

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

PREAMENDED

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

LLS NO. 18-0110.01 Kristen Forrestal x4217

HOUSE BILL 18-1179

HOUSE SPONSORSHIP

Salazar, Melton

SENATE SPONSORSHIP

(None),

House Committees

Health, Insurance, & Environment
Finance

Senate Committees

A BILL FOR AN ACT

101 **CONCERNING A PROHIBITION AGAINST PRICE GOUGING ON CERTAIN**
102 **PRESCRIPTION DRUGS.**

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:

- ! Prohibits a pharmaceutical manufacturer or wholesaler from price gouging on sales of essential off-patent or generic drugs;
- ! Makes the practice of price gouging a deceptive trade practice under the "Colorado Consumer Protection Act";

Shading denotes HOUSE amendment. Double underlining denotes SENATE amendment.
Capital letters or bold & italic numbers indicate new material to be added to existing statute.
Dashes through the words indicate deletions from existing statute.

and
! Requires the state board of pharmacy and the executive director of the department of health care policy and financing to report suspected price gouging to the attorney general. The attorney general is authorized to seek subpoenas and file lawsuits with the appropriate district courts.

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

2 **SECTION 1.** In Colorado Revised Statutes, 6-1-105, **add**
3 (1)(kkk) as follows:

4 **6-1-105. Deceptive trade practices.** (1) A person engages in a
5 deceptive trade practice when, in the course of the person's business,
6 vocation, or occupation, the person:

7 (kkk) ENGAGES IN PRICE GOUGING AS DEFINED IN SECTION
8 12-42.5-135.

9 **SECTION 2.** In Colorado Revised Statutes, **add** 12-42.5-135 as
10 follows:

11 **12-42.5-135. Price gouging prohibited - essential off-patent**
12 **and generic drugs - definitions.** (1) (a) A MANUFACTURER OR
13 WHOLESALER OF PRESCRIPTION DRUGS SHALL NOT ENGAGE IN PRICE
14 GOUGING IN CONNECTION WITH THE SALE OF AN ESSENTIAL OFF-PATENT OR
15 GENERIC DRUG.

16 (b) THIS SECTION DOES NOT PROHIBIT AN INCREASE IN THE PRICE
17 OF AN ESSENTIAL OFF-PATENT OR GENERIC DRUG IF THE PRICE INCREASE
18 IS DIRECTLY ATTRIBUTABLE TO ADDITIONAL COSTS FOR THE DRUG
19 IMPOSED ON THE WHOLESALER OF PRESCRIPTION DRUGS BY THE
20 MANUFACTURER.

21 (2) THE BOARD SHALL NOTIFY THE ATTORNEY GENERAL OF ANY
22 INCREASE IN THE PRICE OF AN ESSENTIAL OFF-PATENT OR GENERIC DRUG

1 WHEN:

2 (a) THE PRICE INCREASE, BY ITSELF OR IN COMBINATION WITH
3 OTHER PRICE INCREASES, WOULD RESULT IN AN INCREASE OF FIFTY
4 PERCENT OR MORE IN THE DRUG'S WHOLESALE ACQUISITION COST WITHIN
5 THE IMMEDIATELY PRECEDING ONE-YEAR PERIOD; AND

6 (b) (I) A THIRTY-DAY SUPPLY OF THE MAXIMUM RECOMMENDED
7 DOSAGE OF THE DRUG FOR ANY INDICATION, ACCORDING TO THE
8 FDA-APPROVED LABEL FOR THE DRUG, WOULD COST MORE THAN EIGHTY
9 DOLLARS AT THE DRUG'S WHOLESALE ACQUISITION COST;

10 (II) A FULL COURSE OF TREATMENT OF THE DRUG WOULD COST
11 MORE THAN EIGHTY DOLLARS AT THE DRUG'S WHOLESALE ACQUISITION
12 COST; OR

13 (III) THE DRUG IS MADE AVAILABLE TO CONSUMERS ONLY IN
14 QUANTITIES THAT DO NOT CORRESPOND TO A THIRTY-DAY SUPPLY, A FULL
15 COURSE OF THE TREATMENT, OR A SINGLE DOSE AND WOULD COST MORE
16 THAN EIGHTY DOLLARS AT THE DRUG'S WHOLESALE ACQUISITION COST TO
17 OBTAIN A THIRTY-DAY SUPPLY OR A FULL COURSE OF TREATMENT.

18 (3) IN ADDITION TO THE POWERS GRANTED TO THE ATTORNEY
19 GENERAL IN SECTIONS 6-1-107 AND 6-1-108, IF THE ATTORNEY GENERAL
20 HAS REASONABLE CAUSE TO BELIEVE THAT A MANUFACTURER HAS
21 VIOLATED SUBSECTION (1) OF THIS SECTION, THE ATTORNEY GENERAL MAY
22 ISSUE A SUBPOENA TO THE MANUFACTURER REQUIRING THE
23 MANUFACTURER TO SUBMIT THE FOLLOWING TO THE ATTORNEY GENERAL:

24 (a) AN ITEMIZATION OF THE COMPONENTS OF THE COST OF
25 PRODUCING THE DRUG;

26 (b) A STATEMENT IDENTIFYING THE CIRCUMSTANCES AND TIMING
27 OF ANY INCREASE IN THE PRICE OF THE DRUG WITHIN THE ONE-YEAR

1 PERIOD IMMEDIATELY PRECEDING THE DATE OF THE PRICE INCREASE;

2 (c) A STATEMENT IDENTIFYING THE CIRCUMSTANCES AND TIMING
3 OF ANY EXPENDITURES MADE BY THE MANUFACTURER TO EXPAND ACCESS
4 TO THE DRUG;

5 (d) AN EXPLANATION OF ANY IMPROVEMENT IN PUBLIC HEALTH
6 ASSOCIATED WITH THE EXPENDITURES DESCRIBED IN SUBSECTION (3)(c)
7 OF THIS SECTION; AND

8 (e) ANY OTHER INFORMATION THE MANUFACTURER BELIEVES TO
9 BE RELEVANT TO A DETERMINATION OF WHETHER A VIOLATION OF THIS
10 SECTION HAS OCCURRED.

11 (4) (a) THE ATTORNEY GENERAL MAY APPLY TO THE APPROPRIATE
12 DISTRICT COURT FOR AN APPROPRIATE ORDER TO EFFECT THE PURPOSES OF
13 THIS SECTION.

14 (b) IF THE DISTRICT COURT FINDS THAT A MANUFACTURER HAS
15 VIOLATED THIS SECTION OR SECTION 6-1-105 (1)(kkk), THE COURT MAY
16 ISSUE AN ORDER THAT:

17 (I) RESTRAINS OR ENJOINS THE ACT OF PRICE GOUGING;

18 (II) RESTORES MONEY ACQUIRED AS A RESULT OF PRICE GOUGING
19 TO A CONSUMER OR THIRD-PARTY PAYER;

20 (III) REQUIRES A MANUFACTURER THAT HAS ENGAGED IN PRICE
21 GOUGING TO MAKE THE DRUG AVAILABLE TO PERSONS COVERED BY A
22 HEALTH BENEFIT PLAN AS DEFINED IN SECTION 10-16-102 (32), OR
23 PERSONS ENROLLED AS RECIPIENTS IN THE "COLORADO MEDICAL
24 ASSISTANCE ACT", ARTICLES 4, 5, AND 6 OF TITLE 25.5, FOR A PERIOD OF
25 UP TO ONE YEAR AT THE PRICE AT WHICH THE DRUG WAS AVAILABLE
26 IMMEDIATELY PRIOR TO THE MANUFACTURER'S VIOLATION OF THIS
27 SECTION.

1 (5) AS USED IN THIS SECTION:

2 (a) (I) "ESSENTIAL OFF-PATENT OR GENERIC DRUG" MEANS AN
3 FDA-APPROVED PRESCRIPTION DRUG FOR WHICH ALL EXCLUSIVE
4 MARKETING RIGHTS UNDER THE FEDERAL ACT AND UNDER FEDERAL
5 PATENT LAW HAVE EXPIRED; AND THAT:

6 (A) APPEARS ON THE MODEL LIST OF ESSENTIAL MEDICINES MOST
7 RECENTLY ADOPTED BY THE WORLD HEALTH ORGANIZATION; OR

8 (B) HAS BEEN DESIGNATED BY THE SECRETARY OF THE UNITED
9 STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES AS AN ESSENTIAL
10 MEDICINE DUE TO ITS EFFICACY IN TREATING A LIFE-THREATENING HEALTH
11 CONDITION OR A CHRONIC HEALTH CONDITION THAT SUBSTANTIALLY
12 IMPAIRS AN INDIVIDUAL'S ABILITY TO ENGAGE IN ACTIVITIES OF DAILY
13 LIVING; OR

14 (C) IS ACTIVELY MANUFACTURED AND MARKETED FOR SALE IN THE
15 UNITED STATES BY THREE OR FEWER MANUFACTURERS AND THAT IS MADE
16 AVAILABLE FOR SALE IN THIS STATE.

17 (II) "ESSENTIAL OFF-PATENT OR GENERIC DRUG" ALSO MEANS A
18 DRUG OR DEVICE COMBINATION PRODUCT USED FOR THE DELIVERY OF A
19 DRUG FOR WHICH ALL EXCLUSIVE MARKETING RIGHTS UNDER THE FEDERAL
20 ACT AND UNDER FEDERAL PATENT LAW HAVE EXPIRED.

21 (b) "FEDERAL ACT" MEANS THE "FEDERAL FOOD, DRUG, AND
22 COSMETIC ACT", 42 U.S.C. SEC. 301 ET SEQ., AS AMENDED.

23 (c) "PRICE GOUGING" MEANS AN INCREASE IN THE PRICE OF A
24 PRESCRIPTION DRUG THAT IS EXCESSIVE AND NOT JUSTIFIED BY THE COST
25 OF PRODUCING THE DRUG, OR BY THE COST OF APPROPRIATE EXPANSION OF
26 ACCESS TO THE DRUG TO PROMOTE PUBLIC HEALTH, AND THAT RESULTS IN
27 CONSUMERS FOR WHOM THE DRUG HAS BEEN PRESCRIBED HAVING NO

1 MEANINGFUL CHOICE ABOUT WHETHER TO PURCHASE THE DRUG AT AN
2 EXCESSIVE PRICE BECAUSE OF THE IMPORTANCE OF THE DRUG TO THEIR
3 HEALTH AND INSUFFICIENT COMPETITION IN THE MARKETPLACE.

4 (d) "WHOLESALE ACQUISITION COST" HAS THE SAME MEANING AS
5 SET FORTH IN 42 U.S.C. SEC. 1395w-3a.

6 **SECTION 3.** In Colorado Revised Statutes, **add 25.5-1-129** as
7 follows:

8 **25.5-1-129. Report of prescription drug price gouging to**
9 **attorney general - definitions.** (1) THE EXECUTIVE DIRECTOR SHALL
10 NOTIFY THE ATTORNEY GENERAL OF ANY PRICE GOUGING IN WHICH THE
11 INCREASE IN THE PRICE OF AN ESSENTIAL OFF-PATENT OR GENERIC DRUG
12 WOULD RESULT IN AN INCREASE OF FIFTY PERCENT OR MORE OF THE PRICE
13 PAID FOR OR REIMBURSED UNDER THE "COLORADO MEDICAL ASSISTANCE
14 ACT", ARTICLES 4, 5, AND 6 OF THIS TITLE 25.5, WITHIN THE IMMEDIATELY
15 PRECEDING ONE-YEAR PERIOD.

16 (2) AS USED IN THIS SECTION:

17 (a) (I) "ESSENTIAL OFF-PATENT OR GENERIC DRUG" MEANS AN
18 FDA-APPROVED PRESCRIPTION DRUG FOR WHICH ALL EXCLUSIVE
19 MARKETING RIGHTS UNDER THE FEDERAL ACT AND UNDER FEDERAL
20 PATENT LAW HAVE EXPIRED; AND THAT:

21 (A) APPEARS ON THE MODEL LIST OF ESSENTIAL MEDICINES MOST
22 RECENTLY ADOPTED BY THE WORLD HEALTH ORGANIZATION; OR

23 (B) HAS BEEN DESIGNATED BY THE SECRETARY OF THE UNITED
24 STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES AS AN ESSENTIAL
25 MEDICINE DUE TO ITS EFFICACY IN TREATING A LIFE-THREATENING HEALTH
26 CONDITION OR A CHRONIC HEALTH CONDITION THAT SUBSTANTIALLY
27 IMPAIRS AN INDIVIDUAL'S ABILITY TO ENGAGE IN ACTIVITIES OF DAILY

1 LIVING; OR

2 (C) IS ACTIVELY MANUFACTURED AND MARKETED FOR SALE IN THE
3 UNITED STATES BY THREE OR FEWER MANUFACTURERS AND THAT IS MADE
4 AVAILABLE FOR SALE IN THIS STATE.

5 (II) "ESSENTIAL OFF-PATENT OR GENERIC DRUG" ALSO MEANS A
6 DRUG OR DEVICE COMBINATION PRODUCT USED FOR THE DELIVERY OF A
7 DRUG FOR WHICH ALL EXCLUSIVE MARKETING AND PATENT RIGHTS UNDER
8 FEDERAL LAW HAVE EXPIRED.

9 (b) "FEDERAL ACT" MEANS THE "FEDERAL FOOD, DRUG, AND
10 COSMETIC ACT", 42 U.S.C. SEC. 301 ET SEQ., AS AMENDED.

11 (c) "PRICE GOUGING" MEANS AN INCREASE IN THE PRICE OF A
12 PRESCRIPTION DRUG THAT IS EXCESSIVE AND NOT JUSTIFIED BY THE COST
13 OF PRODUCING THE DRUG, OR BY THE COST OF APPROPRIATE EXPANSION OF
14 ACCESS TO THE DRUG TO PROMOTE PUBLIC HEALTH, AND THAT RESULTS IN
15 CONSUMERS FOR WHOM THE DRUG HAS BEEN PRESCRIBED HAVING NO
16 MEANINGFUL CHOICE ABOUT WHETHER TO PURCHASE THE DRUG AT AN
17 EXCESSIVE PRICE BECAUSE OF THE IMPORTANCE OF THE DRUG TO THEIR
18 HEALTH AND INSUFFICIENT COMPETITION IN THE MARKETPLACE.

19 **SECTION 4. Act subject to petition - effective date.** This act
20 takes effect at 12:01 a.m. on the day following the expiration of the
21 ninety-day period after final adjournment of the general assembly (August
22 8, 2018, if adjournment sine die is on May 9, 2018); except that, if a
23 referendum petition is filed pursuant to section 1 (3) of article V of the
24 state constitution against this act or an item, section, or part of this act
25 within such period, then the act, item, section, or part will not take effect
26 unless approved by the people at the general election to be held in

- 1 November 2018 and, in such case, will take effect on the date of the
- 2 official declaration of the vote thereon by the governor.