First Regular Session Seventy-fifth General Assembly STATE OF COLORADO

INTRODUCED

LLS NO. 25-1042.01 Brita Darling x2241

SENATE BILL 25-289

SENATE SPONSORSHIP

Cutter,

HOUSE SPONSORSHIP

Brown,

Senate Committees
Health & Human Services

101

House Committees

A BILL FOR AN ACT

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

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.

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:

1

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, including

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1	FDA-APPROVED DRUGS LABELED FOR INVESTIGATIONAL USE.
2	(II) "MEDICINE" INCLUDES:
3	(A) A PRESCRIPTION DRUG THAT REQUIRES REFRIGERATION,
4	FREEZING, OR SPECIAL STORAGE IF THE PRESCRIPTION DRUG HAS BEEN
5	CONTINUALLY MAINTAINED PURSUANT TO THE MANUFACTURER'S STORAGE
6	REQUIREMENTS; 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 entity that has legal authority to possess
25	the materials or to a person legally authorized to dispense the materials.
26	A licensed pharmacist shall review the process of donating the unused
27	medications MEDICINE to the nonprofit entity.

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(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 or entity 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 a nonprofit 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 a nonprofit 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 PURSUANT TO THE
MANUFACTURER'S STORAGE REQUIREMENTS.
(c) The following medications may not be donated MEDICINE IS

NOT ACCEPTABLE FOR DONATION:

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1	(I) Medications MEDICINE THAT IS NOT packaged in A traditional
2	brown or amber pill bottles DISPENSING SYSTEM, AS DEFINED BY THE
3	BOARD BY RULE;
4	(III) $\frac{\text{Medications}}{\text{EXCEPT}}$ EXCEPT AS PROVIDED IN SUBSECTION (2)(b)(IV)
5	OF THIS SECTION, MEDICINE that require REQUIRES refrigeration, freezing,
6	or special storage;
7	(IV) Medications that require special registration with the
8	manufacturer; or
9	(V) Medications MEDICINE that are IS adulterated or misbranded,
10	as determined by a person legally authorized to dispense the medications
11	MEDICINE on behalf of the nonprofit entity OR A PERSON LEGALLY
12	AUTHORIZED TO DISPENSE THE MEDICINE;
13	(VI) COMPOUNDED MEDICINE;
14	(VII) MEDICINE DISPENSED BY PHARMACIES OUTSIDE OF THE
15	UNITED STATES; OR
16	(VIII) MEDICINE THAT IS SUBJECT TO RISK EVALUATION AND
17	MITIGATION UNDER 21 U.S.C. SEC. 355-1 (f)(3) UNLESS ALL OF THE
18	REQUIRED GUIDELINES FOR THE MEDICINE ARE FOLLOWED.
19	(3) Medication MEDICINE dispensed or donated pursuant to this
20	section must not be expired. A medication shall not be dispensed
21	PRESCRIBING PRACTITIONER SHALL NOT DISPENSE MEDICINE that will
22	expire before the use by the patient based on the prescribing practitioner's
23	directions for use.
24	(4) Medication MEDICINE, medical supplies, and medical devices
25	donated pursuant to this section may not be resold for profit. The entity
26	that receives the donated materials may charge the end user a handling
2.7	fee, which fee shall MUST not exceed the amount specified by rule of the

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1	board.
2	(5) The board shall adopt rules that allow a pharmacist to
3	redispense medication pursuant to this section and section 25.5-5-502 and
4	to donate medication pursuant to this section.
5	(6) Nothing in this section or section 25.5-5-502 creates or
6	abrogates any liability on behalf of a prescription drug manufacturer for
7	the storage, donation, acceptance, or dispensing of an unused donated
8	medication MEDICINE or creates any civil cause of action against a
9	prescription drug manufacturer in addition to that which is available
10	under applicable law.
11	SECTION 2. In Colorado Revised Statutes, add 12-280-135.5 as
12	follows:
13	12-280-135.5. Colorado drug donation program - created -
14	rules - records - definitions. (1) AS USED IN THIS SECTION, UNLESS THE
15	CONTEXT OTHERWISE REQUIRES:
16	(a) "COLORADO DRUG DONATION PROGRAM" OR "PROGRAM"
17	MEANS THE COLORADO DRUG DONATION PROGRAM CREATED IN THIS
18	SECTION.
19	(b) "CONTROLLED SUBSTANCE" HAS THE MEANING SET FORTH IN
20	SECTION 18-18-102.
21	(c) (I) "DONATION RECIPIENT" MEANS AN ENTITY THAT:
22	(A) IS LEGALLY AUTHORIZED TO POSSESS MEDICINE;
23	(B) HAS A LICENSE OR REGISTRATION IN GOOD STANDING IN THE
24	STATE IN WHICH THE ENTITY IS LOCATED; AND
25	(C) RECEIVES A DONATION OF MEDICINE.
26	(II) "DONATION RECIPIENT" INCLUDES A WHOLESALER, A
27	DISTRIBUTOR, A THIRD-PARTY LOGISTICS PROVIDER, A REVERSE

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1	DISTRIBUTOR, A REPACKAGER, A HOSPITAL, A PHARMACY, A CLINIC, A
2	HEALTH-CARE PROVIDER, OR A PRESCRIBER OFFICE.
3	(d) (I) "DONOR" MEANS ANY PERSON LEGALLY AUTHORIZED TO
4	POSSESS MEDICINE, INCLUDING AN INDIVIDUAL MEMBER OF THE PUBLIC, A
5	WHOLESALER, A DISTRIBUTOR, A THIRD-PARTY LOGISTICS PROVIDER, A
6	PHARMACY, A DISPENSER, A CLINIC, A SURGICAL OR HEALTH CENTER, A
7	REHABILITATION CENTER, A DETENTION CENTER, A JAIL, A PRISON, A
8	LABORATORY, A PRESCRIBER OR OTHER HEALTH-CARE PROFESSIONAL, OR
9	A LONG-TERM CARE FACILITY OR HEALTH-CARE FACILITY, WHICH PERSON
10	DONATES MEDICINE.
11	(II) "DONOR" INCLUDES GOVERNMENT AGENCIES AND ENTITIES
12	THAT ARE FEDERALLY AUTHORIZED TO POSSESS MEDICINE, INCLUDING
13	MANUFACTURERS, REPACKAGERS, RELABELERS, OUTSOURCING FACILITIES,
14	VETERANS AFFAIRS HOSPITALS, FDA-AUTHORIZED IMPORTERS SUCH AS
15	THOSE DESCRIBED UNDER THE FEDERAL "FOOD, DRUG, AND COSMETIC
16	ACT", 21 U.S.C. SECS. 801 AND 804, AS AMENDED, OR SIMILAR
17	PROVISIONS, AND FEDERAL PRISONS.
18	(e) (I) "ELIGIBLE PATIENT" MEANS AN INDIVIDUAL WITH A NEED
19	FOR DONATED MEDICINE WHO IS INDIGENT, UNINSURED, UNDERINSURED,
20	OR ENROLLED IN A PUBLIC HEALTH BENEFITS PROGRAM.
21	(II) "ELIGIBLE PATIENT" INCLUDES OTHER INDIVIDUALS IF A NEED
22	FOR DONATED MEDICINE IS NOT IDENTIFIED AMONG INDIVIDUALS WHO ARE
23	INDIGENT, UNINSURED, UNDERINSURED, OR ENROLLED IN A PUBLIC HEALTH
24	BENEFITS PROGRAM.
25	(f) "HEALTH-CARE PROFESSIONAL" MEANS AN INDIVIDUAL WHO IS
26	LICENSED TO PRACTICE AS A PHYSICIAN, REGISTERED NURSE, ADVANCED
27	PRACTICE REGISTERED NURSE, PRACTICAL NURSE, OPTOMETRIST, OR

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1	PHARMACIST; A CERTIFIED MIDWIFE WITH PRESCRIPTIVE AUTHORITY
2	PURSUANT TO SECTION 12-255-112; OR ANY OTHER PRACTITIONER
3	AUTHORIZED TO DISPENSE OR ADMINISTER MEDICINE.
4	(g) (I) "MEDICINE" MEANS PRESCRIPTION DRUGS, INCLUDING
5	FDA-APPROVED DRUGS LABELED FOR INVESTIGATIONAL USE.
6	(II) "MEDICINE" INCLUDES:
7	(A) A PRESCRIPTION DRUG THAT REQUIRES REFRIGERATION,
8	FREEZING, OR SPECIAL STORAGE IF THE MEDICINE HAS BEEN CONTINUALLY
9	MAINTAINED PURSUANT TO THE MANUFACTURER'S STORAGE
10	REQUIREMENTS; AND
11	(B) Prescription supplies and devices.
12	(III) "MEDICINE" DOES NOT INCLUDE:
13	(A) COMPOUNDED DRUGS;
14	(B) PRESCRIPTION DRUGS DISPENSED BY PHARMACIES OUTSIDE OF
15	THE UNITED STATES;
16	$(C)\ Prescription\ drugs\ that\ are\ subject\ to\ risk\ evaluation$
17	AND MITIGATION UNDER 21 U.S.C. SEC. 355-1 $(f)(3)$ UNLESS ALL OF THE
18	REQUIRED GUIDELINES FOR THE MEDICINE ARE FOLLOWED; OR
19	(D) CONTROLLED SUBSTANCES.
20	(h) "Prescriber" has the meaning set forth in section
21	12-280-125.7 (1)(f).
22	(i) "RETURNS PROCESSOR" HAS THE MEANING SET FORTH IN 21
23	U.S.C. SEC. 360eee (18) AND INCLUDES A REVERSE DISTRIBUTOR.
24	(j) (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 MAY DONATE MEDICINE TO A DONATION RECIPIENT.
10	A DONATION RECIPIENT MAY RECEIVE DONATED MEDICINE FROM DONORS.
11	(b) PRIOR TO THE FIRST DONATION FROM A PERSON, A DONATION
12	RECIPIENT SHALL RECORD THE PERSON'S NAME, ADDRESS, PHONE NUMBER,
13	AND LICENSE NUMBER, IF APPLICABLE, AND SHALL:
14	(I) VERIFY THAT THE PERSON MEETS THE DEFINITION PROVIDED IN
15	SUBSECTION (1)(d) OF THIS SECTION;
16	(II) CONFIRM THAT THE PERSON AGREES TO MAKE DONATIONS OF
17	MEDICINE ONLY IN ACCORDANCE WITH THIS SECTION AND RULES ADOPTED
18	BY THE BOARD RELATING TO DONATED MEDICINE; AND
19	(III) IF APPLICABLE, CONFIRM THAT THE PERSON AGREES TO
20	REMOVE OR REDACT ANY PATIENT NAMES AND PRESCRIPTION NUMBERS ON
21	DONATED MEDICINE OR TO OTHERWISE MAINTAIN PATIENT
22	CONFIDENTIALITY BY EXECUTING A CONFIDENTIALITY AGREEMENT WITH
23	THE AUTHORIZED DONATION RECIPIENT.
24	(c) NO OTHER INFORMATION OR RECORDS ARE REQUIRED PRIOR TO
25	THE FIRST DONATION FROM A NEW DONOR OTHER THAN AS DESCRIBED IN
26	SUBSECTION (3)(b) OF THIS SECTION.
27	(4) A DONATION RECIPIENT SHALL MAINTAIN A WRITTEN OR AN

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1	ELECTRONIC RECORD OF DONATED MEDICINE CONSISTING OF THE NAME,
2	STRENGTH, QUANTITY, AND LOT NUMBER, IF KNOWN, OF EACH ACCEPTED
3	OR TRANSFERRED DRUG AND THE NAME, ADDRESS, AND PHONE NUMBER OF
4	THE DONOR OR TRANSFERRING ENTITY. NO OTHER RECORD OF DONATION
5	IS REQUIRED.
6	(5) A DONATION RECIPIENT SHALL ENSURE THAT DONATED
7	MEDICINE IS IDENTIFIED PHYSICALLY OR ELECTRONICALLY AS SEPARATE
8	FROM REGULAR STOCK.
9	(6) NOTWITHSTANDING ANY OTHER LAW TO THE CONTRARY, A
10	DONATION RECIPIENT MAY:
11	(a) Transfer donated medicine to another donation
12	RECIPIENT OR TO AN ENTITY PARTICIPATING IN A DRUG DONATION
13	PROGRAM OPERATED BY ANOTHER STATE;
14	(b) Repackage donated medicine in accordance with
15	SUBSECTION (8) OF THIS SECTION AS NECESSARY FOR STORAGE,
16	DISPENSING, ADMINISTRATION, OR TRANSFER; OR
17	(c) IF THE DONATION RECIPIENT IS A PRESCRIPTION DRUG OUTLET
18	OR OTHER OUTLET, REPLENISH MEDICINE OF THE SAME DRUG NAME AND
19	STRENGTH PREVIOUSLY DISPENSED OR ADMINISTERED TO ELIGIBLE
20	PATIENTS IN ACCORDANCE WITH THE FEDERAL 340B DRUG PRICING
21	PROGRAM CODIFIED AT 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	(9) A DONATION RECIPIENT SHALL ONLY ADMINISTER OR
16	REDISPENSE MEDICINE THAT:
17	(a) IS IN UNOPENED, TAMPER-EVIDENT PACKAGING OR HAS BEEN
18	REPACKAGED UNDER THIS PROGRAM;
19	(b) MEETS THE REQUIREMENTS SET FORTH IN THIS SECTION BASED
20	ON AN INSPECTION BY A LICENSED PHARMACIST;
21	(c) IF DISPENSED TO AN ELIGIBLE PATIENT, IS REPACKAGED BY A
22	LICENSED PHARMACIST INTO A NEW CONTAINER OR, IF KEPT IN THE
23	DONATED CONTAINER, IS IN A CONTAINER THAT HAS ALL PREVIOUS
24	PATIENT INFORMATION REDACTED OR REMOVED;
25	(d) IS PROPERLY LABELED IN ACCORDANCE WITH THE RULES
26	ADOPTED BY THE BOARD;
27	(e) HAS AN EXPIRATION OR BEYOND-USE DATE THAT WILL NOT

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1	EXPIRE BEFORE THE MEDICINE IS USED BY THE ELIGIBLE PATIENT BASED ON
2	THE PRESCRIBER'S DIRECTIONS FOR USE; AND
3	(f) If the medicine requires refrigeration, freezing, or
4	SPECIAL STORAGE, HAS BEEN CONTINUALLY MAINTAINED PURSUANT TO
5	THE MANUFACTURER'S STORAGE REQUIREMENTS.
6	(10) A DONATION RECIPIENT:
7	(a) MAY DISPENSE OR ADMINISTER PRESCRIPTION DRUGS TO AN
8	ELIGIBLE PATIENT PURSUANT TO THIS SECTION ONLY IF OTHERWISE
9	PERMITTED BY LAW PURSUANT TO A VALID PRESCRIPTION OR PRESCRIPTION
10	DRUG ORDER; AND
11	(b) SHALL MAINTAIN ELIGIBLE PATIENT-SPECIFIC WRITTEN OR
12	ELECTRONIC RECORDS IN ACCORDANCE WITH RULES ADOPTED BY THE
13	BOARD.
14	(11) A MANUFACTURER, REPACKAGER, DISPENSER, OR
15	WHOLESALER, OTHER THAN A RETURNS PROCESSOR, PARTICIPATING IN THE
16	PROGRAM SHALL COMPLY WITH THE REQUIREMENTS OF 21 U.S.C. SECS.
17	360eee-1 to 360eee-4 relating to drug supply chain security.
18	(12) THE DONATION, TRANSFER, OR RECEIPT OF MEDICINE OR THE
19	FACILITATION OF A DONATION, TRANSFER, OR RECEIPT OF MEDICINE
20	PURSUANT TO THIS SECTION IS NOT WHOLESALE DISTRIBUTION AND DOES
21	NOT REQUIRE LICENSING AS A WHOLESALE DISTRIBUTOR.
22	(13) MEDICINE DONATED TO THE PROGRAM MUST NOT BE RESOLD
23	AND IS CONSIDERED NONSALEABLE; EXCEPT THAT HANDLING, DISPENSING,
24	OR USUAL AND CUSTOMARY CHARGES TO AN ELIGIBLE PATIENT, HEALTH
25	PLAN, PHARMACY BENEFIT MANAGER, PHARMACY SERVICES
26	ADMINISTRATIVE ORGANIZATION, GOVERNMENT AGENCY, OR OTHER
27	ENTITY IS NOT CONSIDERED RESELLING. IF THE DONATION RECIPIENT IS A

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

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1	BY THE DONATION RECIPIENT. IF A RECORD OF THE DONATION'S
2	TRANSACTION INFORMATION OR HISTORY IS REQUIRED, THE HISTORY MUST
3	BEGIN WITH THE DONOR, MUST INCLUDE ALL PRIOR DONATIONS, AND, IF
4	THE MEDICINE WAS PREVIOUSLY DISPENSED, MUST INCLUDE ONLY DRUG
5	INFORMATION THAT IS REQUIRED TO BE ON THE PATIENT LABEL IN
6	ACCORDANCE WITH RULES ADOPTED BY THE BOARD.
7	(17) AN ENTITY PARTICIPATING IN A DRUG DONATION OF
8	REPOSITORY PROGRAM OPERATED BY ANOTHER STATE MAY PARTICIPATE
9	IN THE PROGRAM AND, IF THE REGISTERED ENTITY IS A PRESCRIPTION DRUG
10	OUTLET, MAY DISPENSE DONATED DRUGS TO ELIGIBLE PATIENTS OF THIS
11	STATE. THE REGISTERED ENTITY IS REQUIRED TO COMPLY WITH ALL
12	STATUTES AND RULES IN THIS STATE UNLESS THE STATUTES OR RULES
13	DIFFER FROM OR CONFLICT WITH THE STATUTES OR RULES OF THE STATE
14	IN WHICH THE ENTITY IS LOCATED.
15	(18) The board shall adopt any rules necessary to
16	IMPLEMENT THIS SECTION. THE RULES MUST REQUIRE THE LEAST AMOUNT
17	OF RECORD KEEPING NECESSARY TO ENSURE PATIENT SAFETY AND MUST
18	ALLOW FLEXIBILITY IN THE FORMAT FOR RECORD KEEPING.
19	(19) This section controls the requirements for the
20	DONATION AND DISTRIBUTION OF MEDICINE UNDER THE PROGRAM AND
21	SUPERSEDES ANY INCONSISTENT LAW.
22	(20) When acting in good faith, without negligence or
23	WILLFUL OR WANTON MISCONDUCT, THE FOLLOWING INDIVIDUALS OR
24	ENTITIES ARE NOT SUBJECT TO CIVIL OR CRIMINAL LIABILITY OR
25	PROFESSIONAL DISCIPLINARY ACTION:
26	(a) AN INDIVIDUAL OR ENTITY INVOLVED IN THE SUPPLY CHAIN OF

DONATED MEDICINE, INCLUDING THE DONOR, THE DONATION RECIPIENT,

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1	THE MANUFACTURER, THE REPACKAGER, THE PRESCRIPTION DRUGOUTLET
2	OR OTHER ENTITY REGULATED BY THE BOARD, AND THE ELIGIBLE PATIENT;
3	(b) An individual or entity, including an employee, an
4	OFFICER, A VOLUNTEER, AN OWNER, A PARTNER, A MEMBER, A DIRECTOR,
5	A CONTRACTOR, OR OTHER INDIVIDUAL OR ENTITY ASSOCIATED WITH THE
6	INDIVIDUAL OR ENTITY THAT, IN COMPLIANCE WITH THIS SECTION,
7	PRESCRIBES, DONATES, RECEIVES DONATIONS OF, DISPENSES,
8	ADMINISTERS, TRANSFERS, REPLENISHES, OR REPACKAGES MEDICINE OR
9	FACILITATES ANY OF THE ACTIONS DESCRIBED IN THIS SECTION; AND
10	(c) THE BOARD.
11	(21) A DONATION RECIPIENT OPERATING PRIMARILY FOR THE
12	PURPOSE OF PARTICIPATING IN THIS PROGRAM SHALL NOT BE REQUIRED TO
13	POSSESS A COMPREHENSIVE OR MINIMUM SUPPLY OF MEDICINE.
14	SECTION 3. In Colorado Revised Statutes, 25-15-328, amend
15	(6)(a) as follows:
16	25-15-328. Household medication take-back program -
17	creation - collection and disposal of medication injection devices -
18	liability - definitions - cash fund - rules. (6) Nothing in this section:
19	(a) Affects the authority to collect and reuse medications
20	MEDICINE pursuant to section 12-280-135 OR 12-280-135.5; or
21	SECTION 4. 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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- 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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