

HOUSE COMMITTEE OF REFERENCE AMENDMENT

Committee on Health & Human Services.

SB25-124 be amended as follows:

1 Amend reengrossed bill, page 2, after line 1 insert:

2 "SECTION 1. In Colorado Revised Statutes, 6-1-105, **add**
3 (1)(iii) 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:

7 (iii) VIOLATES ARTICLE 29 OF THIS TITLE 6.

8 **SECTION 2.** In Colorado Revised Statutes, **add** article 29 to title
9 6 as follows:

10 **ARTICLE 29**

11 **Colorado 340B Contract Pharmacy Protection Act**

12 **6-29-101. Short title.** THE SHORT TITLE OF THIS ARTICLE 29 IS THE
13 "COLORADO 340B CONTRACT PHARMACY PROTECTION ACT".

14 **6-29-102. Definitions.** AS USED IN THIS ARTICLE 29, UNLESS THE
15 CONTEXT OTHERWISE REQUIRES:

16 (1) "340B COVERED ENTITY" OR "COVERED ENTITY" HAS THE
17 MEANING SET FORTH IN SECTION 340B (a)(4) OF THE FEDERAL "PUBLIC
18 HEALTH SERVICE ACT", 42 U.S.C. SEC. 256b (a)(4).

19 (2) "340B DRUG" MEANS A DRUG THAT:

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

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

24 (c) IS PURCHASED BY A COVERED ENTITY. AS USED IN THIS
25 SUBSECTION (2)(c), A DRUG IS CONSIDERED "PURCHASED" IF IT WOULD
26 HAVE BEEN PURCHASED BUT FOR THE RESTRICTION OR LIMITATION
27 DESCRIBED IN SECTION 6-29-104.

28 (3) "340B DRUG PRICING PROGRAM" OR "340B PROGRAM" MEANS
29 THE PROGRAM DESCRIBED IN 42 U.S.C. SEC. 256b (a)(1).

30 (4) "340B SAVINGS" MEANS THE DIFFERENCE BETWEEN THE
31 AGGREGATED MARKET RATE COSTS AND THE AGGREGATED ACQUISITION
32 COSTS FOR 340B DRUGS.

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

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

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

1 (a) IS CREATED OR RECEIVED BY A HEALTH-CARE PROVIDER,
2 PHARMACY, HEALTH BENEFIT PLAN, EMPLOYER, OR HEALTH-CARE
3 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 (8) "MANUFACTURER" HAS THE MEANING SET FORTH IN SECTION
9 12-280-103 (27).

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

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

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

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

18 **6-29-103. Applicability.** THIS ARTICLE 29 APPLIES TO A
19 MANUFACTURER, THIRD-PARTY LOGISTICS PROVIDER, OR REPACKAGER OF
20 A MANUFACTURER'S DRUGS DOING BUSINESS IN THIS STATE AND ENGAGED
21 IN THE PRODUCTION, MANUFACTURE, DISTRIBUTION, OR SALE OF A 340B
22 DRUG IN THIS STATE.

23 **6-29-104. Acquisition of 340B drugs - prohibited acts - use of**
24 **savings - enforcement - penalties - nonpreemption - data exclusions.**

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

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

39 (b) A MANUFACTURER SHALL NOT DIRECTLY OR INDIRECTLY
40 REQUIRE, INCLUDING AS A CONDITION, A 340B COVERED ENTITY, A
41 PHARMACY CONTRACTED WITH A 340B COVERED ENTITY, OR ANY OTHER
42 LOCATION AUTHORIZED TO RECEIVE 340B DRUGS BY A 340B COVERED
43 ENTITY TO SUBMIT ANY HEALTH INFORMATION, CLAIMS OR UTILIZATION

1 DATA, PURCHASING DATA, PAYMENT DATA, OR OTHER DATA THAT DOES
2 NOT RELATE TO A CLAIM SUBMITTED TO A FEDERAL HEALTH-CARE
3 PROGRAM, UNLESS THE DATA IS VOLUNTARILY FURNISHED BY THE
4 COVERED ENTITY OR OTHERWISE REQUIRED TO BE FURNISHED PURSUANT
5 TO APPLICABLE FEDERAL LAW.

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

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

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

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

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

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

22 (f) GIFTS OR ENTERTAINMENT EXPENSES.

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

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

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

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

39 (4) **Nonpreemption.** NOTHING IN THIS ARTICLE 29 SHALL BE
40 CONSTRUED OR APPLIED TO BE LESS RESTRICTIVE THAN ANY FEDERAL LAW
41 APPLYING TO PERSONS REGULATED BY THIS SECTION. NOTHING IN THIS
42 SECTION SHALL BE CONSTRUED OR APPLIED TO BE IN CONFLICT WITH ANY
43 OF THE FOLLOWING:

1 (a) APPLICABLE FEDERAL LAW AND RELATED REGULATIONS; OR
2 (b) OTHER LAWS OF THIS STATE, IF THE LAWS ARE COMPATIBLE
3 WITH APPLICABLE FEDERAL LAW.

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

11 **SECTION 3.** In Colorado Revised Statutes, **add 25-3-132** as
12 follows:

13 **25-3-132. 340B drug pricing program transparency -**
14 **definitions.** (1) AS USED IN THIS SECTION:

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

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

20 (c) "HOSPITAL COVERED ENTITY" MEANS A HOSPITAL LICENSED OR
21 CERTIFIED BY THE DEPARTMENT PURSUANT TO THE DEPARTMENT'S
22 AUTHORITY UNDER SECTION 25-1.5-103 (1)(a) AND THAT IS A "COVERED
23 ENTITY" AS DEFINED IN THE FEDERAL "PUBLIC HEALTH SERVICE ACT", 42
24 U.S.C. SEC. 256b (a)(4).

25 (2) EXCEPT AS PROVIDED IN SUBSECTION (3) OF THIS SECTION,
26 EACH HOSPITAL COVERED ENTITY THAT IS A REPORTING HOSPITAL, AS
27 DEFINED IN SECTION 25.5-1-701, SHALL INCLUDE THE FOLLOWING
28 INFORMATION IN THE ANNUAL REPORT SUBMITTED PURSUANT TO SECTION
29 25.5-1-703 (3):

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

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

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

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

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

- 1 EXEMPTED FROM DISCLOSURE UNDER THAT ACT.".
- 2 Renumber succeeding sections accordingly.

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