Second Regular Session
Seventy-first General Assembly
STATE OF COLORADO

INTRODUCED

LLS NO. 18-0110.01 Kristen Forrestal x4217 **HOUSE BILL 18-1179**

HOUSE SPONSORSHIP

Salazar, Melton

SENATE SPONSORSHIP

(None),

House Committees
Health, Insurance, & Environment

Senate Committees

A BILL FOR AN ACT

CONCERNING A PROHIBITION AGAINST PRICE GOUGING ON CERTAIN 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";

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.

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

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

6-1-105. 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:

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

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

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

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

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

WHEN:

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

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

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

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

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

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

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

PERIOD IMMEDIATELY PRECEDING THE DATE OF THE PRICE INCREASE;

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

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

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

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

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

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

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

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

(5) AS USED IN THIS SECTION:

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

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

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

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

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

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

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

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

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

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

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

(2) AS USED IN THIS SECTION:

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

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

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

LIVING; OR

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

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

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

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

SECTION 4. 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 (August 8, 2018, if adjournment sine die is on May 9, 2018); 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 2018 and, in such case, will take effect on the date of the official declaration of the vote thereon by the governor.