HOUSE OF REPRESENTATIVES
THIRTIETH LEGISLATURE, 2020
STATE OF HAWAII

H.B. NO. 2561 H.D. 2

A BILL FOR AN ACT

RELATING TO PRESCRIPTION DRUG RATE SETTING.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. The legislature finds that prescription medications are as important to the health and safety of the residents of this State as traditional public utilities such as transportation, gas, electricity, telecommunications, and water. The State has traditionally regulated the price of utilities charged to consumers because of the monopoly structure of the market.

The cost of many prescription drugs has become increasingly unaffordable for residents, employers, and the government because parts of the prescription drug market are monopolies or oligopolies, and the costs to consumers in these parts of the market are not managed. The difference between the affordability of traditional utilities and the costs of prescription drugs is due in part to the active role that the State plays in directing what consumers will pay for utilities and the corresponding inactive role that the State plays in not directing what consumers will pay for drugs.

The purpose of this Act is to establish a prescription affordability commission to review prescription drug costs and establish levels of reimbursement and rates, thereby protecting state residents, state and local governments, commercial health plans, health care providers, pharmacies licensed in the State, and other consumers within the health care system from high costs of prescription drug products.

SECTION 2. The Hawaii Revised Statutes is amended by adding a new chapter to be appropriately designated and to read as follows:

"**CHAPTER**

PRESCRIPTION AFFORDABILITY

§ -1 Definitions. As used in this chapter, unless the context otherwise requires:

"Advisory committee" means the prescription affordability advisory committee.

"Commission" means the prescription affordability commission established under this chapter.

"Department" means department of commerce and consumer affairs.

"Excess costs" means:

(1) The costs of an appropriate use of a prescription drug that exceed the therapeutic benefit relative to other therapeutic options or alternative treatments; or

(2) The costs of an appropriate use of a prescription drug that are not sustainable to public and private health care systems over a ten-year time frame.

"Health insurance carriers" means accident and health or sickness insurers governed under article 10A, chapter 431, mutual benefit societies governed under article 1, chapter 432, and health maintenance organizations governed under chapter 432D.

§ -2 Commission; established. (a) The prescription affordability commission is established in the department and shall consist of five members appointed by the governor pursuant to section 26-34 who shall have knowledge or experience in health care economics or clinical medicine. The members shall select the chairperson of the commission. The members shall serve in accordance with the requirements of chapter 84.

(b) The chairperson shall hire an executive director and legal counsel without regard to chapter 76.

(c) The executive director, with the approval of the commission, may hire staff, who shall be subject to chapter 76.

§ -3 Powers and duties. (a) The commission shall have the powers and duties to:

(1) Access pricing information for prescription drug products by:

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

(B) Accessing other available pricing information; and

(C) Requiring manufacturers to provide pricing information;

(2) Conduct affordability reviews;

(3) Assess and collect a fee upon manufacturers, pharmacy benefits managers, health insurance carriers, and wholesale distributors;

(4) Set rates, engage in negotiations over rates, limit rates, and make determinations regarding compliance with rate settings; and

(5) Assess a penalty upon manufacturers, pharmacy benefits managers, health insurance carriers, and wholesale distributors for failure to pay the assessment fee under paragraph (3).

(b) In addition to any other powers pursuant to this chapter, the commission may:

(1) Adopt rules pursuant to chapter 91 to implement the requirements of this chapter; and

(2) Contract with an independent third party for any service necessary to carry out the powers and duties of the commission; provided that the contract shall require that unless written permission is granted by the commission, a third party hired by the commission may not release, publish, or otherwise use any information to which the third party has access under its contract.

§ -4 Meetings of the commission; proprietary data. (a) The commission shall hold public meetings at least once every six weeks subject to chapter 92 in order to review prescription drug information submissions; provided that the chair may cancel or postpone a meeting if there are no prescription drugs to

review. The commission shall determine whether to subject a prescription drug to an affordability review and conduct a prescription drug cost analysis when deciding to impose a cost or payment limit on payors for a prescription drug.

(b) Notwithstanding section 92-7(b), the commission shall file written public notice of a public meeting with the office of the lieutenant governor at least two weeks before the meeting. Materials for each meeting shall be made available to the public at the department of commerce and consumer affairs at least one week before the meeting.

(c) The commission may hold an executive meeting as provided in section 92-4 to discuss confidential commercial or financial information that would be authorized to be withheld from the public under section 92F-13(3); provided that protection of this information shall be considered an authorized purpose for holding a meeting closed to the public.

§ -5 Advisory committee; established. (a) There is established in the department a prescription affordability advisory committee to provide advisory assistance to the commission. The advisory committee shall comprise eleven members who shall be appointed by the governor subject to

section 26-34. Initial members shall serve staggered terms of three, four, and five years. The members shall serve in accordance with the requirements of chapter 84.

(b) Members shall be appointed based upon their knowledge of pharmaceutical business models, the practice of medicine, clinical knowledge and training, patients' perspectives, health care cost trends and drivers, clinical and health services research, and the state health care marketplace.

(c) To the extent possible, the governor shall appoint members to represent patients, physicians, commercial payors, government employee benefits, large employer plans, pharmaceutical manufacturers, health services researchers, clinical researchers, and pharmacologists.

§ -6 Prescription affordability special fund. (a) There is established in the state treasury the prescription affordability special fund to be administered by the department, into which shall be deposited all moneys collected under this chapter.

(b) Moneys in the prescription affordability special fund shall consist of:

(1) The prescription affordability fee assessments authorized under section -3(a)(2);

(2) Penalties authorized under section -3(a)(3) for failure to pay the prescription affordability fee assessments;

(3) Any investment earnings of the special fund;

(4) Appropriations from the legislature; and

(5) Any other sources of funding.

(c) Moneys in the prescription affordability special fund shall be used only to provide funding for the commission and for the purposes authorized under this chapter, including costs incurred by the commission in carrying out the purposes of this chapter.

§ -7 Required manufacturer notice of introductory price and price increases. (a) For a patented prescription drug, a manufacturer shall notify the commission if it intends to increase the wholesale acquisition cost of the prescription drug by more than ten per cent or by more than $10,000 during any twelve-month period, or if it intends to introduce to market a brand-name prescription drug that has a wholesale acquisition cost of $30,000 per year or per course of treatment. The notice

shall be provided in writing at least thirty days prior to the planned effective date of the increase or introduction and include a justification as described in subsection (c). After consultation with stakeholders and experts, the commission shall establish a third threshold that, when breached, will trigger manufacturer reporting for brand-name prescription drugs.

(b) For generic prescription drugs, a manufacturer shall notify the commission if it intends to increase the wholesale acquisition cost of the generic prescription drug by more than twenty-five per cent or by more than $300 during any twelve month period, or if it intends to introduce to market a generic prescription drug that has a wholesale acquisition cost of $3,000 or more annually. The notice shall be provided in writing at least thirty days prior to the planned effective date of the increase or introduction and include a justification as described in subsection (c). After consultation with stakeholders and experts, the commission shall establish a third threshold that, when breached, will trigger manufacturer reporting for generic prescription drugs.

(c) Justification for the proposed launch price or price increases specified in subsections (a) and (b) shall include all

documents and research related to the manufacturer's selection of the price increase or introductory price including life cycle management, net average price in the State, market competition and context, projected revenue, and if available, estimated cost effectiveness of the prescription drug.

§ -8 Determining excess costs to payors and consumers. (a) An affordability review of a prescription drug shall include a determination whether the appropriate use of a prescription drug product has led or will lead to excess costs for health care systems in the State.

(b) Factors that the commission may consider in determining cost and excess cost include:

(1) The price at which the prescription drug has been or will be sold in the State;

(2) The average monetary price rebate or discount that the manufacturer provides or is expected to provide to payors in the State, as reported by manufacturers and health plans;

(3) The price at which effective therapeutic alternatives have been or will be sold in the State;

(4) The average monetary price rebate or discount that the manufacturer provides or is expected to provide to health plan payors in the State for effective therapeutic alternatives;

(5) The relative clinical merits of the prescription drug under review compared to effective therapeutic alternatives;

(6) The cost to payors based upon patient access;

(7) The impact on patient access resulting from the cost of the prescription drug relative to insurance benefits;

(8) The current or expected value of manufacturer-supported, drug-specific, patient access programs;

(9) The relative financial impacts to health, medical, and other social services costs; provided that those costs can be quantified and compared to the baseline effects of existing effective therapeutic alternatives; and

(10) Other factors as may be specified by rule by the commission.

(c) If, after considering the factors in subsection (b), the commission is unable to determine whether a prescription

drug will produce or has produced excess costs, the commission may consider the following:

(1) Manufacturer research and development costs, as shown on the company's federal tax filing for the most recent tax year multiplied by the proportion of manufacturer sales in this State to sales nationwide;

(2) That portion of direct-to-consumer marketing costs that are eligible for favorable federal tax treatment in the most recent tax year, that are specific to the prescription drug under review, and that are multiplied by the proportion of total manufacturer sales in the State to sales nationwide for the prescription drug under review;

(3) Gross and net manufacturer revenues for the most recent tax year; and

(4) Any additional factors that the commission considers relevant to the circumstances.

§ -9 Rate setting. (a) If the commission finds that the spending on the prescription drug under review creates excess costs for payors and consumers, the commission shall

establish the level of reimbursement that shall be billed and paid among payors and providers in a deductible period.

(b) Instances of failure to bill and pay at levels established by the commission under subsection (a) shall be referred to the attorney general for further review.

(c) Upon a finding of noncompliance with commission requirements, the attorney general may pursue all available legal remedies.

(d) It shall not be considered noncompliance if a health care stakeholder obtains price concessions from a manufacturer that result in an insurer's net cost that is lower than the rate established by the commission.

§ -10 Appeals and judicial review. (a) Any person aggrieved by a decision of the commission may request an appeal of the decision within thirty days after the decision of the commission.

(b) The commission shall hear the appeal and make a final decision within sixty days after the appeal is requested. The proceeding shall be conducted in accordance with chapter 91.

(c) Any person aggrieved by a final decision of the commission may petition for judicial review by the circuit court

of the first circuit. The review shall be as provided by chapter 91.

§ -11 Annual reports. (a) The commission shall report annually to the legislature and the governor on general prescription drug price trends, the number of companies required to report because of prescription drug pricing decisions, and the number of prescription drugs that were subject to commission review and analysis, including the results of the analysis, as well as the number and disposition of appeals and judicial reviews.

§ -12 Scope of law and relation with other laws; ERISA plans and medicare drug plans. (a) This chapter shall require state-sponsored and state-regulated health plans and health programs to limit drug reimbursements and drug payments to no more than the commission-established upper payment limit.

(b) Subject to subsection (c), this chapter does not apply to ERISA plans and medicare part D plans.

(c) Providers who dispense and administer drugs in the State to individuals in the State shall bill all payors at no more than the upper payment limit to the patient without regard

to whether or not an ERISA plan or medicare part D plan chooses to reimburse the provider above the upper payment limit."

SECTION 3. There is appropriated out of the general revenues of the State of Hawaii the sum of $ or so much thereof as may be necessary for fiscal year 2020-2021 for deposit into the prescription affordability special fund.

SECTION 4. There is appropriated out of the prescription affordability special fund the sum of $ or so much thereof as may be necessary for fiscal year 2020-2021 for the purposes of this Act.

The sum appropriated shall be expended by the department of commerce and consumer affairs for the purposes of this Act.

SECTION 5. If any provision of this Act, or the application thereof to any person or circumstance, is held invalid, the invalidity does not affect other provisions or applications of the Act that can be given effect without the invalid provision or application, and to this end the provisions of this Act are severable.

SECTION 6. This Act shall take effect on July 1, 2050.

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Report Title:
Prescription Drugs; Prescription Affordability Commission; Reimbursement; Rates; Appropriation

Description:
Establishes the prescription affordability commission within the department of commerce and consumer affairs to review prescription drug costs and establish levels of reimbursement. Appropriates funds. Effective 7/1/2050. (HD2)

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