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

## **ENGROSSED**

This Version Includes All Amendments Adopted on Second Reading in the House of Introduction

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 <a href="http://leg.colorado.gov">http://leg.colorado.gov</a>.)

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

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:

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12-280-135. Unused medicine - licensed facilities - correctional

8 **facilities - reuse - definitions - rules.** (1) As used in this section, unless

the context otherwise requires:

(e) (I) "Medication" means a prescription that is not a controlled

substance "Medicine" means prescription <u>drugs.</u>

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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 <u>BY A DONOR</u> PURSUANT TO THE
5	MANUFACTURER'S STORAGE <u>REQUIREMENTS</u> , 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	<u>OR</u>
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

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

- (B) Nothing in this subsection (2)(a)(II) creates or abrogates any liability on behalf of a prescription drug manufacturer for the storage, donation, acceptance, or dispensing of a medication MEDICINE or A product or creates any civil cause of action against a prescription drug manufacturer in addition to that which is available under applicable law.
- (C) A person <u>or entity</u> is not subject to civil or criminal liability or professional disciplinary action for donating, accepting, dispensing, or facilitating the donation of materials in good faith, without negligence OR WILLFUL OR WANTON MISCONDUCT, and in compliance with this section.
- (III) A correctional facility may return unused medications MEDICINE or medical supplies and used or unused medical devices to the pharmacist within the correctional facility or a prescription drug outlet in order for the medication MEDICINE to be redispensed to another patient or donated to <u>a nonprofit AN</u> entity that has the legal authority to possess the materials or to a practitioner authorized by law to prescribe the materials.
- (b) Medications are MEDICINE IS only available to be dispensed to another person or donated to <u>a nonprofit AN</u> entity under this section if the medications are MEDICINE IS:
- (II) Individually packaged and the packaging has not been damaged; or
- (III) In the original, unopened, sealed, and tamper-evident unit dose packaging; OR
- (IV) FOR MEDICINE THAT REQUIRES REFRIGERATION, FREEZING, OR SPECIAL STORAGE, CONTINUALLY MAINTAINED BY THE DONOR PURSUANT

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

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

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- 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.
  - (5) The board shall adopt rules that allow a pharmacist to redispense medication pursuant to this section and section 25.5-5-502 and to donate medication pursuant to this section.
  - (6) Nothing in this section or section 25.5-5-502 creates or abrogates any liability on behalf of a prescription drug manufacturer for the storage, donation, acceptance, or dispensing of an unused donated medication MEDICINE or creates any civil cause of action against a

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1	prescription drug manufacturer in addition to that which is available
2	under applicable law.
3	SECTION 2. In Colorado Revised Statutes, add 12-280-135.5 as
4	follows:
5	12-280-135.5. Colorado drug donation program - created -
6	rules - records - definitions. (1) AS USED IN THIS SECTION, UNLESS THE
7	CONTEXT OTHERWISE REQUIRES:
8	(a) "Colorado drug donation program" or "program"
9	MEANS THE COLORADO DRUG DONATION PROGRAM CREATED IN THIS
10	SECTION.
11	(b) "CONTROLLED SUBSTANCE" HAS THE MEANING SET FORTH IN
12	SECTION 18-18-102.
13	(c) (I) "DONATION RECIPIENT" MEANS AN ENTITY THAT:
14	(A) IS LEGALLY AUTHORIZED TO POSSESS MEDICINE;
15	(B) HAS A LICENSE OR REGISTRATION IN GOOD STANDING IN THE
16	STATE IN WHICH THE ENTITY IS LOCATED; AND
17	(C) RECEIVES A DONATION OF MEDICINE.
18	(II) "DONATION RECIPIENT" INCLUDES A HOSPITAL, A
19	PHARMACY, A CLINIC, A HEALTH-CARE PROVIDER, OR A PRESCRIBER
20	OFFICE.
21	(III) "DONATION RECIPIENT" ALSO INCLUDES A WHOLESALER, A
22	DISTRIBUTOR, A THIRD-PARTY LOGISTICS PROVIDER, A REVERSE
23	DISTRIBUTOR, OR A REPACKAGER IF THE ENTITY IS A NONPROFIT ENTITY OR
24	IS DIRECTLY OR INDIRECTLY OWNED, CONTROLLED, OR COULD BE
25	CONTROLLED BY A NONPROFIT ENTITY.
26	(d) (I) "Donor" means any $\underline{\text{entity}}$ legally authorized to
2.7	POSSESS MEDICINE INCLUDING A WHOLESALER A DISTRIBUTOR A

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1	THIRD-PARTY LOGISTICS PROVIDER, A PHARMACY, A DISPENSER, A CLINIC,
2	A SURGICAL OR HEALTH CENTER, A REHABILITATION CENTER, A DETENTION
3	CENTER, A JAIL, A PRISON, A LABORATORY, A PRESCRIBER OR OTHER
4	HEALTH-CARE PROFESSIONAL, A LONG-TERM CARE FACILITY OR
5	HEALTH-CARE FACILITY, AND ANY OTHER ENTITY REGULATED BY THE
6	BOARD THAT DONATES MEDICINE.
7	(II) "DONOR" INCLUDES GOVERNMENT AGENCIES AND ENTITIES
8	THAT ARE FEDERALLY AUTHORIZED TO POSSESS MEDICINE, INCLUDING
9	MANUFACTURERS, REPACKAGERS, RELABELERS, OUTSOURCING FACILITIES,
10	VETERANS AFFAIRS HOSPITALS, FDA-AUTHORIZED IMPORTERS SUCH AS
11	THOSE DESCRIBED UNDER THE FEDERAL "FOOD, DRUG, AND COSMETIC
12	ACT", 21 U.S.C. SECS. 801 AND 804, AS AMENDED, OR SIMILAR
13	PROVISIONS, AND FEDERAL PRISONS.
14	(e) (I) "ELIGIBLE PATIENT" MEANS AN INDIVIDUAL WITH A NEED
15	FOR DONATED MEDICINE WHO IS INDIGENT, UNINSURED, OR
16	<u>UNDERINSURED.</u>
17	(II) "ELIGIBLE PATIENT" INCLUDES OTHER INDIVIDUALS IF A NEED
18	FOR DONATED MEDICINE IS NOT IDENTIFIED AMONG INDIVIDUALS WHO ARE
19	INDIGENT, UNINSURED, OR UNDERINSURED.
20	(f) "HEALTH-CARE PROFESSIONAL" MEANS AN INDIVIDUAL WHO IS
21	LICENSED TO PRACTICE AS A PHYSICIAN, REGISTERED NURSE, ADVANCED
22	PRACTICE REGISTERED NURSE, PRACTICAL NURSE, OPTOMETRIST, OR
23	PHARMACIST; A CERTIFIED MIDWIFE WITH PRESCRIPTIVE AUTHORITY
24	PURSUANT TO SECTION 12-255-112; OR ANY OTHER PRACTITIONER
25	AUTHORIZED TO DISPENSE OR ADMINISTER MEDICINE.
26	(g) "Individual donor" means a nonlicensed individual
27	MEMBER OF THE PUBLIC.

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1	(h) (1) "MEDICINE" MEANS PRESCRIPTION <u>DRUGS.</u>
2	(II) "MEDICINE" INCLUDES:
3	(A) A PRESCRIPTION DRUG THAT REQUIRES REFRIGERATION,
4	FREEZING, OR SPECIAL STORAGE IF THE MEDICINE HAS BEEN CONTINUALLY
5	MAINTAINED <u>BY THE DONOR</u> PURSUANT TO THE MANUFACTURER'S
6	STORAGE <u>REQUIREMENTS</u> , SO LONG AS THE COLD CHAIN CAN BE VERIFIED;
7	AND
8	(B) Prescription supplies and devices.
9	(III) "MEDICINE" DOES NOT INCLUDE:
10	(A) COMPOUNDED DRUGS;
11	(B) Prescription drugs dispensed by pharmacies outside of
12	THE UNITED STATES;
13	(C) Prescription drugs that are subject to risk evaluation
14	AND MITIGATION <u>STRATEGIES (REMS)</u> UNDER 21 U.S.C. SEC. 355-1 (f)(3)
15	UNLESS ALL OF THE REQUIRED GUIDELINES FOR THE MEDICINE ARE
16	FOLLOWED OR REMS DRUGS THAT WERE INITIALLY DISPENSED BY A
17	PHARMACY PURSUANT TO A RESTRICTED REMS DISTRIBUTION CHANNEL;
18	<u>OR</u>
19	(D) CONTROLLED SUBSTANCES.
20	(i) "Prescriber" has the meaning set forth in section
21	12-280-125.7 (1)(f).
22	(j) "Returns processor" has the meaning set forth in 21
23	U.S.C. SEC. 360eee (18) AND INCLUDES A REVERSE DISTRIBUTOR.
24	(k) (I) "Unopened, tamper-evident packaging" means an
25	INTACT PACKAGING SYSTEM THAT RENDERS MEDICINE INACCESSIBLE
26	WITHOUT OBVIOUS DESTRUCTION OF THE SEAL OR SOME PORTION OF THE
27	PACKAGING SYSTEM.

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1	(II) "Unopened, tamper-evident packaging" may include
2	UNOPENED UNIT-DOSE, MULTIPLE-DOSE, IMMEDIATE, SECONDARY, OR
3	TERTIARY PACKAGING.
4	(2) THERE IS CREATED THE COLORADO DRUG DONATION PROGRAM
5	TO FACILITATE THE SAFE DONATION AND REDISPENSING OF UNUSED
6	MEDICINE TO COLORADANS IN NEED OF THE MEDICINE. PARTICIPATION IN
7	THE PROGRAM IS VOLUNTARY.
8	(3) (a) Notwithstanding any other law or rule to the
9	CONTRARY, A DONOR <u>OR AN INDIVIDUAL DONOR</u> MAY DONATE MEDICINE
10	TO A DONATION RECIPIENT. A DONATION RECIPIENT MAY RECEIVE
11	DONATED MEDICINE FROM <u>A DONOR OR AN INDIVIDUAL DONOR.</u>
12	(b) PRIOR TO THE FIRST DONATION FROM A PERSON, A DONATION
13	RECIPIENT SHALL RECORD THE PERSON'S NAME, ADDRESS, PHONE NUMBER,
14	AND LICENSE NUMBER, IF APPLICABLE, AND SHALL:
15	(I) VERIFY THAT THE PERSON MEETS THE DEFINITION PROVIDED IN
16	SUBSECTION (1)(d) OF THIS SECTION;
17	(II) CONFIRM THAT THE PERSON AGREES TO MAKE DONATIONS OF
18	MEDICINE ONLY IN ACCORDANCE WITH THIS SECTION AND RULES ADOPTED
19	BY THE BOARD RELATING TO DONATED MEDICINE; AND
20	(III) IF APPLICABLE, CONFIRM THAT THE PERSON AGREES TO
21	REMOVE OR REDACT ANY PATIENT NAMES AND PRESCRIPTION NUMBERS ON
22	DONATED MEDICINE OR TO OTHERWISE MAINTAIN PATIENT
23	CONFIDENTIALITY BY EXECUTING A CONFIDENTIALITY AGREEMENT WITH
24	THE AUTHORIZED DONATION RECIPIENT.
25	(c) NO OTHER INFORMATION OR RECORDS ARE REQUIRED PRIOR TO
26	THE FIRST DONATION FROM A NEW DONOR OR A NEW INDIVIDUAL DONOR
27	OTHER THAN AS DESCRIBED IN SUBSECTION (3)(b) OF THIS SECTION.

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1	(4) A DONATION RECIPIENT SHALL MAINTAIN A WRITTEN OR AN
2	ELECTRONIC RECORD OF DONATED MEDICINE CONSISTING OF THE NAME,
3	STRENGTH, QUANTITY, AND LOT NUMBER, IF KNOWN, OF EACH ACCEPTED
4	OR TRANSFERRED DRUG AND THE NAME, ADDRESS, AND PHONE NUMBER OF
5	THE <b>DONOR</b> , INDIVIDUAL DONOR, OR TRANSFERRING ENTITY. NO OTHER
6	RECORD OF DONATION IS REQUIRED.
7	(5) A DONATION RECIPIENT SHALL ENSURE THAT DONATED
8	MEDICINE IS IDENTIFIED PHYSICALLY OR ELECTRONICALLY AS SEPARATE
9	FROM REGULAR STOCK.
10	(6) NOTWITHSTANDING ANY OTHER LAW TO THE CONTRARY, A
11	DONATION RECIPIENT MAY:
12	(a) Transfer donated medicine to another donation
13	RECIPIENT OR TO AN ENTITY PARTICIPATING IN A DRUG DONATION
14	PROGRAM OPERATED BY ANOTHER STATE;
15	(b) Repackage donated medicine in accordance with
16	SUBSECTION (8) OF THIS SECTION AS NECESSARY FOR STORAGE,
17	DISPENSING, ADMINISTRATION, OR TRANSFER; OR
18	(c) IF THE DONATION RECIPIENT IS A PRESCRIPTION DRUG OUTLET
19	OR OTHER OUTLET, $\underline{\text{REPLACE}}$ MEDICINE OF THE SAME DRUG NAME AND
20	STRENGTH PREVIOUSLY DISPENSED OR ADMINISTERED TO ELIGIBLE
21	PATIENTS IN ACCORDANCE WITH 42 U.S.C. SEC. 256b, AS AMENDED.
22	(7) (a) Donated medicine that does not meet the
23	REQUIREMENTS SPECIFIED IN THIS SECTION AND THE RULES ADOPTED BY
24	THE BOARD MUST BE DISPOSED OF BY:
25	(I) RETURNING THE DONATED MEDICINE TO THE DONOR;
26	(II) DESTROYING THE DONATED MEDICINE THROUGH AN
27	INCINERATOR, A MEDICAL WASTE HAULER, A REVERSE DISTRIBUTOR, OR

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1	OTHER LAWFUL METHOD; OR
2	(III) Transferring the donated medicine to a returns
3	PROCESSOR.
4	(b) A DONATION RECIPIENT SHALL MAINTAIN A WRITTEN OR AN
5	ELECTRONIC RECORD OF DISPOSED MEDICINE CONSISTING OF THE DISPOSAL
6	METHOD, AS DESCRIBED IN SUBSECTION $(7)(a)$ OF THIS SECTION; THE DATE
7	OF DISPOSAL; AND THE NAME, STRENGTH, AND QUANTITY OF EACH
8	DISPOSED DRUG. NO OTHER RECORD OF DISPOSAL IS REQUIRED.
9	(8) REPACKAGED MEDICINE MUST BE LABELED WITH THE DRUG
10	NAME, STRENGTH, AND EXPIRATION DATE, IF THE EXPIRATION DATE IS
11	KNOWN, AND IDENTIFIED SEPARATELY FROM REGULAR STOCK UNTIL
12	INSPECTED AND INITIALED BY A LICENSED PHARMACIST. IF MULTIPLE
13	PACKAGED, DONATED MEDICINES WITH VARIED EXPIRATION DATES ARE
14	REPACKAGED TOGETHER, THE EARLIEST EXPIRATION DATE MUST BE USED.
15	Prescription drugs specified by NDC number in a recall notice
16	MUST BE CONSIDERED RECALLED UNLESS THE PRESCRIPTION DRUG HAS AN
17	AFFIXED LOT NUMBER THAT EXCLUDES IT FROM THE RECALL.
18	(9) A DONATION RECIPIENT SHALL ONLY ADMINISTER OR
19	REDISPENSE MEDICINE THAT:
20	(a) IS IN UNOPENED, TAMPER-EVIDENT PACKAGING OR HAS BEEN
21	REPACKAGED UNDER THIS PROGRAM;
22	(b) MEETS THE REQUIREMENTS SET FORTH IN THIS SECTION BASED
23	ON AN INSPECTION BY A LICENSED PHARMACIST;
24	(c) IF DISPENSED TO AN ELIGIBLE PATIENT, IS REPACKAGED BY A
25	LICENSED PHARMACIST INTO A NEW CONTAINER OR, IF KEPT IN THE
26	DONATED CONTAINER, IS IN A CONTAINER THAT HAS ALL PREVIOUS
27	PATIENT INFORMATION REDACTED OR REMOVED;

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1	(d) Is properly labeled in accordance with the rules
2	ADOPTED BY THE BOARD;
3	(e) HAS AN EXPIRATION OR BEYOND-USE DATE THAT WILL NOT
4	EXPIRE BEFORE THE MEDICINE IS USED BY THE ELIGIBLE PATIENT BASED ON
5	THE PRESCRIBER'S DIRECTIONS FOR USE; AND
6	(f) If the medicine requires refrigeration, freezing, or
7	SPECIAL STORAGE, HAS BEEN CONTINUALLY MAINTAINED PURSUANT TO
8	THE MANUFACTURER'S STORAGE REQUIREMENTS, SO LONG AS THE COLD
9	<u>CHAIN CAN BE VERIFIED.</u>
10	(10) A DONATION RECIPIENT:
11	(a) May dispense or administer prescription drugs to an
12	ELIGIBLE PATIENT PURSUANT TO THIS SECTION ONLY IF OTHERWISE
13	PERMITTED BY LAW PURSUANT TO A VALID PRESCRIPTION OR PRESCRIPTION
14	DRUG ORDER; AND
15	(b) SHALL MAINTAIN ELIGIBLE PATIENT-SPECIFIC WRITTEN OR
16	ELECTRONIC RECORDS IN ACCORDANCE WITH RULES ADOPTED BY THE
17	BOARD.
18	(11) A MANUFACTURER, <u>PRESCRIPTION DRUG OUTLET</u> ,
19	REPACKAGER, DISPENSER, OR WHOLESALER, OTHER THAN A RETURNS
20	PROCESSOR, PARTICIPATING IN THE PROGRAM SHALL COMPLY WITH THE
21	REQUIREMENTS OF 21 U.S.C. SECS. 360eee-1 TO 360eee-4 RELATING TO
22	DRUG SUPPLY CHAIN SECURITY.
23	(12) THE DONATION, TRANSFER, OR RECEIPT OF MEDICINE OR THE
24	FACILITATION OF A DONATION, TRANSFER, OR RECEIPT OF MEDICINE
25	PURSUANT TO THIS SECTION IS NOT WHOLESALE DISTRIBUTION AND DOES
26	NOT REQUIRE LICENSING AS A WHOLESALE DISTRIBUTOR.
27	(13) MEDICINE DONATED TO THE PROGRAM MUST NOT BE RESOLD

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1	AND IS CONSIDERED NONSALEABLE; EXCEPT THAT HANDLING, DISPENSING
2	OR USUAL AND CUSTOMARY CHARGES TO AN ELIGIBLE PATIENT, HEALTH
3	PLAN, PHARMACY BENEFIT MANAGER, PHARMACY SERVICES
4	ADMINISTRATIVE ORGANIZATION, GOVERNMENT AGENCY, OR OTHER
5	ENTITY IS NOT CONSIDERED RESELLING. IF THE DONATION RECIPIENT IS A
6	FOR-PROFIT ENTITY, THESE CHARGES MUST NOT EXCEED THE DONATION
7	RECIPIENT'S COST OF PROVIDING THE MEDICINE, INCLUDING THE CURRENT
8	AND ANTICIPATED COSTS OF EDUCATING ELIGIBLE <u>DONORS AND</u>
9	<u>INDIVIDUAL DONORS</u> , PROVIDING TECHNICAL SUPPORT TO PARTICIPATING
10	DONORS AND INDIVIDUAL DONORS, SHIPPING AND HANDLING, LABOR
11	STORAGE, LICENSING, UTILITIES, ADVERTISING, TECHNOLOGY, SUPPLIES,
12	AND EQUIPMENT. EXCEPT AS DESCRIBED IN THIS SUBSECTION (13), THE
13	AMOUNT OF THESE CHARGES IS NOT SUBJECT TO ANY ADDITIONAL
14	LIMITATIONS.
15	(14) When Performing any action associated with the
16	PROGRAM OR OTHERWISE PROCESSING DONATED MEDICINE FOR TAX, A
17	MANUFACTURER CREDIT, OR OTHER CREDIT, A DONATION RECIPIENT IS
18	CONSIDERED TO BE ACTING AS A RETURNS PROCESSOR AND SHALL COMPLY
19	WITH ALL RECORD-KEEPING REQUIREMENTS UNDER FEDERAL LAW FOR
20	NONSALEABLE RETURNS.
21	(15) ALL REQUIRED RECORDS MUST BE RETAINED IN PHYSICAL OR
22	ELECTRONIC FORMAT, ON OR OFF THE DONATION RECIPIENT'S PREMISES.
23	FOR A PERIOD OF TWO YEARS. DONORS OR DONATION RECIPIENTS MAY
24	CONTRACT WITH ONE ANOTHER OR WITH A THIRD PARTY TO CREATE OR
25	MAINTAIN RECORDS. AN IDENTIFIER, SUCH AS A SERIAL NUMBER OR BAR
26	CODE, MAY BE USED IN PLACE OF INFORMATION IF IT ALLOWS FOR THE
27	INFORMATION TO BE READILY RETRIEVABLE. UPON REQUEST BY A STATE

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2	MUST BE REPLACED WITH THE ORIGINAL INFORMATION. AN IDENTIFIER
3	MUST NOT BE USED ON LABELS WHEN DISPENSING OR ADMINISTERING A
4	DRUG TO AN ELIGIBLE PATIENT.
5	(16) A DONATION OR OTHER TRANSFER OF POSSESSION OR
6	CONTROL IS NOT A CHANGE OF OWNERSHIP UNLESS IT IS SPECIFIED AS SUCH
7	BY THE DONATION RECIPIENT. IF A RECORD OF THE DONATION'S
8	TRANSACTION INFORMATION OR HISTORY IS REQUIRED, THE HISTORY MUST
9	BEGIN WITH THE <u>DONOR OR INDIVIDUAL DONOR</u> , MUST INCLUDE ALL PRIOR
10	DONATIONS, AND, IF THE MEDICINE WAS PREVIOUSLY DISPENSED, MUST
11	INCLUDE ONLY DRUG INFORMATION THAT IS REQUIRED TO BE ON THE
12	PATIENT LABEL IN ACCORDANCE WITH RULES ADOPTED BY THE BOARD.
13	(17) An entity participating in a drug donation or
14	REPOSITORY PROGRAM OPERATED BY ANOTHER STATE MAY PARTICIPATE
15	IN THE PROGRAM AND, IF THE REGISTERED ENTITY IS A PRESCRIPTION DRUG
16	OUTLET, MAY DISPENSE DONATED DRUGS TO ELIGIBLE PATIENTS OF THIS
17	STATE. THE REGISTERED ENTITY IS REQUIRED TO COMPLY WITH ALL
18	STATUTES AND RULES IN THIS STATE UNLESS THE STATUTES OR RULES
19	DIFFER FROM OR CONFLICT WITH THE STATUTES OR RULES OF THE STATE
20	IN WHICH THE ENTITY IS LOCATED.
21	(18) The board shall adopt any rules necessary to
22	IMPLEMENT THIS SECTION. THE RULES MUST REQUIRE THE LEAST AMOUNT
23	OF RECORD KEEPING NECESSARY TO ENSURE PATIENT SAFETY AND MUST
24	ALLOW FLEXIBILITY IN THE FORMAT FOR RECORD KEEPING.
25	(19) NOTWITHSTANDING ANY LAW TO THE CONTRARY, THIS
26	SECTION CONTROLS ALL ACTIVITIES UNDER THE PROGRAM AND
27	SUPERSEDES ANY INCONSISTENT LAW OR RULE.

OR FEDERAL REGULATOR, THE IDENTIFIER USED FOR A REQUESTED RECORD

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1	(20) WHEN ACTING IN GOOD FAITH, WITHOUT NEGLIGENCE OR
2	WILLFUL OR WANTON MISCONDUCT, THE FOLLOWING INDIVIDUALS OR
3	ENTITIES ARE NOT SUBJECT TO CIVIL OR CRIMINAL LIABILITY OR
4	PROFESSIONAL DISCIPLINARY ACTION:
5	(a) AN INDIVIDUAL OR ENTITY INVOLVED IN THE SUPPLY CHAIN OF
6	DONATED MEDICINE, INCLUDING THE DONOR, THE INDIVIDUAL DONOR, THE
7	DONATION RECIPIENT, THE MANUFACTURER, THE REPACKAGER, THE
8	PRESCRIPTION DRUG OUTLET OR OTHER ENTITY REGULATED BY THE
9	BOARD, AND THE ELIGIBLE PATIENT;
10	(b) An individual or entity, including an employee, an
11	OFFICER, A VOLUNTEER, AN OWNER, A PARTNER, A MEMBER, A DIRECTOR,
12	A CONTRACTOR, OR OTHER INDIVIDUAL OR ENTITY ASSOCIATED WITH THE
13	INDIVIDUAL OR ENTITY THAT, IN COMPLIANCE WITH THIS SECTION,
14	PRESCRIBES, DONATES, RECEIVES DONATIONS OF, DISPENSES,
15	ADMINISTERS, TRANSFERS, <u>REPLACES</u> , OR REPACKAGES MEDICINE OR
16	FACILITATES ANY OF THE ACTIONS DESCRIBED IN THIS SECTION; AND
17	(c) THE BOARD.
18	(21) A DONATION RECIPIENT OPERATING PRIMARILY FOR THE
19	PURPOSE OF PARTICIPATING IN THIS PROGRAM SHALL NOT BE REQUIRED TO
20	POSSESS A COMPREHENSIVE OR MINIMUM SUPPLY OF MEDICINE.
21	SECTION 3. In Colorado Revised Statutes, 25-15-328, amend
22	(6)(a) as follows:
23	25-15-328. Household medication take-back program -
24	creation - collection and disposal of medication injection devices -
25	liability - definitions - cash fund - rules. (6) Nothing in this section:
26	(a) Affects the authority to collect and reuse medications
27	MEDICINE pursuant to section 12-280-135 OR 12-280-135.5; or

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1	<b>SECTION 4.</b> In Colorado Revised Statutes, add 12-315-127 as
2	<u>follows:</u>
3	12-315-127. Veterinary drug donation program - rules. (1) AN
4	OWNER OF AN ANIMAL MAY DONATE A DRUG THAT IS DISPENSED FOR BUT
5	NOT USED BY THE ANIMAL TO A LICENSED VETERINARIAN OR ANIMAL
6	SHELTER IN WHICH VETERINARY MEDICINE IS PRACTICED IF THE LICENSED
7	VETERINARIAN OR ANIMAL SHELTER ACCEPTS THE DRUG.
8	(2) EXCEPT AS PROVIDED IN SUBSECTION (4)(b) OF THIS SECTION,
9	A LICENSED VETERINARIAN MAY REISSUE A DONATED DRUG ACCEPTED
10	PURSUANT TO THIS SECTION TO FILL OTHER PRESCRIPTIONS DISPENSED BY
11	THE LICENSED VETERINARIAN FREE OF CHARGE FOR AN ANIMAL IF:
12	(a) THE LICENSED VETERINARIAN DETERMINES THAT THE OWNER
13	OF THE ANIMAL IS ELIGIBLE FOR THE REISSUANCE OF THE DRUG BASED ON
14	ECONOMIC NEED;
15	(b) THE LICENSED VETERINARIAN DETERMINES THAT THE DRUG IS
16	SUITABLE FOR REISSUANCE;
17	(c) The drug was originally dispensed by a licensed
18	<u>VETERINARIAN;</u>
19	(d) THE DRUG IS NOT A CONTROLLED SUBSTANCE;
20	(e) THE DRUG IS NOT A COMPOUNDED DRUG;
21	(f) The drug does not require refrigeration before opening
22	AND THE DRUG WAS UNOPENED WHEN DONATED;
23	(g) THE DRUG IS NOT IN A LIQUID FORM OR, IF IN LIQUID FORM, THE
24	DRUG IS PACKAGED IN A SINGLE DOSE IN AN AMPULE OR VIAL;
25	(h) THE DRUG HAS NOT EXPIRED;
26	(i) THE PACKAGING OR BOTTLE CONTAINS THE EXPIRATION DATE
27	OF THE DRUG; AND

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1	(j) THE NAME OF THE ANIMAL AND THE NAME OF THE OWNER OF
2	THE ANIMAL FOR WHICH THE DRUG WAS ORIGINALLY DISPENSED, THE
3	PRESCRIPTION NUMBER, AND ANY OTHER IDENTIFYING MARKS ARE
4	OBLITERATED FROM THE PACKAGING OR BOTTLE BEFORE THE DRUG IS
5	REISSUED.
6	(3) A LICENSED VETERINARIAN SHALL:
7	(a) IDENTIFY AND MAINTAIN SEPARATELY FROM OTHER STOCK A
8	DONATED DRUG ACCEPTED PURSUANT TO THIS SECTION; AND
9	(b) Make a record of each donated drug accepted
10	PURSUANT TO THIS SECTION THAT INCLUDES, AT A MINIMUM:
11	(A) THE DATE ON WHICH THE DRUG WAS DONATED;
12	(B) THE NAME OF THE PERSON WHO DONATED THE DRUG; AND
13	(C) THE EXPIRATION DATE OF THE DRUG.
14	(4) A LICENSED VETERINARIAN SHALL NOT:
15	(a) SELL OR RESELL A DONATED DRUG ACCEPTED PURSUANT TO
16	THIS SECTION; OR
17	(b) Dispense a donated drug accepted pursuant to this
18	SECTION TO FILL OTHER PRESCRIPTIONS DISPENSED BY THE LICENSED
19	VETERINARIAN FOR AN ANIMAL IF THE ANIMAL IS RAISED TO PRODUCE
20	FOOD FOR HUMAN CONSUMPTION OR THE ANIMAL IS ORDINARILY
21	CONSUMED BY ANIMALS THAT ARE RAISED TO PRODUCE FOOD FOR HUMAN
22	CONSUMPTION.
23	(5) (a) A LICENSED VETERINARIAN, ANIMAL SHELTER IN WHICH
24	VETERINARY MEDICINE IS PRACTICED, OR OTHER PERSON WHO EXERCISES
25	REASONABLE CARE IN THE DONATION, ACCEPTANCE, DISTRIBUTION, OR
26	DISPENSATION OF A DRUG IN ACCORDANCE WITH THIS SECTION AND ANY
27	RULES ADOPTED PURSUANT TO THIS SECTION IS NOT SUBJECT TO CIVIL OR

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1	CRIMINAL LIABILITY OR DISCIPLINARY ACTION BY A PROFESSIONAL
2	LICENSING BOARD FOR ANY LOSS, INJURY, OR DEATH THAT RESULTS FROM
3	THE DONATION, ACCEPTANCE, DISTRIBUTION, OR DISPENSATION OF THE
4	<u>DRUG.</u>
5	(b) A MANUFACTURER OF A DRUG IS NOT SUBJECT TO CIVIL OR
6	CRIMINAL LIABILITY FOR ANY CLAIM OR INJURY ARISING FROM THE
7	DONATION, ACCEPTANCE, DISTRIBUTION, OR DISPENSATION OF THE DRUG
8	PURSUANT TO THIS SECTION AND ANY RULES ADOPTED PURSUANT TO THIS
9	<u>SECTION.</u>
10	(6) THE BOARD MAY ADOPT RULES AS NECESSARY TO IMPLEMENT
11	THIS SECTION, INCLUDING:
12	(a) REQUIREMENTS FOR REISSUING DONATED DRUGS PURSUANT TO
13	THIS SECTION, INCLUDING REQUIREMENTS THAT PROVIDE APPROPRIATE
14	SAFEGUARDS FOR ENSURING THAT THE DRUGS ARE NOT COMPROMISED OR
15	ILLEGALLY DIVERTED BEFORE BEING REISSUED;
16	(b) REQUIREMENTS FOR ACCEPTING DRUGS DONATED BY A
17	LICENSED VETERINARIAN OR ANIMAL SHELTER; AND
18	(c) REQUIREMENTS FOR MAINTAINING RECORDS RELATING TO THE
19	ACCEPTANCE AND USE OF DONATED DRUGS TO FILL OTHER PRESCRIPTIONS
20	PURSUANT TO THIS SECTION.
21	SECTION 5. Act subject to petition - effective date. This act
22	takes effect at 12:01 a.m. on the day following the expiration of the
23	ninety-day period after final adjournment of the general assembly; except
24	that, if a referendum petition is filed pursuant to section 1 (3) of article V
25	of the state constitution against this act or an item, section, or part of this
26	act within such period, then the act, item, section, or part will not take
27	effect unless approved by the people at the general election to be held in

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- 1 November 2026 and, in such case, will take effect on the date of the
- 2 official declaration of the vote thereon by the governor.

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