Session of 2025

SENATE BILL No. 212

By Senator Sykes

2-5

AN ACT concerning health and healthcare; enacting the prescription drug cost and affordability review act; establishing the prescription drugs pricing board and prescription drug affordability stakeholder council to review the cost of prescription medications and establish upper payment limits for certain prescription drug products.

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

Section 1. This act shall be known and may be cited as the prescription drug cost and affordability review act.

Sec. 2. As used in sections 1 through 8, and amendments thereto:

(a) "340B-covered entity" means an entity that is participating in the federal 340B drug pricing program authorized by 42 U.S.C. § 256b, including such entity's pharmacy or pharmacies, or any pharmacy or pharmacies contracted for the purpose of dispensing drugs purchased through such program.

(b) "Biologic" means a drug that is produced or distributed in accordance with a biologics license application approved by the United States food and drug administration.

(c) "Biosimilar" means a drug that is produced or distributed in accordance with a biologics license application approved under 42 U.S.C. § 262(k).

(d) "Board" means the prescription drug affordability board created in section 3, and amendments thereto.

(e) "Brand name drug" means a drug other than an authorized generic drug that is produced or distributed in accordance with an original new drug application approved under 21 U.S.C. § 355.

(f) "Commissioner" means the commissioner of insurance.

(g) "Consumer price index" means the United States consumer price index for all urban consumers as defined and reported by the United States department of labor, bureau of labor statistics.

(h) "Council" means the prescription drug affordability stakeholder council created in section 4, and amendments thereto.

(i) "Department" means the Kansas insurance department.

(j) "Fund" means the prescription drug affordability fund created in section 7, and amendments thereto.

(k) "Generic drug" means any of the following:

(1) A retail drug that is marketed or distributed in accordance with an abbreviated new drug application approved under 21 U.S.C. § 355;

(2) an authorized generic drug as such term is defined in 42 C.F.R. 447.502; or

(3) a drug that entered the market before 1962 that was not originally marketed under a new drug application.

(l) "Health insurer" means the same as defined in K.S.A. 40-4602, and amendments thereto.

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

(n) "Person" means an individual, corporation or other legal entity.

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

(p) "Prescription drug product" means a brand name drug, a generic drug, a biologic or a biosimilar.

(q) "Prescription drug product purchaser" means an entity that purchases and takes ownership of a prescription drug product for resale or providing to patients.

(r) "Rule" means a rule and regulation adopted by the board.

(s) "Third-party payor" means a payor that reimburses a pharmacy for drugs or services, including a pharmacy benefits manager. "Third-party payor" does not include the Kansas program of medical assistance under K.S.A. 39-709, and amendments thereto, or a managed care organization providing state medicaid or children's health insurance program services under the Kansas medical assistance or the state healthcare benefits program.

(t) "Wholesale acquisition cost" means such term as defined in 42 U.S.C. § 1395w-3a(c)(6)(B).

Sec. 3. (a) There is hereby established the prescription drug affordability board as created as an autonomous entity within the department.

(b) (1) The board shall consists of five members, which shall be appointed by the governor. The members of the board shall include individuals who have expertise in healthcare economics, health policy, health equity and clinical medicine.

(2) The governor shall not appoint an individual to the board if the individual:

(A) Is employed by, a consultant to or a board member of a manufacturer or a trade association for a manufacturer;

(B) has a personal or financial interest that has the potential to bias or has the appearance of biasing the individual's decision in matters related to the board or in conducting the board's activities; or

(C) is a lobbyist who is registered in this state.

(3) An individual who is appointed to the board shall not register as a lobbyist in this state for a period of five years after the individual's term on the board expires.

(4) The governor shall appoint two of the initial members of the board to one-year terms and three of the initial members to two-year terms. After the initial appointments, the term of a member of the board is four years or until a successor is appointed, whichever is later.

(5) If a vacancy occurs on the board, the governor shall appoint an individual to fill the vacancy for the remaining term in the same manner as the original appointment.

(6) The governor may remove a member of the board for incompetence, malfeasance, misfeasance or nonfeasance in office, or any other good cause.

(c) (1) The governor shall call the first meeting of the board. At the first meeting, the board shall elect from among its members a chairperson and other officers as such board considers necessary or appropriate. After the first meeting, the board shall meet at least quarterly or more frequently at the call of the chairperson or if requested by a quorum of its members.

(2) A majority of the members of the board shall constitute a quorum for transacting business. Except as otherwise provided in this subsection, a majority of the members present and serving is required for official action of the board.

(d) Except as otherwise provided in this subsection, a writing that is prepared, owned, used, in the possession of or retained by the board in performing an official function is subject to the Kansas open records act. A writing containing a trade secret or proprietary information shall be confidential and privileged and not be subject to the provisions of the Kansas open records act as provided by K.S.A. 45-215 et seq., and amendments thereto. The provisions of this subsection shall expire on July 1, 2030, unless the legislature reviews and reenacts this provision pursuant to K.S.A. 45-229, and amendments thereto, prior to July 1, 2030.

(e) The salaries and other expenses incurred by members of the board shall be subject to appropriations.

(f) As used in this section, "health equity" means attaining the highest level of health for all individuals, in which an individual has a fair and just opportunity to attain such individual's optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language or other factor that affects access to healthcare and health outcomes.

Sec. 4. (a) There is hereby established the prescription drug affordability stakeholder council within the department.

(1) Subject to paragraph 2, the council shall consist of the following 21 members:

(A) Seven members appointed by the governor as follows:

(i) One individual representing manufacturers of brand name drugs;

(ii) one individual representing manufacturers of generic drugs;

(iii) one individual representing employers;

(iv) one individual representing pharmacy benefit managers;

(v) one individual representing pharmacists;

(vi) one individual representing a mutual insurance company. The mutual insurance company under this subparagraph shall not be an entity that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with the managed care organization; and

(vii) one member of the public;

(B) seven members appointed by the governor from a list of nominees submitted by the speaker of the house of representatives. The list of nominees shall include individuals who represent the following:

(i) A statewide organization that advocates for senior citizens;

(ii) a statewide organization that advocates for healthcare;

(iii) a statewide organization that advocates for diversity within communities;

(iv) a labor union;

(v) researchers who specialize in prescription drug products; and

(vi) the public; and

(C) seven members appointed by the governor from a list of nominees submitted by the senate majority leader. The list of nominees shall include individuals who represent each of the following:

(i) Physicians;

(ii) nurses;

(iii) hospitals;

(iv) managed care organizations. The managed care organization under this clause shall not be an entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with the mutual insurance company under paragraph (1)(A)(vi);

(v) clinical researchers; and

(vi) the public.

(2) The governor shall ensure that the members appointed to the council have knowledge in one or more of the following areas:

(A) The pharmaceutical business model;

(B) supply chain business models;

(C) the practice of medicine or clinical training;

(D) consumer or patient perspectives;

(E) healthcare costs trends; and

(F) clinical and health services research.

(b) The governor shall appoint seven of the initial members of the

council to one-year-terms, seven of the initial members to two-year terms and seven of the initial members to three year terms. After the initial appointments, the term of a member of the council is three years or until a successor is appointed, whichever is later.

(1) If a vacancy occurs on the council, the governor shall appoint an individual to fill the vacancy for the remaining term in the same manner as the original appointment.

(2) The governor may remove a member of the council for incompetence, malfeasance, misfeasance or nonfeasance in office or any other good cause.

(3) At the first meeting of the council, the council shall elect from among its members a chairperson and other officers as such council considers necessary or appropriate. After the first meeting, the council shall meet at least quarterly or more frequently at the call of the chairperson or if requested by a quorum of its members.

(4) A majority of the members of the council shall constitute a quorum for transacting business. A majority of the members present and serving is required for official action of the council.

(c) Except as otherwise provided in this subsection, a writing that is prepared, owned, used, in the possession of, or retained by the council in performing an official function is subject to the Kansas open records act. A writing containing a trade secret or proprietary information shall be confidential and privileged and not be subject to the provisions of the Kansas open records act as provided by K.S.A. 45-215 et seq., and amendments thereto. The provisions of this subsection shall expire on July 1, 2030, unless the legislature reviews and reenacts this provision pursuant to K.S.A. 45-229, and amendments thereto, prior to July 1, 2030.

(d) Members of the council attending meetings authorized by the council shall be paid amounts as provided in K.S.A. 75-3223(3), and amendments thereto.

(e) The council shall assist the board in making decisions required under this act.

Sec. 5. (a) Beginning on January 1, 2027, subject to subsection (b), the board, in

consultation with the council, shall select one or more prescription drug products based on any of the following criteria:

(1) The prescription drug product is a brand name drug or a biologic that, as adjusted annually for inflation in accordance with the consumer price index, has a wholesale acquisition cost of $60,000 or more per year or per course of treatment has a wholesale acquisition cost increase of $3,000 or more in any 12-month period;

(2) the prescription drug product is a biosimilar that has a wholesale acquisition cost that is not at least 15% lower than the referenced brand

biologic; or

(3) the prescription drug product is a generic drug that, as adjusted annually for inflation in accordance with the consumer price index, has a wholesale acquisition cost that:

(A) Is $100 or more for any of the following:

(i) A 30-day supply that lasts a patient for a period of 30 consecutive days based on the recommended dosage approved for labeling by the United States food and drug administration;

(ii) a supply that lasts a patient for less than 30 days based on the recommended dosage approved for labeling by the United States food and drug administration; and

(iii) one unit of the drug if the labeling approved by the United States food and drug administration does not recommend a finite dosage; and

(B) increased by 200% or more during the immediately preceding 12-month period, as determined by the difference between the resulting wholesale acquisition cost and the average wholesale acquisition cost reported over the immediately preceding 12 months; or

(4) the prescription drug product is a prescription drug product that may create affordability challenges for healthcare systems in this state and patients, including, but not limited to, a prescription drug product needed to address a public health emergency.

(b) In selecting one or more prescription drug products under subsection (a), the board shall not be required to identify each prescription drug product that meets the criteria described in subsection (a).

(1) The board shall determine whether to conduct a cost and affordability review for each prescription drug product that is selected under subsection (a). In making a determination under this subsection, the board shall consider input from the council and the average patient cost share for each prescription drug product.

(2) If the board conducts a cost and affordability review of a prescription drug product, the board may consider when conducting the review any document or research related to the manufacturer's selection of the introductory price or price increase of the prescription drug product, including life cycle management, net average price in this state, market competition, projected revenue and, subject to subsection (e), the estimated cost-effectiveness of the prescription drug product. In its review, the board shall determine whether the use of a prescription drug product that is fully consistent with the labeling approved by the United States food and drug administration or standard medical practice for the prescription drug product has led or will lead to affordability challenges to healthcare systems in this state or high out-of-pocket costs for patients in this state. In making its determination under this subsection, the board shall consider any information that a manufacturer chooses to provide to

the board and all of the following factors, to the extent practicable:

(A) The wholesale acquisition cost for the prescription drug product sold in this state;

(B) the average monetary price concession, discount or rebate that the manufacturer provides or is expected to provide to health insurers and pharmacy benefit managers in this state, expressed as a percent of the wholesale acquisition cost for the prescription drug product under review;

(C) the price at which therapeutic alternatives for the prescription drug product have been sold in this state;

(D) the average monetary concession, discount or rebate that another manufacturer provides or is expected to provide to health insurers and pharmacy benefit managers in this state for therapeutic alternatives;

(E) the cost to health insurers based on patient access consistent with United States food and drug administration labeled indications or recognized standard medical practice;

(F) the impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design;

(G) the current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer;

(H) the relative financial impact to health, medical or social service costs as can be quantified and compared to baseline effects of existing therapeutic alternatives;

(I) the average patient copay or other cost-sharing measures for the prescription drug product in this state; and

(J) any other factor established by the board.

(c) If the board determines that spending on a prescription drug product reviewed under this section has led or will lead to affordability challenges to healthcare systems in this state or high out-of-pocket costs for patients in this state, the board may, subject to subsection (d), adopt rules and regulations establishing an upper payment limit for the prescription drug product. In establishing an upper payment limit under this subsection, the board shall consider all of the following:

(1) Relevant administrative costs related to supplying or stocking the prescription drug product; and

(2) the impact of an upper payment limit for the prescription drug product on 340-B program entities.

(d) An upper payment limit established under this section shall not include professional dispensing fees.

(e) If the board considers the estimated cost-effectiveness of a prescription drug product under this section, the board:

(1) Shall not use a cost-per-quality adjusted life year, or a similar measure, to identify a subpopulation for which a prescription drug product would be less cost-effective due to severity of illness, age or preexisting

disability; and

(2) if the board uses a cost-effectiveness analysis for a prescription drug product that extends an individual's life, the board shall use a cost-effectiveness analysis that weighs the value of all additional lifetime gained equally for any individual, regardless of the severity of illness, age or preexisting disability.

(f) An upper payment limit established under this section shall take effect on the date adopted by the board by rule and regulation, except that such date shall not be sooner than six months after the date that the upper payment limit is established.

Sec. 6. (a) Except as otherwise provided in subsection (b), if the board establishes an upper payment limit under section 5, and amendments thereto, for a prescription drug product intended for use by individuals in this state, beginning on the effective date of the upper payment limit, a prescription drug product purchaser or third-party payer shall not purchase, bill or reimburse for the prescription drug product in an amount that exceeds the upper payment limit, regardless of whether the prescription drug product is dispensed or distributed in person, by mail or by other means.

(b) A prescription drug product purchaser or third-party payer shall not reimburse a pharmacy for a prescription drug product in an amount that is less than an upper payment limit established under section 5, and amendments thereto, for the prescription drug product.

(c) The attorney general may investigate a violation of this section and may commence a civil action against a person for appropriate relief, including, but not limited to, injunctive relief for a violation of this section.

(d) This section shall not prohibit any other sanction against a prescription drug product purchaser or third-party payor as provided by law.

(e) A person aggrieved by a decision of the board under this act may request an appeal within 30 days. A hearing and appeal is subject to the Kansas administrative procedure act.

(f) The board may adopt rules and regulations to implement and administer this act, and the board may enter into contracts with third parties to assist the board in carrying out its duties under this act.

Sec. 7. There is hereby established in the state treasury the prescription drug affordability fund, which shall be administered by the commissioner. All expenditures from the prescription drug affordability fund shall be to fund the board and for costs expended by the department to implement and administer the prescription drug cost and affordability review act. All expenditures from the prescription drug affordability 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 commissioner or the designee of the commissioner. All moneys received by the board for the prescription drug cost and affordability review act shall be deposited in the state treasury in accordance with the provisions of K.S.A. 75-4215, and amendments thereto. Upon receipt of each such remittance, the state treasurer shall deposit the entire amount in the state treasury to the credit of the prescription drug affordability fund.

Sec. 8. (a) Beginning in 2026, on or before December 31 of each year, the board shall submit a written report to the legislature that includes all of the following information:

(1) Price trends for prescription drug products;

(2) the number of prescription drug products that were subject to board review, including the results of the review and the number and disposition of appeals of board decisions; and

(3) any recommendations that the board may have on further legislation to make prescription drug products more affordable in this state.

(b) Prior to the first date of the regular legislative session of 2027, the board shall conduct a one-time study on all of the following and report its findings to the legislature:

(1) The prices of generic drugs on a year-to-year basis;

(2) the degree to which the prices of generic drugs affect yearly insurance premium charges;

(3) annual changes in insurance cost-sharing for generic drugs;

(4) the potential for and history of drug shortages;

(5) the degree to which the prices of generic drugs affect yearly medical assistance program spending in this state;

(6) the impact of an upper payment limit on 340-B program entities; and

(7) any other issue that the board considers relevant.

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