

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

ENGROSSED

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

LLS NO. 23-0428.01 Kristen Forrestal x4217

HOUSE BILL 23-1002

HOUSE SPONSORSHIP

Mabrey and Jodeh,

SENATE SPONSORSHIP

Roberts,

House Committees

Health & Insurance
Appropriations

Senate Committees

A BILL FOR AN ACT

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

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>.)

Effective January 1, 2024, the bill creates an epinephrine auto-injector affordability program (program) to provide low-cost epinephrine auto-injectors to individuals who:

- Are residents of this state;
- Are not enrolled in the state medicaid program or the federal medicare program;

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.*

HOUSE
Amended 2nd Reading
March 7, 2023

- Have a prescription for an epinephrine auto-injector; and
- Are not enrolled in prescription drug coverage that limits the total amount of cost sharing that the enrollee is required to pay for an epinephrine auto-injector.

The bill requires the division of insurance in the department of regulatory agencies (division) to create an application for the program and requires the division and the department of health care policy and financing to make the application available on their websites and to promote the availability of the program.

The bill requires a carrier that provides coverage for prescription epinephrine auto-injectors to 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 \$60 for a 2-pack of epinephrine auto-injectors.

A pharmacy that dispenses epinephrine auto-injectors is authorized to collect a copayment not to exceed \$60 from the individual to cover the pharmacy's costs of processing and dispensing a 2-pack of epinephrine auto-injectors.

A manufacturer of epinephrine auto-injectors:

- Is required to make epinephrine auto-injectors available to individuals through the program; and
- May be required to reimburse the dispensing pharmacy an amount that covers the difference between the pharmacy's wholesale acquisition cost for the number of epinephrine auto-injectors dispensed through the program and the amount the recipients of the epinephrine auto-injectors paid for the same number of epinephrine auto-injectors or send the pharmacy a replacement supply of the same number of epinephrine auto-injectors.

If a manufacturer fails to comply with the requirements of the bill, the manufacturer may be subject to a fine.

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

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

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

8 (b) Epinephrine works quickly to improve breathing, stimulate the

1 heart, raise dropping blood pressure, prevent airways from closing,
2 prevent or decrease shock, reverse hives, and reduce swelling of the face,
3 lips, and throat;

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

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

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

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

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

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

1 **SECTION 2.** In Colorado Revised Statutes, **add** 10-16-158 as
2 follows:

3 **10-16-158. Cost sharing - prescription epinephrine - limits -**
4 **rules - definition.** (1) AS USED IN THIS SECTION, UNLESS THE CONTEXT
5 OTHERWISE REQUIRES, "EPINEPHRINE AUTO-INJECTOR" HAS THE SAME
6 MEANING AS SET FORTH IN SECTION 12-280-141 (1)(c).

7 (2) A CARRIER THAT PROVIDES COVERAGE FOR PRESCRIPTION
8 EPINEPHRINE AUTO-INJECTORS PURSUANT TO THE TERMS OF A HEALTH
9 COVERAGE PLAN THE CARRIER OFFERS SHALL CAP THE TOTAL AMOUNT
10 THAT A COVERED PERSON IS REQUIRED TO PAY FOR ALL COVERED
11 PRESCRIPTION EPINEPHRINE AUTO-INJECTORS AT AN AMOUNT NOT TO
12 EXCEED SIXTY DOLLARS FOR A TWO-PACK OF EPINEPHRINE
13 AUTO-INJECTORS, REGARDLESS OF THE AMOUNT OR TYPE OF EPINEPHRINE
14 NEEDED TO FILL THE COVERED PERSON'S PRESCRIPTION.

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

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

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

24 **SECTION 3.** In Colorado Revised Statutes, **add** 12-280-141 as
25 follows:

26 **12-280-141. Epinephrine auto-injector affordability program**
27 **- record keeping - reimbursement - definitions.** (1) AS USED IN THIS

1 SECTION:

2 (a) "CONSUMER PRICE INDEX" MEANS THE UNITED STATES
3 DEPARTMENT OF LABOR'S BUREAU OF LABOR STATISTICS CONSUMER PRICE
4 INDEX FOR DENVER-AURORA-LAKEWOOD FOR ALL ITEMS PAID BY ALL
5 URBAN CONSUMERS, OR ITS APPLICABLE PREDECESSOR OR SUCCESSOR
6 INDEX.

7 (b) "DIVISION OF INSURANCE" MEANS THE DIVISION OF INSURANCE
8 IN THE DEPARTMENT OF REGULATORY AGENCIES, CREATED IN SECTION
9 10-1-103.

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

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


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

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

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

27 (I) A COLORADO-ISSUED DRIVER'S LICENSE OR COLORADO

- 1 IDENTIFICATION CARD;
- 2 (II) A PRINTED BILL, INCLUDING A UTILITY, TELEPHONE, INTERNET,
3 CABLE, INSURANCE, MORTGAGE, RENT, WASTE DISPOSAL, WATER OR
4 SEWER, MEDICAL, OR OTHER BILL;
- 5 (III) A CREDIT CARD OR BANK STATEMENT;
- 6 (IV) A PAY STUB OR EARNINGS STATEMENT;
- 7 (V) A PIECE OF POST-MARKED FIRST-CLASS MAIL OR UNITED
8 STATES POSTAL SERVICE CHANGE OF ADDRESS CONFIRMATION;
- 9 (VI) A PRINTED RENT RECEIPT OR RESIDENTIAL LEASE;
- 10 (VII) A TRANSCRIPT OR REPORT CARD FROM AN ACCREDITED
11 SCHOOL;
- 12 (VIII) A VEHICLE TITLE OR REGISTRATION;
- 13 (IX) AN INSURANCE POLICY;
- 14 (X) A GOVERNMENT-ISSUED LETTER OR STATE OR FEDERAL
15 GOVERNMENT-ISSUED CHECK; OR
- 16 (XI) A RECORD OF MEDICAL SERVICE FROM A SHELTER,
17 TREATMENT FACILITY, OR ASSISTED LIVING FACILITY, INCLUDING A
18 HOMELESS SHELTER, WOMEN'S SHELTER, OTHER NONPROFIT SHELTER,
19 HALFWAY HOUSE, NURSING HOME, OR REHABILITATION FACILITY.

20 

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

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

3 (a) DEMONSTRATE PROOF OF RESIDENCY IN COLORADO;

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

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

10 AND

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

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

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

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

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

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

16 (6) (a) UPON RECEIPT OF AN INDIVIDUAL'S PROOF OF RESIDENCY
17 AND COMPLETED, SIGNED, AND DATED APPLICATION FORM
18 DEMONSTRATING THAT THE INDIVIDUAL IS ELIGIBLE PURSUANT TO
19 SUBSECTION (3) OF THIS SECTION, A PHARMACIST SHALL DISPENSE THE
20 PRESCRIBED EPINEPHRINE AUTO-INJECTORS. AN INDIVIDUAL WHO IS
21 ELIGIBLE TO RECEIVE EPINEPHRINE AUTO-INJECTORS THROUGH THE
22 PROGRAM MAY RECEIVE EPINEPHRINE AUTO-INJECTORS AS PRESCRIBED
23 FOR TWELVE MONTHS.

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

25 (I) THAT THE INDIVIDUAL MAY BE ELIGIBLE FOR MEDICAL
26 ASSISTANCE PROGRAMS PURSUANT TO THE "COLORADO MEDICAL
27 ASSISTANCE ACT", ARTICLES 4 TO 6 OF TITLE 25.5, OR AN AFFORDABLE

1 INSURANCE PRODUCT ON THE HEALTH BENEFIT EXCHANGE CREATED IN
2 SECTION 10-22-104; AND

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

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

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

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

26 (b) BY JANUARY 1, 2024, EACH MANUFACTURER SHALL DEVELOP
27 A PROCESS FOR A PHARMACY TO SUBMIT AN ELECTRONIC CLAIM FOR

1 REIMBURSEMENT, INCLUDING AN ACCESSIBLE ONLINE APPLICATION FOR
2 REIMBURSEMENT CLAIMS FROM PHARMACIES UNDER THE PROGRAM, AS
3 PROVIDED IN SUBSECTION (8)(a) OF THIS SECTION.

4 (c) IF THE PHARMACY SUBMITS AN ELECTRONIC CLAIM TO THE
5 MANUFACTURER PURSUANT TO SUBSECTION (8)(a) OF THIS SECTION, THE
6 MANUFACTURER OR THE MANUFACTURER'S DELEGATED REPRESENTATIVE,
7 SUBCONTRACTOR, OR OTHER VENDOR SHALL, WITHIN THIRTY DAYS AFTER
8 RECEIPT OF THE CLAIM, REIMBURSE THE PHARMACY THE AMOUNT THAT
9 THE PHARMACY PAID THE MANUFACTURER FOR THE NUMBER OF
10 EPINEPHRINE AUTO-INJECTORS DISPENSED THROUGH THE PROGRAM.

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

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

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

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

24 (b) ENGAGES IN A DECEPTIVE TRADE PRACTICE UNDER SECTION
25 6-1-105 (1)(uuu).

26 **SECTION 4.** In Colorado Revised Statutes, 6-1-105, **amend**
27 (1)(uuu) as follows:

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

4 (uuu) FAILS TO COMPLY WITH THE REQUIREMENTS OF SECTION
5 12-280-141.

6 **SECTION 5. Appropriation.** For the 2023-24 state fiscal year,
7 \$58,291 is appropriated to the department of regulatory agencies for use
8 by the division of insurance. This appropriation is from the division of
9 insurance cash fund created in section 10-1-103 (3), C.R.S. To implement
10 this act, the division may use this appropriation as follows:

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

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

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