As Amended by Senate Committee

Session of 2025

SENATE BILL No. 284

By Committee on Federal and State Affairs

3-3

AN ACT concerning prescription drugs; relating to the federal 340B drug pricing program; enacting the defense of drug delivery act to prohibit manufacturer interference relating to 340B drug distribution.

Be it enacted by the Legislature of the State of Kansas:

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

Sec. 2. As used in this act:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sec. 6. The board may investigate any complaint of a violation of section 3, and amendments thereto, by a person or entity subject to registration or permitting requirements of the board ~~and upon~~***, including any wholesaler that may possess evidence supporting such complaint. Upon*** a finding of a violation, ***the board*** may impose discipline, suspension or revocation of the registration or permit of any such person or entity.

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

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

Sec. 8. Nothing in this act shall be construed or applied to be less restrictive than any federal law as to any person or entity referenced in or

regulated by this act. Nothing in this act shall be construed or applied to be in conflict with applicable federal law and related regulation or other laws of this state that are compatible with applicable federal law.

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

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