

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
Appropriations

Senate Committees

A BILL FOR AN ACT

101 **CONCERNING A PROHIBITION AGAINST PRICE GOUGING ON CERTAIN**
102 **PRESCRIPTION DRUGS, AND, IN CONNECTION THEREWITH,**
103 **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>.)

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

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.

practice under the "Colorado Consumer Protection Act";
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

1 INCREASE IN THE PRICE OF AN ESSENTIAL OFF-PATENT OR GENERIC DRUG
2 WHEN:

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

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

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

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

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

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

27 (b) A STATEMENT IDENTIFYING THE CIRCUMSTANCES AND TIMING

1 OF ANY INCREASE IN THE PRICE OF THE DRUG WITHIN THE ONE-YEAR
2 PERIOD IMMEDIATELY PRECEDING THE DATE OF THE PRICE INCREASE;

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

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

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

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

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

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

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

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

1 SECTION.

2 (5) AS USED IN THIS SECTION:

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

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

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

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

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

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

24 (c) "PRICE GOUGING" MEANS AN INCREASE IN THE PRICE OF A
25 PRESCRIPTION DRUG THAT IS EXCESSIVE AND NOT JUSTIFIED BY THE COST
26 OF PRODUCING THE DRUG, OR BY THE COST OF APPROPRIATE EXPANSION OF
27 ACCESS TO THE DRUG TO PROMOTE PUBLIC HEALTH, AND THAT RESULTS IN

1 CONSUMERS FOR WHOM THE DRUG HAS BEEN PRESCRIBED HAVING NO
2 MEANINGFUL CHOICE ABOUT WHETHER TO PURCHASE THE DRUG AT AN
3 EXCESSIVE PRICE BECAUSE OF THE IMPORTANCE OF THE DRUG TO THEIR
4 HEALTH AND INSUFFICIENT COMPETITION IN THE MARKETPLACE.

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

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

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

17 (2) AS USED IN THIS SECTION:

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

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

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

1 IMPAIRS AN INDIVIDUAL'S ABILITY TO ENGAGE IN ACTIVITIES OF DAILY
2 LIVING; OR

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

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

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

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

20 **SECTION 4. Appropriation.** (1) For the 2018-19 state fiscal
21 year, \$154,164 is appropriated to the department of regulatory agencies.
22 This appropriation is from the division of professions and occupations
23 cash fund created in section 24-34-105 (2)(b)(I), C.R.S. To implement
24 this act, the division may use this appropriation as follows:

25 (a) \$129,242 for use by the division of professions and
26 occupations for personal services, which amount is based on an
27 assumption that the division will require an additional 1.8 FTE;

1 (b) \$14,266 for use by the division of professions and occupations
2 for operating expenses; and

3 (c) \$10,656 for the purchase of legal services.

4 (2) For the 2018-19 state fiscal year, \$10,656 is appropriated to
5 the department of law. This appropriation is from reappropriated funds
6 received from the department of regulatory agencies under subsection
7 (1)(c) of this section. To implement this act, the department of law may
8 use this appropriation to provide legal services for the department of
9 regulatory agencies.

10 (3) For the 2018-19 state fiscal year, \$41,448 is appropriated to
11 the department of law. This appropriation is from the general. To
12 implement this act, the department may use this appropriation as follows:

13 (a) \$36,270 for personal services, which amount is based on an
14 assumption that the department will require an additional 0.4 FTE; and

15 (b) \$5,178 for operating expenses.

16 **SECTION 5. Act subject to petition - effective date.** This act
17 takes effect at 12:01 a.m. on the day following the expiration of the
18 ninety-day period after final adjournment of the general assembly (August
19 8, 2018, if adjournment sine die is on May 9, 2018); except that, if a
20 referendum petition is filed pursuant to section 1 (3) of article V of the
21 state constitution against this act or an item, section, or part of this act
22 within such period, then the act, item, section, or part will not take effect
23 unless approved by the people at the general election to be held in
24 November 2018 and, in such case, will take effect on the date of the
25 official declaration of the vote thereon by the governor.