

An Act

SENATE BILL 25-071

BY SENATOR(S) Michaelson Jenet and Rich, Hinrichsen, Amabile, Exum, Frizell, Kolker, Liston, Marchman, Mullica, Pelton R., Roberts, Snyder, Coleman;
also REPRESENTATIVE(S) Martinez and Taggart, Bird, Bradley, Gilchrist, Gonzalez R., Mauro, McCormick, Ricks, Soper, Stewart K., McCluskie.

CONCERNING CERTAIN PRACTICES BY PERSONS PARTICIPATING IN THE SUPPLY CHAIN OF DRUGS PURCHASED UNDER THE FEDERAL 340B DRUG PRICING PROGRAM.

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

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

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

(oooo) VIOLATES ARTICLE 29 OF THIS TITLE 6.

Capital letters or bold & italic numbers indicate new material added to existing law; dashes through words or numbers indicate deletions from existing law and such material is not part of the act.

SECTION 2. In Colorado Revised Statutes, **add** article 29 to title 6 as follows:

ARTICLE 29
Colorado 340B Contract Pharmacy Protection Act

6-29-101. Short title. THE SHORT TITLE OF THIS ARTICLE 29 IS THE "COLORADO 340B CONTRACT PHARMACY PROTECTION ACT".

6-29-102. Legislative declaration. (1) THE GENERAL ASSEMBLY FINDS AND DETERMINES THAT:

(a) THE 340B DRUG PRICING PROGRAM REQUIRES DRUG MANUFACTURERS TO PROVIDE DRUG DISCOUNTS ON IDENTIFIED OUTPATIENT DRUGS TO 340B COVERED ENTITIES AS A CONDITION OF MEDICAID AND MEDICARE PART B COVERING THOSE DRUGS;

(b) CONGRESS CREATED THE 340B PROGRAM IN 1992, STATING THAT THE PROGRAM'S BENEFITS "ENABLE [COVERED] ENTITIES TO STRETCH SCARCE FEDERAL RESOURCES AS FAR AS POSSIBLE, REACHING MORE ELIGIBLE PATIENTS AND PROVIDING MORE COMPREHENSIVE SERVICES." (H.R. REP. NO. 102-384 (II), AT 12 (1992)).

(c) THE 340B PROGRAM SUPPORTS COLORADO'S MEDICALLY VULNERABLE AND UNDERSERVED POPULATIONS BY PROVIDING ADDITIONAL RESOURCES TO 340B COVERED ENTITIES AND ALLOWING THESE ENTITIES TO DETERMINE THE MOST EFFECTIVE USE OF THESE RESOURCES;

(d) THE 340B PROGRAM IS A CRITICAL COMPONENT OF COLORADO'S SAFETY NET INFRASTRUCTURE;

(e) COLORADO HAS SIXTY-EIGHT HOSPITALS STATEWIDE THAT PARTICIPATE IN THE 340B PROGRAM, WITH NEARLY NINETY PERCENT OF THESE HOSPITALS OPERATING UNDER UNSUSTAINABLE LONG-TERM MARGINS;

(f) ADDITIONALLY, COLORADO HAS TWENTY FEDERALLY QUALIFIED HEALTH CENTERS, OR FQHCs, ALL OF WHICH PARTICIPATE IN THE 340B PROGRAM AND SIXTY-FIVE PERCENT OF WHICH CURRENTLY OPERATE WITH NEGATIVE MARGINS;

(g) COLORADO HOSPITALS PARTICIPATING IN THE 340B PROGRAM UTILIZE PROGRAM BENEFITS TO ADDRESS THEIR COMMUNITIES' UNIQUE NEEDS, WHICH INCLUDE PROVIDING DIRECT PRESCRIPTION DRUG DISCOUNTS, SUBSIDIZING UNCOMPENSATED CHARITY CARE AND MEDICAID UNDERPAYMENTS TO REMAIN FINANCIALLY OPERATIONAL, SUPPORTING OPIOID USE DISORDER TREATMENT, FUNDING MOBILE HEALTH-CARE AND IMMUNIZATION CLINICS, AND PAYING FOR CHEMOTHERAPY AND INFUSION CENTERS;

(h) COLORADO'S FQHCs ARE THE PRIMARY CARE MEDICAL HOME FOR ONE IN SEVEN COLORADANS, WITH EIGHTY-NINE PERCENT OF FQHCs' PATIENTS IN 2023 LIVING WITH FAMILY INCOMES BELOW TWO HUNDRED PERCENT OF THE FEDERAL POVERTY GUIDELINE AND TWENTY-THREE PERCENT WERE UNINSURED;

(i) COLORADO'S FQHCs UTILIZE 340B PROGRAM BENEFITS TO ADDRESS THEIR COMMUNITIES' UNIQUE NEEDS, WHICH INCLUDE REDUCED DRUG PRICES FOR PATIENTS, PROVIDER RECRUITMENT AND RETENTION, AND EXPANSION OF ORAL HEALTH AND BEHAVIORAL HEALTH SERVICES THAT THE FQHCs WOULD OTHERWISE NOT BE ABLE TO OFFER;

(j) FURTHER, COLORADO'S FQHCs EXPERIENCED AN ESTIMATED LOSS OF FOUR MILLION THREE HUNDRED DOLLARS IN 340B PROGRAM SAVINGS IN THE LAST TWO YEARS;

(k) CONVERSELY, IN 2023, SIXTEEN OF THE LARGEST PHARMACEUTICAL COMPANIES REPORTED SIX HUNDRED EIGHTY-FOUR BILLION DOLLARS IN EARNINGS IN THEIR ANNUAL FINANCIAL REPORTS, A FIGURE THAT WAS HIGHER THAN THE GROSS DOMESTIC PRODUCT OF EIGHTY-EIGHT PERCENT OF THE COUNTRIES IN THE WORLD;

(l) IN ADDITION, THE EIGHT LARGEST PHARMACEUTICAL COMPANIES PAID A COMBINED TWO BILLION DOLLARS IN FEDERAL TAXES ON TWO HUNDRED FOURTEEN BILLION DOLLARS OF DOMESTIC REVENUE IN 2022, ACCORDING TO THEIR 10-K ANNUAL FINANCIAL REPORTS;

(m) IN 2022, COLORADO HOSPITALS PROVIDED TWO BILLION ONE HUNDRED MILLION DOLLARS OF COMMUNITY BENEFIT;

(n) STARTING IN 2020, PHARMACEUTICAL MANUFACTURERS BEGAN

TO UNLAWFULLY PLACE RESTRICTIONS ON 340B COVERED ENTITIES USING CONTRACT PHARMACIES TO DISPENSE DRUGS TO PATIENTS, UNILATERALLY LIMITING THE 340B PROGRAM'S BENEFITS; AND

(o) IN A LETTER DATED JULY 28, 2023, FROM WILLIAM TONG, ATTORNEY GENERAL OF CONNECTICUT, TO THE UNITED STATES SENATE 340B WORKING GROUP, AND SIGNED BY TWENTY-TWO OTHER BIPARTISAN ATTORNEYS GENERAL, THE ATTORNEYS GENERAL DECLARED THAT "OUTPATIENT PHARMACIES ARE A KEY MECHANISM FOR THE DELIVERY OF LIFE-SAVING DRUGS TO ELIGIBLE PATIENTS, INCLUDING THOSE WHO HAVE LIMITED ACCESS TO TRANSPORTATION, LIVE IN REMOTE OR RURAL AREAS, OR ARE CONFINED TO THEIR HOMES AND RELY ON MAIL-ORDER PHARMACIES."

(2) THEREFORE, THE GENERAL ASSEMBLY DECLARES THAT THIS ARTICLE 29 PROHIBITING PHARMACEUTICAL MANUFACTURERS FROM IMPOSING LIMITATIONS OR PLACING RESTRICTIVE CONDITIONS ON 340B COVERED ENTITIES IS NECESSARY TO PROTECT COLORADO'S VULNERABLE PATIENTS AND SAFETY NET PROVIDERS AND TO ENSURE THAT MUCH-NEEDED FINANCIAL RESOURCES GENERATED BY THE 340B PROGRAM REMAIN IN COLORADO FOR THE BENEFIT OF THE PUBLIC.

6-29-103. Definitions. AS USED IN THIS ARTICLE 29, UNLESS THE CONTEXT OTHERWISE REQUIRES:

(1) "340B COVERED ENTITY" OR "COVERED ENTITY" HAS THE MEANING SET FORTH IN SECTION 340B (a)(4) OF THE FEDERAL "PUBLIC HEALTH SERVICE ACT", 42 U.S.C. SEC. 256b (a)(4).

(2) "340B DRUG" MEANS A DRUG THAT:

(a) IS A COVERED OUTPATIENT DRUG WITHIN THE MEANING SET FORTH IN 42 U.S.C. SEC. 256b;

(b) HAS BEEN SUBJECT TO ANY OFFER FOR REDUCED PRICES BY A MANUFACTURER PURSUANT TO 42 U.S.C. SEC. 256b (a)(1); AND

(c) IS PURCHASED BY A COVERED ENTITY. AS USED IN THIS SUBSECTION (2)(c), A DRUG IS CONSIDERED "PURCHASED" IF IT WOULD HAVE BEEN PURCHASED BUT FOR THE RESTRICTION OR LIMITATION DESCRIBED IN SECTION 6-29-105.

(3) "340B DRUG PRICING PROGRAM" OR "340B PROGRAM" MEANS THE PROGRAM DESCRIBED IN 42 U.S.C. SEC. 256b (a)(1).

(4) "340B SAVINGS" MEANS THE DIFFERENCE BETWEEN THE AGGREGATED MARKET RATE COSTS AND THE AGGREGATED ACQUISITION COSTS FOR 340B DRUGS.

(5) "BOARD" MEANS THE STATE BOARD OF PHARMACY CREATED IN SECTION 12-280-104.

(6) "FEDERAL HEALTH CARE PROGRAM" HAS THE MEANING SET FORTH IN SECTION 42 U.S.C. SEC. 1320a-7b (f).

(7) "HEALTH INFORMATION" MEANS INFORMATION, INCLUDING DEMOGRAPHIC INFORMATION COLLECTED FROM AN INDIVIDUAL OR A GROUP OF INDIVIDUALS THAT:

(a) IS CREATED OR RECEIVED BY A HEALTH-CARE PROVIDER, PHARMACY, HEALTH BENEFIT PLAN, EMPLOYER, OR HEALTH-CARE CLEARINGHOUSE; AND

(b) RELATES TO THE PAST, PRESENT, OR FUTURE PHYSICAL OR MENTAL HEALTH OR CONDITION OF AN INDIVIDUAL, THE PROVISION OF HEALTH CARE TO AN INDIVIDUAL, OR THE PAST, PRESENT, OR FUTURE PAYMENT FOR THE PROVISION OF HEALTH CARE TO AN INDIVIDUAL.

(8) "MANUFACTURER" HAS THE MEANING SET FORTH IN SECTION 12-280-103 (27).

(9) "PACKAGE" HAS THE MEANING SET FORTH IN 21 U.S.C. SEC. 360eee (11)(A).

(10) "PHARMACY" HAS THE MEANING SET FORTH IN SECTION 12-280-103 (43).

(11) "REPACKAGER" HAS THE MEANING SET FORTH IN SECTION 12-280-103 (46).

(12) "THIRD-PARTY LOGISTICS PROVIDER" HAS THE MEANING SET FORTH IN SECTION 12-280-103 (52.5).

6-29-104. Applicability. THIS ARTICLE 29 APPLIES TO A MANUFACTURER, THIRD-PARTY LOGISTICS PROVIDER, OR REPACKAGER OF A MANUFACTURER'S DRUGS DOING BUSINESS IN THIS STATE AND ENGAGED IN THE PRODUCTION, MANUFACTURE, DISTRIBUTION, OR SALE OF A 340B DRUG IN THIS STATE.

6-29-105. Acquisition of 340B drugs - prohibited acts - use of savings - enforcement - penalties - nonpreemption - data exclusions.

(1) Prohibited acts. ON AND AFTER THE EFFECTIVE DATE OF THIS ARTICLE 29:

(a) UNLESS THE RECEIPT OF THE 340B DRUGS IS PROHIBITED BY THE FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES, A MANUFACTURER, THIRD-PARTY LOGISTICS PROVIDER, OR REPACKAGER, OR AN AGENT, CONTRACTOR, OR AFFILIATE OF A MANUFACTURER, THIRD-PARTY LOGISTICS PROVIDER, OR REPACKAGER, INCLUDING AN ENTITY THAT COLLECTS OR PROCESSES HEALTH INFORMATION, SHALL NOT, DIRECTLY OR INDIRECTLY, DENY, RESTRICT, PROHIBIT, DISCRIMINATE AGAINST, OR OTHERWISE LIMIT THE ACQUISITION OF A 340B DRUG BY, OR DELIVERY OF A 340B DRUG TO, A 340B COVERED ENTITY, A PHARMACY CONTRACTED WITH A 340B COVERED ENTITY, OR A LOCATION OTHERWISE AUTHORIZED BY A 340B COVERED ENTITY TO RECEIVE AND DISPENSE 340B DRUGS; AND

(b) A MANUFACTURER SHALL NOT DIRECTLY OR INDIRECTLY REQUIRE, INCLUDING AS A CONDITION, A 340B COVERED ENTITY, A PHARMACY CONTRACTED WITH A 340B COVERED ENTITY, OR ANY OTHER LOCATION AUTHORIZED TO RECEIVE 340B DRUGS BY A 340B COVERED ENTITY TO SUBMIT ANY HEALTH INFORMATION, CLAIMS OR UTILIZATION DATA, PURCHASING DATA, PAYMENT DATA, OR OTHER DATA THAT DOES NOT RELATE TO A CLAIM SUBMITTED TO A FEDERAL HEALTH CARE PROGRAM, UNLESS SUCH DATA IS VOLUNTARILY FURNISHED BY SUCH COVERED ENTITY OR OTHERWISE REQUIRED TO BE FURNISHED UNDER APPLICABLE FEDERAL LAW.

(2) A COVERED ENTITY THAT IS A REPORTING HOSPITAL, AS DEFINED IN SECTION 25.5-1-701, SHALL NOT USE 340B SAVINGS FOR THE FOLLOWING PURPOSES:

(a) MORE THAN THIRTY-FIVE PERCENT OF TOTAL ANNUAL COMPENSATION OR EXPENSE REIMBURSEMENT FOR THE HOSPITAL'S BOARD

OF DIRECTORS;

(b) TAX PENALTIES OR FINES ISSUED AGAINST THE HOSPITAL;

(c) EXPENSES RELATED TO ADVERTISING AND PUBLIC RELATIONS THAT PROMOTE THE HOSPITAL'S IMAGE, SERVICES, OR PROPOSALS, NOT INCLUDING COMMUNICATIONS REQUIRED BY LAW OR THAT ARE ESSENTIAL FOR PATIENT SAFETY AND PATIENT INFORMATION;

(d) LOBBYING EXPENSES AND OTHER COSTS INTENDED TO INFLUENCE LEGISLATION OR BALLOT MEASURES AT THE LOCAL, STATE, OR FEDERAL LEVEL;

(e) TRAVEL, LODGING, FOOD, OR BEVERAGE EXPENSES FOR THE HOSPITAL'S BOARD OF DIRECTORS AND OFFICERS; AND

(f) GIFTS OR ENTERTAINMENT EXPENSES.

(3) **Enforcement - penalties.** (a) THE ATTORNEY GENERAL MAY INVESTIGATE A COMPLAINT CONCERNING A VIOLATION OF THIS ARTICLE 29. A PERSON THAT VIOLATES THIS ARTICLE 29 RISKS THE PUBLIC'S HEALTH AND ENGAGES IN AN UNFAIR OR DECEPTIVE TRADE PRACTICE PURSUANT TO SECTION 6-1-105 (1)(oooo) AND IS SUBJECT TO THE ENFORCEMENT PROVISIONS, CIVIL PENALTIES, AND DAMAGES SET FORTH IN ARTICLE 1 OF THIS TITLE 6.

(b) EACH PACKAGE OF A 340B DRUG THAT CONSTITUTES A PROHIBITED ACT UNDER THIS ARTICLE 29 CONSTITUTES A SEPARATE VIOLATION OF SUBSECTION (1) OF THIS SECTION.

(c) LIMITED DISTRIBUTION OF A DRUG REQUIRED UNDER 21 U.S.C. SEC. 355-1 DOES NOT CONSTITUTE A VIOLATION OF THIS ARTICLE 29.

(d) A PERSON REGULATED BY THE STATE BOARD OF PHARMACY CREATED IN SECTION 12-280-104 MAY BE SUBJECT TO DISCIPLINE PURSUANT TO SECTION 12-280-108 (1)(c), (1)(d), OR (1)(i) FOR VIOLATING THIS ARTICLE 29.

(4) **Nonpreemption.** NOTHING IN THIS ARTICLE 29 SHALL BE CONSTRUED OR APPLIED TO BE LESS RESTRICTIVE THAN ANY FEDERAL LAW

APPLYING TO PERSONS REGULATED BY THIS SECTION. NOTHING IN THIS SECTION SHALL BE CONSTRUED OR APPLIED TO BE IN CONFLICT WITH ANY OF THE FOLLOWING:

(a) APPLICABLE FEDERAL LAW AND RELATED REGULATIONS; OR

(b) OTHER LAWS OF THIS STATE, IF THE LAWS ARE COMPATIBLE WITH APPLICABLE FEDERAL LAW.

(5) **Data exclusions.** SUBSECTION (1) OF THIS SECTION DOES NOT PROHIBIT A MANUFACTURER FROM REQUIRING HEALTH INFORMATION OR OTHER DATA THAT A COVERED ENTITY IS REQUIRED TO FURNISH TO THE MANUFACTURER UNDER APPLICABLE FEDERAL LAW, INCLUDING DATA RELATING TO AN AUDIT IN ACCORDANCE WITH PROCEDURES ESTABLISHED BY THE FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES UNDER 42 U.S.C. SEC. 256b (a)(5)(C).

SECTION 3. In Colorado Revised Statutes, **add** 25-3-134 as follows:

25-3-134. 340B drug pricing program transparency - definitions.

(1) AS USED IN THIS SECTION:

(a) "340B DRUG PRICING PROGRAM" OR "340B PROGRAM" MEANS THE PROGRAM DESCRIBED IN 42 U.S.C. SEC. 256b (a)(1).

(b) "340B SAVINGS" MEANS THE DIFFERENCE BETWEEN THE AGGREGATED MARKET RATE COSTS AND THE AGGREGATED ACQUISITION COSTS FOR 340B DRUGS.

(c) "HOSPITAL COVERED ENTITY" MEANS A HOSPITAL LICENSED OR CERTIFIED BY THE DEPARTMENT PURSUANT TO THE DEPARTMENT'S AUTHORITY UNDER SECTION 25-1.5-103 (1)(a) AND THAT IS A "COVERED ENTITY" AS DEFINED IN 42 U.S.C. SEC. 256b (a)(4).

(2) EXCEPT AS PROVIDED IN SUBSECTION (3) OF THIS SECTION, EACH HOSPITAL COVERED ENTITY THAT IS A REPORTING HOSPITAL, AS DEFINED IN SECTION 25.5-1-701, SHALL INCLUDE THE FOLLOWING INFORMATION IN THE ANNUAL REPORT SUBMITTED PURSUANT TO SECTION 25.5-1-703 (3):

(a) THE ANNUAL, REPORTED 340B SAVINGS TO THE HOSPITAL COVERED ENTITY RESULTING FROM ITS ABILITY TO ACQUIRE PHARMACEUTICALS AT A DISCOUNT THROUGH THE 340B DRUG PRICING PROGRAM;

(b) A DESCRIPTION OF HOW THE HOSPITAL COVERED ENTITY USES SAVINGS FROM PARTICIPATION IN THE 340B PROGRAM;

(c) THE AGGREGATED MARKET RATE COSTS AND THE AGGREGATED ACQUISITION COSTS FOR 340B DRUGS USED TO CALCULATE 340B SAVINGS; AND

(d) THE TOTAL OPERATING COSTS OF THE HOSPITAL COVERED ENTITY AND COSTS RELATING TO PROVIDING CHARITY CARE.

(3) NOTHING IN THIS SECTION REQUIRES THE PUBLIC DISCLOSURE OF RECORDS THAT ARE PUBLIC RECORDS UNDER THE "COLORADO OPEN RECORDS ACT", PART 2 OF ARTICLE 72 OF TITLE 24, BUT THAT ARE EXEMPTED FROM DISCLOSURE UNDER THAT ACT.

SECTION 4. Severability. If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity does not affect other provisions or applications of the act that can be given effect without the invalid provision or application, and to this end the provisions of this act are declared to be severable.

SECTION 5. 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; 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 2026 and, in such case, will take effect on the date of the official declaration of the vote thereon by the governor.

James Rashad Coleman, Sr.
PRESIDENT OF
THE SENATE

Julie McCluskie
SPEAKER OF THE HOUSE
OF REPRESENTATIVES

Esther van Mourik
SECRETARY OF
THE SENATE

Vanessa Reilly
CHIEF CLERK OF THE HOUSE
OF REPRESENTATIVES

APPROVED _____
(Date and Time)

Jared S. Polis
GOVERNOR OF THE STATE OF COLORADO