## First Regular Session Seventy-fifth General Assembly STATE OF COLORADO

# **INTRODUCED**

LLS NO. 25-0361.02 Brita Darling x2241

**SENATE BILL 25-071** 

SENATE SPONSORSHIP

Michaelson Jenet and Rich, Hinrichsen

#### **HOUSE SPONSORSHIP**

Martinez and Taggart,

Senate Committees Health & Human Services **House Committees** 

### A BILL FOR AN ACT

101 CONCERNING CERTAIN PRACTICES BY PERSONS PARTICIPATING IN THE

102 SUPPLY CHAIN OF DRUGS PURCHASED UNDER THE FEDERAL 340B

103 DRUG PRICING PROGRAM.

#### **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 <u>http://leg.colorado.gov</u>.)

Under the federal 340B drug pricing program (340B program), a covered entity, including certain hospitals, programs, and federally qualified health centers (covered entity), that serves patients with low income receives discounted outpatient drugs (340B drugs) from manufacturers that participate in the federal medicaid and medicare

programs.

Unless the receipt of 340B drugs is prohibited by the federal department of health and human services, the bill prohibits a manufacturer, wholesaler, third-party logistics provider, or repackager in this state, or an agent, contractor, or affiliate of those entities, including an entity that collects or processes health information, from directly or indirectly denying, restricting, prohibiting, discriminating against, or otherwise limiting the acquisition of a 340B drug by, or delivery of a 340B drug to, a covered entity, a pharmacy contracted with a covered entity, or a location otherwise authorized by a covered entity to receive and dispense 340B drugs.

The bill also prohibits a manufacturer from directly or indirectly requiring a covered entity, a pharmacy contracted with a covered entity, or any other location authorized to receive 340B drugs by a covered entity to submit any health information, claims or utilization data, or other specified data that does not relate to a claim submitted to certain federal health care programs, unless the data is voluntarily furnished or required to be furnished under federal law.

A violation of the prohibitions in the bill is an unfair or deceptive trade practice under the "Colorado Consumer Protection Act" (act), and the violator is subject to the enforcement provisions and penalties contained in that act. The attorney general may investigate and enforce the provisions of the bill, as well as a business harmed by a violation of the provisions of the bill. In addition, a person regulated by the state board of pharmacy (pharmacy board) that violates the provisions of the bill may be subject to discipline by the pharmacy board against the person's license, certification, or registration, as well as other penalties.

The bill requires a covered entity that is a hospital to annually post on its public-facing website information concerning the annual, estimated, aggregate financial benefit to the hospital covered entity resulting from its ability to acquire pharmaceuticals at a discount through the 340B program and a description of how the hospital covered entity uses savings from participation in the 340B program.

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

2

SECTION 1. In Colorado Revised Statutes, 6-1-105, add (1)(iiii)

3 as follows:

4

6-1-105. Unfair or deceptive trade practices - definitions.

5 (1) A person engages in a deceptive trade practice when, in the course of

6 the person's business, vocation, or occupation, the person:

1	(iiii) VIOLATES ARTICLE 29 OF THIS TITLE 6.
2	SECTION 2. In Colorado Revised Statutes, add article 29 to title
3	6 as follows:
4	ARTICLE 29
5	<b>Colorado 340B Contract Pharmacy Protection Act</b>
6	6-29-101. Short title. The short title of this article 29 is the
7	"COLORADO 340B CONTRACT PHARMACY PROTECTION ACT".
8	6-29-102. Legislative declaration. (1) THE GENERAL ASSEMBLY
9	FINDS AND DETERMINES THAT:
10	(a) The 340B drug pricing program requires drug
11	MANUFACTURERS TO PROVIDE DRUG DISCOUNTS ON IDENTIFIED
12	outpatient drugs to $340B$ covered entities as a condition of
13	MEDICAID AND MEDICARE PART $B$ COVERING THOSE DRUGS;
14	(b) Congress created the 340B program in 1992, stating
15	THAT THE PROGRAM'S BENEFITS "ENABLE [COVERED] ENTITIES TO STRETCH
16	SCARCE FEDERAL RESOURCES AS FAR AS POSSIBLE, REACHING MORE
17	ELIGIBLE PATIENTS AND PROVIDING MORE COMPREHENSIVE SERVICES."
18	(H.R. REP. NO.102-384 (II), AT 12 (1992)).
19	(c) The 340B program supports Colorado's medically
20	VULNERABLE AND UNDERSERVED POPULATIONS BY PROVIDING
21	Additional resources to $340B$ covered entities and allowing
22	THESE ENTITIES TO DETERMINE THE MOST EFFECTIVE USE OF THESE
23	RESOURCES;
24	(d) The $340B$ program is a critical component of
25	COLORADO'S SAFETY NET INFRASTRUCTURE;
26	(e) COLORADO HAS SIXTY-EIGHT HOSPITALS STATEWIDE THAT
27	PARTICIPATE IN THE $340B$ program, with nearly ninety percent of

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THESE HOSPITALS OPERATING UNDER UNSUSTAINABLE LONG-TERM
 MARGINS;

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

7 (g) COLORADO HOSPITALS PARTICIPATING IN THE 340B PROGRAM 8 UTILIZE PROGRAM BENEFITS TO ADDRESS THEIR COMMUNITIES' UNIQUE 9 NEEDS, WHICH INCLUDE PROVIDING DIRECT PRESCRIPTION DRUG 10 DISCOUNTS, SUBSIDIZING UNCOMPENSATED CHARITY CARE AND MEDICAID 11 UNDERPAYMENTS TO REMAIN FINANCIALLY OPERATIONAL, SUPPORTING 12 OPIOID USE DISORDER TREATMENT, FUNDING MOBILE HEALTH-CARE AND 13 IMMUNIZATION CLINICS, AND PAYING FOR CHEMOTHERAPY AND INFUSION 14 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;

20 (i) COLORADO'S FQHCS UTILIZE 340B PROGRAM BENEFITS TO
21 ADDRESS THEIR COMMUNITIES' UNIQUE NEEDS, WHICH INCLUDE REDUCED
22 DRUG PRICES FOR PATIENTS, PROVIDER RECRUITMENT AND RETENTION,
23 AND EXPANSION OF ORAL HEALTH AND BEHAVIORAL HEALTH SERVICES
24 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;

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(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;

6 (1) IN ADDITION, THE EIGHT LARGEST PHARMACEUTICAL
7 COMPANIES PAID A COMBINED TWO BILLION DOLLARS IN FEDERAL TAXES
8 ON TWO HUNDRED FOURTEEN BILLION DOLLARS OF DOMESTIC REVENUE IN
9 2022, ACCORDING TO THEIR 10-K ANNUAL FINANCIAL REPORTS;

10 (m) IN 2022, COLORADO HOSPITALS PROVIDED TWO BILLION ONE
11 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

16 (o) IN A LETTER DATED JULY 28, 2023, FROM WILLIAM TONG, ATTORNEY GENERAL OF CONNECTICUT, TO THE UNITED STATES SENATE 17 18 340B WORKING GROUP, AND SIGNED BY TWENTY-TWO OTHER BIPARTISAN 19 ATTORNEYS GENERAL, THE ATTORNEYS GENERAL DECLARED THAT 20 "OUTPATIENT PHARMACIES ARE A KEY MECHANISM FOR THE DELIVERY OF 21 LIFE-SAVING DRUGS TO ELIGIBLE PATIENTS, INCLUDING THOSE WHO HAVE 22 LIMITED ACCESS TO TRANSPORTATION, LIVE IN REMOTE OR RURAL AREAS, 23 OR ARE CONFINED TO THEIR HOMES AND RELY ON MAIL-ORDER 24 PHARMACIES."

(2) THEREFORE, THE GENERAL ASSEMBLY DECLARES THAT THIS
 ARTICLE 29 PROHIBITING PHARMACEUTICAL MANUFACTURERS FROM
 IMPOSING LIMITATIONS OR PLACING RESTRICTIVE CONDITIONS ON 340B

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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.

5 6-29-103. Definitions. As used in this article 29, unless the
6 CONTEXT OTHERWISE REQUIRES:

7 (1) "340B COVERED ENTITY" OR "COVERED ENTITY" HAS THE
8 MEANING SET FORTH IN SECTION 340B (a)(4) OF THE FEDERAL "PUBLIC
9 HEALTH SERVICE ACT", 42 U.S.C. SEC. 256b (a)(4).

10

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

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

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

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

19 (3) "340B DRUG PRICING PROGRAM" OR "340B PROGRAM" MEANS
20 THE PROGRAM DESCRIBED IN 42 U.S.C. SEC. 256b (a)(1).

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

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

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

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

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

8 (7) "MANUFACTURER" HAS THE MEANING SET FORTH IN SECTION
9 12-280-103 (27).

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

12 (9) "PHARMACY" HAS THE MEANING SET FORTH IN SECTION
13 12-280-103 (43).

14 (10) "REPACKAGER" HAS THE MEANING SET FORTH IN SECTION
15 12-280-103 (46).

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

18 (12) "WHOLESALER" HAS THE MEANING SET FORTH IN SECTION
19 12-280-103 (55).

6-29-104. Applicability. This article 29 applies to a
MANUFACTURER, WHOLESALER, 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 enforcement - penalties - nonpreemption - data exclusions.
(1) Prohibited acts. ON AND AFTER THE EFFECTIVE DATE OF THIS

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1 ARTICLE 29:

2 (a) UNLESS THE RECEIPT OF THE 340B DRUGS IS PROHIBITED BY 3 THE FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES, A 4 MANUFACTURER, WHOLESALER, THIRD-PARTY LOGISTICS PROVIDER, OR 5 REPACKAGER, OR AN AGENT, CONTRACTOR, OR AFFILIATE OF A 6 MANUFACTURER, WHOLESALER, THIRD-PARTY LOGISTICS PROVIDER, OR 7 REPACKAGER, INCLUDING AN ENTITY THAT COLLECTS OR PROCESSES 8 HEALTH INFORMATION, SHALL NOT, DIRECTLY OR INDIRECTLY, DENY, 9 RESTRICT, PROHIBIT, DISCRIMINATE AGAINST, OR OTHERWISE LIMIT THE 10 ACQUISITION OF A 340B DRUG BY, OR DELIVERY OF A 340B DRUG TO, A 11 340B COVERED ENTITY, A PHARMACY CONTRACTED WITH A 340B 12 COVERED ENTITY, OR A LOCATION OTHERWISE AUTHORIZED BY A 340B 13 COVERED ENTITY TO RECEIVE AND DISPENSE 340B DRUGS; AND

14 (b) A MANUFACTURER SHALL NOT DIRECTLY OR INDIRECTLY 15 REQUIRE, INCLUDING AS A CONDITION, A 340B COVERED ENTITY, A 16 PHARMACY CONTRACTED WITH A 340B COVERED ENTITY, OR ANY OTHER 17 LOCATION AUTHORIZED TO RECEIVE 340B DRUGS BY A 340B COVERED 18 ENTITY TO SUBMIT ANY HEALTH INFORMATION, CLAIMS OR UTILIZATION 19 DATA, PURCHASING DATA, PAYMENT DATA, OR OTHER DATA THAT DOES 20 NOT RELATE TO A CLAIM SUBMITTED TO A FEDERAL HEALTH CARE 21 PROGRAM. UNLESS SUCH DATA IS VOLUNTARILY FURNISHED BY SUCH 22 COVERED ENTITY OR OTHERWISE REQUIRED TO BE FURNISHED UNDER 23 APPLICABLE FEDERAL LAW.

(2) Enforcement - penalties. (a) THE ATTORNEY GENERAL MAY
INVESTIGATE A COMPLAINT CONCERNING A VIOLATION OF THIS ARTICLE
29. A PERSON THAT VIOLATES THIS ARTICLE 29 ENGAGES IN AN UNFAIR OR
DECEPTIVE TRADE PRACTICE PURSUANT TO SECTION 6-1-105 (1)(iiii) AND

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IS SUBJECT TO THE ENFORCEMENT PROVISIONS, CIVIL PENALTIES, AND
 DAMAGES SET FORTH IN ARTICLE 1 OF THIS TITLE 6.

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

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

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

12 (3) Nonpreemption. NOTHING IN THIS ARTICLE 29 SHALL BE
13 CONSTRUED OR APPLIED TO BE LESS RESTRICTIVE THAN ANY FEDERAL LAW
14 APPLYING TO PERSONS REGULATED BY THIS SECTION. NOTHING IN THIS
15 SECTION SHALL BE CONSTRUED OR APPLIED TO BE IN CONFLICT WITH ANY
16 OF THE FOLLOWING:

17 (a) APPLICABLE FEDERAL LAW AND RELATED REGULATIONS; OR

18 (b) OTHER LAWS OF THIS STATE, IF THE LAWS ARE COMPATIBLE19 WITH APPLICABLE FEDERAL LAW.

(4) 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).

27 SECTION 3. In Colorado Revised Statutes, add 25-3-132 as

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1 follows:

2 25-3-132. 340B drug pricing program transparency 3 definitions. (1) AS USED IN THIS SECTION:

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

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

10 (2) EXCEPT AS PROVIDED IN SUBSECTION (3) OF THIS SECTION,
11 EACH HOSPITAL COVERED ENTITY SHALL ANNUALLY POST THE FOLLOWING
12 INFORMATION ON ITS PUBLIC-FACING WEBSITE:

(a) THE ANNUAL, ESTIMATED, AGGREGATE FINANCIAL BENEFIT TO
THE HOSPITAL COVERED ENTITY RESULTING FROM ITS ABILITY TO ACQUIRE
PHARMACEUTICALS AT A DISCOUNT THROUGH THE 340B DRUG PRICING
PROGRAM, USING A STANDARDIZED METHODOLOGY DEVELOPED AND
PUBLISHED PUBLICLY BY A STATEWIDE ASSOCIATION OF HOSPITALS; AND
(b) A DESCRIPTION OF HOW THE HOSPITAL COVERED ENTITY USES
SAVINGS FROM PARTICIPATION IN THE 340B PROGRAM.

20 (3) NOTHING IN THIS SECTION REQUIRES THE PUBLIC DISCLOSURE
21 OF RECORDS THAT ARE PUBLIC RECORDS UNDER THE "COLORADO OPEN
22 RECORDS ACT", PART 2 OF ARTICLE 72 OF TITLE 24, BUT THAT ARE
23 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

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1 this end the provisions of this act are declared to be severable.

2 SECTION 5. Act subject to petition - effective date. This act 3 takes effect at 12:01 a.m. on the day following the expiration of the 4 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 5 6 of the state constitution against this act or an item, section, or part of this 7 act within such period, then the act, item, section, or part will not take 8 effect unless approved by the people at the general election to be held in 9 November 2026 and, in such case, will take effect on the date of the official declaration of the vote thereon by the governor. 10