LEGISLATURE OF NEBRASKA

ONE HUNDRED EIGHTH LEGISLATURE

SECOND SESSION

LEGISLATIVE BILL 833

Introduced by Blood, 3.

Read first time January 03, 2024

Committee:

- 1 A BILL FOR AN ACT relating to public health; to adopt the Prescription
- 2 Drug Affordability Act.
- 3 Be it enacted by the people of the State of Nebraska,

1 Section 1. Sections 1 to 16 of this act shall be known and may be

- 2 <u>cited as the Prescription Drug Affordability Act.</u>
- 3 Sec. 2. (1) The Legislature finds that:
- 4 (a) Excessive costs for prescription drugs (i) negatively impacts
- 5 the ability of Nebraskans to obtain prescription drugs and price
- 6 increases that exceed reasonable levels endanger the health and safety of
- 7 Nebraskans, (ii) threaten the economic well-being of Nebraskans and
- 8 endanger their ability to pay for other necessary and essential goods and
- 9 services, including housing, food, and utilities, (iii) contribute
- 10 significantly to a dramatic and unsustainable rise in health care costs
- 11 and health insurance premiums that threaten the financial health of
- 12 <u>Nebraskans and their ability to maintain their physical health, (iv) pose</u>
- 13 <u>a threat to the health and safety of all Nebraskans and</u>
- 14 <u>disproportionately harm people of color and Nebraskans with low incomes,</u>
- 15 and (v) contribute significantly to rising costs for health care provided
- 16 to public employees, including employees of state, county, and local
- 17 governments, school districts, and institutions of higher education, and
- 18 to public retirees whose health care costs are funded by public programs,
- 19 thereby threatening the ability of state and local governments to
- 20 adequately fund those programs and other important services, such as
- 21 <u>public education and public safety;</u>
- 22 (b) Lack of transparency in health insurance costs and wholesaler
- 23 and pharmacy benefit manager discounts and margins prevent policymakers
- 24 and the public from gaining a true understanding of the cost of
- 25 prescription drugs; and
- 26 (c) Information relating to the cost of prescription drugs in
- 27 Nebraska is necessary to provide accountability to the state and to all
- 28 Nebraskans for prescription drug pricing.
- 29 (2) The Legislature therefore declares that it is imperative that
- 30 Nebraska take measures to reduce excessive prescription drug costs for
- 31 Nebraskans who cannot afford prescription drugs and create a prescription

1 drug affordability board with the authority to review prescription drug

- 2 costs and protect Nebraska residents and entities who purchase or
- 3 reimburse for prescription drugs from the excessive costs of prescription
- 4 drugs, including, but not limited to, state and local governments,
- 5 contractors and vendors, commercial health plans, providers, and
- 6 pharmacies.
- 7 Sec. 3. For purposes of the Prescription Drug Affordability Act:
- 8 <u>(1) Advisory council means the Nebraska Prescription Drug</u>
- 9 Affordability Advisory Council created in section 11 of this act;
- 10 (2) Affordability review means an affordability review of a
- 11 prescription drug performed by the board pursuant to section 5 of this
- 12 <u>act;</u>
- 13 (3) Authorized generic drug has the same meaning as set forth in 42
- 14 <u>C.F.R.</u> 447.502;
- 15 (4) Biological product has the same meaning as set forth in 42
- 16 U.S.C. 262(i)(1);
- 17 (5) Biosimilar drug means a prescription drug produced or
- 18 distributed in accordance with a biological product license issued
- 19 pursuant to 42 U.S.C. 262(k)(3);
- 20 <u>(6) Board means the Nebraska Prescription Drug Affordability Review</u>
- 21 Board created in section 4 of this act;
- 22 (7) Brand name drug means a prescription drug produced or
- 23 distributed in accordance with an original new drug application approved
- 24 pursuant to 21 U.S.C. 355 and does not include an authorized generic
- 25 drug;
- 26 <u>(8) Carrier means any entity that provides health coverage in this</u>
- 27 <u>state, including a franchise insurance plan, a fraternal benefit society,</u>
- 28 <u>a health maintenance organization, a nonprofit hospital and health</u>
- 29 <u>service corporation, a sickness and accident insurance company, and any</u>
- 30 other entity providing a plan of health insurance or health benefits
- 31 subject to the insurance laws of Nebraska;

- 1 (9) Conflict of interest means an association, including a financial
- 2 or personal association, that has the potential to bias or appear to bias
- 3 an individual's decisions in matters related to the board or the advisory
- 4 council or the conduct of the activities of the board or the advisory
- 5 council. Conflict of interest includes any instance in which a board
- 6 member, an advisory council member, or a staff member or a contractor of
- 7 the Department of Health and Human Services, on behalf of the board, or
- 8 an immediate family member of a board member, an advisory council member,
- 9 or a staff member or a contractor of the department, on behalf of the
- 10 board, has received or could receive a financial benefit (a) of any
- 11 <u>amount derived from the results or findings of a study or determination</u>
- 12 <u>reached by or for the board or (b) from an individual that owns or</u>
- 13 <u>manufactures a prescription drug service or item that is being or will be</u>
- 14 <u>studied by the board;</u>
- 15 (10) Department means the Division of Public Health of the
- 16 Department of Health and Human Services;
- 17 <u>(11) Financial benefit means honoraria, fees, stock, or any other</u>
- 18 form of compensation, including increases to the value of existing stock
- 19 <u>holdings;</u>
- 20 <u>(12) Generic drug means (a) a prescription drug marketed or</u>
- 21 <u>distributed in accordance with an abbreviated new drug application</u>
- 22 approved pursuant to 21 U.S.C. 355(j), (b) an authorized generic drug, or
- 23 (c) a prescription drug introduced for retail sale before 1962 that was
- 24 <u>not originally marketed under a new drug application;</u>
- 25 (13) Health benefit plan means any hospital or medical expense
- 26 policy or certificate, hospital or medical service corporation contract,
- 27 <u>or health maintenance organization subscriber contract or any other</u>
- 28 similar health contract available for use, offered, or sold in Nebraska.
- 29 Health benefit plan does not include (a) accident only, (b) credit, (c)
- 30 dental, (d) vision, (e) medicare supplement, (f) benefits for long-term
- 31 care, home health care, community-based care, or any combination thereof,

- 1 (g) disability income insurance, (h) liability insurance including
- 2 general liability insurance and automobile liability insurance, (i)
- 3 coverage for onsite medical clinics, (j) coverage issued as a supplement
- 4 to liability insurance, workers' compensation, or similar insurance, (k)
- 5 <u>automobile medical payment insurance</u>, or (1) specified disease, hospital
- 6 <u>confinement indemnity</u>, <u>or limited benefit health insurance if the types</u>
- 7 of coverage do not provide coordination of benefits and are provided
- 8 under separate policies or certificates;
- 9 (14)(a) Large employer means any person, firm, corporation, or
- 10 <u>association that (i) is actively engaged in business, (ii) employed an</u>
- 11 average of more than one hundred eligible employees on business days
- 12 during the immediately preceding calendar year, except as provided in
- 13 <u>subdivision (c) of this subdivision, and (iii) was not formed primarily</u>
- 14 for the purpose of purchasing insurance.
- 15 (b) For purposes of determining whether an employer is a large
- 16 <u>employer</u>, the number of eligible employees is calculated using the method
- 17 <u>set forth in 26 U.S.C. 4980H(c)(2)(E).</u>
- 18 (c) In the case of an employer not in existence throughout the
- 19 preceding calendar quarter, the determination of whether the employer is
- 20 <u>a large employer is based on the average number of employees that the</u>
- 21 employer is reasonably expected to employ on business days in the current
- 22 calendar year;
- 23 (15) Manufacturer means a person that (a) engages in the manufacture
- 24 of a prescription drug sold to purchasers in this state or (b) enters
- 25 into a lease or other contractual agreement with a manufacturer to market
- 26 and distribute a prescription drug under the person's own name and sets
- 27 <u>or changes the wholesale acquisition cost of the prescription drug in</u>
- 28 this state;
- 29 (16) Optional participating plan means a self-funded health benefit
- 30 plan offered in Nebraska that elects to subject its purchases of, or
- 31 payer reimbursements for, prescription drugs for its members to the

- 1 requirements of section 9 of this act;
- 2 (17) Practitioner means a person licensed in Nebraska to prescribe
- 3 <u>any drug or device;</u>
- 4 (18) Prescription drug means a drug that is only intended for human
- 5 use that (a) is required by any applicable federal or state law to be
- 6 dispensed only pursuant to an order, (b) is restricted by any applicable
- 7 federal or state law to use by practitioners only, or (c) prior to being
- 8 dispensed or delivered, is required under federal law to be labeled with
- 9 one of the following statements: (i) "Rx only"; or (ii) "Caution: Federal
- 10 <u>law restricts this drug to use by or on the order of a licensed</u>
- 11 veterinarian";
- 12 (19) Pricing information means information about the price of a
- 13 prescription drug, including information that explains or helps explain
- 14 how the price was determined;
- 15 (20)(a) Small employer means any person, firm, corporation,
- 16 partnership, or association that (i) is actively engaged in business,
- 17 (ii) has employed an average of at least one but not more than one
- 18 hundred eligible employees on business days during the immediately
- 19 preceding calendar year, except as provided in subdivision (d) of this
- 20 <u>subdivision</u>, and (iii) was not formed primarily for the purpose of
- 21 <u>purchasing insurance.</u>
- 22 (b) For purposes of determining whether an employer is a small
- 23 employer, the number of eligible employees is calculated using the method
- 24 <u>set forth in 26 U.S.C. 4980H(c)(2)(E).</u>
- 25 (c) In order to be classified as a small employer with more than one
- 26 employee when only one employee enrolls in the small employer's health
- 27 <u>benefit plan, the small employer shall submit to the small employer</u>
- 28 <u>carrier the two most recent quarterly employment and tax statements</u>
- 29 <u>substantiating that the employer had two or more eligible employees. Such</u>
- 30 small employer group shall also meet the participation requirements of
- 31 the small employer carrier.

- 1 (d) In the case of an employer that was not in existence throughout
- 2 the preceding calendar quarter, the determination of whether the employer
- 3 is a small employer is based on the average number of employees that the
- 4 employer is reasonably expected to employ on business days in the current
- 5 calendar year.
- 6 (e) The following employers are single employers for purposes of
- 7 determining the number of employees: (i) A person or entity that is a
- 8 single employer pursuant to 26 U.S.C. 414(b), (c), (m), or (o); and (ii)
- 9 an employer and any predecessor employer;
- 10 (21) State entity means any agency of state government that
- 11 purchases or reimburses payers for prescription drugs on behalf of the
- 12 <u>state for a person whose health care is paid for by the state, including</u>
- 13 any agent, vendor, contractor, or other party acting on behalf of the
- 14 state;
- 15 (22) Upper payment limit means the maximum amount that may be paid
- 16 or billed for a prescription drug dispensed or distributed in Nebraska in
- 17 any financial transaction concerning the purchase of, or reimbursement
- 18 for, a prescription drug;
- 19 (23) Wholesale acquisition cost has the same meaning as set forth in
- 20 <u>42 U.S.C. 1395w-3a(c)(6)(B); and</u>
- 21 (24) Wholesaler means a person engaged in the wholesale distribution
- 22 of prescription drugs to persons, other than consumers, that are
- 23 authorized by law to possess prescription drugs.
- 24 Sec. 4. (1) The Nebraska Prescription Drug Affordability Review
- 25 Board is created in the Division of Public Health of the Department of
- 26 Health and Human Services.
- 27 <u>(2)(a) The board consists of five members, who shall each have an</u>
- 28 advanced degree and experience or expertise in health care economics or
- 29 <u>clinical medicine.</u>
- 30 (b) The Governor shall appoint each board member, subject to
- 31 confirmation by a majority of members of the Legislature.

- 1 (c) The term of office of each board member is three years, except
- 2 that, as to the terms of the members who are first appointed to the
- 3 board, two such members shall serve three-year initial terms, two such
- 4 members shall serve two-year initial terms, and one such member shall
- 5 serve a one-year initial term, to be determined by the Governor.
- 6 (d) The Governor shall designate one member of the board to serve as
- 7 the chairperson. A majority of the board constitutes a quorum. The
- 8 concurrence of a majority of the board in any matter within its powers
- 9 and duties is required for any determination made by the board.
- 10 (3)(a) An individual who is being considered for appointment to the
- 11 board shall disclose any conflict of interest. When appointing a member
- 12 <u>of the board, the Governor shall consider any conflict of interest</u>
- 13 <u>disclosed by the prospective member.</u>
- 14 (b) A board member shall not be an employee, board member, or
- 15 consultant of: (i) A manufacturer or a trade association of
- 16 <u>manufacturers; (ii) a carrier or a trade association of carriers; or</u>
- 17 (iii) a pharmacy benefit manager or a trade association of pharmacy
- 18 benefit managers.
- 19 (c) Board members, staff members, and contractors of the department,
- 20 on behalf of the board, shall recuse themselves from any board activity
- 21 or vote in any case in which they have a conflict of interest.
- 22 (d) On and after January 1, 2025, the department shall maintain a
- 23 page on its public website for the board to use for its purposes. The
- 24 board shall publish on the website each conflict of interest that is
- 25 disclosed to the board pursuant to subdivision (3)(c) of this section and
- 26 section 11 of this act.
- 27 (e) Board members, staff members, contractors of the department, on
- 28 behalf of the board, and immediate family members of board members, staff
- 29 members, or contractors shall not accept a financial benefit or gifts,
- 30 bequests, or donations of services or property that suggest a conflict of
- 31 interest or have the appearance of creating bias in the work of the

- 1 board.
- 2 Sec. 5. (1) To protect Nebraska consumers from excessive
- 3 prescription drug costs, the board shall:
- 4 (a) Collect and evaluate information concerning the cost of
- 5 prescription drugs sold to Nebraska consumers, as described in section 7
- 6 of this act;
- 7 (b) Perform affordability reviews of prescription drugs, as
- 8 described in section 8 of this act;
- 9 <u>(c) Establish upper payment limits for prescription drugs, as</u>
- 10 <u>described in section 9 of this act; and</u>
- 11 (d) Make policy recommendations to the Legislature to improve the
- 12 <u>affordability of prescription drugs for Nebraska consumers, as described</u>
- 13 <u>in subdivision (1)(h) of section 16 of this act.</u>
- 14 (2) The board may establish ad hoc work groups to consider matters
- 15 related to the work of the board pursuant to the Prescription Drug
- 16 Affordability Act. Ad hoc work groups may include members of the public.
- 17 <u>(3) The department, on behalf of the board, may enter into a</u>
- 18 <u>contract with a qualified independent third party for any service</u>
- 19 <u>necessary to carry out the powers and duties of the board. A third party</u>
- 20 with which the department contracts pursuant to this subsection,
- 21 including any of the third party's directors, officers, employees,
- 22 contractors, or agents, shall not release or publish any information that
- 23 the third party acquires pursuant to its performance under the contract.
- 24 Any third party with which the department contracts pursuant to this
- 25 subsection shall disclose any conflict of interest to the board.
- 26 (4) In carrying out its duties on behalf of the board, the
- 27 department shall be exempt from the state contracting requirements
- 28 provided in sections 73-501 to 73-510.
- 29 (5) The department may adopt and promulgate rules and regulations to
- 30 <u>carry out the Prescription Drug Affordability Act.</u>
- 31 (6) The department, on behalf of the board, may seek, accept, and

1 expend gifts, grants, and donations from private or public sources for

- 2 the purposes of the act, except that the department shall not accept any
- 3 gift, grant, or donation that creates a conflict of interest or the
- 4 appearance of any conflict of interest for any board member.
- 5 Sec. 6. (1) The board shall hold its first meeting within six weeks
- 6 after all board members are appointed and shall meet at least every six
- 7 weeks thereafter to review prescription drugs, except that the
- 8 <u>chairperson may cancel or postpone a meeting if the board has no</u>
- 9 prescription drugs to review or for good cause.
- 10 (2) The board is a public body for purposes of the Open Meetings
- 11 Act, and the board's meetings and the meetings of ad hoc work groups are
- 12 <u>public meetings.</u>
- 13 (3) The board shall meet in executive session to discuss proprietary
- 14 information. The board and any board members, officers, directors,
- 15 employees, contractors, and agents shall not disclose or otherwise make
- 16 available to the public any materials or information containing trade
- 17 secret, confidential, or proprietary data that is not otherwise available
- 18 to the public. Electronic recordings of such executive sessions are not
- 19 permitted if they would result in the disclosure of any materials or
- 20 information containing trade secret, confidential, or proprietary data,
- 21 and in no case shall minutes from such executive sessions disclose or
- 22 include materials or information containing trade secret, confidential,
- 23 or proprietary data. The board shall not take any of the following
- 24 <u>actions while meeting in executive session:</u>
- 25 (a) Deliberations concerning whether to subject a prescription drug
- 26 to an affordability review as described in section 8 of this act;
- 27 <u>(b) Votes concerning whether to establish an upper payment limit on</u>
- 28 a prescription drug; or
- 29 <u>(c) Any final decision of the board.</u>
- 30 Sec. 7. (1) Beginning January 1, 2025, for all prescription drugs
- 31 dispensed at a pharmacy in this state and paid for by a carrier pursuant

- 1 to a health benefit plan during the immediately preceding calendar year,
- 2 including brand name drugs, authorized generic drugs, biological
- 3 products, and biosimilar drugs, each carrier and each pharmacy benefit
- 4 management firm acting on behalf of a carrier shall report to the
- 5 department the following information:
- 6 (a) The top fifteen prescription drugs for which the carrier paid by
- 7 volume, calculated by unit;
- 8 <u>(b) The fifteen costliest prescription drugs for which the carrier</u>
- 9 paid, as determined by total annual plan spending;
- 10 (c) The fifteen prescription drugs paid for by the carrier that
- 11 accounted for the highest increase in total annual plan spending when
- 12 <u>compared with the total annual plan spending for the same prescription</u>
- 13 <u>drugs in the year immediately preceding the year for which the</u>
- 14 <u>information is reported;</u>
- 15 (d) The fifteen prescription drugs that caused the greatest
- 16 increases in the carrier's premiums;
- 17 (e) The fifteen prescription drugs for which the carrier paid most
- 18 frequently and for which the carrier received a rebate from
- 19 <u>manufacturers;</u>
- 20 <u>(f) The fifteen prescription drugs for which the carrier received</u>
- 21 the highest rebates, as determined by percentages of the price of the
- 22 prescription drug;
- 23 (g) The fifteen prescription drugs for which the carrier received
- 24 <u>the largest rebates;</u>
- 25 (h) The total spending for each of the following categories of
- 26 prescription drugs: (i) Brand name drugs purchased from retail
- 27 pharmacies; (ii) authorized generic drugs purchased from retail
- 28 pharmacies; (iii) brand name drugs purchased from mail-order pharmacies;
- 29 (iv) authorized generic drugs purchased from mail-order pharmacies; (v)
- 30 prescription drugs dispensed by a practitioner; (vi) prescription drugs
- 31 administered in an inpatient hospital setting; and (vii) prescription

- 1 drugs administered in an outpatient hospital setting; and
- 2 <u>(i) The total spending for the prescription drugs described in</u>
- 3 <u>subdivision</u> (h) of this subsection paid for by a carrier pursuant to a
- 4 health benefit plan during the immediately preceding calendar year for
- 5 each of the following market sectors:
- 6 (i) Individual;
- 7 (ii) Small employer; and
- 8 <u>(iii) Large employer.</u>
- 9 (2) The department shall provide to the Department of Insurance the
- 10 <u>information reported by carriers and pharmacy benefit management firms</u>
- 11 pursuant to subsection (1) of this section.
- 12 (3)(a) Except as provided in subdivision (3)(b) of this section, the
- 13 Department of Insurance shall: (i) Post the information reported by
- 14 carriers and pharmacy benefit management firms pursuant to this section
- 15 on the Department of Insurance's website; and (ii) provide the
- 16 information reported by carriers and pharmacy benefit management firms
- 17 pursuant to this section to the board, in a form and manner prescribed by
- 18 the board.
- 19 (b) If a carrier or pharmacy benefit management firm claims that
- 20 information submitted pursuant to this section is confidential or
- 21 proprietary, the Department of Insurance shall review the information and
- 22 redact specific items that the carrier or pharmacy benefit management
- 23 firm demonstrates to be confidential or proprietary. The Department of
- 24 Insurance shall not disclose redacted items to any person, except (i) as
- 25 may be required by sections 84-712 to 84-712.09 and (ii) to employees of
- 26 the Department of Insurance, as necessary.
- 27 (4) The requirement in this section to report information relating
- 28 to the cost of prescription drugs is intended to create transparency in
- 29 <u>prescription drug pricing and does not:</u>
- 30 (a) Prohibit a manufacturer of a prescription drug from making
- 31 pricing decisions about its prescription drugs; or

1 (b) Prohibit purchasers, both public and private, or pharmacy

- 2 <u>benefit management firms from negotiating discounts and rebates</u>
- 3 <u>consistent with existing state and federal law.</u>
- 4 Sec. 8. (1) The board may conduct affordability reviews of
- 5 prescription drugs in accordance with this section. The board shall
- 6 <u>identify</u>, for purposes of determining whether to conduct an affordability
- 7 review:
- 8 <u>(a) Any prescription drug that has:</u>
- 9 (i) A wholesale acquisition cost of three thousand dollars or more;
- 10 (ii) An increase of three hundred dollars or more above the
- 11 wholesale acquisition cost for the prescription drug in the preceding
- 12 twelve months;
- 13 (iii) An increase of two hundred percent or more above the wholesale
- 14 <u>acquisition cost for the prescription drug in the preceding twelve</u>
- 15 months; or
- 16 <u>(iv) A current wholesale acquisition cost for an average course of</u>
- 17 treatment per person per year of thirty thousand dollars or more;
- 18 (b) Any biosimilar drug that has an initial wholesale acquisition
- 19 cost that is not at least fifteen percent lower than the wholesale
- 20 acquisition cost of the corresponding biological product; and
- 21 <u>(c) A generic drug:</u>
- 22 (i) That, as adjusted annually for inflation, has a wholesale
- 23 acquisition cost of one hundred dollars or more for:
- 24 (A) A thirty-day supply based on the recommended dosage approved for
- 25 labeling by the federal Food and Drug Administration;
- 26 (B) A supply that lasts less than thirty days based on the
- 27 recommended dosage approved for labeling by the federal Food and Drug
- 28 Administration; or
- 29 <u>(C) One dose of the generic drug if the labeling approved by the</u>
- 30 federal Food and Drug Administration does not recommend a finite dosage;
- 31 <u>and</u>

- 1 (ii) For which the wholesale acquisition cost increased by two
- 2 <u>hundred percent or more during the immediately preceding twelve months,</u>
- 3 as determined by comparing the current wholesale acquisition cost to the
- 4 average wholesale acquisition cost reported during the immediately
- 5 <u>preceding twelve months.</u>
- 6 (2) After identifying prescription drugs as described in subsection
- 7 (1) of this section, the board shall determine whether to conduct an
- 8 affordability review for an identified prescription drug by:
- 9 (a) Evaluating the class of the prescription drug and whether any
- 10 therapeutically equivalent prescription drugs are available for sale;
- 11 (b) Evaluating aggregated data;
- 12 (c) Seeking and considering input from the advisory council about
- 13 the prescription drug; and
- 14 (d) Considering the average patient's out-of-pocket cost for the
- 15 prescription drug.
- 16 (3) If the board conducts an affordability review of a prescription
- 17 drug, the affordability review shall determine whether use of the
- 18 prescription drug consistent with the labeling approved for the
- 19 prescription drug by the federal Food and Drug Administration or with
- 20 <u>standard medical practice is unaffordable for Nebraska consumers.</u>
- 21 (4) In performing an affordability review, to the extent
- 22 practicable, the board shall consider:
- 23 (a) The wholesale acquisition cost of the prescription drug;
- 24 (b) The cost and availability of therapeutic alternatives to the
- 25 prescription drug in the state;
- 26 <u>(c) The effect of the price on Nebraska consumers' access to the</u>
- 27 prescription drug;
- 28 <u>(d) The relative financial effects on health, medical, or social</u>
- 29 <u>services costs, as the effects can be quantified and compared to baseline</u>
- 30 effects of existing therapeutic alternatives to the prescription drug;
- 31 (e) The patient copayment or other cost sharing that is associated

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1 with the prescription drug and typically required pursuant to health

- 2 benefit plans issued by carriers in the state;
- 3 (f) The impact on safety net providers if the prescription drug is
- 4 available through the federal Public Health Service Act, 42 U.S.C. 256b;
- 5 (g) Orphan drug status;
- 6 (h) Input from (i) patients and caregivers affected by the condition
- 7 or disease that is treated by the prescription drug that is under review
- 8 by the board and (ii) individuals who possess scientific or medical
- 9 training with respect to a condition or disease treated by the
- 10 prescription drug that is under review by the board;
- 11 (i) Any other information that a manufacturer, carrier, pharmacy
- 12 <u>benefit management firm, or other entity chooses to provide; and</u>
- (j) Any other factors as determined by the board.
- 14 (5) Trade secret, confidential, or proprietary information obtained
- 15 by the board pursuant to this section may be accessed only by board
- 16 members and staff or by a qualified independent third party that has
- 17 contracted with the department pursuant to section 5 of this act and is
- 18 subject to a nondisclosure agreement prohibiting disclosure of such
- 19 information. Any person with access to such information shall protect the
- 20 information from direct or indirect publication or release to any person.
- 21 (6) In performing an affordability review of a prescription drug,
- 22 the board may consider any documents and information relating to the
- 23 manufacturer's selection of the introductory price or price increase of
- 24 the prescription drug, including documents and information relating to:
- 25 (a) Life-cycle management;
- 26 (b) The average cost of the prescription drug in the state;
- 27 (c) Market competition and context;
- 28 (d) Projected revenue;
- 29 (e) The estimated cost-effectiveness of the prescription drug; and
- 30 <u>(f) Off-label usage of the prescription drug.</u>
- 31 (7)(a) To the extent practicable, the board may access pricing

- 1 information for prescription drugs by:
- 2 <u>(i) Accessing publicly available pricing information from a state to</u>
- 3 which manufacturers report pricing information;
- 4 (ii) Accessing available pricing information from the department and
- 5 <u>from state entities; and</u>
- 6 (iii) Accessing information that is available from other countries.
- 7 <u>(b) To the extent that there is no publicly available information</u>
- 8 with which to conduct an affordability review, the board may request that
- 9 a manufacturer, carrier, or pharmacy benefit management firm provide
- 10 pricing information for any prescription drug identified pursuant to
- 11 <u>subsection</u> (1) of this <u>section</u>. The failure of an entity to provide
- 12 <u>pricing information to the board for an affordability review does not</u>
- 13 affect the authority of the board to conduct the affordability review.
- 14 (8) The board shall issue a report summarizing the data that the
- 15 board considered in making the board's determination as to whether a
- 16 prescription drug is unaffordable to the extent permitted by section 6 of
- 17 this act. The board shall make the report available on its website.
- 18 Sec. 9. (1)(a) The board may establish an upper payment limit for
- 19 any prescription drug for which the board has performed an affordability
- 20 review pursuant to section 8 of this act and determined that the use of
- 21 <u>the prescription drug is unaffordable for Nebraska consumers, except</u>
- 22 <u>that:</u>
- 23 <u>(i) The board may not establish an upper payment limit for more than</u>
- 24 twelve prescription drugs in each calendar year for three years beginning
- 25 January 1, 2025, unless the board determines that there is a need to
- 26 establish upper payment limits for more than twelve prescription drugs,
- 27 <u>in which case the board may establish an upper payment limit for up to</u>
- 28 eighteen prescription drugs so long as the board has sufficient staff
- 29 support to do so; and
- 30 (ii) For each prescription drug for which the board establishes an
- 31 upper payment limit, the board may include multiple national drug codes,

1 as described in 21 C.F.R. 207.33, that are indicated for the prescription

- 2 <u>drug.</u>
- 3 (b) The failure of an entity to provide information to the board
- 4 pursuant to subdivision (7)(b) of section 8 of this act does not affect
- 5 the authority of the board to establish an upper payment limit for a
- 6 prescription drug.
- 7 (2) The board shall determine the methodology for establishing an
- 8 upper payment limit for a prescription drug to protect consumers from the
- 9 excessive cost of prescription drugs and ensure they can access
- 10 prescription drugs necessary for their health. The methodology shall
- 11 <u>consider:</u>
- 12 <u>(a) The cost of administering or dispensing the prescription drug;</u>
- 13 (b) The cost of distributing the prescription drug to consumers;
- 14 (c) The status of the prescription drug on the drug shortage list
- 15 published by the drug shortage program within the federal Food and Drug
- 16 Administration; and
- 17 (d) Other relevant costs related to the prescription drug.
- 18 (3) The methodology determined by the board pursuant to subsection
- 19 (2) of this section:
- 20 <u>(a) Shall not consider research or methods that employ a dollars-</u>
- 21 per-quality adjusted life year, or similar measure, that discounts the
- 22 value of a life because of an individual's disability or age; and
- 23 <u>(b) Shall authorize a pharmacy licensed by the state to charge</u>
- 24 reasonable fees, to be paid by the providing health benefit plan of the
- 25 consumer, for dispensing or delivering a prescription drug for which the
- 26 board has established an upper payment limit.
- 27 (4) An upper payment limit applies to all purchases of, and payer
- 28 reimbursements for, a prescription drug that is dispensed or administered
- 29 to individuals in the state in person, by mail, or by other means and for
- 30 which an upper payment limit is established. The board shall provide an
- 31 effective date for any upper payment limit established by the board,

- 1 which shall be at least six months after the establishment of the upper
- 2 payment limit. An upper payment limit shall apply only to purchases,
- 3 contracts, and plans that are issued on, or renewed after, the effective
- 4 date.
- 5 (5) The board shall notify consumers of any decision to establish an
- 6 upper payment limit pursuant to this section in a manner determined by
- 7 the board.
- 8 (6) Any information submitted to the board in accordance with this
- 9 section or section 7 or 8 of this act is subject to public inspection
- 10 only to the extent allowed under sections 84-712 to 84-712.09, and in no
- 11 <u>case shall trade secret, confidential, or proprietary information be</u>
- 12 <u>disclosed to any person who is not authorized to access such information</u>
- 13 pursuant to section 8 of this act.
- 14 <u>(7) For any upper payment limit established by the board pursuant to</u>
- 15 this section, the board shall:
- 16 (a) Inquire of manufacturers of the prescription drug as to whether
- 17 each such manufacturer is able to make the prescription drug available
- 18 for sale in the state and request the rationale for the manufacturer's
- 19 response; and
- 20 (b) Submit annually to the Health and Human Services Committee of
- 21 the Legislature the response of each manufacturer to the inquiry
- 22 described in subdivision (7)(a) of this section.
- 23 Sec. 10. (1) The following board functions are not final agency
- 24 actions subject to administrative review under the Administrative
- 25 Procedure Act:
- 26 (a) Identification of eligible prescription drugs pursuant to
- 27 <u>subsection (1) of section 8 of this act;</u>
- 28 (b) Selection of a prescription drug pursuant to subsection (2) of
- 29 section 8 of this act; and
- 30 (c) Determination that a prescription drug is unaffordable pursuant
- 31 to subsection (3) of section 8 of this act.

1 (2) The establishment of an upper payment limit by the board is a

- 2 final agency action subject to administrative review under the
- 3 Administrative Procedure Act. A party seeking administrative review of an
- 4 upper payment limit may seek review of whether the prescription drug
- 5 satisfies the necessary criteria in section 8 of this act to be eliqible
- 6 for an upper payment limit.
- 7 Sec. 11. (1)(a) The Nebraska Prescription Drug Affordability
- 8 Advisory Council is created in the department to provide stakeholder
- 9 input to the board regarding the affordability of prescription drugs. The
- 10 advisory council consists of fourteen members appointed by the board as
- 11 follows:
- 12 (i) Two members who are health care consumers or who represent
- 13 <u>health care consumers;</u>
- 14 (ii) One member representing a statewide health care consumer
- 15 <u>advocacy organization;</u>
- 16 (iii) One member representing health care consumers who are living
- 17 with chronic diseases;
- 18 (iv) One member representing a labor union;
- 19 (v) One member representing employers;
- 20 (vi) One member representing carriers;
- 21 (vii) One member representing pharmacy benefit management firms;
- 22 (viii) One member representing health care professionals with
- 23 prescribing authority;
- 24 (ix) One member who is employed by an organization that performs
- 25 research concerning prescription drugs, including research concerning
- 26 pricing information;
- 27 (x) One member representing manufacturers of brand name drugs;
- 28 (xi) One member representing manufacturers of generic drugs;
- 29 (xii) One member representing pharmacists; and
- 30 (xiii) One member representing wholesalers.
- 31 (b) To the extent possible, the board shall appoint council members

1 who have experience serving underserved communities and reflect the

- 2 <u>diversity of the state with regard to race, ethnicity, immigration</u>
- 3 status, income, wealth, disability, age, gender identity, and geography.
- 4 (c) The initial members of the advisory council shall be appointed
- 5 by January 1, 2025.
- 6 (2) Each member of the advisory council shall possess knowledge of
- 7 at least one of the following subject matters:
- 8 (a) The pharmaceutical business model;
- 9 <u>(b) Supply chain business models;</u>
- 10 (c) The practice of medicine or clinical training;
- (d) Health care consumer or patient perspectives;
- 12 <u>(e) Health care cost trends and drivers;</u>
- 13 <u>(f) Clinical and health services research; or</u>
- 14 (g) The state's health care marketplace.
- 15 (3) The term of each member of the advisory council is three years.
- 16 (4) The chairperson of the board shall designate one member of the
- 17 advisory council to serve as chairperson of the advisory council.
- 18 (5)(a) An individual who is being considered for appointment to the
- 19 advisory council shall disclose any conflict of interest to the board in
- 20 <u>a form and manner prescribed by the board. When appointing a member of</u>
- 21 <u>the advisory council, the board shall consider any conflict of interest</u>
- 22 <u>disclosed by the prospective member.</u>
- 23 (b) The chairperson of the advisory council shall report to the
- 24 board any conflict of interest that is disclosed to the advisory council.
- 25 The board shall include information concerning such disclosures on its
- 26 <u>public website pursuant to subdivision (3)(d) of section 4 of this act.</u>
- 27 <u>(6) The advisory council shall meet at least once every three</u>
- 28 months.
- 29 <u>(7) The advisory council shall conduct all of its meetings in public</u>
- 30 except that it may meet privately in groups of three or fewer members to
- 31 gather and understand data or to establish, organize, and plan for the

- 1 business of the advisory council.
- 2 Sec. 12. (1) Any savings generated for a health benefit plan that
- 3 is attributable to the establishment of an upper payment limit
- 4 established by the board pursuant to section 9 of this act shall be used
- 5 by the carrier that issues the health benefit plan to reduce costs to
- 6 consumers, prioritizing the reduction of out-of-pocket costs for
- 7 prescription drugs.
- 8 (2) On or before March 15, 2026, and on or before March 15 of each
- 9 year thereafter, each state entity and each carrier that issues a health
- 10 benefit plan or optional participating plan shall submit to the board a
- 11 report describing the savings achieved during the preceding plan year for
- 12 <u>each prescription drug for which the board established an upper payment</u>
- 13 <u>limit during the preceding year and how those savings were used to</u>
- 14 <u>satisfy the requirement described in subsection (1) of this section.</u>
- 15 (3) On or before November 1, 2025, the board shall establish a
- 16 formula for calculating savings for the purpose of complying with
- 17 subsection (1) of this section and shall publish such formula on its
- 18 website.
- 19 Sec. 13. (1) On and after January 1, 2026, it is unlawful for any
- 20 person to purchase or reimburse a payer for a prescription drug for which
- 21 the board has established an upper payment limit pursuant to section 9 of
- 22 this act at an amount that exceeds the upper payment limit established by
- 23 the board for that prescription drug, regardless of whether the
- 24 prescription drug is dispensed or distributed in person, by mail, or by
- 25 other means.
- 26 (2) On and after January 1, 2026, each state entity, carrier, and
- 27 <u>optional participating plan shall require compliance with an upper</u>
- 28 payment limit established by the board.
- 29 (3) The Attorney General is authorized to enforce the Prescription
- 30 Drug Affordability Act on behalf of any state entity or any consumer of
- 31 prescription drugs.

1 (4) As used in this section, a person is not an individual who

- 2 <u>acquires a prescription drug for the individual's own use or for a family</u>
- 3 member's use.
- 4 (5) A carrier or state agency that is required by state or federal
- 5 law to purchase or reimburse a payer for a prescription drug for which
- 6 the board has established an upper payment limit pursuant to section 9 of
- 7 this act is not subject to an enforcement action for a violation of
- 8 subsection (1) or (2) of this section for such prescription drug.
- 9 Sec. 14. (1) Any manufacturer that intends to withdraw a
- 10 prescription drug from sale or distribution for which the board has
- 11 <u>established an upper payment limit pursuant to section 9 of this act</u>
- 12 <u>shall provide a notice of withdrawal in writing at least one hundred</u>
- 13 <u>eighty days before the withdrawal to:</u>
- 14 (a) The Department of Insurance;
- 15 (b) The Attorney General; and
- 16 (c) Each entity in the state with which the manufacturer has
- 17 contracted for the sale or distribution of the prescription drug.
- 18 (2) The board shall notify consumers of the intent of any
- 19 manufacturer to withdraw a prescription drug from sale or distribution
- 20 within the state, as described in subsection (1) of this section, in a
- 21 manner determined by the board.
- 22 (3) The Department of Insurance may require a manufacturer to pay a
- 23 penalty not to exceed five hundred thousand dollars if it determines that
- 24 the manufacturer failed to provide the notice required by subsection (1)
- 25 of this section before withdrawing a prescription drug from sale or
- 26 distribution for which the board has established an upper payment limit
- 27 pursuant to section 9 of this act.
- 28 Sec. 15. An optional participating plan that elects to subject its
- 29 purchases of, or payer reimbursements for, prescription drugs in Nebraska
- 30 to the requirements of the Prescription Drug Affordability Act shall
- 31 notify the Department of Insurance in writing within thirty days after

- 1 such election.
- 2 Sec. 16. (1) On or before July 1, 2026, and on or before July 1 of
- 3 each year thereafter, the board shall submit a report to the Governor and
- 4 the Health and Human Services Committee of the Legislature summarizing
- 5 the work of the board during the preceding calendar year. The report
- 6 shall include:
- 7 (a) Publicly available data concerning price trends for prescription
- 8 <u>drugs;</u>
- 9 (b) The number of prescription drugs that were subjected to an
- 10 <u>affordability review by the board pursuant to section 8 of this act,</u>
- 11 <u>including the results of each affordability review;</u>
- 12 <u>(c) A list of each prescription drug for which the board established</u>
- 13 an upper payment limit pursuant to section 9 of this act, including the
- 14 amount of the upper payment limit;
- 15 (d) The impact of any upper payment limits established by the board
- 16 pursuant to section 9 of this act on health care providers, pharmacies,
- 17 <u>and patients' ability to access any prescription drug;</u>
- 18 (e) A summary of the administrative reviews of board decisions,
- 19 <u>including the outcome of each review;</u>
- 20 <u>(f) A description of each conflict of interest that was disclosed to</u>
- 21 the board during the preceding year;
- 22 (g) A description of any violations of any of the provisions of the
- 23 Prescription Drug Affordability Act, including any enforcement action
- 24 <u>taken in response to any such violation; and</u>
- 25 (h) Any recommendations the board has for the Legislature concerning
- 26 policy changes to increase the affordability of prescription drugs and
- 27 <u>reduce the effects of excess costs on consumers and commercial health</u>
- 28 insurance premiums in the state.
- 29 (2) The board shall publish the report described in subsection (1)
- 30 of this section on its website pursuant to subdivision (3)(d) of section
- 31 4 of this act.

- 1 (3) The chairperson of the board shall present to the Health and
- 2 <u>Human Services Committee of the Legislature, information concerning each</u>
- 3 prescription drug for which the board established an upper payment limit
- 4 <u>during the preceding calendar year. The chairperson shall summarize for</u>
- 5 <u>the committee members:</u>
- 6 (a) The affordability review of each prescription drug, including
- 7 the results of the board's considerations as described in subsection (4)
- 8 of section 8 of this act and, if applicable, subsection (6) of section 8
- 9 of this act; and
- 10 (b) The establishment of the upper payment limit, including a
- 11 <u>summary of the methodology used to establish the upper payment limit.</u>