NOTE: This bill has been prepared for the signatures of the appropriate legislative officers and the Governor. To determine whether the Governor has signed the bill or taken other action on it, please consult the legislative status sheet, the legislative history, or the Session Laws.

SENATE BILL 25-289

BY SENATOR(S) Cutter, Catlin, Frizell, Hinrichsen, Jodeh, Kipp, Michaelson Jenet, Sullivan, Wallace, Winter F.;
also REPRESENTATIVE(S) Brown and Sirota, Bird, Boesenecker, Clifford, Duran, Feret, Garcia, Hamrick, Joseph, Lieder, Lindsay, Mabrey, Paschal, Rutinel, Rydin, Smith, Stewart K., Story, Titone, Willford, McCluskie.

CONCERNING THE CREATION OF A DRUG DONATION PROGRAM.

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

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

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

Capital letters or bold & italic numbers indicate new material added to existing law; dashes through words or numbers indicate deletions from existing law and such material is not part of the act.

~~substance~~ "MEDICINE" MEANS PRESCRIPTION DRUGS.

(II) "MEDICINE" INCLUDES:

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

(B) PRESCRIPTION SUPPLIES AND DEVICES.

(III) "MEDICINE" DOES NOT INCLUDE:

(A) COMPOUNDED DRUGS;

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

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

(D) CONTROLLED SUBSTANCES.

(2) (a) (I) If donated by the patient, the resident, or the patient's or resident's next of kin, a licensed facility may return unused ~~medications~~ MEDICINE or medical supplies and used or unused medical devices to a pharmacist within the licensed facility or a prescription drug outlet in order for the materials 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 dispense the materials.

(II) (A) A licensed facility or a prescription drug outlet may donate materials to ~~a nonprofit~~ AN entity that has legal authority to 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 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~~ AN 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~~ AN 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 TO THE MANUFACTURER'S STORAGE REQUIREMENTS, SO LONG AS THE COLD CHAIN CAN BE VERIFIED.

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

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

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

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

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

(VI) COMPOUNDED MEDICINE;

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

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

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

(4) ~~Medication~~ MEDICINE, medical supplies, and medical devices donated pursuant to this section ~~may~~ SHALL not be resold ~~for profit. The entity that receives the donated materials may charge the end user a handling fee, which fee shall not exceed the amount specified by rule of the board~~ AND ARE CONSIDERED NONSALEABLE; EXCEPT THAT HANDLING, DISPENSING, OR USUAL AND CUSTOMARY CHARGES TO AN ELIGIBLE PATIENT, HEALTH PLAN, PHARMACY BENEFIT MANAGER, PHARMACY SERVICE, ADMINISTRATIVE ORGANIZATION, GOVERNMENT AGENCY, OR OTHER ENTITY IS NOT CONSIDERED RESELLING. IF THE DONATION RECIPIENT IS A FOR-PROFIT ENTITY, THESE CHARGES MUST NOT EXCEED THE DONATION RECIPIENT'S COST OF PROVIDING THE MEDICINE, INCLUDING THE CURRENT AND

ANTICIPATED COSTS OF EDUCATING ELIGIBLE DONORS AND INDIVIDUAL DONORS, PROVIDING TECHNICAL SUPPORT TO PARTICIPATING DONORS AND INDIVIDUAL DONORS, SHIPPING AND HANDLING, LABOR, STORAGE, LICENSING, UTILITIES, ADVERTISING, TECHNOLOGY, SUPPLIES, AND EQUIPMENT. EXCEPT AS DESCRIBED IN THIS SUBSECTION (4), THE AMOUNT OF THESE CHARGES IS NOT SUBJECT TO 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) (a) EXCEPT AS PROVIDED IN SUBSECTION (6)(b) OF THIS SECTION, 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 prescription drug manufacturer in addition to that which is available under applicable law.

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

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

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

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

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

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

(A) IS LEGALLY AUTHORIZED TO POSSESS MEDICINE;

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

(C) RECEIVES A DONATION OF MEDICINE.

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

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

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

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

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

(II) "ELIGIBLE PATIENT" INCLUDES OTHER INDIVIDUALS IF A NEED FOR DONATED MEDICINE IS NOT IDENTIFIED AMONG INDIVIDUALS WHO ARE

INDIGENT, UNINSURED, OR UNDERINSURED.

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

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

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

(II) "MEDICINE" INCLUDES:

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

(B) PRESCRIPTION SUPPLIES AND DEVICES.

(III) "MEDICINE" DOES NOT INCLUDE:

(A) COMPOUNDED DRUGS;

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

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

(D) CONTROLLED SUBSTANCES.

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

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

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

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

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

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

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

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

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

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

(c) NO OTHER INFORMATION OR RECORDS ARE REQUIRED PRIOR TO

THE FIRST DONATION FROM A NEW DONOR OR A NEW INDIVIDUAL DONOR OTHER THAN AS DESCRIBED IN SUBSECTION (3)(b) OF THIS SECTION.

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

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

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

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

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

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

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

(I) RETURNING THE DONATED MEDICINE TO THE DONOR;

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

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

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

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

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

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

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

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

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

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

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

(10) A DONATION RECIPIENT:

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

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

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

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

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

OF THESE CHARGES IS NOT SUBJECT TO ANY ADDITIONAL LIMITATIONS.

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

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

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

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

(18) THE BOARD SHALL ADOPT ANY RULES NECESSARY TO

IMPLEMENT THIS SECTION. THE RULES MUST REQUIRE THE LEAST AMOUNT OF RECORD KEEPING NECESSARY TO ENSURE PATIENT SAFETY AND MUST ALLOW FLEXIBILITY IN THE FORMAT FOR RECORD KEEPING.

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

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

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

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

(c) THE BOARD.

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

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

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

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

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

SECTION 4. Act subject to petition - effective date. This act takes effect at 12:01 a.m. on the day following the expiration of the ninety-day period after final adjournment of the general assembly; except that, if a referendum petition is filed pursuant to section 1 (3) of article V of the state constitution against this act or an item, section, or part of this act within such period, then the act, item, section, or part will not take effect unless approved by the people at the general election to be held in

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

James Rashad Coleman, Sr. PRESIDENT OF THE SENATE	Julie McCluskie SPEAKER OF THE HOUSE OF REPRESENTATIVES
Esther van Mourik SECRETARY OF THE SENATE	Vanessa Reilly CHIEF CLERK OF THE HOUSE OF REPRESENTATIVES

APPROVED_____
(Date and Time)

_____
Jared S. Polis
GOVERNOR OF THE STATE OF COLORADO