

**House File 2408 - Introduced**

HOUSE FILE 2408

BY JACOBY

**A BILL FOR**

1 An Act relating to prescription drug affordability, including  
2 the creation of a prescription drug affordability board.  
3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

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

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

4 1. "*Biologic*" means a drug that is produced or distributed  
5 in accordance with a biologics license issued under 42 C.F.R.  
6 §601.4.

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

10 3. "*Brand-name drug*" means a drug that is produced or  
11 distributed in accordance with an original new drug application  
12 approved under 21 U.S.C. §355(c). "*Brand-name drug*" does not  
13 include an authorized generic drug as defined by 42 C.F.R.  
14 §447.502.

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

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

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

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

25 b. An authorized generic drug as defined by 42 C.F.R.  
26 §447.502.

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

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

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

1 C.F.R. §447.502.

2 9. *"Prescription drug affordability board"* or *"board"* means  
3 the prescription drug affordability board created in section  
4 135S.2.

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

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

10 Sec. 2. NEW SECTION. 135S.2 Prescription drug affordability  
11 board.

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

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

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

1 shall select a chairperson annually.

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

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

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

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

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

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

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

23 (3) Any significant decision by the board.

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

26 8. The board shall provide public notice of each board  
27 meeting at least two weeks in advance of the meeting.

28 Materials for each meeting shall be made available to the  
29 public at least one week in advance of the meeting.

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

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

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

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

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

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

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

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

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

1 appearance of biasing the work of the board.

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

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

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

9 b. Assessing spending for prescription drugs in the state.

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

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

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

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

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

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

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

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

- 7 (1) The pharmaceutical business model.
- 8 (2) Supply chain business models.
- 9 (3) The practice of medicine or clinical training.
- 10 (4) Consumer or patient perspectives.
- 11 (5) Health care costs trends and drivers.
- 12 (6) Clinical and health services research.
- 13 (7) The state's health care marketplace.

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

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

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

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

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

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

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

1 following:

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

11    *k.* Any information a manufacturer chooses to provide.

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

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

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

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

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

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

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

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

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

15 EXPLANATION

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

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

21 The bill provides definitions used in the bill.

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

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

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

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

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

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

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

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

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

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