

House _____ Amendment NO. _____

Offered By

1 AMEND House Committee Substitute for Senate Substitute No. 2 for Senate Bill No. 862, Page 40,
2 Section 337.618, Line 16, by inserting after all of said section and line the following:

3
4 "376.411. 1. For purposes of this section, the following terms mean:

5 (1) "Clinician-administered drug", any legend drug, as defined in section 338.330, that is
6 administered by a health care provider who is authorized to administer the drug;

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

8 (3) "Participating provider", the same meaning given to the term in section 376.1350;

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

10 2. A health carrier, a pharmacy benefits manager, or an agent or affiliate of such health
11 carrier or pharmacy benefits manager shall not:

12 (1) Impose any penalty, impediment, differentiation, or limitation on a participating provider
13 for providing medically necessary clinician-administered drugs regardless of whether the
14 participating provider obtains such drugs from a provider that is in the network including, but not
15 limited to, refusing to approve or pay or reimbursing less than the contracted payment amount;

16 (2) Impose any penalty, impediment, differentiation, or limitation on a covered person who
17 is administered medically necessary clinician-administered drugs regardless of whether the
18 participating provider obtains such drugs from a provider that is in the network including, but not
19 limited to, limiting coverage or benefits; requiring an additional fee, higher co-payment, or higher
20 coinsurance amount; or interfering with a patient's ability to obtain a clinician-administered drug
21 from the patient's provider or pharmacy of choice by any means including, but not limited to,
22 inducing, steering, or offering financial or other incentives; or

23 (3) Impose any penalty, impediment, differentiation, or limitation on any pharmacy,
24 including any class B hospital pharmacy as defined in section 338.220, that is dispensing medically
25 necessary clinician-administered drugs regardless of whether the participating provider obtains such
26 drugs from a provider that is in the network including, but not limited to, requiring a pharmacy to
27 dispense such drugs to a patient with the intention that the patient will transport the medication to a
28 health care provider for administration.

29 3. The provisions of this section shall not apply if the clinician-administered drug is not
30 otherwise covered by the health carrier or pharmacy benefits manager.

Action Taken _____ Date _____

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

2 (1) "340B drug", a drug that:

3 (a) Is a covered outpatient drug within the meaning of Section 340B of the Public Health
4 Service Act, 42 U.S.C. Section 256b, enacted by Section 602 of the Veterans Health Care Act of
5 1992, Pub. L. 102-585;

6 (b) Has been subject to any offer for reduced prices by a manufacturer under 42 U.S.C.
7 Section 256b(a)(1); and

8 (c) Is purchased by a covered entity;

9 (2) "Covered entity", the same meaning given to the term in Section 340B(a)(4) of the
10 Public Health Service Act, 42 U.S.C. Section 256b(a)(4);

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

12 (4) "Package", the same meaning given to the term in 21 U.S.C. Section 360eee(11)(A);

13 (5) "Pharmaceutical manufacturer", an entity that is engaged in the production, preparation,
14 propagation, compounding, conversion, or processing of covered outpatient drugs, whether directly
15 or indirectly, by extraction from substances of natural origin, independently by means of chemical
16 synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the
17 packaging, repackaging, labeling, relabeling, or distribution of covered outpatient drugs;

18 (6) "Pharmacy", the same meaning given to the term in section 338.210;

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

20 (8) "Third-party logistics provider", the same meaning given to the term in section 338.330;

21 (9) "Wholesale drug distributor", the same meaning given to the term in section 338.330.

22 2. A health carrier, a pharmacy benefits manager, or an agent or affiliate of such health
23 carrier or pharmacy benefits manager shall not discriminate against a covered entity or a pharmacy,
24 including but not limited to by doing any of the following:

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

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

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

35 (b) Professional dispensing fees;

36 (c) Restrictions or requirements regarding participation in standard or preferred pharmacy
37 networks;

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

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

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

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

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

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

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

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

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

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

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

24 3. A pharmaceutical manufacturer, wholesale drug distributor, third-party logistics provider,
25 or an agent or affiliate of such pharmaceutical manufacturer, wholesale drug distributor, or third-
26 party logistics provider, shall not deny, restrict, or prohibit, either directly or indirectly, the
27 acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with,
28 or otherwise authorized by, a covered entity to receive 340B drugs on behalf of the covered entity
29 unless such receipt is prohibited by the United States Department of Health and Human Services.

30 4. 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 subsection 2 of this section. Such
33 penalty shall not exceed five thousand dollars per violation per day.

34 5. The commission of any act prohibited by subsection 3 of this section shall constitute an
35 unlawful practice within the meaning of section 407.020, and any action authorized in sections
36 407.010 to 407.130 may be taken. Each package of 340B drugs determined to be subject to a
37 prohibited act under subsection 3 of this section shall constitute a separate violation under
38 subsection 3 of this section.

1 6. The board of pharmacy is authorized to investigate any complaint of a violation of
2 subsection 3 of this section by an individual or entity licensed by the board of pharmacy, and to
3 impose discipline, suspension, or revocation of the license of any such individual or entity.

4 7. The director of the department of commerce and insurance shall promulgate rules to
5 implement the provisions of subsection 2 of this section. The board of pharmacy may promulgate
6 rules to implement the provisions of subsection 3 of this section. Any rule or portion of a rule, as
7 that term is defined in section 536.010, that is created under the authority delegated in this section
8 shall become effective only if it complies with and is subject to all of the provisions of chapter 536
9 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the
10 powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective
11 date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of
12 rulemaking authority and any rule proposed or adopted after August 28, 2024, shall be invalid and
13 void.

14 8. Nothing in this section shall be construed or applied to be less restrictive than any federal
15 law as to any person or entity regulated by this section. Nothing in this section shall be construed or
16 applied to be in conflict with any of the following:

17 (1) Applicable federal law and related regulation; or

18 (2) Other laws of this state, if the state law is compatible with applicable federal law.

19 9. Limited distribution of a drug required under 21 U.S.C. Section 355-1 shall not be
20 construed as a violation of subsection 3 of this section.

21 10. No covered entity shall intentionally act in a nefarious manner with the sole purpose of
22 defrauding the 340B program. The department of health and senior services shall have sole
23 authority to initiate suit pursuant to this section against a Missouri-based covered entity in a court of
24 competent jurisdiction in Missouri. A finding by such court that a covered entity has intentionally
25 acted in a nefarious manner with the sole purpose of defrauding the 340B program may result in the
26 imposition of a fine not to exceed one million dollars for a covered entity with at least five hundred
27 inpatient beds and not to exceed five hundred thousand dollars for all other covered entities. No
28 action shall be initiated by the department pursuant to this section against a covered entity until the
29 conduct and claims at issue are substantiated by the Office of Pharmacy Affairs within the Health
30 Resources and Services Administration through a final, formal audit finding of intentional fraud
31 against the 340B program by the covered entity with damages in excess of two hundred fifty
32 thousand dollars; and such conduct and claims are fully and finally adjudicated and substantiated
33 through all permissible or required administrative actions or hearings; and all available court
34 challenges or appeals. Any fine paid pursuant to this section shall be submitted to the department of
35 mental health to fund mental health services.

36 376.415. 1. For purposes of this section, the following terms mean:

37 (1) "Biological product", the same meaning given to the term in 42 U.S.C. Section 262(i);

38 (2) "Biosimilar", the same meaning given to the term in 42 U.S.C. Section 262(i);

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

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

2 (5) "Reference product", the same meaning given to the term in 42 U.S.C. Section 262(i).

3 2. A health carrier, a pharmacy benefits manager, or an agent or affiliate of such health
4 carrier or pharmacy benefits manager that provides coverage for a reference product or a biological
5 product that is biosimilar to the reference product shall provide coverage for the reference product
6 and all biological products that have been deemed biosimilar to the reference product. The scope,
7 extent, and amount of such required coverage shall be the same including, but not limited to, any
8 payment limitations or cost-sharing obligations."; and

9
10 Further amend said bill by amending the title, enacting clause, and intersectional references
11 accordingly.