Senate File 2238 - Introduced

SENATE FILE 2238
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A BILL FOR

An Act relating to prescription drug affordability, including the creation of a prescription drug affordability board.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. NEW SECTION. **135S.1 Definitions.**

As used in this chapter, unless the context otherwise requires:

1. *"Biologic"* means a drug that is produced or distributed in accordance with a biologics license issued under 42 C.F.R. §601.4.

2. *"Biosimilar"* means a drug that is produced or distributed in accordance with a biologics license application approved under 42 C.F.R. §262(k)(3).

3. *"Brand-name drug"* means a drug that is produced or distributed in accordance with an original new drug application approved under 21 U.S.C. §355(c). *"Brand-name drug"* does not include an authorized generic drug as defined by 42 C.F.R. §447.502.

4. *"Drug product"* means a brand-name drug, a generic drug, a biologic or biosimilar, or an over-the-counter drug.

5. *"Employee retirement income security Act plan"* or *"ERISA plan"* means any self-funded employee welfare benefit plan governed by the requirements of the Employee Retirement Income Security Act of 1974, as codified at 29 U.S.C. §1001 et seq.

6. *"Generic drug"* means any of the following:

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

b. An authorized generic drug as defined by 42 C.F.R. §447.502.

c. A drug that entered the market before 1962 that was not originally marketed under a new drug application.

7. *"Manufacturer"* means an entity that engages in the manufacture of a drug product, or that enters into a lease with another manufacturer to market and distribute a prescription drug product under the entity's own name, and that sets or changes the wholesale acquisition cost of the prescription drug product it manufactures or markets.

8. *"Over-the-counter drug"* means the same as defined in 42

C.F.R. §447.502.

9. *"Prescription drug affordability board"* or *"board"* means the prescription drug affordability board created in section 135S.2.

10. *"Prescription drug affordability stakeholder council"* or *"stakeholder council"* means the prescription drug affordability stakeholder council created in section 135S.4.

11. *"Prescription drug product"* means a brand-name drug, a generic drug, a biologic, or a biosimilar.

Sec. 2. NEW SECTION. **135S.2 Prescription drug affordability board.**

1. A prescription drug affordability board is created for the purpose of protecting state residents, particularly patients experiencing physical and mental illnesses and communities affected by the opioid crisis; state and local governments; commercial health plans; health care providers; pharmacies; and other stakeholders within the health care system from the high costs of prescription drug products.

2. The board shall be composed of five members, appointed by the governor, subject to confirmation by the senate, who have expertise in health care, health care economics, or clinical medicine. A member shall not be an employee of, a board member of, or a consultant to, a manufacturer or trade association for manufacturers. Any conflict of interest, including whether an individual has an association such as a financial or personal association that has the potential to bias or has the appearance of biasing the individual's decisions in matters related to the board or the conduct of the board's activities shall be disclosed and considered when appointing members to the board.

3. The members shall serve five-year terms beginning and ending as provided in section 69.19. Membership on the board shall be bipartisan as provided in section 69.16 and gender balanced as provided in section 69.16A. Vacancies shall be filed in the manner of the original appointment. The board

shall select a chairperson annually.

4. The board shall hire an executive director, general counsel, and staff to support the board's activities, who shall each receive a salary as provided in the budget for the board. Each member of the board shall receive a per diem and shall be reimbursed for all actual and necessary expenses incurred in the performance of their duties as a member.

5. A majority of the members of the board shall constitute a quorum for the purposes of conducting the business of the board.

6. The board shall meet in open session at least four times annually to review prescription drug product information. The following provisions shall also apply to meetings of the board:

a. The chairperson may cancel or postpone a meeting if there is no business to transact.

b. The following actions by the board shall be made in open session:

(1) Deliberations on whether to subject a prescription drug product to an affordability review.

(2) Any vote on whether to recommend imposing an upper payment limit on purchases and payer reimbursements of prescription drug products in the state.

(3) Any significant decision by the board.

7. The board may meet in closed session to discuss proprietary data and information.

8. The board shall provide public notice of each board meeting at least two weeks in advance of the meeting. Materials for each meeting shall be made available to the public at least one week in advance of the meeting.

9. The board shall provide an opportunity for public comment at each open meeting of the board. The board shall provide the public with the opportunity to submit written comments on pending decisions of the board.

10. The board may allow expert testimony at its meetings, including when the board meets in closed session.

11. *a.* Members of the board shall recuse themselves from decisions related to prescription drug products if the member, or an immediate family member of the member, has received or could receive either of the following:

(1) A direct financial benefit of any amount deriving from the result or finding of a study or determination by or for the board.

(2) A financial benefit from any person that owns, manufactures, or provides prescription drug products, services, or items to be studied by the board that in the aggregate exceeds five thousand dollars per year.

b. For the purposes of this subsection, a financial benefit includes honoraria, fees, stock, the value of the member's or immediate family member's stock holdings, and any direct financial benefit deriving from the finding of a review conducted pursuant to this chapter.

12. *a.* A conflict of interest shall be disclosed by the board when hiring board staff, by the appointing authority when appointing members to the board and to the stakeholder council, and by the board when a member of the board is recused in any final decision resulting from a review of a prescription drug product. A conflict of interest shall be disclosed in advance of the first open meeting after the conflict is identified or within five days after the conflict is identified, whichever is sooner.

b. A conflict of interest disclosed pursuant to this section shall be posted on the internet site of the board unless the chair of the board recuses the member from any final decision resulting from a review of a prescription drug product. Such posting shall include the type, nature, and magnitude of the interests of the member involved.

13. Members of the board, the executive director, the general counsel, board staff, and third-party contractors shall not accept any gift or donation of services or property that indicates a potential conflict of interest, or that has the

appearance of biasing the work of the board.

Sec. 3. NEW SECTION. **135S.3 Powers and duties of the board.**

1. To the extent practicable, the board shall access pricing information for prescription drug products by doing all of the following:

a. Entering into a memorandum of understanding with another state to which manufacturers already report pricing information.

b. Assessing spending for prescription drugs in the state.

c. Accessing other available pricing information based on state reporting and transparency requirements.

2. The board may enter into a contract with a qualified, independent third party for any service necessary to carry out the powers and duties of the board. Unless permission is granted by the board, a third party hired by the board shall not release, publish, or otherwise use any information to which the third party has access under its contract with the board.

3. The board shall adopt rules pursuant to chapter 17A to administer this chapter.

Sec. 4. NEW SECTION. **135S.4 Prescription drug affordability stakeholder council.**

1. The board shall create a prescription drug affordability stakeholder council for the purpose of providing stakeholder input to assist the board in making decisions as required under this chapter. The stakeholder council shall consist of nineteen members appointed in accordance with this section. Members shall include manufacturers of brand-name and generic prescription drugs, health care providers that dispense or administer prescription drugs, prescription drug suppliers, and consumers of prescription drugs. A single organization or entity shall not be represented by more than one council member.

2. *a.* Three members shall be appointed by the majority leader of the senate, two members shall be appointed by the minority leader of the senate, four members shall be appointed

by the speaker of the house of representatives, three members shall be appointed by the minority leader of the house of representatives, and seven members shall be appointed by the governor, subject to confirmation by the senate.

b. The members of the stakeholder council shall have knowledge in one or more of the following subjects:

(1) The pharmaceutical business model.

(2) Supply chain business models.

(3) The practice of medicine or clinical training.

(4) Consumer or patient perspectives.

(5) Health care costs trends and drivers.

(6) Clinical and health services research.

(7) The state's health care marketplace.

c. The stakeholder council shall select a chairperson and a co-chairperson annually from the council membership. The members shall serve three-year staggered terms.

d. A member of the stakeholder council shall not receive a per diem but shall be reimbursed for actual and necessary expenses incurred in the performance of duties as a member.

Sec. 5. NEW SECTION. **135S.5 Drug cost affordability review.**

1. The board shall identify the following prescription drug products offered for sale in the state:

a. Brand-name drugs or biologics that, as adjusted annually for inflation in accordance with the consumer price index, have a launch wholesale acquisition cost of thirty thousand dollars or more per year or per course of treatment, or a wholesale acquisition cost increase of three thousand dollars or more in any consecutive twelve-month period.

b. Biosimilar drugs that have a launch wholesale acquisition cost that is not at least fifteen percent lower than the referenced brand biologic at the time the biosimilar is launched.

c. (1) Generic drugs that, as adjusted for inflation in accordance with the consumer price index, have a wholesale acquisition cost of one hundred dollars or more for any of the

following:

(a) A thirty-day supply lasting a patient for a period of thirty consecutive days based on the recommended dosage approved for labeling by the United States food and drug administration.

(b) A supply lasting a patient fewer than thirty consecutive days based on the recommended dosage approved for labeling by the United States food and drug administration.

(c) One unit of the drug if the labeling approved by the United States food and drug administration does not recommend any finite dosage.

(2) Generic drugs that, as adjusted for inflation in accordance with the consumer price index, have a wholesale acquisition cost that increased by two hundred percent or more during the immediately preceding twelve-month period, as determined by the difference between the resulting wholesale acquisition cost and the average of the wholesale acquisition cost reported over the immediately preceding twelve months.

d. Other prescription drug products that may create affordability challenges for the state health care system and for patients, including drugs used to address public health emergencies.

2. *a.* After identifying prescription drug products as required by subsection 1, the board shall determine whether to conduct an affordability review for each identified prescription drug product by seeking stakeholder council input about the prescription drug product and considering the average patient cost share of the prescription drug product.

b. Relevant information for conducting an affordability review may include any document or research related to the manufacturer's selection of the introductory price or a price increase of the prescription drug product, including lifecycle management, net average prices in the state, market competition and context, projected revenue, and the estimated value or cost effectiveness of the prescription drug product. Failure of a

manufacturer to provide the board with relevant information for an affordability review shall not affect the board's authority to conduct such a review.

3. An affordability review conducted by the board shall determine whether the prescription drug product that is fully consistent with the labeling approved by the United States food and drug administration or standard medical practice has led or will lead to affordability challenges for the state health care system or high out-of-pocket costs for patients. To the extent practicable, in determining whether a prescription drug product has led or will lead to an affordability challenge, the board shall consider the following factors:

a. The wholesale acquisition cost for the prescription drug product sold in the state.

b. The average monetary price concession, discount, or rebate the manufacturer provides, or is expected to provide, to health plans in the state as reported by manufacturers and health plans, expressed as a percentage of the wholesale acquisition cost for the prescription drug product under review.

c. The total amount of the price concession, discount, or rebate the manufacturer provides to each pharmacy benefits manager operating in the state for the prescription drug product under review, as reported by manufacturers and pharmacy benefits managers, expressed as a percentage of the wholesale acquisition cost for the prescription drug under review.

d. The price at which therapeutic alternatives have been sold in the state.

e. The average monetary concession, discount, or rebate the manufacturer provides, or is expected to provide, to health plan payors and pharmacy benefits managers in the state for therapeutic alternatives.

f. The cost to health plans based on patient access consistent with the United State food and drug administration label indications and recognized standard medical practice.

g. The impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design.

h. The current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer.

i. The relative financial impacts to the costs of health, medical, or social services as can be quantified and compared to baseline effects of existing therapeutic alternatives.

j. The average patient copay or other cost-sharing for the prescription drug product in the state.

k. Any information a manufacturer chooses to provide.

l. Any other factors as determined by the board through rules adopted by the board.

4. If the board finds that the spending on a prescription drug product reviewed under this section has led or will lead to an affordability challenge, the board shall submit a report to the general assembly of the board's findings, including a recommended upper payment limit for the prescription drug product. The upper payment limit recommendation shall be made after considering the cost of administering the prescription drug product, the cost of delivering the prescription drug product to consumers, and other relevant administrative costs related to the prescription drug product.

5. Any information submitted to the board in accordance with this section shall be subject to public inspection only to the extent provided under section 22.1.

6. This section shall not be construed to prevent a manufacturer from marketing a prescription drug product approved by the United States food and drug administration in this state while the prescription drug product is under review by the board.

Sec. 6. NEW SECTION. **135S.6 Reporting requirements.**

1. On or before December 31, 2024, and annually thereafter, the board shall submit a report to the general assembly that includes all of the following:

a. Price trends for prescription drug products sold, distributed, and administered in the state.

b. Any recommendations regarding further legislation needed to improve prescription drug affordability in the state.

2. On or before July 1, 2025, the board shall submit a report to the general assembly on the operation of the generic drug market in the United States, including a review of physician-administered drugs, that considers the prices of generic drugs on a year-over-year basis, the degree to which generic drug prices affect yearly insurance premium changes, annual changes in insurance cost-sharing for generic drugs, the potential for and history of drug shortages, the degree to which generic drug prices affect yearly state Medicaid spending, and any other relevant issues.

EXPLANATION

The inclusion of this explanation does not constitute agreement with the explanation's substance by the members of the general assembly.

This bill relates to prescription drug affordability measures, including the creation of a prescription drug affordability board.

The bill provides definitions used in the bill.

The bill creates the prescription drug affordability board (board) for the purpose of protecting stakeholders within the health care system from the high costs of prescription drug products (product or products). The bill provides for the membership and functioning of the board; the hiring of an executive director and other staff for the board; salaries, per diems, and reimbursement of expenses of the executive director, general counsel, staff, and members; and other provisions that apply to the meetings of the board. The board shall meet in open session at least four times annually to review product information, and may meet in closed session to discuss proprietary data and information. The board shall provide public notice of each board meeting at least two weeks in advance of the meeting, make materials for each meeting

available to the public in advance of the meeting, provide an opportunity for public comment at each open meeting of the board, and provide the opportunity for the public to submit written comments on pending decisions of the board.

The board may allow expert testimony at its meetings, including when the board meets in closed session. Members of the board shall recuse themselves from decisions related to products if the member, or an immediate family member of the member, has received or could receive certain financial benefits from the work of the board. The bill provides for disclosure of conflicts of interest relative to the work of the board, and prohibits the members of the board, the executive director, the general counsel, board staff, and third-party contractors from accepting certain gifts or donations.

The bill provides that, to the extent practicable, the board shall access pricing information for products through various means including by entering into memoranda of understanding with another state to which manufacturers already report pricing information; assessing spending for prescription drugs in this state; and accessing other available pricing information based on state reporting and transparency requirements. The board may enter into a contract with a qualified, independent third party for any service necessary to carry out the powers and duties of the board, and shall adopt rules to administer the bill.

The bill requires the board to create a prescription drug affordability stakeholder council (council) to assist the board in making decisions. The council shall consist of 19 members including manufacturers of brand-name and generic prescription drugs, providers that dispense or administer prescription drugs, prescription drug suppliers, and consumers of prescription drugs. Members are appointed by the majority leader of the senate, the minority leader of the senate, the speaker of the house of representatives, the minority leader of the house of representatives, and the governor. The members of

the council shall have knowledge in certain areas as specified in the bill. The bill provides for the annual selection of a chairperson and co-chairperson, terms, and reimbursement of actual and necessary expenses of the members.

The board is required to identify certain brand-name drugs or biologics, biosimilars, generic drugs, and other products that may create affordability challenges for the state health care system and for patients, including drugs used to address public health emergencies.

After identifying the products, the board shall determine whether to conduct an affordability review by seeking council input about the product and considering the average patient cost share of the product. The bill specifies relevant information that may be included in conducting an affordability review. If the board finds that the spending on a product reviewed has led or will lead to an affordability challenge, the board shall submit a report to the general assembly of the board's findings, including a recommended upper payment limit. The upper pay limit for the product shall be determined by considering the cost of administering the product, the cost of delivering the product to consumers, and other relevant administrative costs related to the product. Any information submitted to the board in accordance with the bill is subject to public inspection only to the extent provided under the state's open records law.

The bill requires the board, on or before December 31, 2024, and annually thereafter, to submit to the general assembly a report that includes price trends for products in the state; and any recommendations regarding further legislation needed to improve prescription drug affordability in the state. On or before July 1, 2025, the board shall submit a report to the general assembly on the operation of the generic drug market in the United States that considers the prices of generic drugs on a year-over-year basis, the degree to which generic drug prices affect yearly insurance premium changes, annual changes

in insurance cost-sharing for generic drugs, the potential for and history of drug shortages, the degree to which generic drug prices affect yearly state Medicaid spending, and any other relevant issues.