SENATE AMENDMENTS TO SENATE BILL 289

By COMMITTEE ON HEALTH CARE

March 19

In line 2 of the printed bill, after "drugs" insert "; amending ORS 646A.689, 646A.694, 646A.696 and 646A.697".

Delete lines 4 through 8 and insert:

"**SECTION 1.** ORS 646A.689 is amended to read:

"646A.689. (1) As used in ORS 646A.680 to 646A.697:

"(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 pre-

scription' 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 subsection (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 ORS 646A.694, the department shall provide to the Prescription Drug Affordability Board established in ORS 646A.693:

"(a) Each calendar [*quarter*] **year**, 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.

"(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. Any personally identifiable information about a consumer included in a notification provided to the department under this subsection, such as a consumer's name, address, telephone number or electronic mail address, is confidential and not subject to disclosure under ORS 192.311 to 192.478.

"(13) The department may adopt rules as necessary for carrying out the provisions of this section.

"(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 2.** ORS 646A.694, as amended by section 12, chapter 87, Oregon Laws 2024, is amended to read:

"646A.694. (1) The Department of Consumer and Business Services shall provide to the Prescription Drug Affordability Board each calendar [*quarter*] **year** 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 646A.683 and 743.025 and a list of insulin drugs marketed in this state during the previous calendar year. Each calendar year, the board shall identify **up to** 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 licensed 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 zero and one.

"(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.** ORS 646A.696 is amended to read:

"646A.696. 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 ORS 646A.694 (1);

"(2) The prescription drugs that were reviewed under ORS 646A.694 (1);

"**(3) The status of the generic drug market as described in ORS 646A.697;** and

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

"**SECTION 4.** ORS 646A.697 is amended to read:

"646A.697. (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*] **status of the generic drug market includes but is not limited to**:

"(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; **and**

"(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*].".
