

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.

An Act

HOUSE BILL 23-1002

BY REPRESENTATIVE(S) Mabrey and Jodeh, Amabile, Bacon, Bird, Boesenecker, Brown, Daugherty, Dickson, Duran, Froelich, Garcia, Kipp, Lieder, Lindsay, Lukens, Martinez, McCormick, McLachlan, Michaelson Jenet, Parenti, Ricks, Sharbini, Sirota, Snyder, Story, Titone, Valdez, Velasco, Vigil, Weissman, Willford, Woodrow, Young, McCluskie, deGruy Kennedy, English, Hamrick, Joseph, Weinberg;
also SENATOR(S) Roberts, Buckner, Coleman, Cutter, Danielson, Exum, Ginal, Gonzales, Hansen, Hinrichsen, Kolker, Marchman, Moreno, Priola, Sullivan, Winter F., Fenberg.

CONCERNING THE AFFORDABILITY OF EPINEPHRINE AUTO-INJECTORS, AND,
IN CONNECTION THEREWITH, MAKING AN APPROPRIATION.

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

SECTION 1. Legislative declaration. (1) The general assembly finds and declares that:

(a) Individuals who have moderate to severe allergies, severe asthma, or genetic conditions such as angioedema are at risk of reactions that can occur within seconds or minutes and that can lead to anaphylaxis, a potentially fatal reaction;

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.

(b) Epinephrine works quickly to improve breathing, stimulate the heart, raise dropping blood pressure, prevent airways from closing, prevent or decrease shock, reverse hives, and reduce swelling of the face, lips, and throat;

(c) Delay in appropriate treatment for anaphylaxis almost certainly contributes to death in individuals, so it is critical that all anaphylaxis reactions are treated as a medical emergency;

(d) In Colorado, there are approximately 565,824 individuals with life-threatening food allergies, which is more than the population of Colorado Springs; of these individuals, 101,848 are under 18 years of age, which means that the number of children with food allergies in Colorado is larger than the population of Longmont;

(e) Epinephrine auto-injectors are essential because they are the easiest and most efficient way to potentially save the life of an individual exhibiting symptoms of or experiencing anaphylactic shock;

(f) Many individuals are unable to afford an epinephrine auto-injector because they cannot pay the copayment amount required under their insurance plan or, if they are uninsured, the cost of an epinephrine auto-injector; these individuals risk their lives every day by not having access to this life-saving medicine if faced with an allergic reaction; and

(g) Rising costs of epinephrine auto-injectors make this life-saving medication difficult or impossible to obtain for many people, even those with private health insurance or who are enrolled in a public health benefit program.

(2) Therefore, it is the intent of the general assembly to establish an epinephrine auto-injector affordability program to ensure Colorado residents have greater access to epinephrine.

SECTION 2. In Colorado Revised Statutes, **add** 10-16-160 as follows:

10-16-160. Cost sharing - prescription epinephrine - limits - rules - definition. (1) AS USED IN THIS SECTION, UNLESS THE CONTEXT

OTHERWISE REQUIRES, "EPINEPHRINE AUTO-INJECTOR" HAS THE SAME MEANING AS SET FORTH IN SECTION 12-280-142 (1)(c).

(2) FOR HEALTH COVERAGE PLANS ISSUED OR RENEWED ON OR AFTER JANUARY 1, 2024, IF A CARRIER PROVIDES COVERAGE FOR PRESCRIPTION EPINEPHRINE AUTO-INJECTORS, THE CARRIER SHALL CAP THE TOTAL AMOUNT THAT A COVERED PERSON IS REQUIRED TO PAY FOR ALL COVERED PRESCRIPTION EPINEPHRINE AUTO-INJECTORS AT AN AMOUNT NOT TO EXCEED SIXTY DOLLARS FOR A TWO-PACK OF EPINEPHRINE AUTO-INJECTORS, REGARDLESS OF THE AMOUNT OR TYPE OF EPINEPHRINE NEEDED TO FILL THE COVERED PERSON'S PRESCRIPTION.

(3) NOTHING IN THIS SECTION PREVENTS A CARRIER FROM REDUCING A COVERED PERSON'S COST SHARING TO AN AMOUNT THAT IS LOWER THAN THE AMOUNT SPECIFIED IN SUBSECTION (2) OF THIS SECTION.

(4) THE COVERAGE REQUIRED BY THIS SECTION MAY BE OFFERED THROUGH A HIGH DEDUCTIBLE PLAN THAT INCLUDES A HEALTH SAVINGS ACCOUNT PURSUANT TO 26 U.S.C. SEC. 223 OF THE FEDERAL "INTERNAL REVENUE CODE OF 1986"; EXCEPT THAT A CARRIER MAY APPLY DEDUCTIBLE AMOUNTS FOR THE REQUIRED COVERAGE IF THE COVERAGE IS NOT CONSIDERED BY THE UNITED STATES DEPARTMENT OF THE TREASURY TO BE PREVENTIVE OR TO HAVE AN ACCEPTABLE DEDUCTIBLE AMOUNT.

(5) THE COMMISSIONER MAY USE ANY OF THE COMMISSIONER'S ENFORCEMENT POWERS TO OBTAIN A CARRIER'S COMPLIANCE WITH THIS SECTION.

(6) THE COMMISSIONER MAY PROMULGATE RULES AS NECESSARY TO IMPLEMENT AND ADMINISTER THIS SECTION AND TO ALIGN WITH FEDERAL REQUIREMENTS.

SECTION 3. In Colorado Revised Statutes, **add** 12-280-142 as follows:

12-280-142. Epinephrine auto-injector affordability program - record keeping - reimbursement - definitions. (1) AS USED IN THIS SECTION:

(a) "CONSUMER PRICE INDEX" MEANS THE UNITED STATES

DEPARTMENT OF LABOR'S BUREAU OF LABOR STATISTICS CONSUMER PRICE INDEX FOR DENVER-AURORA-LAKEWOOD FOR ALL ITEMS PAID BY ALL URBAN CONSUMERS, OR ITS APPLICABLE PREDECESSOR OR SUCCESSOR INDEX.

(b) "DIVISION OF INSURANCE" MEANS THE DIVISION OF INSURANCE IN THE DEPARTMENT OF REGULATORY AGENCIES, CREATED IN SECTION 10-1-103.

(c) "EPINEPHRINE AUTO-INJECTOR" MEANS AN AUTOMATIC INJECTION DEVICE FOR INJECTING A MEASURED DOSE OF EPINEPHRINE BASED ON THE WEIGHT OF THE PERSON WHO IS TO RECEIVE THE INJECTION.

(d) "MANUFACTURER" MEANS A PERSON ENGAGED IN MANUFACTURING EPINEPHRINE AUTO-INJECTORS THAT ARE AVAILABLE FOR PURCHASE IN THIS STATE.

(e) "PHARMACY" MEANS A PHARMACY OUTLET REGISTERED PURSUANT TO THIS ARTICLE 280 WHERE PRESCRIPTIONS ARE COMPOUNDED AND DISPENSED.

(f) "PROGRAM" MEANS THE EPINEPHRINE AUTO-INJECTOR AFFORDABILITY PROGRAM CREATED IN SUBSECTION (2) OF THIS SECTION.

(g) "PROOF OF RESIDENCY" MEANS A CURRENT AND VALID DOCUMENT THAT IS IN ENGLISH, OR IS TRANSLATED INTO ENGLISH AND IS UNALTERED, AND THAT INCLUDES THE INDIVIDUAL'S, OR IN THE CASE OF A MINOR, THE MINOR'S PARENT'S OR GUARDIAN'S, PRINTED NAME AND COLORADO RESIDENTIAL ADDRESS. DOCUMENTS THAT MAY BE USED FOR PROOF OF RESIDENCY ARE:

(I) A COLORADO-ISSUED DRIVER'S LICENSE OR COLORADO IDENTIFICATION CARD;

(II) A PRINTED BILL, INCLUDING A UTILITY, TELEPHONE, INTERNET, CABLE, INSURANCE, MORTGAGE, RENT, WASTE DISPOSAL, WATER OR SEWER, MEDICAL, OR OTHER BILL;

(III) A CREDIT CARD OR BANK STATEMENT;

(IV) A PAY STUB OR EARNINGS STATEMENT;

(V) A PIECE OF POST-MARKED FIRST-CLASS MAIL OR UNITED STATES POSTAL SERVICE CHANGE OF ADDRESS CONFIRMATION;

(VI) A PRINTED RENT RECEIPT OR RESIDENTIAL LEASE;

(VII) A TRANSCRIPT OR REPORT CARD FROM AN ACCREDITED SCHOOL;

(VIII) A VEHICLE TITLE OR REGISTRATION;

(IX) AN INSURANCE POLICY;

(X) A GOVERNMENT-ISSUED LETTER OR STATE OR FEDERAL GOVERNMENT-ISSUED CHECK; OR

(XI) A RECORD OF MEDICAL SERVICE FROM A SHELTER, TREATMENT FACILITY, OR ASSISTED LIVING FACILITY, INCLUDING A HOMELESS SHELTER, WOMEN'S SHELTER, OTHER NONPROFIT SHELTER, HALFWAY HOUSE, NURSING HOME, OR REHABILITATION FACILITY.

(2) EFFECTIVE JANUARY 1, 2024, THE EPINEPHRINE AUTO-INJECTOR AFFORDABILITY PROGRAM IS CREATED TO PROVIDE LOW-COST EPINEPHRINE AUTO-INJECTORS TO ELIGIBLE INDIVIDUALS. BY JANUARY 1, 2024, EACH MANUFACTURER SHALL ESTABLISH PROCEDURES TO AND SHALL MAKE EPINEPHRINE AUTO-INJECTORS AVAILABLE IN ACCORDANCE WITH THIS SECTION TO ELIGIBLE INDIVIDUALS WHO HOLD A VALID PRESCRIPTION FOR EPINEPHRINE AUTO-INJECTORS.

(3) TO BE ELIGIBLE TO RECEIVE EPINEPHRINE AUTO-INJECTORS THROUGH THE PROGRAM, AN INDIVIDUAL MUST:

(a) DEMONSTRATE PROOF OF RESIDENCY IN COLORADO;

(b) NOT BE ELIGIBLE FOR ASSISTANCE PROVIDED THROUGH THE "COLORADO MEDICAL ASSISTANCE ACT", ARTICLES 4 TO 6 OF TITLE 25.5, OR THE FEDERAL "HEALTH INSURANCE FOR THE AGED ACT", TITLE XVIII OF THE FEDERAL "SOCIAL SECURITY ACT", 42 U.S.C. SEC. 1395 ET SEQ., AS AMENDED;

(c) HAVE A VALID EPINEPHRINE AUTO-INJECTOR PRESCRIPTION; AND

(d) NOT BE ENROLLED IN PRESCRIPTION DRUG COVERAGE THAT LIMITS THE TOTAL AMOUNT OF COST SHARING THAT THE ENROLLEE IS REQUIRED TO PAY FOR A COVERED PRESCRIPTION TO NOT MORE THAN SIXTY DOLLARS FOR A TWO-PACK OF EPINEPHRINE AUTO-INJECTORS, REGARDLESS OF THE AMOUNT OR TYPE OF EPINEPHRINE NEEDED TO FILL THE PRESCRIPTION.

(4)(a) THE DIVISION OF INSURANCE SHALL DEVELOP AN APPLICATION FORM TO BE USED BY AN INDIVIDUAL WHO IS SEEKING EPINEPHRINE AUTO-INJECTORS THROUGH THE PROGRAM. AT A MINIMUM, THE APPLICATION FORM MUST:

(I) PROVIDE INFORMATION RELATED TO PROGRAM ELIGIBILITY AND COVERAGE IN ENGLISH, SPANISH, AND IN EACH LANGUAGE SPOKEN BY AT LEAST TWO AND ONE-HALF PERCENT OF THE POPULATION OF ANY COUNTY IN WHICH SUCH POPULATION SPEAKS ENGLISH LESS THAN VERY WELL, AS DEFINED BY THE UNITED STATES BUREAU OF THE CENSUS AMERICAN COMMUNITY SURVEY OR COMPARABLE CENSUS DATA, AND SPEAKS A SHARED MINORITY LANGUAGE AT HOME; AND

(II) REQUIRE THE INDIVIDUAL TO SHOW PROOF THAT THE INDIVIDUAL MEETS THE REQUIREMENTS OF SUBSECTION (3) OF THIS SECTION.

(b) THE DIVISION OF INSURANCE AND THE DEPARTMENT OF HEALTH CARE POLICY AND FINANCING SHALL MAKE THE APPLICATION FORM AVAILABLE ON EACH AGENCY'S WEBSITE. THE DIVISION OF INSURANCE SHALL ALSO MAKE THE APPLICATION FORM AVAILABLE TO PHARMACIES, HEALTH-CARE PROVIDERS, AND HEALTH FACILITIES THAT PRESCRIBE OR DISPENSE EPINEPHRINE AUTO-INJECTORS.

(5) TO ACCESS EPINEPHRINE AUTO-INJECTORS THROUGH THE PROGRAM, AN INDIVIDUAL MUST PRESENT, AT A PHARMACY, A COMPLETED, SIGNED, AND DATED APPLICATION FORM WITH PROOF OF RESIDENCY. IF THE INDIVIDUAL IS UNDER EIGHTEEN YEARS OF AGE, THE INDIVIDUAL'S PARENT OR LEGAL GUARDIAN MAY PROVIDE THE PHARMACIST WITH PROOF OF RESIDENCY.

(6)(a) UPON RECEIPT OF AN INDIVIDUAL'S PROOF OF RESIDENCY AND COMPLETED, SIGNED, AND DATED APPLICATION FORM DEMONSTRATING THAT THE INDIVIDUAL IS ELIGIBLE PURSUANT TO SUBSECTION (3) OF THIS SECTION,

A PHARMACIST SHALL DISPENSE THE PRESCRIBED EPINEPHRINE AUTO-INJECTORS. AN INDIVIDUAL WHO IS ELIGIBLE TO RECEIVE EPINEPHRINE AUTO-INJECTORS THROUGH THE PROGRAM MAY RECEIVE EPINEPHRINE AUTO-INJECTORS AS PRESCRIBED FOR TWELVE MONTHS.

(b) THE PHARMACIST IS ENCOURAGED TO INFORM THE INDIVIDUAL:

(I) THAT THE INDIVIDUAL MAY BE ELIGIBLE FOR MEDICAL ASSISTANCE PROGRAMS PURSUANT TO THE "COLORADO MEDICAL ASSISTANCE ACT", ARTICLES 4 TO 6 OF TITLE 25.5, OR AN AFFORDABLE INSURANCE PRODUCT ON THE HEALTH BENEFIT EXCHANGE CREATED IN SECTION 10-22-104; AND

(II) OF ANY MANUFACTURER-SPONSORED PROGRAMS THAT ASSIST INDIVIDUALS WHO CANNOT AFFORD THEIR PRESCRIPTION EPINEPHRINE AUTO-INJECTORS.

(c) THE PHARMACIST SHALL RETAIN A COPY OF THE APPLICATION FORM SUBMITTED BY THE INDIVIDUAL FOR TWO YEARS AFTER THE DATE THE EPINEPHRINE AUTO-INJECTOR WAS INITIALLY DISPENSED.

(7) A PHARMACY THAT DISPENSES EPINEPHRINE AUTO-INJECTORS PURSUANT TO SUBSECTION (6)(a) OF THIS SECTION MAY COLLECT A COPAYMENT FROM THE INDIVIDUAL TO COVER THE PHARMACY'S COSTS OF PROCESSING AND DISPENSING THE EPINEPHRINE AUTO-INJECTOR, WHICH COPAYMENT AMOUNT MUST NOT EXCEED SIXTY DOLLARS FOR EACH TWO-PACK OF EPINEPHRINE AUTO-INJECTORS THAT THE PHARMACY DISPENSES TO THE INDIVIDUAL.

(8)(a) EXCEPT AS PROVIDED IN SUBSECTION (8)(d) OF THIS SECTION, UNLESS THE MANUFACTURER AGREES TO SEND TO THE PHARMACY A REPLACEMENT SUPPLY OF THE SAME NUMBER OF EPINEPHRINE AUTO-INJECTORS DISPENSED THROUGH THE PROGRAM, THE PHARMACY MAY SUBMIT TO THE MANUFACTURER OF THE DISPENSED EPINEPHRINE AUTO-INJECTORS, DIRECTLY OR THROUGH THE MANUFACTURER'S DELEGATED REPRESENTATIVE, SUBCONTRACTOR, OR OTHER VENDOR, AN ELECTRONIC CLAIM FOR PAYMENT THAT IS MADE IN ACCORDANCE WITH THE NATIONAL COUNCIL FOR PRESCRIPTION DRUG PROGRAMS' STANDARDS FOR ELECTRONIC CLAIMS PROCESSING.

(b) BY JANUARY 1, 2024, EACH MANUFACTURER SHALL DEVELOP A PROCESS FOR A PHARMACY TO SUBMIT AN ELECTRONIC CLAIM FOR REIMBURSEMENT, INCLUDING AN ACCESSIBLE ONLINE APPLICATION FOR REIMBURSEMENT CLAIMS FROM PHARMACIES UNDER THE PROGRAM, AS PROVIDED IN SUBSECTION (8)(a) OF THIS SECTION.

(c) IF THE PHARMACY SUBMITS AN ELECTRONIC CLAIM TO THE MANUFACTURER PURSUANT TO SUBSECTION (8)(a) OF THIS SECTION, THE MANUFACTURER OR THE MANUFACTURER'S DELEGATED REPRESENTATIVE, SUBCONTRACTOR, OR OTHER VENDOR SHALL, WITHIN THIRTY DAYS AFTER RECEIPT OF THE CLAIM, EITHER:

(I) REIMBURSE THE PHARMACY IN AN AMOUNT THAT THE PHARMACY PAID FOR THE NUMBER OF EPINEPHRINE AUTO-INJECTORS DISPENSED THROUGH THE PROGRAM; OR

(II) SEND THE PHARMACY A REPLACEMENT SUPPLY OF EPINEPHRINE AUTO-INJECTORS IN AN AMOUNT EQUAL TO THE NUMBER OF EPINEPHRINE AUTO-INJECTORS DISPENSED THROUGH THE PROGRAM PURSUANT TO SUBSECTION (6)(a) OF THIS SECTION.

(9) THE DIVISION OF INSURANCE AND THE DEPARTMENT OF HEALTH CARE POLICY AND FINANCING SHALL PROMOTE THE AVAILABILITY OF THE PROGRAM TO COLORADANS. THE PROMOTIONAL MATERIAL MUST INCLUDE INFORMATION ABOUT EACH MANUFACTURER'S CONSUMER EPINEPHRINE AUTO-INJECTOR PROGRAM, AS APPLICABLE. EACH AGENCY MAY SEEK AND ACCEPT GIFTS, GRANTS, AND DONATIONS TO FULFILL THE REQUIREMENTS OF THIS SUBSECTION (9).

(10) A MANUFACTURER'S REIMBURSEMENT PURSUANT TO SUBSECTION (8)(c) OF THIS SECTION IS NOT A KICKBACK.

(11) A MANUFACTURER THAT FAILS TO COMPLY WITH THE REQUIREMENTS OF THIS SECTION:

(a) IS SUBJECT TO A FINE OF TEN THOUSAND DOLLARS FOR EACH MONTH OF NONCOMPLIANCE; AND

(b) ENGAGES IN A DECEPTIVE TRADE PRACTICE UNDER SECTION 6-1-105 (1)(zzz).

SECTION 4. In Colorado Revised Statutes, 6-1-105, **add** (1)(zzz) as follows:

6-1-105. Unfair or deceptive trade practices. (1) A person engages in a deceptive trade practice when, in the course of the person's business, vocation, or occupation, the person:

(zzz) FAILS TO COMPLY WITH THE REQUIREMENTS OF SECTION 12-280-142.

SECTION 5. Appropriation. (1) For the 2023-24 state fiscal year, \$58,291 is appropriated to the department of regulatory agencies for use by the division of insurance. This appropriation is from the division of insurance cash fund created in section 10-1-103 (3), C.R.S. To implement this act, the division may use this appropriation as follows:

(a) \$49,176 for personal services, which amount is based on an assumption that the division will require an additional 0.7 FTE; and

(b) \$9,115 for operating expenses.

SECTION 6. 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 2024 and, in such case, will take effect on the date of the official declaration of the vote thereon by the governor.

Julie McCluskie
SPEAKER OF THE HOUSE
OF REPRESENTATIVES

Steve Fenberg
PRESIDENT OF
THE SENATE

Robin Jones
CHIEF CLERK OF THE HOUSE
OF REPRESENTATIVES

Cindi L. Markwell
SECRETARY OF
THE SENATE

APPROVED _____
(Date and Time)

Jared S. Polis
GOVERNOR OF THE STATE OF COLORADO