Second Regular Session Seventy-first General Assembly STATE OF COLORADO

INTRODUCED

LLS NO. 18-0139.01 Kristen Forrestal x4217

SENATE BILL 18-152

SENATE SPONSORSHIP

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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";

! 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.

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

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

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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

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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
2.7	SECTION

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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
2.7	CONSUMERS FOR WHOM THE DRUG HAS BEEN PRESCRIBED HAVING NO

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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 FOR UNDER THE "COLORADO MEDICAL
14	Assistance Act", articles 4, 5, and 6 of this title 25.5, within the
15	IMMEDIATELY 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	IMPAIDS AN INDIVIDUAL'S ABILITY TO ENGAGE IN ACTIVITIES OF DAILY

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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 RIGHTS UNDER THE FEDERAL
8	ACT AND UNDER FEDERAL PATENT 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

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

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