SB 844-A9
(LC 3689)
6/15/21 (LHF/ps)

Requested by Senator COURTNEY

PROPOSED AMENDMENTS TO
A-ENGROSSED SENATE BILL 844

On page 1 of the printed A-engrossed bill, line 2, after "drugs" insert "; creating new provisions; and amending ORS 646A.689".

Delete lines 4 through 25 and delete pages 2 through 9 and insert:

"SECTION 1. (1) The Prescription Drug Affordability Board is established in the Department of Consumer and Business Services to protect residents of this state, state and local governments, commercial health plans, health care providers, pharmacies licensed in this state and other stakeholders within the health care system in this state from the high costs of prescription drugs.

"(2) The board consists of five members and three alternates appointed by the Governor.

"(3) The term of office of each member of the board is four years, but a member serves at the pleasure of the Governor. Before the expiration of the term of a member, the Governor shall appoint a successor whose term begins on January 1 next following. A member is eligible for reappointment. If there is a vacancy for any cause, the Governor shall make an appointment to become immediately effective for the unexpired term.

"(4) The appointment of each member of the board is subject to confirmation by the Senate in the manner prescribed in ORS 171.562 and 171.565.

"(5) A member of the board is entitled to compensation and expenses as provided in ORS 292.495.

"(6) The members of the board must be residents of this state with expertise in health care economics and clinical medicine.

"(7) A member of the board may not be an employee of, a board member of or a consultant to a manufacturer or a trade association of manufacturers.

"(8) The board shall select one of its members as chairperson and another as vice chairperson, for terms and with duties and powers necessary for the performance of the functions of the offices as the board determines.

"(9) A majority of the members of the board constitutes a quorum for the transaction of business.

"(10) The department shall appoint an executive director for the board, may employ consultants, investigators or other staff and shall provide staff support to the board to carry out its duties.

"(11) The board shall meet at least once every six weeks at a time and place determined by the chairperson. The chairperson may cancel or postpone a regular meeting if there is no prescription drug to review. The board may also meet at other times and places specified by the call of the chairperson or of a majority of the members of the board.

"(12)(a) The following actions by the board shall be open to the public in accordance with ORS 192.610 to 192.690:

"(A) Any deliberation on whether to conduct an affordability review of a prescription drug under section 3 of this 2021 Act; and

"(B) Any decision or deliberation toward a decision on any matter before the board except as provided in paragraph (b) of this subsection.

"(b) The board may meet in executive session to discuss trade secret information.

"(13) The board shall:

"(a) Provide public notice of each board meeting at least two weeks in advance of the meeting;

"(b) Make materials for each board meeting available to the public at least one week in advance of the meeting;

"(c) Provide an opportunity for public comment at each open meeting of the board; and

"(d) Provide the public with the opportunity to submit written comments on any pending decision of the board.

"(14) The board may allow expert testimony at board meetings, including when the board meets in executive session.

"(15)(a) A member of the board shall recuse the member from decisions related to a prescription drug if the member, or an immediate family member of the member, has received or could receive any of the following:

"(A) A direct financial benefit of any amount deriving from the result or finding of a study, review or determination by or for the board; or

"(B) A financial benefit from any person that owns, manufactures, or provides prescription drugs, services or items to be reviewed by the board that in the aggregate exceeds $5,000 per year.

"(b) For the purposes of paragraph (a) 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 result or finding of a study, review or determination by or for the board.

"(c) A conflict of interest shall be disclosed:

"(A) By the board when hiring board staff;

"(B) By the Governor when appointing members and alternate members to the board; and

"(C) By the board, when a member of the board is recused in any final decision resulting from a review of a prescription drug.

"(d) A conflict of interest shall be disclosed at the earlier of:

"(A) Prior to the first board meeting after the conflict is identified; or

"(B) Within five days after the conflict is identified.

"(e) A conflict of interest disclosed under this section shall be posted on the website of the board unless the chairperson of the board recuses the member from any final decision resulting from a review of a prescription drug.

"(f) A posting under paragraph (e) of this subsection shall include the type, nature and magnitude of the conflict of interest of the member involved.

"(16) Members and alternate members of the board, staff and third parties that contract with the board may not accept any gift or donation of services or property that creates a potential conflict of interest or has the appearance of biasing the work of the board.

"(17)(a) 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.

"(b) Unless permission is granted by the board, a third party hired by the board may not release, publish or otherwise use any information to which the third party has access under its contract.

"(18) In accordance with applicable provisions of ORS chapter 183, the board may adopt rules necessary for the administration of sections 1 to 3 of this 2021 Act.

"SECTION 2. (1) The Department of Consumer and Business Services shall provide to the Prescription Drug Affordability Board each calendar quarter a list of prescription drugs included in reports submitted to the department under ORS 646A.689 (2) and (6), a list of

drugs included in reports submitted to the department under ORS 743.025 and a list of insulin drugs marketed in this state during the previous calendar year. Each calendar year, the board shall identify nine drugs and at least one insulin product from the lists provided under this subsection that the board determines may create affordability challenges for health care systems or high out-of-pocket costs for patients in this state based on criteria adopted by the board by rule, including but not limited to:

"(a) Whether the prescription drug has led to health inequities in communities of color;

"(b) The number of residents in this state prescribed the prescription drug;

"(c) The price for the prescription drug sold in this state;

"(d) The estimated average monetary price concession, discount or rebate the manufacturer provides to health insurance plans in this state or is expected to provide to health insurance plans in this state, expressed as a percentage of the price for the prescription drug under review;

"(e) The estimated total amount of the price concession, discount or rebate the manufacturer provides to each pharmacy benefit manager registered in this state for the prescription drug under review, expressed as a percentage of the prices;

"(f) The estimated price for therapeutic alternatives to the drug that are sold in this state;

"(g) The estimated average price concession, discount or rebate the manufacturer provides or is expected to provide to health insurance plans and pharmacy benefit managers in this state for therapeutic alternatives;

"(h) The estimated costs to health insurance plans based on patient use of the drug consistent with the labeling approved by the United

States Food and Drug Administration and recognized standard medical practice;

"(i) The impact on patient access to the drug considering standard prescription drug benefit designs in health insurance plans offered in this state;

"(j) The relative financial impacts to health, medical or social services costs as can be quantified and compared to the costs of existing therapeutic alternatives;

"(k) The estimated average patient copayment or other cost-sharing for the prescription drug in this state;

"(L) Any information a manufacturer chooses to provide; and

"(m) Any other factors as determined by the board in rules adopted by the board.

"(2) A drug that is designated by the Secretary of the United States Food and Drug Administration, under 21 U.S.C. 360bb, as a drug for a rare disease or condition is not subject to review under subsection (1) of this section.

"(3) The board shall accept testimony from patients and caregivers affected by a condition or disease that is treated by a prescription drug under review by the board and from individuals with scientific or medical training with respect to the disease or condition.

"(4)(a) If the board considers the cost-effectiveness of a prescription drug in criteria adopted by the board under subsection (1) of this section, the board may not use quality-adjusted life-years, or similar formulas that take into account a patient's age or severity of illness or disability, to identify subpopulations for which a prescription drug would be less cost-effective. For any prescription drug that extends life, the board's analysis of cost-effectiveness must weigh the value of the quality of life equally for all patients, regardless of the patients' age or severity of illness or disability.

"(b) As used in this subsection:

"(A) 'Health utility' means a measure of the degree to which having a particular form of disease or disability or having particular functional limitations negatively impacts the quality of life as compared to a state of perfect health, expressed as a number between 0 and 1.

"(B) 'Quality-adjusted life-year' is the product of a health utility multiplied by the extra months or years of life that a patient might gain as a result of a treatment.

"(5) To the extent practicable, the board shall access pricing information for prescription drugs by:

"(a) Accessing pricing information collected by the department under ORS 646A.689 and 743.025;

"(b) Accessing data reported to the Oregon Health Authority under ORS 442.373;

"(c) Entering into a memorandum of understanding with another state to which manufacturers already report pricing information; and

"(d) Accessing other publicly available pricing information.

"(6) The information used to conduct an affordability review may include any document and research related to the introductory price or price increase of a prescription drug, including life cycle management, net average price in this state, market competition and context, projected revenue and the estimated value or cost-effectiveness of the prescription drug.

"(7) The department and the board shall keep strictly confidential any information collected, used or relied upon for the review conducted under this section if the information is:

"(a) Information submitted to the department by a manufacturer under ORS 646A.689; and

"(b) Confidential, proprietary or a trade secret as defined in ORS 192.345.

"SECTION 3. (1) The Department of Consumer Business Services shall adopt by rule, in consultation with the Prescription Drug Affordability Board, annual fees to be paid by manufacturers that sell prescription drugs in this state. The fees shall be established in amounts necessary to meet the costs of the department and the board in administering sections 1 to 3 of this 2021 Act. The fees shall be imposed based on a manufacturer's share of gross revenue from sales of prescription drugs in this state.

"(2) Fees collected under this section shall be deposited in the Prescription Drug Affordability Account established in section 4 of this 2021 Act.

"SECTION 4. The Prescription Drug Affordability Account is established as a subaccount in the Consumer and Business Services Fund created in ORS 705.145, consisting of moneys collected under section 3 of this 2021 Act and moneys that may be appropriated for deposit into the Prescription Drug Affordability Account by the Legislative Assembly. Interest earned on the account shall be credited to the account. Moneys in the account are continuously appropriated to the Prescription Drug Affordability Board to carry out sections 1 to 3 of this 2021 Act.

"SECTION 5. No later than December 31 of each year, the Prescription Drug Affordability Board shall report to the Health Care Cost Growth Target program established in ORS 442.386 and to the interim committees of the Legislative Assembly related to health, in the manner provided in ORS 192.245, the following information:

"(1) Price trends for the list of prescription drugs provided to the board by the Department of Consumer and Business Services under section 2 (1) of this 2021 Act;

"(2) The prescription drugs that were reviewed under section 2 of this 2021 Act; and

"(3) Recommendations, if any, for legislative changes necessary to make prescription drug products more affordable in this state.

"SECTION 6. (1) As used in this section, 'generic drug' means:

"(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 as defined by 42 C.F.R. 447.502; or

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

"(2) The Prescription Drug Affordability Board shall annually conduct a study of the operation of the United States market for generic drugs, both drugs dispensed by pharmacists and drugs administered by physicians, including:

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

"(b) The degree to which generic drug prices affect insurance premiums;

"(c) Annual changes in health insurance cost-sharing for generic drugs;

"(d) The potential for and history of generic drug shortages;

"(e) The degree to which generic drug prices affect annual spending in the state medical assistance program; and

"(f) Any other topic the board considers relevant to the cost of generic drugs.

"(3) No later than June 1 of each calendar year, the board shall report to the Legislative Assembly the findings of the board's study in the manner provided in ORS 192.245.

SECTION 7. (1) The Prescription Drug Affordability Board shall study the entire prescription drug distribution and payment system in this state and polices adopted by other states and countries that are designed to lower the list price of prescription drugs including but not

limited to the following options:

(a) Establishing upper payment limits for all financial transactions in this state involving a drug and specifying the methodology used to determine the upper payment limit that does not undermine the viability of any part of the prescription drug supply chain;

(b) Using a reverse auction marketplace for the purchase of prescription drugs by state and local governments; and

(c) Implementing a bulk purchasing process for state and local governments to purchase prescription drugs.

(2) No later than December 31, 2022, the board shall complete the study described in subsection (1) of this section and report to the interim committees of the Legislative Assembly related to health in the manner provided in ORS 192.245:

(a) The board's findings including findings for each option described in subsection (1) of this section; and

(b) Recommendations for policies to lower the list prices of prescription drugs sold in this state and for legislative changes necessary to implement the policies.

"SECTION 8. ORS 646A.689 is amended to read:

"646A.689. (1) As used in this section **and sections 1 to 3 of this 2021 Act**:

"(a) 'Drug' has the meaning given that term in ORS 689.005.

"(b) 'Health care facility' has the meaning given that term in ORS 442.015.

"(c) 'Health care service contractor' has the meaning given that term in ORS 750.005.

"(d)(A) 'Manufacture' means:

"(i) The production, preparation, propagation, compounding, conversion or processing of a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; and

"(ii) The packaging or repackaging of a drug or labeling or relabeling of a drug container.

"(B) 'Manufacture' does not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug:

"(i) By a health care practitioner incidental to administering or dispensing a drug in the course of professional practice;

"(ii) By a health care practitioner or at the practitioner's authorization and supervision for the purpose of or incidental to research, teaching or chemical analysis activities and not for sale;

"(iii) By a health care service contractor for dispensing to a subscriber or delivery to a health care facility or outpatient clinic owned or operated by the health care service contractor or an affiliate of the health care service contractor;

"(iv) By a centralized repackaging operation for distribution to subscribers of health care service contractors or to pharmacies, health care facilities or outpatient clinics operated by or affiliated with a health care service contractor; or

"(v) By a health care facility for dispensing to a patient or other person.

"(e) 'Manufacturer' means a person that manufactures a prescription drug that is sold in this state.

"(f) 'New prescription drug' has the meaning prescribed by the Department of Consumer and Business Services by rule.

"(g) 'Patient assistance program' means a program that a manufacturer offers to the general public in which a consumer may reduce the consumer's out-of-pocket costs for prescription drugs by using coupons or discount cards, receiving copayment assistance or by other means.

"(h) 'Prescription drug' means a drug that must:

"(A) Under federal law, be labeled 'Caution: Federal law prohibits dispensing without prescription' prior to being dispensed or delivered; or

"(B) Under any applicable federal or state law or regulation, be dispensed only by prescription or restricted to use only by health care practitioners.

"(i) 'Price' means the wholesale acquisition cost as defined in 42 U.S.C. 1395w-3a(c)(6)(B).

"(2) No later than March 15 of each year, a manufacturer shall report the information described in subsection (3) of this section to the department regarding each prescription drug for which:

"(a) The price was $100 or more for a one-month supply or for a course of treatment lasting less than one month; and

"(b) There was a net increase of 10 percent or more in the price of the prescription drug described in paragraph (a) of this subsection over the course of the previous calendar year.

"(3) For each prescription drug described in subsection (2) of this section, a manufacturer shall report to the department, in the form and manner prescribed by the department:

"(a) The name and price of the prescription drug and the net increase, expressed as a percentage, in the price of the drug over the course of the previous calendar year;

"(b) The length of time the prescription drug has been on the market;

"(c) The factors that contributed to the price increase;

"(d) The name of any generic version of the prescription drug available on the market;

"(e) The research and development costs associated with the prescription drug that were paid using public funds;

"(f) The direct costs incurred by the manufacturer:

"(A) To manufacture the prescription drug;

"(B) To market the prescription drug;

"(C) To distribute the prescription drug; and

"(D) For ongoing safety and effectiveness research associated with the prescription drug;

"(g) The total sales revenue for the prescription drug during the previous calendar year;

"(h) The manufacturer's profit attributable to the prescription drug during the previous calendar year;

"(i) The introductory price of the prescription drug when it was approved for marketing by the United States Food and Drug Administration and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years;

"(j) The 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States;

"(k) Any other information that the manufacturer deems relevant to the price increase described in subsection (2)(b) of this section; and

"(L) The documentation necessary to support the information reported under this subsection.

"(4) The department may use any prescription drug price information the department deems appropriate to verify that manufacturers have properly reported price increases as required by subsections (2) and (3) of this section.

"(5) A manufacturer shall accompany the report provided under subsection (2) of this section with the following information about each patient assistance program offered by the manufacturer to consumers residing in this state for the prescription drugs described in subsection (2) of this section:

"(a) The number of consumers who participated in the program;

"(b) The total value of the coupons, discounts, copayment assistance or other reduction in costs provided to consumers in this state who participated in the program;

"(c) For each drug, the number of refills that qualify for the program, if applicable;

"(d) If the program expires after a specified period of time, the period of time that the program is available to each consumer; and

"(e) The eligibility criteria for the program and how eligibility is verified

for accuracy.

"(6) No later than 30 days after a manufacturer introduces a new prescription drug for sale in the United States at a price that exceeds the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program, the manufacturer shall notify the department, in the form and manner prescribed by the department, of all the following information:

"(a) A description of the marketing used in the introduction of the new prescription drug;

"(b) The methodology used to establish the price of the new prescription drug;

"(c) Whether the United States Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;

"(d) If the new prescription drug was not developed by the manufacturer, the date of and the price paid for acquisition of the new prescription drug by the manufacturer;

"(e) The manufacturer's estimate of the average number of patients who will be prescribed the new prescription drug each month; and

"(f) The research and development costs associated with the new prescription drug that were paid using public funds.

"(7)(a) After receiving the report or information described in subsections (2), (3), (5) or (6) of this section, the department may make a written request to the manufacturer for supporting documentation or additional information concerning the report. The department shall prescribe by rule the periods:

"(A) Following the receipt of the report or information during which the department may request additional information; and

"(B) Following a request by the department for additional information during which a manufacturer may respond to the request.

"(b) The department may extend the period prescribed under paragraph

(a)(B) of this subsection, as necessary, on a case-by-case basis.

"(8) A manufacturer may be subject to a civil penalty, as provided in ORS 646A.692, for:

"(a) Failing to submit timely reports or notices as required by this section;

"(b) Failing to provide information required under this section;

"(c) Failing to respond in a timely manner to a written request by the department for additional information under subsection (7) of this section; or

"(d) Providing inaccurate or incomplete information under this section.

"(9) Except as provided in subsection (10) of this section, the department shall post to its website all of the following information:

"(a) A list of the prescription drugs reported under subsection (2) of this section and the manufacturers of those prescription drugs;

"(b) Information reported to the department under subsections (3) and (5) to (7) of this section; and

"(c) Written requests by the department for additional information under subsection (7) of this section.

"(10)(a) The department may not post to its website any information described in subsection (9) of this section if:

"(A) The information is conditionally exempt from disclosure under ORS 192.345 as a trade secret; and

"(B) The public interest does not require disclosure of the information.

"(b) If the department withholds any information from public disclosure pursuant to this subsection, the department shall post to its website a report describing the nature of the information and the department's basis for withholding the information from disclosure.

"(c) A person may petition the Attorney General, as provided in ORS 192.411, to review a decision by the department to withhold information pursuant to paragraph (a) of this subsection.

"**(11) In accordance with section 2 of this 2021 Act, the department shall provide to the Prescription Drug Affordability Board established in section 1 of this 2021 Act:**

"(a) Each calendar quarter, a list of prescription drugs included in reports submitted under subsections (2) and (6) of this section; and

"(b) Access to pricing information submitted to the department under subsections (3), (6) and (7) of this section.

"[*(11)*] **(12)** The department shall make available to consumers, online and by telephone, a process for consumers to notify the department about an increase in the price of a prescription drug.

"[*(12)*] **(13)** The department may adopt rules as necessary for carrying out the provisions of this section, including but not limited to rules establishing fees to be paid by manufacturers to be used solely to pay the costs of the department in carrying out the provisions of this section.

"[*(13)*] **(14)** No later than December 15 of each year, the department shall compile and report the information collected by the department under this section to the interim committees of the Legislative Assembly related to health. The report shall include recommendations for legislative changes, if any, to contain the cost of prescription drugs and reduce the impact of price increases on consumers, the Department of Corrections, the Public Employees' Benefit Board, the Oregon Health Authority, the Department of Human Services, the Oregon Educators Benefit Board and health insurance premiums in the commercial market.

"SECTION 9. Notwithstanding the term of office specified by section 1 of this 2021 Act, of the members first appointed to the Prescription Drug Affordability Board:

"(1) One member and one alternate shall serve for a term ending December 31, 2024.

"(2) Two members and one alternate shall serve for a term ending December 31, 2025.

"(3) Two members, including the chairperson, and one alternate shall serve for a term ending December 31, 2026.

"SECTION 10. There is appropriated to the Department of Consumer and Business Services, for the biennium beginning July 1, 2021, out of the General Fund, the amount of $1,786,192 for the purpose of carrying out the provisions of sections 1 to 7 of this 2021 Act.".
