FIRST REGULAR SESSION

HOUSE BILL NO. 781

103RD GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE KEATHLEY.

0839H.011 JOSEPH ENGLER, Chief Clerk

AN ACT

To amend chapter 191, RSMo, by adding thereto one new section relating to the 340B drug program.

Be it enacted by the General Assembly of the state of Missouri, as follows:

Section A. Chapter 191, RSMo, is amended by adding thereto one new section, to be known as section 191.1065, to read as follows:

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

- 3 (1) "340B drug", the same meaning given to the term in section 376.414;
- 4 (2) "340B drug proceeds", the greater of the following amounts:

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- 5 (a) The difference between the 340B acquisition cost for a 340B drug and the 6 reimbursement amount secured from any payer for that drug; or
 - (b) The amount retained by any party, other than the patient, for the 340B drug;
- 8 (3) "Covered entity", the same meaning given to the term in section 376.414;
 - (4) "Department", the department of health and senior services;
- 10 (5) "Direct patient care", the provision of health care services directly to 11 individuals being treated for or suspected of having physical or mental illness;
 - (6) "Drug", the same meaning given to the term in section 376.1350;
- 13 (7) "Health care service", the same meaning given to the term in section 14 376.1350;
- 15 (8) "Out-of-pocket costs", any portion of the cost of a health care service 16 provided to an individual for which the individual is responsible for making payment
- 17 including, but not limited to, any co-payment, coinsurance, or deductible;

EXPLANATION — Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

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- (9) "Vulnerable patient", an individual who is uninsured and had an income of 19 not more than four hundred percent of the federal poverty level established by the 20 United States Department of Health and Human Services during the calendar year immediately preceding the date on which such person was dispensed a 340B drug.
 - 2. A covered entity shall:
 - (1) Ensure that all 340B drug proceeds realized from the dispensing of 340B drugs are used to offset out-of-pocket costs for, or provide direct patient care to, vulnerable patients; and
 - (2) Before September 1, 2026, and annually thereafter, certify to the department that the covered entity has met the requirements of this section and used all 340B drug proceeds from the dispensing of 340B drugs to offset out-of-pocket costs for, or provide direct patient care to, vulnerable patients and report the following:
 - (a) The total amount of 340B drug proceeds realized by the covered entity for 340B drugs for the fiscal year preceding the report; and
 - (b) An itemized summary of how the covered entity used the 340B drug proceeds including, but not limited to:
- 34 a. All uses to directly offset out-of-pocket costs for 340B drugs for vulnerable 35 patients;
- 36 b. All uses to directly offset out-of-pocket costs for vulnerable patients other 37 than for 340B drugs;
 - c. All uses to provide direct patient care to vulnerable patients;
- 39 d. The assumptions, evaluations, and metrics used to make use determinations about 340B drug proceeds; and 40
 - e. Any other information the department may deem relevant by rule.
- 42 3. Nothing in this section shall require a covered entity to disclose personally 43 identifiable patient information or information otherwise protected by law from 44 disclosure.
- 45 4. Nothing in this section shall be construed or interpreted to be less restrictive than, or in conflict with, any state or federal law. 46
 - 5. The department shall investigate violations of this section and may discipline, suspend, or revoke the license of any entity under its jurisdiction found to be in violation. No entity in violation of this section shall be eligible to receive state or local public funds.
- 51 6. Before December 31, 2026, and annually thereafter, the department shall 52 submit a written report to the governor, the president pro tempore of the senate, and the 53 speaker of the house of representatives summarizing the information required to be

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reported under this section. The department shall make its report in a manner that protects against the disclosure of proprietary information.

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

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