House Bill 2696

Sponsored by Representative NOSSE; Representative SANCHEZ (Presession filed.)

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure **as introduced.**

Establishes Drug Cost Review Commission to determine excess costs for certain prescription drugs and to set maximum payment rates for certain prescription drugs sold in this state by suppliers other than manufacturers. Requires investigation by Attorney General of complaints of payment rates that exceed payment rates established by commission. Adds new provisions considered unlawful trade practices.

A BILL FOR AN ACT

Relating to the cost of prescription drugs; creating new provisions; and amending ORS 646.607.

Be It Enacted by the People of the State of Oregon:

DRUG COST REVIEW COMMISSION

(Establishment and Membership)

SECTION 1. (1) The Drug Cost Review Commission is established.

(2) The commission consists of five members with expertise in health care economics or clinical medicine who are appointed as follows:

(a) The Governor shall appoint three members;

(b) The President of the Senate shall appoint one member; and

(c) The Speaker of the House of Representatives shall appoint one member.

(3) The Governor shall appoint two individuals with expertise in health care economics or clinical medicine to serve as alternates. An alternate shall participate in the deliberations and vote as a member of the commission in the place of a commissioner who must be excluded from deliberations or a vote of the commission due to a conflict of interest in accordance with ORS 244.120.

(4) The term of office of each member of the commission is four years. Before the expiration of the term of a member, the appointing authority 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 appointing authority shall make an appointment to become immediately effective for the unexpired term.

(5) The appointment of each member of the commission appointed by the Governor is subject to confirmation by the Senate in the manner prescribed in ORS 171.562 and 171.565.

(6) The Governor shall select one of the members of the commission to serve as chairperson, and the chairperson shall appoint a cochairperson, for terms and with duties and powers necessary for the performance of the functions of the offices as determined by the commission.

(7) A majority of the members of the commission constitutes a quorum for the trans-

NOTE: Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

action of business. For the purposes of a quorum or a vote on any official action, an alternate appointed under subsection (3) of this section shall be counted as a member of the commission if acting in place of a commissioner excluded due to a conflict of interest in accordance with ORS 244.120.

(8) Any official action of the commission must be taken by a vote of a majority of the members of the commission.

(9) A member of the commission is entitled to compensation and expenses as provided in ORS 292.495.

(10) The commission shall appoint an executive director to serve at the pleasure of the commission.

(11) The designation of the executive director must be by written order, filed with the Secretary of State.

(12) Subject to any applicable provisions of ORS chapter 240, the executive director shall appoint all subordinate officers and employees of the commission, prescribe their duties and fix their compensation.

(13) In accordance with applicable provisions of ORS chapter 183, the commission may adopt rules necessary for the administration of the laws that the commission is charged with administering.

(Meetings and Duties)

SECTION 2. (1) The Drug Cost Review Commission shall meet at least once every six weeks at a time and place determined by the chairperson. The chairperson may cancel or postpone any meeting if there are no drug cost reviews pending. The commission may meet at other times and places specified by the call of the chairperson or of a majority of the members of the commission. Meetings of the commission are subject to ORS 192.610 to 192.690.

(2) The commission shall provide public notice of a meeting of the commission no less than two weeks prior to the scheduled meeting date.

(3) Except as provided in subsection (7) of this section, the commission shall make all materials to be considered at a meeting of the commission available to the public at least seven days prior to the scheduled meeting date.

(4) The commission shall provide opportunities for public testimony to be presented at meetings of the commission and shall accept written comments from the public.

(5) The commission may allow expert testimony to be presented at commission meetings and during executive sessions.

(6) The commission may not meet in executive session to:

(a) Deliberate on whether to undertake a drug cost review;

(b) Discuss or determine excess costs; or

(c) Deliberate or vote on payment rates established under section 13 of this 2019 Act.

(7) The commission shall adopt by rule criteria for withholding from public disclosure, as proprietary information, information submitted to the commission by manufacturers.

(8) The chairperson, cochairperson and executive director of the commission and authorized representatives of the chairperson, cochairperson and executive director may administer oaths, take depositions and issue subpoenas to compel the attendance of witnesses

and the production of documents or other written information necessary to carry out the provisions of this section and sections 1, 4 and 6 to 13 of this 2019 Act. If any person fails to comply with a subpoena issued under this section or refuses to testify on matters on which the person lawfully may be interrogated, the procedure set out in ORS 183.440 shall be followed to compel obedience.

SECTION 3. Notwithstanding the term of office specified by section 1 of this 2019 Act, of the members first appointed to the Drug Cost Review Commission, the Governor shall select:

(1) One member appointed by the Governor to serve for a term ending December 31, 2021.

(2) One member to serve for a term ending December 31, 2022.

(3) One member to serve for a term ending December 31, 2023.

(4) Two members to serve for terms ending December 31, 2024.

(Drug Cost Review Commission
Advisory Committee)

SECTION 4. (1) The Governor shall appoint an 11-member Drug Cost Review Commission Advisory Committee to advise the Drug Cost Review Commission on drug cost issues and to represent stakeholder views.

(2) The term of office of each member of the advisory committee is two years. The Governor shall select one of the members of the advisory committee to serve as chairperson, and the chairperson shall appoint a cochairperson, for terms and with duties and powers necessary for the functions of the offices as determined by the Governor.

(3) Members of the advisory committee shall be selected based on their knowledge of one or more of the following subjects:

(a) The business model of the pharmaceutical industry;

(b) The practice of medicine or clinical training;

(c) Patients' perspectives;

(d) Health care cost trends and drivers;

(e) Research in clinical and health services; or

(f) The health care marketplace in this state.

(4) The advisory committee must include:

(a) Two members representing the interests of patients and health care consumers;

(b) Two members representing the interests of physicians and providers with prescribing privileges;

(c) Two members representing the interests of commercial payers, the Public Employees' Benefit Board and large employers;

(d) One member representing the interests of pharmaceutical manufacturers;

(e) One member involved in health care research;

(f) One member involved in clinical research;

(g) One member who is a pharmacologist; and

(h) One member from the Oregon Department of Administrative Services.

(5) Members of the advisory committee are not entitled to compensation but, in the discretion of the chairperson, may be reimbursed from funds available to the commission for actual and necessary travel and other expenses incurred by the members of the advisory

committee in the performance of official duties in the manner and amount provided in ORS 292.495.

SECTION 5. Notwithstanding the term of office specified by section 4 of this 2019 Act, of the members first appointed to the Drug Cost Review Commission Advisory Committee, the Governor shall select:

(1) Three members to serve for terms ending December 31, 2021.

(2) Four members to serve for terms ending December 31, 2022.

(3) Four members to serve for terms ending December 31, 2023.

(Conflicts of Interest)

SECTION 6. (1) To the greatest extent practicable, an appointing authority shall avoid appointing an individual with a conflict of interest to the Drug Cost Review Commission or a senior staff position in the commission and shall disclose conflicts of interest, if any, at the time of appointment.

(2) A member of the commission with a conflict of interest with regard to any prescription drug subject to a drug cost review shall disclose the conflict of interest by the earlier of the fifth day after a conflict is identified or in advance of any public meeting. If a member of the commission discloses a conflict of interest after official action has been taken on the matter, the chairperson of the commission shall schedule a new vote on the matter without participation of the member who has the conflict of interest.

(3) A staff person to the commission with a conflict of interest concerning a drug subject to a drug cost review may neither advise the commission, the Drug Cost Review Commission Advisory Committee or any member of the commission or advisory committee nor provide research or other assistance to the commission, advisory committee or a member with respect to the drug that is being considered in a drug cost review.

(4) Members of the commission and staff to the commission are prohibited from accepting gifts, bequests or donations of services or property that may create the appearance of bias in the commission's or staff's work.

DEFINITIONS

SECTION 7. As used in sections 1, 2, 4 and 6 to 13 of this 2019 Act:

(1) "Brand name prescription drug" means a prescription drug that:

(a) Is sold under a proprietary or trade name by its manufacturer; and

(b)(A) Is patented or has exclusive marketing rights granted by the United States Food and Drug Administration; or

(B) Has an expired patent or had exclusive marketing rights granted by the United States Food and Drug Administration that have expired.

(2) "Conflict of interest" means, for purposes of ORS 244.120:

(a) An association, including a financial or personal association, that has the potential to bias or has the appearance of biasing an individual's decision in matters related to the Drug Cost Review Commission; and

(b) Receipt by a member of the commission or a member's relative, as defined in ORS 244.020, of:

(A) A direct financial benefit of any amount deriving from any findings of the commission or a determination by the commission; and

(B) A financial benefit exceeding $5,000 per year from a person that manufactures a prescription drug that is subject to a drug cost review.

(3) "Drug cost review" means the process described in section 12 of this 2019 Act.

(4) "Excess costs" means:

(a) The cost of an appropriate use of a prescription drug that exceeds the cost of alternative treatment options with equivalent therapeutic benefits; or

(b) The cost of an appropriate use of a prescription drug that is not financially sustainable for public and private health care systems over a period of 10 years.

(5) "Financial benefit" means:

(a) Honoraria;

(b) Fees;

(c) Stock;

(d) Improvement in the current value of the existing stock holdings of a member of the Drug Cost Review Commission or a member's relative; or

(e) Other pecuniary benefit.

(6) "Generic drug" means a prescription drug that:

(a) Is not patented;

(b) Does not have exclusive marketing rights granted by the United States Food and Drug Administration; and

(c) Is considered to be therapeutically equivalent to a brand name prescription drug.

(7)(a) "Manufacture" means:

(A) 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

(B) 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:

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

(B) 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;

(C) 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;

(D) 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

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

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

(9) "Payer" means any person that purchases one or more prescription drugs or that pays claims for reimbursement of the cost of a prescription drug.

(10) "Payment rate" means the amount of reimbursement claimed for a prescription drug by a supplier of the drug.

(11) "Prescription drug" or "drug" means a drug, including a biologic and a biosimilar 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 administered by a health care practitioner.

(12) "Supplier" means any entity in the supply chain of a prescription drug other than the manufacturer of the drug.

(13) "Wholesale acquisition cost" has the meaning given that term in 42 U.S.C. 1395w-3a(c)(6)(B).

DRUG COST REVIEW

(Manufacturer Notice for Patented Products)

SECTION 8. (1) A manufacturer shall notify the Drug Cost Review Commission if the manufacturer intends to increase the wholesale acquisition cost of a patented brand name prescription drug by more than 10 percent or by $3,000 or more during any 12-month period, or if the manufacturer intends to introduce to the market a patented brand name prescription drug that will have a wholesale acquisition cost of $30,000 or more per course of treatment. The notice must be provided in writing at least 30 days prior to the planned effective date of the increase in the wholesale acquisition cost or the introduction of the drug to the market and must include the justification described in section 10 of this 2019 Act.

(2) After consultation with stakeholders and experts, the commission shall adopt by rule criteria for determining whether an increase in the wholesale acquisition cost of a patented brand name prescription drug or the introductory wholesale acquisition cost of a new patented brand name prescription drug, not otherwise subject to the notice requirements under subsection (1) of this section, makes the drug unaffordable to patients residing in this state who are or will be prescribed the drug. A manufacturer shall provide the justification described in section 10 of this 2019 Act for any increase in the wholesale acquisition cost of a patented brand name prescription drug meeting the criteria adopted under this subsection or for the introductory wholesale acquisition cost of a new patented brand name prescription drug meeting the criteria adopted under this subsection.

(Manufacturer Notice for Generic Products and Off-Patent Brand Name Products)

SECTION 9. (1) A manufacturer shall notify the Drug Cost Review Commission if the manufacturer intends to:

(a) Increase the wholesale acquisition cost of a generic drug by more than 25 percent or by $300 or more;

(b) Increase the wholesale acquisition cost of an off-patent brand name prescription drug

by more than 25 percent or by $10,000 or more; and

(c) Introduce to the market a generic drug that will have a wholesale acquisition cost of $3,000 or more per course of treatment.

(2) The notice provided under subsection (1) of this section must be provided in writing at least 30 days prior to the planned effective date of the increase in the wholesale acquisition cost or the introduction of the drug and must include the justification described in section 10 of this 2019 Act.

(3) After consultation with stakeholders and experts, the commission shall adopt by rule criteria for determining whether an increase in the wholesale acquisition cost of a generic drug or an off-patent brand name prescription drug or the introductory wholesale acquisition cost of a new generic drug or an off-patent brand name prescription drug, not otherwise subject to the notice requirements under subsection (1) of this section, makes the drug unaffordable to patients residing in this state who are or will be prescribed the drug. A manufacturer shall provide the justification described in section 10 of this 2019 Act for any increase in the wholesale acquisition cost of a generic drug or an off-patent brand name prescription drug meeting the criteria adopted under this subsection or for the introductory wholesale acquisition cost of a new generic drug or off-patent brand name prescription drug meeting the criteria adopted under this subsection.

(Justification)

SECTION 10. A justification submitted to the Drug Cost Review Commission in accordance with section 8 or 9 of this 2019 Act shall include:

(1) All documents and research related to the manufacturer's determination of the proposed increase in the wholesale acquisition cost of a prescription drug or the proposed introductory wholesale acquisition cost of a drug, including but not limited to:

(a) The average price for the drug in this state minus all price concessions except in-kind concessions;

(b) Market competition for the drug;

(c) Projected revenue from the drug; and

(d) If available, estimated value or cost-effectiveness of the drug; and

(2) Any other documentation prescribed by the commission by rule.

(Criteria for Selection of Drugs for Cost Review)

SECTION 11. (1) The Drug Cost Review Commission shall make publicly available all information provided in a notice under section 8 or 9 of this 2019 Act except for proprietary information meeting the criteria adopted by the commission under section 2 (7) of this 2019 Act. The commission shall provide the public with an opportunity to request that the commission undertake a drug cost review of an increase in the wholesale acquisition cost or the introductory wholesale acquisition cost of any prescription drug reported under section 8 or 9 of this 2019 Act.

(2) The chairperson of the commission shall consider the public requests and decide whether to undertake a drug cost review of a drug described in section 8 or 9 of this 2019 Act. The chairperson of the commission may also choose to undertake a drug cost review

despite receiving no public requests concerning an increase in the wholesale acquisition cost or the introductory wholesale acquisition cost of a drug that was the subject of a notification under section 8 or 9 of this 2019 Act.

(3) A majority of the members of the commission may vote to undertake or decline to undertake a drug cost review if they do not agree with the decision of the chairperson.

(Evaluating for Excess Costs)

SECTION 12. (1) In a drug cost review, the Drug Cost Review Commission shall evaluate whether the use of a prescription drug, as approved by the United States Food and Drug Administration, will result in excess costs for consumers and health care systems in this state by considering the following factors, as appropriate and applicable:

(a) The price charged to consumers and health care systems in this state for the prescription drug.

(b) The average price concession, discount or rebate the manufacturer provides to payers in this state or is expected to provide to payers in this state for the drug as reported by manufacturers and health plans.

(c) The average price concessions, discounts or rebates the manufacturer provides to payers in this state or is expected to provide to payers in this state for drugs that are therapeutic alternatives to the drug being reviewed.

(d) The payment rates claimed by manufacturers and suppliers for therapeutic alternatives to the drug that are sold in this state.

(e) The relative clinical merits of the prescription drug compared to the merits of therapeutic alternatives.

(f) The cost to payers based on reported or expected patient use of the drug as approved by the United States Food and Drug Administration.

(g) The impact of the cost of the drug on patient access to the drug assuming standard insurance coverage requirements.

(h) The value of programs offered by manufacturers to reduce the cost of the drug.

(i) The health, medical and other social services costs of the drug, if quantifiable, compared to the health, medical and other social services costs of existing therapeutic alternatives.

(j) Other factors specified by the commission by rule.

(2) If, after considering the factors in subsection (1) of this section, the commission is unable to determine if the prescription drug will result in excess costs, the commission may consider the following:

(a) The manufacturer's research and development costs for the drug, as shown on the manufacturer's federal tax filing for the most recent tax year, multiplied by the proportion of the manufacturer's sales of the drug in this state to the manufacturer's total sales of the drug in the United States;

(b) The portion of the manufacturer's direct consumer marketing costs for the drug that were eligible for favorable federal tax treatment in the most recent tax year multiplied by the ratio of the manufacturer's sales of the drug in this state to the manufacturer's total sales of the drug in the United States;

(c) The manufacturer's gross and net revenues for the most recent tax year; and

(d) Any additional factors proposed by the manufacturer that the commission considers relevant to the circumstances, as specified by rule.

(Drug Cost Review Commission's Determinations of Allowable Payment Rates)

SECTION 13. (1) If the Drug Cost Review Commission finds, based on a drug cost review, that the cost of a prescription drug will result in excess costs for payers in this state, the commission shall establish the maximum payment rate that may be claimed for the drug:

(a) By a pharmacy or other provider administering the drug in this state;

(b) By a wholesaler in this state; and

(c) By any other supplier in this state.

(2) A determination of the commission under subsection (1) of this section is a final order and may be challenged by any person in a contested case hearing conducted in accordance with ORS chapter 183 if requested no later than 30 days after the date of the order. The information provided in a notice under section 8 or 9 of this 2019 Act or a finding made by the commission in conducting a drug cost review shall be admissible as evidence in the contested case proceeding.

(3) The commission shall annually report on general drug price trends, the number of manufacturers submitting notices under sections 8 and 9 of this 2019 Act, the number of prescription drugs that were subject to drug cost reviews, the results of each drug cost review and the number and disposition of appeals of drug cost review final orders.

SECTION 14. (1) The Attorney General shall investigate any complaints of payment rates that exceed the maximum payment rates established by the Drug Cost Review Commission under section 13 of this 2019 Act.

(2) It is an unlawful trade practice under ORS 646.607:

(a) For a manufacturer to fail to provide notice as required by section 8 or 9 of this 2019 Act.

(b) For a pharmacy, provider, wholesaler or other person subject to section 13 of this 2019 Act to establish a payment rate for a prescription drug that exceeds the maximum payment rates established under section 13 of this 2019 Act.

(3) The Attorney General shall provide guidance to pharmacies, administering providers, wholesalers and other persons subject to section 13 of this 2019 Act concerning activities that may be in violation of section 13 of this 2019 Act.

DRUG COST REVIEW COMMISSION FUND

SECTION 15. The Drug Cost Review Commission Fund is established in the State Treasury, separate and distinct from the General Fund. Moneys in the Drug Cost Review Commission Fund are continuously appropriated to the Drug Cost Review Commission for carrying out sections 1, 2, 4 and 6 to 13 of this 2019 Act. Moneys in the fund shall consist of moneys appropriated by the Legislative Assembly and fees, charges, gifts, donations or grants that may be paid to the commission.

PLAN FOR FINANCING DRUG COST REVIEW COMMISSION

SECTION 16. The Drug Cost Review Commission shall develop a plan for financing the operations of the commission. No later than September 20, 2020, the commission shall report to the interim committees of the Legislative Assembly related to health, in the manner provided in ORS 192.245, recommendations for legislation to implement the plan developed by the commission.

VIOLATIONS CONSTITUTING UNLAWFUL TRADE PRACTICES

SECTION 17. ORS 646.607 is amended to read:

646.607. A person engages in an unlawful trade practice if in the course of the person's business, vocation or occupation the person:

(1) Employs any unconscionable tactic in connection with selling, renting or disposing of real estate, goods or services, or collecting or enforcing an obligation;

(2) Fails to deliver all or any portion of real estate, goods or services as promised, and at a customer's request, fails to refund money that the customer gave to the person to purchase the undelivered real estate, goods or services and that the person does not retain pursuant to any right, claim or defense the person may assert in good faith. This subsection does not create a warranty obligation and does not apply to a dispute over the quality of real estate, goods or services delivered to a customer;

(3) Violates ORS 401.965 (2);

(4) Violates a provision of ORS 646A.725 to 646A.750;

(5) Violates ORS 646A.530;

(6) Employs a collection practice that is unlawful under ORS 646.639;

(7) Is a beneficiary that violates ORS 86.726 (1)(a) or (2), 86.729 (4) or 86.732 (1) or (2);

(8) Violates ORS 646A.093;

(9) Violates a provision of ORS 646A.600 to 646A.628;

(10) Violates ORS 646A.808 (2);

(11) Violates ORS 336.184; [*or*]

(12) Publishes on a website related to the person's business, or in a consumer agreement related to a consumer transaction, a statement or representation of fact in which the person asserts that the person, in a particular manner or for particular purposes, will use, disclose, collect, maintain, delete or dispose of information that the person requests, requires or receives from a consumer and the person uses, discloses, collects, maintains, deletes or disposes of the information in a manner that is materially inconsistent with the person's statement or representation[.]**;**

(13) Fails to provide notice as required by section 8 or 9 of this 2019 Act; or

(14) Claims a payment rate of reimbursement for a prescription drug that exceeds the payment rate established in section 13 of this 2019 Act.

APPROPRIATION

SECTION 18. There is appropriated to the Drug Cost Review Commission, for the biennium beginning July 1, 2019, out of the General Fund, the amount of $_____ for carrying out the provisions of sections 1, 2, 4 and 6 to 13 of this 2019 Act.

CAPTIONS

SECTION 19. The unit captions used in this 2019 Act are provided only for the convenience of the reader and do not become part of the statutory law of this state or express any legislative intent in the enactment of this 2019 Act.