SESSION OF 2025

SUPPLEMENTAL NOTE ON SENATE BILL NO. 284

As Amended by Senate Committee on Financial Institutions and Insurance

Brief*

SB 284, as amended, would enact the Defense of Drug Delivery Act (Act), pertaining to the federal 340B Drug Pricing Program (340B Program). The Act would prohibit limitations on the acquisition or delivery of a 340B drug to a covered entity and prohibit manufacturers from requiring health information not otherwise required by the 340B Program as a condition of receiving 340B drugs. The bill would provide for the Attorney General to adopt rules and regulations and the creation of a fund in the State Treasury for the implementation of the Act. The bill would also provide for civil penalties to be assessed for violations of the Act and empower the State Board of Pharmacy (Board) to investigate complaints.

Definitions (Section 2)

The bill would define terms used in the Act, including:

- "340B drug" would mean a drug that:
    - Is a covered outpatient drug within the federal 340B Drug Pricing Program;
    - Has been subject to any offer for reduced prices by a manufacturer under federal law; and
    - Is purchased by a covered entity–a drug would be considered purchased if the drug

*Supplemental notes are prepared by the Legislative Research Department and do not express legislative intent. The supplemental note and fiscal note for this bill may be accessed on the Internet at https://klrd.gov/

would have been purchased except for the restriction or limitation described in the Act;

- "Covered entity" would mean the same as defined in federal law, which includes federally qualified health centers and look-alikes; Ryan White HIV/AIDS Program grantees; certain hospitals, including critical access hospitals and disproportionate share hospitals; and specialized clinics, including sexually transmitted disease clinics and tuberculosis clinics;

- "Health information" would mean any information, including demographic information collected from an individual or a group of individuals that:
    - Is created or received by a health care provider, pharmacy, health plan, employer, or health care clearinghouse; and
    - Relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual;

- "Manufacturer" would mean:
    - A person that holds an application approved under the Federal Food, Drug, and Cosmetic Act or a license issued under the Federal Public Health Service Act for a drug or, if the drug is not the subject of an approved application or license, the person who manufactured the drug;
    - A co-licensed partner of the person described above that obtains the drug directly from an approved person or affiliate; or
    - An affiliate of a person described above that receives the product directly from such person;

- "Repackager" would mean a person who owns or operates a facility that repackages;

- "Third-party logistics provider" would mean an entity that provides or coordinates warehousing or other logistic services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser, but does not take ownership of the product or have responsibility to direct the sale or disposition of the product;

- "Virtual wholesale distributor" would mean a wholesale distributor that sells, brokers, or transfers a drug or device but never physically possesses the product; and

- "Wholesale distributor" would mean any person engaged in wholesale distribution or reverse distribution of drugs or devices, other than a manufacturer, co-licensed partner, or third-party logistics provider.

Delivery of Drugs and Sharing of Health Information (Section 3)

The bill would state that a manufacturer, third-party logistics provider or repackager, or an agent, contractor, or affiliate, including an entity that collects or processes health information, could 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 the receipt is prohibited by the U.S. Department of Health and Human Services or applicable state law.

Under the bill, a manufacturer could 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 the information or data is required to be furnished under applicable federal or state law.

Implementation of the Act (Section 4)

The bill would provide for the Attorney General (AG) to adopt rules and regulations as necessary to implement and administer the Act.

Defense of Drug Delivery Fund

The bill would establish the Defense of Drug Delivery Fund (Fund) in the State Treasury to be administered by the AG. All moneys received by the AG from fines or penalties collected under the Act would be remitted to the State Treasurer, and the State Treasurer would be required to deposit the entire amount to the Fund. All expenditures from the Fund would be made in accordance with appropriation acts pursuant to vouchers approved by the AG or the AG's designee. All moneys credited to the Fund would be required to be expended for the administration of the Act.

Enforcement (Section 5)

If, by the AG's own inquiries or as a result of complaints, the AG has reason to believe that a person or entity has violated the provisions of the Act related to delivery of drugs and sharing of health information, the bill would provide for the AG or Assistant AG to administer oaths and affirmations, subpoena witnesses or matter, and collect evidence. The Board could assist the AG in any investigation related to a suspected violation of the Act.

Upon a finding that a person or entity has violated the provisions of the Act, the bill would provide for the AG to impose a civil penalty. In addition to any penalty provided by

law, a person or entity could incur a civil penalty of not more than $50,000 for each violation.

A civil penalty would not be imposed under the Act except upon the written order of the AG to the person or entity responsible for the violation. The order would be a final order for purposes of judicial review and would be required to 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.

Under the bill, each package of 340B drugs found to be subject to a violation would constitute a separate violation of the Act.

Investigation of Complaints (Section 6)

The bill would provide for the Board to investigate any complaint of a violation of the provisions of the Act pertaining to delivery of drugs and sharing of health information by a person or entity subject to registration or permitting requirements of the Board, including any wholesaler that could possess evidence supporting the complaint. Upon a finding of a violation, the Board could impose discipline, suspension, or revocation of the registration or permit of such person or entity.

Limitations of the Act (Sections 7 and 8)

The bill would state that limited distribution of a drug required under federal law pertaining to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act would not be construed as a violation of the Act.

The bill would provide for provisions of the Act pertaining to delivery of drugs and sharing of health information (Section 3) would 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. This would include data related to an audit in accordance with procedures established by the U.S. Department of Health and Human Services under federal law regarding limitations on prices of drugs purchased by covered entities.

The bill would provide that the Act could not be construed or applied to be less restrictive than or to be in conflict with federal law or other Kansas laws that are compatible with applicable federal law.

Severability (Section 9)

The bill would declare the provisions of the Act severable. If any provision of the Act were declared unconstitutional or invalid, or the application of any portion of the Act to any person or circumstance were held unconstitutional or invalid, the bill would provide for the invalidity to not affect other portions of the Act that could be given effect without the invalid portion or application. The applicability of other portions of the Act would remain valid and enforceable.

Background

The bill was introduced by the Senate Committee on Federal and State Affairs at the request of Senator Murphy.

Senate Committee on Financial Institutions and Insurance

In the Senate Committee hearing, **proponent** testimony was provided by Senator Murphy and representatives of Community Care Network of Kansas, Eureka Pharmacy, Holton Community Hospital, PrairieStar Health Center, and Salina Family Healthcare Center. The proponents generally stated that manufacturers requiring covered entities to

contract with a single pharmacy has created challenges for facilitating the 340B Program, which helps patients afford their medications and supports safety net providers, which are particularly impactful to rural communities. The proponents also noted that some manufacturers have begun requiring data in addition to the information required by the 340B Program to receive their stock, creating an administrative burden.

Written-only proponent testimony was provided by representatives of AmberMed, Community Health Center of Southeast Kansas, FirstCare Clinic, GraceMed Health Clinic, Health Forward Foundation, Health Ministries Clinic, Heartland Community Health Center, Kansas Action for Children, Kansas Association of Counties, Kansas Pharmacists Association, Mercy & Truth Healthcare Ministry, Mountain Region CommonSpirit Health, Vibrant Health, and 62 hospitals.

Opponent testimony was provided by representatives of AdAstra BIO and BioKansas, Healthcare Distribution Alliance, the Kansas Chamber, and PhRMA, who generally stated that the 340B Program has grown substantially, but suggested the patient benefit has not grown in kind. The opponents stated the increase in cost to manufacturers could lead to increased operating costs and could restrain resources dedicated to research and development of new pharmaceuticals.

Written-only opponent testimony was provided by representatives of Amgen, Inc.; Consumer Action for a Strong Economy; Domestic Policy Caucus; Infusion Access Foundation; Merck Human Health; National Taxpayers Union; Pfizer; and a coalition of groups including Biomarker Collaborative, Community Liver Alliance, Exon 20 Group, H.E.A.L.S. Of the South, Hispanic Business Alliance, International Cancer Advocacy Network, Mental Health America of the Heartland, MET Crusaders, National Alliance on Mental Illness (NAMI) Kansas, PD-L1 Amplifieds, and SLC6A1 Connect.

No other testimony was provided.

The Senate Committee amended the bill to specify that wholesalers that may posses evidence supporting a complaint of a violation under the Act could be investigated by the Board and to remove wholesalers and virtual wholesalers from those entities prohibited from, directly or indirectly, denying, restricting, prohibiting, discriminating against, or otherwise limiting the acquisition or delivery of a 340B drug to a covered entity or a location otherwise authorized by a covered entity to receive a drug unless such receipt is prohibited by the U.S. Department of Health and Human Services or state law.

Fiscal Information

According to the fiscal note prepared by the Division of the Budget on the bill, as introduced, the Board indicates that enactment of the bill would have a fiscal effect on expenditures of the Board. The Board estimates that it would have increased expenditures of $220,000 from the Board of Pharmacy Fee Fund for an additional 2.0 positions' salaries, fringe benefits, and other operating expenses. Currently, the Board does not have any expertise in the area of 340B drugs, contracts, or processes and is not engaged in any investigations related to those contemplated by the bill. The Board would need to hire a subject matter expert to learn about and implement investigation and enforcement activity. The Board anticipates that complaints, investigations, and enforcement activity would be significant in the first three to five years of implementation and then taper off as market participants adjust their policies and business models. Additionally, most drug manufacturers and distributors registered with the Board are non-resident facilities, which would make investigations and audits more cumbersome and resource intensive. These staff would also be responsible for collaborating with the Office of the Attorney General. The Board also anticipates attorney contractual expenses related

to enforcement actions ($160/hour) would increase, but the Board is unable to estimate these amounts.

The Board states that no revenue would be anticipated by the bill and the Board does not carry a balance in the fee fund for additional expenditures. If the Board would have disciplinary and enforcement authority, there would be a potential revenue source to the Board from fines associated with discipline. However, since these amounts are unpredictable, the Board would likely need to increase facility registration fees to off-set increased expenditures.

The Office of the Attorney General (Office) indicates that enactment of SB 284 would increase expenditures by $156,526 for FY 2026 and $164,352 for FY 2027 from the State General Fund for 1.0 Assistant AG position and other operating expenses. These expenses would continue in future years. The Office would be required to administer the Defense of Drug Delivery Fund under this Act. The management of this fund could be handled with current positions. A person or entity who would violate the provisions of the Act, in addition to any other penalty provided by law, could incur a civil penalty in an amount up to $50,000 for each violation. It is unclear how many violations would take place annually under this Act. Therefore, the Office cannot forecast a revenue increase resulting from this Act becoming law. The Office would be required to defend orders made by the agency if an assessment of a civil penalty would be appealed under the Judicial Review Act. Existing staff would likely be able to handle this review if the position above is funded.

The Department of Administration, Kansas Department of Health and Environment, and the Kansas Insurance Department indicate that enactment of the bill would have no fiscal effect on the agencies. Any fiscal effect associated with enactment of the bill is not reflected in *The FY 2026 Governor's Budget Report*.

340B; prescription drugs; drug pricing; Defense of Drug Delivery Act; Attorney General