

**Second Regular Session
Seventy-fourth General Assembly
STATE OF COLORADO**

PREAMENDED

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

LLS NO. 24-0545.01 Brita Darling x2241

SENATE BILL 24-061

SENATE SPONSORSHIP

Rodriguez,

HOUSE SPONSORSHIP

(None),

Senate Committees

Health & Human Services
Appropriations

House Committees

A BILL FOR AN ACT

101 **CONCERNING THE CREATION OF A COLORADO DRUG DONATION**
102 **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 creates the Colorado drug donation program (program) to facilitate the safe donation and redispensing of medicine, including prescription and nonprescription or over-the-counter drugs, FDA-approved drugs labeled for investigational use, and medical devices.

Under the program, a donor donates medicine to a donation recipient for redispensing to eligible patients. Donated medicine is

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.

prioritized first for Colorado residents who are indigent, uninsured, underinsured, or enrolled in a public health benefits program (eligible patient). An eligible patient or the patient's health insurance is not charged for the medicine, other than handling or dispensing charges and other customary charges.

Donors may include individual members of the public as well as drug manufacturers and distributors, pharmacies, clinics, health centers, government agencies, and other donors described in the bill (donor). Donors may donate to a donation recipient, including a wholesaler or distributor, hospital, pharmacy, clinic, and health-care provider or prescriber's office, among other entities (donation recipient).

The donation recipient may:

- Transfer donated medicine to another donation recipient; and
- If the donation recipient is a prescription drug outlet, repackage donated medicine as necessary for storage, redispensing, administration, or transfer or replenish medicine previously dispensed to eligible patients.

The bill includes provisions relating to:

- Record-keeping requirements for donated medicine;
- The type, condition, and age of medicine that may be donated;
- The segregation of medicine and inspection by a licensed pharmacist before medicine is accepted into inventory;
- The disposal of medicine that does not meet donation standards; and
- The repackaging, labeling, and redispensing of medicine to eligible patients.

The state board of pharmacy is required to promulgate rules necessary to implement the program.

When acting in good faith, without willful or wanton misconduct, the state board of pharmacy, donors, donation recipients, and other individuals and entities involved in the program are not subject to civil or criminal liability or professional disciplinary action relating to their participation in the program.

The bill makes conforming amendments to existing law relating to the reuse of unused medications by other patients in correctional facilities and in certain licensed facilities, such as hospitals, hospices, and assisted living facilities.

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

2 **SECTION 1. In Colorado Revised Statutes, add 12-280-135.5 as**

1 follows:

2 12-280-135.5. Colorado drug donation program - created -
3 rules - records - definitions. (1) AS USED IN THIS SECTION, UNLESS THE
4 CONTEXT OTHERWISE REQUIRES:

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

8 (b) "CONTROLLED SUBSTANCE" HAS THE MEANING SET FORTH IN
9 SECTION 18-18-102 (5).

10 (c) (I) "DONATION RECIPIENT" MEANS ANY ENTITY THAT:

11 (A) IS LEGALLY AUTHORIZED TO POSSESS MEDICINE;

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

14 (C) RECEIVES A DONATION OF MEDICINE.

15 (II) "DONATION RECIPIENT" INCLUDES THE DRUG REPOSITORY, A
16 DISTRIBUTOR, A THIRD-PARTY LOGISTICS PROVIDER, A REVERSE
17 DISTRIBUTOR, A REPACKAGER, A HOSPITAL, A PHARMACY, A CLINIC, A
18 HEALTH-CARE PROVIDER, OR A PRESCRIBER OFFICE.

19 (d) (I) "DONOR" MEANS ANY PERSON LEGALLY AUTHORIZED TO
20 POSSESS MEDICINE, INCLUDING AN INDIVIDUAL MEMBER OF THE PUBLIC,
21 THE DRUG REPOSITORY, A DISTRIBUTOR, A THIRD-PARTY LOGISTICS
22 PROVIDER, A PHARMACY, A DISPENSER, A CLINIC, A SURGICAL OR HEALTH
23 CENTER, A DETENTION AND REHABILITATION CENTER, A JAIL, A PRISON, A
24 LABORATORY, A PRESCRIBER OR OTHER HEALTH-CARE PROFESSIONAL, OR
25 A LONG-TERM CARE FACILITY OR HEALTH-CARE FACILITY, WHICH PERSON
26 DONATES MEDICINE.

27 (II) "DONOR" INCLUDES GOVERNMENT AGENCIES AND ENTITIES

1 THAT ARE FEDERALLY AUTHORIZED TO POSSESS MEDICINE, INCLUDING
2 MANUFACTURERS, REPACKAGERS, RELABELERS, OUTSOURCING FACILITIES,
3 VETERANS AFFAIRS HOSPITALS, AND FDA-AUTHORIZED IMPORTERS SUCH
4 AS THOSE DESCRIBED UNDER THE "FEDERAL FOOD, DRUG, AND COSMETIC
5 ACT", 21 U.S.C. SECS. 801 AND 804, AS AMENDED, OR SIMILAR
6 PROVISIONS, AND FEDERAL PRISONS.

7 (e) "DRUG REPOSITORY" MEANS THE ENTITY PROVIDING DRUG
8 REPOSITORY SERVICES FOR THE PROGRAM PURSUANT TO SECTION
9 25-1.5-121.

10 (f) "ELIGIBLE PATIENT" MEANS A COLORADO RESIDENT WITH A
11 NEED FOR DONATED MEDICINE WHO IS INDIGENT, UNINSURED,
12 UNDERINSURED, OR ENROLLED IN A PUBLIC HEALTH BENEFITS PROGRAM.
13 OTHER PATIENTS ARE CONSIDERED "ELIGIBLE PATIENTS" IF A NEED FOR A
14 DONATED MEDICINE IS NOT IDENTIFIED AMONG COLORADO RESIDENTS
15 WHO ARE INDIGENT, UNINSURED, UNDERINSURED, OR ENROLLED IN A
16 PUBLIC HEALTH BENEFITS PROGRAM.

17 (g) "HEALTH-CARE PROFESSIONAL" MEANS A PERSON WHO IS
18 LICENSED TO PRACTICE AS A PHYSICIAN, REGISTERED NURSE, PRACTICAL
19 NURSE, OPTOMETRIST, OR PHARMACIST; A CERTIFIED MIDWIFE WITH
20 PRESCRIPTIVE AUTHORITY PURSUANT TO SECTION 12-255-112; OR ANY
21 OTHER PRACTITIONER AUTHORIZED TO DISPENSE OR ADMINISTER
22 MEDICINE.

23 (h) (I) "MEDICINE" MEANS BOTH PRESCRIPTION AND
24 NONPRESCRIPTION OR OVER-THE-COUNTER DRUGS, INCLUDING
25 FDA-APPROVED DRUGS LABELED FOR INVESTIGATIONAL USE.

26 (II) "MEDICINE" INCLUDES:

27 (A) MEDICINE THAT REQUIRES REFRIGERATION, FREEZING, OR

1 SPECIAL STORAGE IF THE MEDICINE IS DONATED DIRECTLY BY AN ENTITY
2 REGULATED BY THE BOARD AND THE MEDICINE HAS BEEN CONTINUALLY
3 MAINTAINED PURSUANT TO THE MANUFACTURER'S STORAGE
4 REQUIREMENTS; AND

5 (B) PRESCRIPTION AND NONPRESCRIPTION SUPPLIES AND DEVICES.

6 (III) "MEDICINE" DOES NOT INCLUDE:

7 (A) COMPOUNDED MEDICINE; OR

8 (B) MEDICATIONS DISPENSED BY PHARMACIES OUTSIDE OF THE
9 UNITED STATES.

10 (i) "PRESCRIBER" HAS THE MEANING SET FORTH IN SECTION
11 12-280-125.7 (1)(f).

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

14 (k) "UNOPENED TAMPER-EVIDENT PACKAGING" MEANS AN INTACT
15 PACKAGING SYSTEM THAT RENDERS MEDICINE INACCESSIBLE WITHOUT
16 OBVIOUS DESTRUCTION OF THE SEAL OR SOME PORTION OF THE PACKAGING
17 SYSTEM. "UNOPENED TAMPER-EVIDENT PACKAGING" MAY INCLUDE
18 UNOPENED UNIT-DOSE, MULTIPLE-DOSE, IMMEDIATE, SECONDARY, AND
19 TERTIARY PACKAGING.

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

23 (b) PURSUANT TO SECTION 25-1.5-121, THE DEPARTMENT OF
24 PUBLIC HEALTH AND ENVIRONMENT CREATED IN SECTION 25-1-102 SHALL
25 CONTRACT FOR DRUG REPOSITORY SERVICES, INCLUDING THE RECEIPT OF,
26 SAFE STORAGE OF, DISTRIBUTION OF, AND DISPENSING OF MEDICINE; AN
27 ELECTRONIC INVENTORY OF MEDICINE; A PUBLIC-FACING WEBSITE; AN

1 OUTREACH AND MARKETING CAMPAIGN TO INFORM POTENTIAL DONORS,
2 DONATION RECIPIENTS, HEALTH-CARE PROFESSIONALS, ELIGIBLE PATIENTS,
3 AND THE GENERAL PUBLIC; AND OTHER SERVICES NECESSARY TO
4 IMPLEMENT THE PROGRAM, AS DETERMINED BY THE DEPARTMENT OF
5 PUBLIC HEALTH AND ENVIRONMENT, IN CONJUNCTION WITH THE BOARD.

6 (3) (a) NOTWITHSTANDING ANY OTHER LAW OR RULE TO THE
7 CONTRARY, A DONOR MAY DONATE MEDICINE TO A DONATION RECIPIENT.
8 A DONATION RECIPIENT MAY RECEIVE DONATED MEDICINE FROM DONORS.

9 (b) PRIOR TO THE FIRST DONATION FROM A NEW DONOR, A
10 DONATION RECIPIENT SHALL RECORD THE DONOR'S NAME, ADDRESS,
11 PHONE NUMBER, AND LICENSE NUMBER, IF APPLICABLE, AND, WITH
12 RESPECT TO THE FOLLOWING:

13 (I) VERIFY THAT THE DONOR MEETS THE DEFINITION PROVIDED IN
14 SUBSECTION (1)(d) OF THIS SECTION;

15 (II) CONFIRM THAT THE DONOR AGREES TO MAKE DONATIONS OF
16 MEDICINE ONLY IN ACCORDANCE WITH THIS SECTION AND RULES
17 PROMULGATED BY THE BOARD RELATING TO DONATED MEDICINE; AND

18 (III) IF APPLICABLE, CONFIRM THAT THE DONOR AGREES TO
19 REMOVE OR REDACT ANY PATIENT NAMES AND PRESCRIPTION NUMBERS ON
20 DONATED MEDICINE OR OTHERWISE MAINTAIN PATIENT CONFIDENTIALITY
21 BY EXECUTING A CONFIDENTIALITY AGREEMENT WITH THE AUTHORIZED
22 DONATION RECIPIENT.

23 (c) NO OTHER INFORMATION OR RECORDS ARE REQUIRED PRIOR TO
24 RECEIVING THE FIRST DONATION FROM A NEW DONOR OTHER THAN AS
25 DESCRIBED IN SUBSECTION (3)(b) OF THIS SECTION.

26 (4) A DONATION RECIPIENT SHALL MAINTAIN A WRITTEN OR
27 ELECTRONIC RECORD OF DONATED MEDICINE CONSISTING OF THE NAME,

1 STRENGTH, QUANTITY, AND LOT NUMBER, IF KNOWN, OF EACH ACCEPTED
2 OR TRANSFERRED DRUG AND THE NAME, ADDRESS, AND PHONE NUMBER OF
3 THE DONOR OR TRANSFERRING ENTITY. NO OTHER RECORD OF DONATION
4 IS REQUIRED.

5 (5) A DONATION RECIPIENT SHALL ENSURE THAT DONATED
6 MEDICINE IS IDENTIFIED SEPARATELY FROM REGULAR STOCK.

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

9 (a) TRANSFER DONATED MEDICINE TO ANOTHER DONATION
10 RECIPIENT OR TO AN ENTITY PARTICIPATING IN A DRUG DONATION
11 PROGRAM OPERATED BY ANOTHER STATE;

12 (b) IF THE DONATION RECIPIENT IS A PRESCRIPTION DRUG OUTLET,
13 REPACKAGE DONATED MEDICINE IN ACCORDANCE WITH SUBSECTION (8) OF
14 THIS SECTION AS NECESSARY FOR STORAGE, DISPENSING, ADMINISTRATION,
15 OR TRANSFER; OR

16 (c) IF THE DONATION RECIPIENT IS A PRESCRIPTION DRUG OUTLET,
17 REPLENISH MEDICINE OF THE SAME DRUG NAME AND STRENGTH
18 PREVIOUSLY DISPENSED OR ADMINISTERED TO ELIGIBLE PATIENTS IN
19 ACCORDANCE WITH THE FEDERAL 340B DRUG PRICING PROGRAM CODIFIED
20 AT 42 U.S.C. SEC. 256b, AS AMENDED.

21 (7) (a) DONATED MEDICINE THAT DOES NOT MEET THE
22 REQUIREMENTS SPECIFIED IN THIS SECTION AND RULES PROMULGATED BY
23 THE BOARD MUST BE DISPOSED OF BY:

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

25 (II) DESTROYING THE DONATED MEDICINE THROUGH AN
26 INCINERATOR, A MEDICAL WASTE HAULER, A REVERSE DISTRIBUTOR, OR
27 OTHER LAWFUL METHOD; OR

1 (III) TRANSFERRING THE DONATED MEDICINE TO A RETURNS
2 PROCESSOR.

3 (b) A DONATION RECIPIENT SHALL MAINTAIN A WRITTEN OR
4 ELECTRONIC RECORD OF DISPOSED MEDICINE CONSISTING OF THE DISPOSAL
5 METHOD, AS DESCRIBED IN THIS SUBSECTION (7); THE DATE OF DISPOSAL;
6 AND THE NAME, STRENGTH, AND QUANTITY OF EACH DISPOSED DRUG. NO
7 OTHER RECORD OF DISPOSAL IS REQUIRED.

8 (8) REPACKAGED MEDICINE MUST BE LABELED WITH THE DRUG
9 NAME, STRENGTH, AND EXPIRATION DATE, IF THE EXPIRATION DATE IS
10 KNOWN, AND IDENTIFIED SEPARATELY FROM REGULAR STOCK UNTIL
11 INSPECTED AND INITIALED BY A LICENSED PHARMACIST. IF MULTIPLE
12 PACKAGED, DONATED MEDICINES WITH VARIED EXPIRATION DATES ARE
13 REPACKAGED TOGETHER, THE EARLIEST EXPIRATION DATE MUST BE USED.

14 (9) A DONATION RECIPIENT SHALL ONLY ADMINISTER OR
15 REDISPENSE MEDICINE THAT:

16 (a) MEETS THE REQUIREMENTS SET FORTH IN THIS SECTION BASED
17 ON INSPECTION BY A LICENSED PHARMACIST;

18 (b) IF DISPENSED TO AN ELIGIBLE PATIENT, IS REPACKAGED BY A
19 LICENSED PHARMACIST INTO A NEW CONTAINER OR A CONTAINER THAT
20 HAS ALL PREVIOUS PATIENT INFORMATION ON THE DONATED CONTAINER
21 REDACTED OR REMOVED;

22 (c) IS PROPERLY LABELED IN ACCORDANCE WITH THE RULES OF THE
23 BOARD;

24 (d) HAS AN EXPIRATION OR BEYOND-USE DATE BROUGHT FORWARD
25 FROM THE DONATED MEDICINE THAT WILL NOT EXPIRE BEFORE THE
26 MEDICINE IS USED BY THE ELIGIBLE PATIENT BASED ON THE PRESCRIBER'S
27 DIRECTIONS FOR USE OR, FOR OVER-THE-COUNTER MEDICINE, ON THE

1 PACKAGE'S LABEL; AND

2 (e) IF THE MEDICINE REQUIRES REFRIGERATION, FREEZING, OR
3 SPECIAL STORAGE, IS DONATED DIRECTLY BY AN ENTITY REGULATED BY
4 THE BOARD AND HAS BEEN CONTINUALLY MAINTAINED PURSUANT TO THE
5 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 BOARD RULES.

13 (11) WHEN A PRESCRIBED MEDICINE DOES NOT USE A UNIQUE
14 DELIVERY SYSTEM TECHNOLOGY, A DONATION RECIPIENT MAY SUBSTITUTE
15 AN ORAL TABLET, CAPSULE, OR LIQUID FORM OF THE PRESCRIBED MEDICINE
16 SO LONG AS THE FORM DISPENSED HAS THE SAME DOSE SCHEDULE AND IS
17 A GENERIC EQUIVALENT TO THE PRESCRIBED MEDICINE.

18 (12) THE DONATION, TRANSFER, RECEIPT, OR FACILITATION OF
19 DONATIONS, TRANSFERS, AND RECEIPT OF MEDICINE PURSUANT TO THIS
20 SECTION IS NOT WHOLESALE DISTRIBUTION AND DOES NOT REQUIRE
21 LICENSING AS A WHOLESALE DISTRIBUTOR. THE PROGRAM EXISTS UNDER
22 A PRESCRIPTION DRUG OUTLET LICENSE AND IS SUBJECT TO THE
23 REQUIREMENTS FOR THAT LICENSE TYPE.

24 (13) MEDICINE DONATED TO THE PROGRAM MUST NOT BE RESOLD
25 AND IS CONSIDERED NONSALEABLE; EXCEPT THAT HANDLING, DISPENSING,
26 OR USUAL AND CUSTOMARY CHARGES TO AN ELIGIBLE PATIENT, HEALTH
27 PLAN, PHARMACY BENEFIT MANAGER, PHARMACY SERVICES

1 ADMINISTRATIVE ORGANIZATION, GOVERNMENT AGENCY, OR OTHER
2 ENTITY IS NOT CONSIDERED RESELLING. IF THE DONATION RECIPIENT IS A
3 FOR-PROFIT ENTITY, THESE CHARGES MUST NOT EXCEED THE DONATION
4 RECIPIENT'S COST OF PROVIDING THE MEDICINE, INCLUDING THE CURRENT
5 AND ANTICIPATED COSTS OF EDUCATING ELIGIBLE DONORS, PROVIDING
6 TECHNICAL SUPPORT TO PARTICIPATING DONORS, SHIPPING AND HANDLING,
7 LABOR, STORAGE, LICENSING, UTILITIES, ADVERTISING, TECHNOLOGY,
8 SUPPLIES, AND EQUIPMENT. EXCEPT AS DESCRIBED IN THIS SUBSECTION
9 (13), THE AMOUNT OF THESE CHARGES IS NOT SUBJECT TO ANY
10 ADDITIONAL LIMITATIONS.

11 (14) WHEN PERFORMING ANY ACTION ASSOCIATED WITH THE
12 PROGRAM OR OTHERWISE PROCESSING DONATED MEDICINE FOR TAX,
13 MANUFACTURER, OR OTHER CREDIT, A DONATION RECIPIENT IS
14 CONSIDERED TO BE ACTING AS A RETURNS PROCESSOR AND SHALL COMPLY
15 WITH ALL RECORD-KEEPING REQUIREMENTS UNDER FEDERAL LAW FOR
16 NONSALEABLE RETURNS.

17 (15) ALL REQUIRED RECORDS MUST BE RETAINED IN PHYSICAL OR
18 ELECTRONIC FORMAT, ON OR OFF THE DONATION RECIPIENT'S PREMISES,
19 FOR A PERIOD OF TWO YEARS. DONORS OR DONATION RECIPIENTS MAY
20 CONTRACT WITH ONE ANOTHER OR WITH A THIRD PARTY TO CREATE OR
21 MAINTAIN RECORDS. AN IDENTIFIER, SUCH AS A SERIAL NUMBER OR
22 BARCODE, MAY BE USED IN PLACE OF INFORMATION IF IT ALLOWS FOR THE
23 INFORMATION TO BE READILY RETRIEVABLE. UPON REQUEST BY A STATE
24 OR FEDERAL REGULATOR, THE IDENTIFIER USED FOR A REQUESTED RECORD
25 MUST BE REPLACED WITH THE ORIGINAL INFORMATION. AN IDENTIFIER
26 MUST NOT BE USED ON LABELS WHEN DISPENSING OR ADMINISTERING A
27 DRUG TO AN ELIGIBLE PATIENT.

1 (16) A DONATION OR OTHER TRANSFER OF POSSESSION OR
2 CONTROL IS NOT A CHANGE OF OWNERSHIP UNLESS IT IS SPECIFIED AS SUCH
3 BY THE DONATION RECIPIENT. IF A RECORD OF THE DONATION'S
4 TRANSACTION INFORMATION OR HISTORY IS REQUIRED, THE HISTORY MUST
5 BEGIN WITH THE DONOR, MUST INCLUDE ALL PRIOR DONATIONS, AND, IF
6 THE MEDICINE WAS PREVIOUSLY DISPENSED, MUST INCLUDE ONLY DRUG
7 INFORMATION THAT IS REQUIRED TO BE ON THE PATIENT LABEL IN
8 ACCORDANCE WITH BOARD RULES.

9 (17) AN ENTITY PARTICIPATING IN A DRUG DONATION OR
10 REPOSITORY PROGRAM OPERATED BY ANOTHER STATE MAY PARTICIPATE
11 IN THE PROGRAM IF THE ENTITY IS REGISTERED WITH THIS STATE AND, IF
12 THE REGISTERED ENTITY IS A PRESCRIPTION DRUG OUTLET, MAY DISPENSE
13 DONATED DRUGS TO RESIDENTS OF THIS STATE. THE REGISTERED ENTITY
14 IS REQUIRED TO COMPLY WITH ALL STATUTES AND RULES IN THIS STATE
15 UNLESS THE STATUTES OR RULES DIFFER FROM OR CONFLICT WITH THE
16 STATUTES OR RULES OF THE STATE IN WHICH THE ENTITY IS LOCATED.

17 (18) THE BOARD SHALL PROMULGATE ANY RULES NECESSARY TO
18 IMPLEMENT THIS SECTION. THE RULES MUST REQUIRE THE LEAST AMOUNT
19 OF RECORD KEEPING NECESSARY TO ENSURE PATIENT SAFETY AND MUST
20 ALLOW FLEXIBILITY IN THE FORMAT FOR RECORD KEEPING.

21 (19) THE PROVISIONS OF THIS SECTION CONTROL THE PROGRAM
22 AND SUPERSEDE ANY INCONSISTENT LAW.

23 (20) WHEN ACTING IN GOOD FAITH, WITHOUT NEGLIGENCE OR
24 WILLFUL OR WANTON MISCONDUCT, THE FOLLOWING INDIVIDUALS OR
25 ENTITIES ARE NOT SUBJECT TO CIVIL OR CRIMINAL LIABILITY OR
26 PROFESSIONAL DISCIPLINARY ACTION:

27 (a) AN INDIVIDUAL OR ENTITY INVOLVED IN THE SUPPLY CHAIN OF

1 DONATED MEDICINE, INCLUDING THE DONOR, THE DRUG REPOSITORY, THE
2 DONATION RECIPIENT, THE MANUFACTURER, THE REPACKAGER, THE
3 PRESCRIPTION DRUG OUTLET OR OTHER ENTITY REGULATED BY THE
4 BOARD, AND THE ELIGIBLE PATIENT;

5 (b) AN INDIVIDUAL OR ENTITY, INCLUDING AN EMPLOYEE, AN
6 OFFICER, A VOLUNTEER, AN OWNER, A PARTNER, A MEMBER, A DIRECTOR,
7 A CONTRACTOR, OR OTHER INDIVIDUAL OR ENTITY ASSOCIATED WITH THE
8 INDIVIDUAL OR ENTITY THAT, IN COMPLIANCE WITH THIS SECTION,
9 PRESCRIBES, DONATES, RECEIVES DONATIONS OF, DISPENSES,
10 ADMINISTERS, TRANSFERS, REPLENISHES, OR REPACKAGES MEDICINE OR
11 FACILITATES ANY OF THE ACTIONS DESCRIBED IN THIS SECTION; AND

12 (c) THE BOARD.

13 **SECTION 2.** In Colorado Revised Statutes, 12-280-135, **amend**
14 **(2)(a)(II)(C), (2)(b)(II), (2)(b)(III), (2)(c) introductory portion, (2)(c)(I),**
15 **and (2)(c)(III); repeal (2)(c)(IV) and (5); and add (2)(b)(IV), (2)(c)(VI),**
16 **and (2)(c)(VII) as follows:**

17 **12-280-135. Unused medication - licensed facilities -**
18 **correctional facilities - reuse - definitions - rules. (2) (a) (II) (C) A**
19 **person or entity is not subject to civil or criminal liability or professional**
20 **disciplinary action for donating, accepting, dispensing, or facilitating the**
21 **donation of materials in good faith, without negligence OR WILLFUL OR**
22 **WANTON MISCONDUCT, and in compliance with this section.**

23 (b) Medications are only available to be dispensed to another
24 person or donated to a nonprofit entity under this section if the
25 medications are:

26 (II) Individually packaged and the packaging has not been
27 damaged; or

1 (III) In the original, unopened, sealed, and tamper-evident
2 unit-dose packaging; OR

3 (IV) FORMEDICATIONS THAT REQUIRE REFRIGERATION, FREEZING,
4 OR SPECIAL STORAGE, DONATED DIRECTLY BY AN ENTITY REGULATED BY
5 THE BOARD AND CONTINUALLY MAINTAINED PURSUANT TO THE
6 MANUFACTURER'S STORAGE REQUIREMENTS.

7 (c) The following medications ~~may not be donated~~ ARE NOT
8 ACCEPTABLE FOR DONATION:

9 (I) Medications THAT ARE NOT packaged in A traditional ~~brown or~~
10 ~~amber pill bottles~~ DISPENSING SYSTEM, AS DEFINED IN RULES
11 PROMULGATED BY THE BOARD;

12 (III) EXCEPT AS PROVIDED IN SUBSECTION (2)(b)(IV) OF THIS
13 SECTION, medications that require refrigeration, freezing, or special
14 storage;

15 (IV) Medications that require special registration with the
16 manufacturer; or

17 (VI) COMPOUNDED MEDICATIONS; AND

18 (VII) MEDICATIONS DISPENSED BY PHARMACIES OUTSIDE OF THE
19 UNITED STATES.

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

23 SECTION 3. In Colorado Revised Statutes, ~~add~~ 25-1.5-121 as
24 follows:

25 **25-1.5-121. Colorado drug donation program - contract for**
26 **drug repository services - electronic inventory - website - outreach**
27 **and marketing campaign - definitions. (1) AS USED IN THIS SECTION,**

1 UNLESS THE CONTEXT OTHERWISE REQUIRES:

2 (a) "BOARD OF PHARMACY" MEANS THE STATE BOARD OF
3 PHARMACY CREATED IN SECTION 12-280-104.

4 (b) "COLORADO DRUG DONATION PROGRAM" OR "CDDP" MEANS
5 THE COLORADO DRUG DONATION PROGRAM CREATED IN SECTION
6 12-280-135.5.

7 (c) "CONTRACTOR" MEANS THE ENTITY OR ENTITIES WITH WHICH
8 THE DEPARTMENT CONTRACTS PURSUANT TO SUBSECTION (2) OF THIS
9 SECTION.

10 (d) "DONATION RECIPIENT" HAS THE MEANING SET FORTH IN
11 SECTION 12-280-135.5.

12 (e) "DONOR" HAS THE MEANING SET FORTH IN SECTION
13 12-280-135.5.

14 (f) "DRUG REPOSITORY" MEANS THE ENTITY CONTRACTED BY THE
15 DEPARTMENT PURSUANT TO SUBSECTION (2) OF THIS SECTION TO PROVIDE
16 REPOSITORY SERVICES FOR THE CDDP.

17 (g) "ELIGIBLE PATIENT" HAS THE MEANING SET FORTH IN SECTION
18 12-280-135.5.

19 (h) "MEDICINE" HAS THE MEANING SET FORTH IN SECTION
20 12-280-135.5.

21 (2) SUBJECT TO AVAILABLE APPROPRIATIONS, THE DEPARTMENT,
22 IN CONSULTATION WITH THE BOARD OF PHARMACY, SHALL CONTRACT
23 WITH AN ENTITY OR ENTITIES TO IMPLEMENT THE COLORADO DRUG
24 DONATION PROGRAM CREATED IN SECTION 12-280-135.5. THE CDDP
25 EXISTS UNDER A PRESCRIPTION DRUG OUTLET LICENSE AND IS SUBJECT TO
26 THE REQUIREMENTS FOR THAT LICENSE TYPE AND ANY OTHER
27 REQUIREMENTS SPECIFIED BY THE BOARD OF PHARMACY OR THE

1 DEPARTMENT. THE CDDP CONTRACT MUST INCLUDE THE FOLLOWING:

2 (a) DRUG REPOSITORY SERVICES AT ONE LOCATION IN COLORADO,
3 INCLUDING THE RECEIPT OF, SAFE STORAGE OF, DISTRIBUTION OF, AND
4 DISPENSING OF MEDICINE TO FACILITATE THE SAFE DONATION AND
5 REDISPENSING OF UNUSED MEDICINE TO COLORADANS AND OTHERS IN
6 NEED OF THE MEDICINE;

7 (b) AN ELECTRONIC, SEARCHABLE INVENTORY OF CDDP
8 MEDICINE;

9 (c) THE CREATION OF A PUBLIC-FACING WEBSITE WITH
10 INFORMATION ON THE CDDP, INCLUDING THE MISSION OF THE CDDP, THE
11 REQUIREMENTS FOR MEDICINE TO BE ELIGIBLE FOR DONATION, THE
12 METHODS OF DONATING UNUSED MEDICINE, AND HOW AN ELIGIBLE
13 PATIENT MAY ACCESS UNUSED MEDICINE; AND

14 (d) THE CREATION AND IMPLEMENTATION OF AN OUTREACH AND
15 MARKETING CAMPAIGN TO INFORM POTENTIAL DONORS OF MEDICINE,
16 DONATION RECIPIENTS, HEALTH-CARE PROFESSIONALS, ELIGIBLE PATIENTS,
17 AND THE GENERAL PUBLIC ABOUT THE COLORADO DRUG DONATION
18 PROGRAM AND TO ENCOURAGE PARTICIPATION IN THE CDDP.

19 (3) (a) SUBJECT TO THE PROVISIONS SPECIFIED IN THE CONTRACT
20 AND THE AMOUNT OF THE CONTRACT, THE CDDP OUTREACH AND
21 MARKETING CAMPAIGN MUST INCLUDE OUTREACH AND MARKETING TO
22 POTENTIAL DONORS OF MEDICINE, DONATION RECIPIENTS, HEALTH-CARE
23 PROFESSIONALS, ELIGIBLE PATIENTS, AND THE GENERAL PUBLIC.

24 (b) (I) THE INITIAL PHASE OF THE CDDP OUTREACH AND
25 MARKETING CAMPAIGN MUST FOCUS ON BUILDING SUFFICIENT INVENTORY
26 OF DONATED MEDICINE, AS SPECIFIED IN THE CONTRACT.

27 (II) TO BUILD THE INVENTORY OF DONATED MEDICINE, THE

1 CONTRACTOR, IN CONSULTATION WITH THE DEPARTMENT AND THE BOARD
2 OF PHARMACY, MAY:

3 (A) BUILD RELATIONSHIPS WITH LARGE NURSING FACILITIES AND
4 THE PHARMACIES THAT SERVICE THOSE NURSING FACILITIES;

5 (B) BUILD RELATIONSHIPS WITH CORRECTIONAL FACILITIES;

6 (C) MEET WITH THE SCHOOLS OF PHARMACY IN COLORADO TO
7 CREATE AN AWARENESS PROGRAM FOR THE CDDP THAT PROVIDES
8 OPPORTUNITIES FOR PHARMACY STUDENTS TO ENGAGE IN CO-CURRICULAR
9 ACTIVITIES AND TO COMMUNICATE INFORMATION ABOUT CDDP WHEN
10 INTERACTING WITH PATIENTS, HEALTH-CARE PROFESSIONALS AND
11 PRESCRIBERS, AND HEALTH FACILITIES; AND

12 (D) ESTABLISH PARTNERSHIPS WITH PHARMACIES IN THE DENVER
13 METROPOLITAN AREA TO SERVE AS CONSUMER DONATION SITES AND
14 ESTABLISH PARTNERSHIPS FOR ADDITIONAL DONATION SITES IN OTHER
15 AREAS OF THE STATE.

16 (III) THE CONTRACTOR, IN CONSULTATION WITH THE DEPARTMENT
17 AND THE BOARD OF PHARMACY, MAY CREATE A SUPPLY OF
18 SELF-ADDRESSED, POSTAGE-PAID MAILING ENVELOPES FOR INDIVIDUAL
19 CONSUMERS TO USE TO MAIL UNUSED MEDICINE TO THE DRUG REPOSITORY.
20 THE DEPARTMENT AND THE BOARD OF PHARMACY SHALL ESTABLISH A
21 PROCESS TO MAKE MAILERS CREATED PURSUANT TO THIS SUBSECTION
22 (3)(b)(III) AVAILABLE TO INTERESTED PERSONS AND MAY DISTRIBUTE THE
23 MAILERS AT PHARMACY AND PUBLIC HEALTH CONFERENCES.

24 (c) THE SECOND PHASE OF THE CDDP OUTREACH AND MARKETING
25 PLAN MUST CREATE AWARENESS AMONG INDIVIDUALS WHO MAY BENEFIT
26 FROM RECEIVING DONATED MEDICINE. AS SPECIFIED IN THE CONTRACT,
27 ACTIVITIES TO INCREASE AWARENESS MAY INCLUDE:

1 (I) A GENERAL LISTING OF MEDICINE ON THE CDDP WEBSITE THAT
2 IS AVAILABLE FOR REUSE;

3 (II) OUTREACH TO SAFETY-NET AND PATIENT OUTREACH GROUPS
4 IN COLORADO, INCLUDING THE COLORADO COMMUNITY HEALTH
5 NETWORK, THE CHRONIC CARE COLLABORATIVE, LOCAL AREA AGENCIES
6 ON AGING, AND OTHER GROUPS;

7 (III) OUTREACH TO PHARMACY ORGANIZATIONS, SUCH AS RXPLUS
8 PHARMACIES, INC., THE COLORADO PHARMACISTS SOCIETY, AND OTHERS,
9 TO CREATE AWARENESS OF THE CDDP AND TO PROVIDE INFORMATION ON
10 HOW TO OBTAIN DONATED MEDICINE, AS WELL AS DISTRIBUTING ANY
11 POSTERS OR OTHER MARKETING MATERIAL CREATED FOR THE CDDP;

12 (IV) OUTREACH TO LEGISLATORS, IN CONSULTATION WITH THE
13 DEPARTMENT AND THE BOARD OF PHARMACY, TO INCREASE AWARENESS
14 AMONG CONSTITUENTS IN COLORADO'S LEGISLATIVE DISTRICTS;

15 (V) ONCE THE CDDP IS FULLY OPERATIONAL, OUTREACH TO
16 COLORADO MEDIA CONCERNING THE CDDP, AS WELL AS DISTRIBUTING
17 ANY RELEVANT MARKETING MATERIALS; AND

18 (VI) ANY OTHER OUTREACH AND MARKETING EFFORTS, AS
19 SPECIFIED IN THE CONTRACT.

20 (4) THE CONTRACTOR SHALL REPORT DATA AND INFORMATION
21 REGARDING THE DRUG REPOSITORY AND OTHER SERVICES PROVIDED BY
22 THE CONTRACTOR TO THE DEPARTMENT AND TO THE BOARD OF PHARMACY
23 IN THE MANNER AND FREQUENCY DETERMINED BY THE DEPARTMENT AND
24 THE BOARD OF PHARMACY.

25 **SECTION 4. In Colorado Revised Statutes, 25-15-328, amend**
26 **(6)(a) as follows:**

27 **25-15-328. Household medication take-back program -**

1 creation - collection and disposal of medication injection devices -
2 liability - definitions - cash fund - rules. (6) Nothing in this section:

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

5 **SECTION 5. Act subject to petition - effective date.** This act
6 takes effect at 12:01 a.m. on the day following the expiration of the
7 ninety-day period after final adjournment of the general assembly; except
8 that, if a referendum petition is filed pursuant to section 1 (3) of article V
9 of the state constitution against this act or an item, section, or part of this
10 act within such period, then the act, item, section, or part will not take
11 effect unless approved by the people at the general election to be held in
12 November 2024 and, in such case, will take effect on the date of the
13 official declaration of the vote thereon by the governor.