

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

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

1 AMEND House Bill No. 398, Page 2, Section 191.648, Line 43, by inserting after all of said section  
2 and line the following:

3  
4 "191.1065. 1. As used in this section, unless the context clearly indicates otherwise, the  
5 following terms shall mean:

6 (1) "340B drug", the same meaning given to the term in section 376.414;

7 (2) "340B drug proceeds", the greater of the following amounts:

8 (a) The difference between the 340B acquisition cost for a 340B drug and the  
9 reimbursement amount secured from any payer for that drug; or

10 (b) The amount retained by any party, other than the patient, for the 340B drug;

11 (3) "Covered entity", the same meaning given to the term in section 376.414;

12 (4) "Department", the department of health and senior services;

13 (5) "Direct patient care", the provision of health care services directly to individuals being  
14 treated for or suspected of having physical or mental illness;

15 (6) "Drug", the same meaning given to the term in section 376.1350;

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

17 (8) "Out-of-pocket costs", any portion of the cost of a health care service provided to an  
18 individual for which the individual is responsible for making payment including, but not limited to,  
19 any co-payment, coinsurance, or deductible;

20 (9) "Vulnerable patient", an individual who is uninsured and had an income of not more  
21 than four hundred percent of the federal poverty level established by the United States Department  
22 of Health and Human Services during the calendar year immediately preceding the date on which  
23 such person was dispensed a 340B drug.

24 2. A covered entity shall:

25 (1) Ensure that all 340B drug proceeds realized from the dispensing of 340B drugs are used  
26 to offset out-of-pocket costs for, or provide direct patient care to, vulnerable patients; and

27 (2) Before September 1, 2026, and annually thereafter, certify to the department that the  
28 covered entity has met the requirements of this section and used all 340B drug proceeds from the  
29 dispensing of 340B drugs to offset out-of-pocket costs for, or provide direct patient care to,  
30 vulnerable patients and report the following:

Action Taken \_\_\_\_\_ Date \_\_\_\_\_

1        (a) The total amount of 340B drug proceeds realized by the covered entity for 340B drugs  
 2 for the fiscal year preceding the report; and

3        (b) An itemized summary of how the covered entity used the 340B drug proceeds including,  
 4 but not limited to:

5            a. All uses to directly offset out-of-pocket costs for 340B drugs for vulnerable patients;

6            b. All uses to directly offset out-of-pocket costs for vulnerable patients other than for 340B  
 7 drugs;

8            c. All uses to provide direct patient care to vulnerable patients;

9            d. The assumptions, evaluations, and metrics used to make use determinations about 340B  
 10 drug proceeds; and

11           e. Any other information the department may deem relevant by rule.

12        3. Nothing in this section shall require a covered entity to disclose personally identifiable  
 13 patient information or information otherwise protected by law from disclosure.

14        4. Nothing in this section shall be construed or interpreted to be less restrictive than, or in  
 15 conflict with, any state or federal law.

16        5. The department shall investigate violations of this section and may discipline, suspend, or  
 17 revoke the license of any entity under its jurisdiction found to be in violation. No entity in violation  
 18 of this section shall be eligible to receive state or local public funds.

19        6. Before December 31, 2026, and annually thereafter, the department shall submit a written  
 20 report to the governor, the president pro tempore of the senate, and the speaker of the house of  
 21 representatives summarizing the information required to be reported under this section. The  
 22 department shall make its report in a manner that protects against the disclosure of proprietary  
 23 information.

24        7. The department may promulgate rules for the implementation of this section. Any rule or  
 25 portion of a rule, as that term is defined in section 536.010, that is created under the authority  
 26 delegated in this section shall become effective only if it complies with and is subject to all of the  
 27 provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are  
 28 nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to  
 29 review, to delay the effective date, or to disapprove and annul a rule are subsequently held  
 30 unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after  
 31 August 28, 2025, shall be invalid and void."; and

32  
 33 Further amend said bill by amending the title, enacting clause, and intersectional references  
 34 accordingly.