

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

Offered By

1 AMEND House Committee Substitute for House Bill No. 198, Pages 2-3, Section 376.413, Lines 1-  
2 43, by deleting all of said lines from the bill and inserting in lieu thereof the following:

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4 "376.413. 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);

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

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

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

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

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

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

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

29 (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) Requiring a covered entity or pharmacy to identify, either directly or through a third  
13 party, 340B drugs. However, a pharmaceutical manufacturer may enter into a contract to utilize an  
14 industry standard platform to identify a 340B dispensation no sooner than forty-five days after the  
15 point of sale of the 340B drug. A health carrier, pharmacy benefits manager, or agent or affiliate of  
16 such health carrier or pharmacy benefits manager may only use such identification information to  
17 comply with rebate transparency requirements of a pharmaceutical manufacturer;

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

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

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

24           (6) Denying the covered entity the ability to purchase drugs at 340B program pricing by  
25 substituting a rebate discount;

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

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

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

34           4. The director of the department of commerce and insurance shall promulgate rules to  
35 implement the provisions of this section. Any rule or portion of a rule, as that term is defined in  
36 section 536.010, that is created under the authority delegated in this section shall become effective  
37 only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable,  
38 section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested  
39 with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to

1 disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking  
2 authority and any rule proposed or adopted after August 28, 2023, shall be invalid and void."; and

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4 Further amend said bill, Pages 3-5, Section 376.414, Lines 1-74, by deleting all of said section from  
5 the bill; and

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7 Further amend said bill by amending the title, enacting clause, and intersectional references  
8 accordingly.