

## SENATE BILL No. 284

By Committee on Federal and State Affairs

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1 AN ACT concerning prescription drugs; relating to the federal 340B drug  
2 pricing program; enacting the defense of drug delivery act to prohibit  
3 manufacturer interference relating to 340B drug distribution.  
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5 *Be it enacted by the Legislature of the State of Kansas:*

6 Section 1. Sections 1 through 9, and amendments thereto, shall be  
7 known and may be cited as the defense of drug delivery act.

8 Sec. 2. As used in this act:

9 (a) "340B drug" means a drug that:

10 (1) Is a covered outpatient drug within the federal 340B drug pricing  
11 program authorized by 42 U.S.C. § 256b;

12 (2) has been subject to any offer for reduced prices by a manufacturer  
13 under 42 U.S.C. § 256b(a)(1); and

14 (3) is purchased by a covered entity. A drug shall be considered  
15 purchased if such drug would have been purchased except for the  
16 restriction or limitation described in section 3, and amendments thereto.

17 (b) "Attorney general" means the attorney general of the state of  
18 Kansas or the attorney general's designee.

19 (c) "Biological product" means the same as defined in 42 U.S.C. §  
20 262(i), as in effect on January 1, 2025.

21 (d) "Board" means the state board of pharmacy created by K.S.A. 74-  
22 1603, and amendments thereto.

23 (e) "Covered entity" means the same as defined in 42 U.S.C. §  
24 256b(a)(4), as in effect on January 1, 2025.

25 (f) "Distribute" or "distribution" means the same as defined in K.S.A.  
26 65-1626, and amendments thereto.

27 (g) "Federal healthcare program" means any plan or program that  
28 provides health benefits, whether directly, through insurance or otherwise,  
29 that is funded directly, in whole or in part, by the United States  
30 government or any state health care program as defined in 42 U.S.C. §  
31 1320a-7(h), as in effect on January 1, 2025.

32 (h) "Health information" means any information, including  
33 demographic information collected from an individual or a group of  
34 individuals, that:

35 (1) Is created or received by a healthcare provider, pharmacy, health  
36 plan, employer or healthcare clearinghouse; and

1 (2) relates to the past, present or future physical or mental health or  
2 condition of an individual, the provision of healthcare to an individual or  
3 the past, present or future payment for the provision of healthcare to an  
4 individual.

5 (i) "Manufacturer" means the same as defined in K.S.A. 65-1626, and  
6 amendments thereto.

7 (j) "Package" means the smallest individual saleable unit of product  
8 for distribution by a manufacturer or repackager that is intended by the  
9 manufacturer for ultimate sale to the dispenser of such product.

10 (k) "Repackager" means the same as defined in K.S.A. 65-1626, and  
11 amendments thereto.

12 (l) "Third-party logistics provider" means the same as defined in  
13 K.S.A. 65-1626, and amendments thereto.

14 (m) "Virtual wholesale distributor" means the same as defined in  
15 K.S.A. 65-1626, and amendments thereto.

16 (n) "Wholesale distributor" means the same as defined in K.S.A. 65-  
17 1626, and amendments thereto.

18 Sec. 3. (a) A manufacturer, wholesaler, virtual wholesaler, third party  
19 logistics provider or repackager or an agent, contractor or affiliate thereof,  
20 including an entity that collects or processes health information, shall not,  
21 directly or indirectly, deny, restrict, prohibit, discriminate against or  
22 otherwise limit the acquisition or delivery of a 340B drug to a covered  
23 entity or a location otherwise authorized by a covered entity to receive a  
24 340B drug unless such receipt is prohibited by the United States  
25 department of health and human services or applicable state law.

26 (b) A manufacturer shall not directly or indirectly require, including  
27 as a condition, a covered entity or a location authorized by a covered entity  
28 to receive 340B drugs, to submit any health information, claims or  
29 utilization data, purchasing, payment or other data, unless such  
30 information or data is voluntarily furnished by such covered entity or  
31 otherwise required to be furnished under applicable federal or state law.

32 Sec. 4. (a) The attorney general may adopt rules and regulations as  
33 necessary to implement and administer the provisions of this act.

34 (b) There is hereby established in the state treasury the defense of  
35 drug delivery fund to be administered by the attorney general. All moneys  
36 received by the attorney general from fines or penalties collected under the  
37 provisions of this act shall be remitted to the state treasurer in accordance  
38 with the provisions of K.S.A. 75-4215, and amendments thereto. The state  
39 treasurer shall deposit the entire amount thereof in the state treasury to the  
40 credit of the defense of drug delivery fund. All expenditures from such  
41 fund shall be made in accordance with appropriation acts upon warrants of  
42 the director of accounts and reports issued pursuant to vouchers approved  
43 by the attorney general or the attorney general's designee. All moneys

1 credited to the defense of drug delivery fund shall be expended for the  
2 administration of the duties, functions and operating expenses incurred  
3 under the provisions of this act.

4 Sec. 5. (a) If, by the attorney general's own inquiries or as a result of  
5 complaints, the attorney general has reason to believe that a person or  
6 entity has violated the provisions of section 3, and amendments thereto,  
7 the attorney general or assistant attorney general may administer oaths and  
8 affirmations, subpoena witnesses or matter and collect evidence. The  
9 board may assist the attorney general in any investigation related to a  
10 suspected violation of section 3, and amendments thereto.

11 (b) The attorney general, upon a finding that a person or entity has  
12 violated the provisions of section 3, and amendments thereto, may impose  
13 a civil penalty upon such person or entity.

14 (c) A person or entity who violates the provisions of section 3, and  
15 amendments thereto, in addition to any other penalty provided by law, may  
16 incur a civil penalty in an amount of not to exceed \$50,000 for each  
17 violation.

18 (d) A civil penalty shall not be imposed pursuant to this section  
19 except upon the written order of the attorney general to the person or entity  
20 who is responsible for the violation. Such order is a final order for  
21 purposes of judicial review and shall state the violation, the penalty to be  
22 imposed, and the right of such person or entity to appeal as provided in the  
23 Kansas judicial review act.

24 (e) Each package of 340B drugs found to be subject to a violation  
25 under section 3, and amendments thereto, shall constitute a separate  
26 violation of this act.

27 Sec. 6. The board may investigate any complaint of a violation of  
28 section 3, and amendments thereto, by a person or entity subject to  
29 registration or permitting requirements of the board and upon a finding of  
30 a violation, may impose discipline, suspension or revocation of the  
31 registration or permit of any such person or entity.

32 Sec. 7. (a) Limited distribution of a drug required under 21 U.S.C. §  
33 355-1 shall not be construed as a violation of this act.

34 (b) Section 3, and amendments thereto, shall not be construed as  
35 prohibiting a manufacturer from requiring health information or other data  
36 that a covered entity is required to furnish to the manufacturer under  
37 applicable state and federal law, including data related to an audit in  
38 accordance with procedures established by the United States department of  
39 health and human services under 42 U.S.C. § 256b (a)(5)(C).

40 Sec. 8. Nothing in this act shall be construed or applied to be less  
41 restrictive than any federal law as to any person or entity referenced in or  
42 regulated by this act. Nothing in this act shall be construed or applied to be  
43 in conflict with applicable federal law and related regulation or other laws

1 of this state that are compatible with applicable federal law.

2 Sec. 9. The provisions of this act are severable. If any provision of  
3 the act is declared unconstitutional or invalid, or the application of any  
4 portion of the act to any person or circumstance is held unconstitutional or  
5 invalid, the invalidity shall not affect other portions of the act that can be  
6 given effect without the invalid portion or application, and the  
7 applicability of such other portions of the act to any person or  
8 circumstance shall remain valid and enforceable.

9 Sec. 10. This act shall take effect and be in force from and after its  
10 publication in the statute book.