDIVIDUAL
18 MEMBER OF THE PUBLIC.

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

20 (II) "MEDICINE" INCLUDES:

21 (A) A PRESCRIPTION DRUG THAT REQUIRES REFRIGERATION,
22 FREEZING, OR SPECIAL STORAGE IF THE MEDICINE HAS BEEN CONTINUALLY
23 MAINTAINED PURSUANT TO THE MANUFACTURER'S STORAGE SO LONG AS
24 THE COLD CHAIN CAN BE VERIFIED; AND

25 (B) PRESCRIPTION SUPPLIES AND DEVICES.

26 (III) "MEDICINE" DOES NOT INCLUDE:

27 (A) COMPOUNDED DRUGS;

1 (B) PRESCRIPTION DRUGS DISPENSED BY PHARMACIES OUTSIDE OF
2 THE UNITED STATES;

3 (C) PRESCRIPTION DRUGS THAT ARE SUBJECT TO RISK EVALUATION
4 AND MITIGATION UNDER 21 U.S.C. SEC. 355-1 (f)(3) UNLESS ALL OF THE
5 REQUIRED GUIDELINES FOR THE MEDICINE ARE FOLLOWED; OR

6 (D) CONTROLLED SUBSTANCES.

7 (i) "PRESCRIBER" HAS THE MEANING SET FORTH IN SECTION
8 12-280-125.7 (1)(f).

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

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

15 (II) "UNOPENED, TAMPER-EVIDENT PACKAGING" MAY INCLUDE
16 UNOPENED UNIT-DOSE, MULTIPLE-DOSE, IMMEDIATE, SECONDARY, OR
17 TERTIARY PACKAGING.

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

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

26 (b) PRIOR TO THE FIRST DONATION FROM A PERSON, A DONATION
27 RECIPIENT SHALL RECORD THE PERSON'S NAME, ADDRESS, PHONE NUMBER,

1 AND LICENSE NUMBER, IF APPLICABLE, AND SHALL:

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

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

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

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

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

21 (5) A DONATION RECIPIENT SHALL ENSURE THAT DONATED
22 MEDICINE IS IDENTIFIED PHYSICALLY OR ELECTRONICALLY AS SEPARATE
23 FROM REGULAR STOCK.

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

26 (a) TRANSFER DONATED MEDICINE TO ANOTHER DONATION
27 RECIPIENT OR TO AN ENTITY PARTICIPATING IN A DRUG DONATION

1 PROGRAM OPERATED BY ANOTHER STATE;

2 (b) REPACKAGE DONATED MEDICINE IN ACCORDANCE WITH
3 SUBSECTION (8) OF THIS SECTION AS NECESSARY FOR STORAGE,
4 DISPENSING, ADMINISTRATION, OR TRANSFER; OR

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

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

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

13 (II) DESTROYING THE DONATED MEDICINE THROUGH AN
14 INCINERATOR, A MEDICAL WASTE HAULER, A REVERSE DISTRIBUTOR, OR
15 OTHER LAWFUL METHOD; OR

16 (III) TRANSFERRING THE DONATED MEDICINE TO A RETURNS
17 PROCESSOR.

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

23 (8) REPACKAGED MEDICINE MUST BE LABELED WITH THE DRUG
24 NAME, STRENGTH, AND EXPIRATION DATE, IF THE EXPIRATION DATE IS
25 KNOWN, AND IDENTIFIED SEPARATELY FROM REGULAR STOCK UNTIL
26 INSPECTED AND INITIALED BY A LICENSED PHARMACIST. IF MULTIPLE
27 PACKAGED, DONATED MEDICINES WITH VARIED EXPIRATION DATES ARE

1 REPACKAGED TOGETHER, THE EARLIEST EXPIRATION DATE MUST BE USED.
2 PREScription DRUGS SPECIFIED BY NDC NUMBER IN A RECALL NOTICE
3 MUST BE CONSIDERED RECALLED UNLESS THE PRESCRIPTION DRUG HAS AN
4 AFFIXED LOT NUMBER THAT EXCLUDES IT FROM THE RECALL.

5 (9) A DONATION RECIPIENT SHALL ONLY ADMINISTER OR
6 REDISPENSE MEDICINE THAT:

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

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

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

15 (d) IS PROPERLY LABELED IN ACCORDANCE WITH THE RULES
16 ADOPTED BY THE BOARD;

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

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

24 (10) A DONATION RECIPIENT:

25 (a) MAY DISPENSE OR ADMINISTER PRESCRIPTION DRUGS TO AN
26 ELIGIBLE PATIENT PURSUANT TO THIS SECTION ONLY IF OTHERWISE
27 PERMITTED BY LAW PURSUANT TO A VALID PRESCRIPTION OR PRESCRIPTION

1 DRUG ORDER; AND

2 (b) SHALL MAINTAIN ELIGIBLE PATIENT-SPECIFIC WRITTEN OR
3 ELECTRONIC RECORDS IN ACCORDANCE WITH RULES ADOPTED BY THE
4 BOARD.

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

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

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

1 LIMITATIONS.

2 (14) WHEN PERFORMING ANY ACTION ASSOCIATED WITH THE
3 PROGRAM OR OTHERWISE PROCESSING DONATED MEDICINE FOR TAX, A
4 MANUFACTURER CREDIT, OR OTHER CREDIT, A DONATION RECIPIENT IS
5 CONSIDERED TO BE ACTING AS A RETURNS PROCESSOR AND SHALL COMPLY
6 WITH ALL RECORD-KEEPING REQUIREMENTS UNDER FEDERAL LAW FOR
7 NONSALABLE RETURNS.

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

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

27 (17) AN ENTITY PARTICIPATING IN A DRUG DONATION OR

1 REPOSITORY PROGRAM OPERATED BY ANOTHER STATE MAY PARTICIPATE
2 IN THE PROGRAM AND, IF THE REGISTERED ENTITY IS A PRESCRIPTION DRUG
3 OUTLET, MAY DISPENSE DONATED DRUGS TO ELIGIBLE PATIENTS OF THIS
4 STATE. THE REGISTERED ENTITY IS REQUIRED TO COMPLY WITH ALL
5 STATUTES AND RULES IN THIS STATE UNLESS THE STATUTES OR RULES
6 DIFFER FROM OR CONFLICT WITH THE STATUTES OR RULES OF THE STATE
7 IN WHICH THE ENTITY IS LOCATED.

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

12 (19) NOTWITHSTANDING ANY LAW TO THE CONTRARY, THIS
13 SECTION CONTROLS ALL ACTIVITIES UNDER THE PROGRAM AND
14 SUPERSEDES ANY INCONSISTENT LAW OR RULE.

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

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

24 (b) AN INDIVIDUAL OR ENTITY, INCLUDING AN EMPLOYEE, AN
25 OFFICER, A VOLUNTEER, AN OWNER, A PARTNER, A MEMBER, A DIRECTOR,
26 A CONTRACTOR, OR OTHER INDIVIDUAL OR ENTITY ASSOCIATED WITH THE
27 INDIVIDUAL OR ENTITY THAT, IN COMPLIANCE WITH THIS SECTION,

1 PRESCRIBES, DONATES, RECEIVES DONATIONS OF, DISPENSES,
2 ADMINISTERS, TRANSFERS, REPLACES, OR REPACKAGES MEDICINE OR
3 FACILITATES ANY OF THE ACTIONS DESCRIBED IN THIS SECTION; AND

4 (c) THE BOARD.

5 (21) A DONATION RECIPIENT OPERATING PRIMARILY FOR THE
6 PURPOSE OF PARTICIPATING IN THIS PROGRAM SHALL NOT BE REQUIRED TO
7 POSSESS A COMPREHENSIVE OR MINIMUM SUPPLY OF MEDICINE.

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

10 **25-15-328. Household medication take-back program -**
11 **creation - collection and disposal of medication injection devices -**
12 **liability - definitions - cash fund - rules.** (6) Nothing in this section:

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

15 **SECTION 4. Act subject to petition - effective date.** This act
16 takes effect at 12:01 a.m. on the day following the expiration of the
17 ninety-day period after final adjournment of the general assembly; except
18 that, if a referendum petition is filed pursuant to section 1 (3) of article V
19 of the state constitution against this act or an item, section, or part of this
20 act within such period, then the act, item, section, or part will not take
21 effect unless approved by the people at the general election to be held in
22 November 2026 and, in such case, will take effect on the date of the
23 official declaration of the vote thereon by the governor.