SB 560-A5
(LC 2147)
5/27/21 (LHF/ps)

Requested by Senator GELSER

PROPOSED AMENDMENTS TO
A-ENGROSSED SENATE BILL 560

On page 1 of the printed A-engrossed bill, line 2, after "ORS" insert "646A.689,".

Delete line 7.

In line 8, delete "(b)" and insert "(a)".

After line 8, insert:

"(b)(A) 'Generic equivalent' means a drug that meets applicable standards of strength, quality and purity according to the United States Pharmacopeia or other national recognized compendium and that, compared to a brand name drug:

"(i) Has an identical amount of the same active chemical ingredients and the same dosage form; and

"(ii) If administered in the same amounts, will provide comparable therapeutic effects.

"(B) 'Generic equivalent' does not include a drug that is listed by the United States Food and Drug Administration as having unresolved bioequivalence concerns according to the administration's most recent publication of approved drug products with therapeutic equivalence evaluations.".

On page 2, delete lines 8 through 10 and insert:

"(e) 'Pharmacy benefit manager' means a pharmacy benefit manager, as defined in ORS 735.530, that manages pharmacy benefits for a health plan.

"(2) To the extent permitted by federal law, an insurer offering a health plan that provides pharmacy benefits and a pharmacy benefit manager shall include all amounts paid by an enrollee or paid by another person on behalf of an enrollee toward the cost of a covered prescription drug when calculating the enrollee's contribution to an out-of-pocket maximum, deductible, copayment, coinsurance or other cost-sharing requirement applied to the drug if:

"(a) The drug does not have a generic equivalent; or

"(b) The drug has a generic equivalent and the enrollee has:

"(A) Obtained prior authorization from the insurer or pharmacy benefit manager;

"(B) Complied with a step therapy protocol; or

"(C) Received approval from the insurer or pharmacy benefit manager through the insurer's or the pharmacy benefit manager's exceptions, appeal or review process.".

On page 8, delete lines 42 through 44 and insert:

"SECTION 7. ORS 646A.689 is amended to read:

"646A.689. (1) As used in this section:

"(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 dur-

ing 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**; and**

"(f) The total amount of money the manufacturer estimates will be spent by the manufacturer for the patient assistance program in the

first year the drug is available for sale in this state.

"(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) 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) 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) 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 8. Section 2 of this 2021 Act and the amendments to ORS 646A.689, 743B.001 and 750.055 by sections 3 to 7 of this 2021 Act apply to health plans, as defined in section 2 of this 2021 Act, issued, renewed or extended on or after the effective date of this 2021 Act.".
