

House \_\_\_\_\_ Amendment NO. \_\_\_\_\_

Offered By \_\_\_\_\_

1 AMEND Senate Substitute for Senate Committee Substitute for Senate Bill No. 41, Page 8, Section  
2 338.012, Line 24, by inserting after all of said section and line the following:

3  
4 "376.414. 1. For purposes of this section, the following terms mean:

5 (1) "340B drug", a drug that is:

6 (a) A covered outpatient drug as defined in Section 340B of the Public Health Service Act,  
7 42 U.S.C. Section 256b, enacted by Section 602 of the Veterans Health Care Act of 1992, Pub. L.  
8 102-585; and

9 (b) Purchased under an agreement entered into under 42 U.S.C. Section 256b;

10 (2) "Covered entity", the same meaning given to the term in Section 340B(a)(4) of the  
11 Public Health Service Act, 42 U.S.C. Section 256b(a)(4), except that such term shall not include a  
12 hospital licensed under chapter 197;

13 (3) "Health carrier", the same meaning given to the term in section 376.1350;

14 (4) "Pharmacy", an entity licensed under chapter 338;

15 (5) "Pharmacy benefits manager", the same meaning given to the term in section 376.388;

16 2. A health carrier, a pharmacy benefits manager, or an agent or affiliate of such health  
17 carrier or pharmacy benefits manager, not including a pharmaceutical manufacturer, shall not  
18 discriminate against a covered entity or a pharmacy including, but not limited to, by doing any of  
19 the following:

20 (1) Reimbursing a covered entity or pharmacy for a quantity of a 340B drug in an amount  
21 less than it would pay to any other similarly situated pharmacy that is not a covered entity or a  
22 pharmacy for such quantity of such drug on the basis that the entity or pharmacy is a covered entity  
23 or pharmacy or that the entity or pharmacy dispenses 340B drugs;

24 (2) Imposing any terms or conditions on covered entities or pharmacies that differ from such  
25 terms or conditions applied to other similarly situated pharmacies or entities that are not covered  
26 entities on the basis that the entity or pharmacy is a covered entity or pharmacy or that the entity or  
27 pharmacy dispenses 340B drugs including, but not limited to, terms or conditions with respect to  
28 any of the following:

29 (a) Fees, chargebacks, clawbacks, adjustments, or other assessments;

30 (b) Professional dispensing fees;

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1       (c) Restrictions or requirements regarding participation in standard or preferred pharmacy  
2 networks;

3       (d) Requirements relating to the frequency or scope of audits or to inventory management  
4 systems using generally accepted accounting principles; and

5       (e) Any other restrictions, conditions, practices, or policies that, as specified by the director  
6 of the department of commerce and insurance, interfere with the ability of a covered entity to  
7 maximize the value of discounts provided under 42 U.S.C. Section 256b;

8       (3) Interfering with an individual's choice to receive a 340B drug from a covered entity or  
9 pharmacy, whether in person or via direct delivery, mail, or other form of shipment, by any means  
10 including, but not limited to, modifying a patient's payment limitations or cost-sharing obligations  
11 on the basis of participation, in whole or in part, in the 340B drug pricing program;

12       (4) Discriminating in reimbursement to a covered entity or pharmacy based on the  
13 determination or indication a drug is a 340B drug;

14       (5) Requiring a covered entity or pharmacy to identify, either directly or through a third  
15 party, a 340B drug sooner than forty-five days after the point of sale of the 340B drug;

16       (6) Refusing to contract with a covered entity or pharmacy for reasons other than those that  
17 apply equally to entities that are not covered entities or similarly situated pharmacies, or on the basis  
18 that:

19           (a) The entity is a covered entity; or

20           (b) The entity or pharmacy is described in any of subparagraphs (A) to (O) of 42 U.S.C.  
21 Section 256b(a)(4);

22       (7) Denying the covered entity the ability to purchase drugs at 340B program pricing by  
23 substituting a rebate discount;

24       (8) Refusing to cover drugs purchased under the 340B drug pricing program; or

25       (9) Requiring a covered entity or pharmacy to reverse, resubmit, or clarify a 340B-drug  
26 pricing claim after the initial adjudication unless these actions are in the normal course of pharmacy  
27 business and not related to 340B drug pricing, except as required by federal law.

28       3. The director of the department of commerce and insurance shall impose a civil penalty on  
29 any health carrier, pharmacy benefits manager, or agent or affiliate of such health carrier or  
30 pharmacy benefits manager that violates the requirements of this section. Such penalty shall not  
31 exceed five thousand dollars per violation per day.

32       4. The director of the department of commerce and insurance shall promulgate rules to  
33 implement the provisions of this section. Any rule or portion of a rule, as that term is defined in  
34 section 536.010, that is created under the authority delegated in this section shall become effective  
35 only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable,  
36 section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested  
37 with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to  
38 disapprove or annul a rule are subsequently held unconstitutional, then the grant of rulemaking  
39 authority and any rule proposed or adopted after August 28, 2023, shall be invalid and void.

1       376.448. 1. As used in this section, the following terms mean:

2       (1) "Cost-sharing", any co-payment, coinsurance, deductible, amount paid by an enrollee for  
3 health care services in excess of a coverage limitation, or similar charge required by or on behalf of  
4 an enrollee in order to receive a specific health care service covered by a health benefit plan,  
5 whether covered under medical benefits or pharmacy benefits. The term "cost-sharing" shall  
6 include cost-sharing as defined in 42 U.S.C. Section 18022(c);

7       (2) "Enrollee", the same meaning given to the term in section 376.1350;

8       (3) "Health benefit plan", the same meaning given to the term in section 376.1350;

9       (4) "Health care service", the same meaning given to the term in section 376.1350;

10       (5) "Health carrier", the same meaning given to the term in section 376.1350;

11       (6) "Pharmacy benefits manager", the same meaning given to the term in section 376.388.

12       2. When calculating an enrollee's overall contribution to any out-of-pocket maximum or any  
13 cost-sharing requirement under a health benefit plan, a health carrier or pharmacy benefits manager  
14 shall include any amounts paid by the enrollee or paid on behalf of the enrollee for any medication  
15 where a generic substitute for said medication is not available. This subsection shall not apply when  
16 the cost-sharing requirement is waived by the health carrier or pharmacy benefits manager and no  
17 third-party payment satisfied such requirement.

18       3. If, under federal law, application of the requirement under subsection 2 of this section  
19 would result in health savings account ineligibility under Section 223 of the Internal Revenue Code,  
20 the requirement under subsection 2 of this section shall apply to health savings account-qualified  
21 high deductible health plans with respect to any cost-sharing of such a plan after the enrollee has  
22 satisfied the minimum deductible under Section 223, except with respect to items or services that  
23 are preventive care under Section 223(c)(2)(C) of the Internal Revenue Code, in which case the  
24 requirement of subsection 2 of this section shall apply regardless of whether the minimum  
25 deductible under Section 223 has been satisfied.

26       4. Nothing in this section shall prohibit a health carrier or health benefit plan from utilizing  
27 step therapy pursuant to section 376.2034."; and

28  
29 Further amend said bill by amending the title, enacting clause, and intersectional references  
30 accordingly.