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# A BILL FOR AN ACT

RELATING TO PRESCRIPTION DRUG RATE SETTING.

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

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

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





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

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

7 "Health insurance carriers" means accident and health or  
8 sickness insurers governed under article 10A, chapter 431,  
9 mutual benefit societies governed under article 1, chapter 432,  
10 and health maintenance organizations governed under chapter  
11 432D.

12 **§ -2 Commission; established.** (a) The prescription  
13 affordability commission is established in the department and  
14 shall consist of five members appointed by the governor pursuant  
15 to section 26-34 who shall have knowledge or experience in  
16 health care economics or clinical medicine. The members shall  
17 select the chairperson of the commission. The members shall  
18 serve in accordance with the requirements of chapter 84.

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



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

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

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

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

10 (B) Accessing other available pricing information;  
11 and

12 (C) Requiring manufacturers to provide pricing  
13 information;

14 (2) Conduct affordability reviews;

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

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



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

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

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

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

17          **§ -4 Meetings of the commission; proprietary data.** (a)

18 The commission shall hold public meetings at least once every  
19 six weeks subject to chapter 92 in order to review prescription  
20 drug information submissions; provided that the chair may cancel  
21 or postpone a meeting if there are no prescription drugs to



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

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

11 (c) Pursuant to sections 92-4 and 92-5(8), the commission  
12 may hold an executive meeting closed to the public to discuss  
13 proprietary data and information.

14 (d) Subject to subsection (e), all submissions to the  
15 commission pertaining to a prescription drug cost review shall  
16 be deemed government records that are subject to chapter 92F.

17 (e) Proprietary data and information discussed in an  
18 executive meeting closed to the public pursuant to subsection  
19 (c) shall be exempt from public disclosure under chapter 92F.

20 **§ -5 Advisory committee; established.** (a) There is  
21 established in the department a prescription affordability



1 advisory committee to provide advisory assistance to the  
2 commission. The advisory committee shall comprise eleven  
3 members who shall be appointed by the governor subject to  
4 section 26-34. Initial members shall serve staggered terms of  
5 three, four, and five years. The members shall serve in  
6 accordance with the requirements of chapter 84.

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

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

17 **§ -6 Prescription affordability special fund.** (a)  
18 There is established in the state treasury the prescription  
19 affordability special fund to be administered by the department,  
20 into which shall be deposited all moneys collected under this  
21 chapter.



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

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

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

8 (3) Any investment earnings of the special fund;

9 (4) Appropriations from the legislature; and

10 (5) Any other sources of funding.

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

16 **§ -7 Required manufacturer notice of introductory price**  
17 **and price increases.** (a) For a patented prescription drug, a  
18 manufacturer shall notify the commission if it intends to  
19 increase the wholesale acquisition cost of the prescription drug  
20 by more than ten per cent or by more than \$10,000 during any  
21 twelve-month period, or if it intends to introduce to market a



1 brand-name prescription drug that has a wholesale acquisition  
2 cost of \$30,000 per year or per course of treatment. The notice  
3 shall be provided in writing at least thirty days prior to the  
4 planned effective date of the increase or introduction and  
5 include a justification as described in subsection (c). After  
6 consultation with stakeholders and experts, the commission shall  
7 establish a third threshold that, when breached, will trigger  
8 manufacturer reporting for brand-name prescription drugs.

9 (b) For generic prescription drugs, a manufacturer shall  
10 notify the commission if it intends to increase the wholesale  
11 acquisition cost of the generic prescription drug by more than  
12 twenty-five per cent or by more than \$300 during any twelve  
13 month period, or if it intends to introduce to market a generic  
14 prescription drug that has a wholesale acquisition cost of  
15 \$3,000 or more annually. The notice shall be provided in  
16 writing at least thirty days prior to the planned effective date  
17 of the increase or introduction and include a justification as  
18 described in subsection (c). After consultation with  
19 stakeholders and experts, the commission shall establish a third  
20 threshold that, when breached, will trigger manufacturer  
21 reporting for generic prescription drugs.



1 (c) Justification for the proposed launch price or price  
2 increases specified in subsections (a) and (b) shall include all  
3 documents and research related to the manufacturer's selection  
4 of the price increase or introductory price including life cycle  
5 management, net average price in the State, market competition  
6 and context, projected revenue, and if available, estimated cost  
7 effectiveness of the prescription drug.

8 **§ -8 Determining excess costs to payors and consumers.**

9 (a) An affordability review of a prescription drug shall  
10 include a determination whether the appropriate use of a  
11 prescription drug product has led or will lead to excess costs  
12 for health care systems in the State.

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

- 15 (1) The price at which the prescription drug has been or  
16 will be sold in the State;
- 17 (2) The average monetary price rebate or discount that the  
18 manufacturer provides or is expected to provide to  
19 payors in the State, as reported by manufacturers and  
20 health plans;



- 1           (3) The price at which effective therapeutic alternatives
- 2                    have been or will be sold in the State;
- 3           (4) The average monetary price rebate or discount that the
- 4                    manufacturer provides or is expected to provide to
- 5                    health plan payors in the State for effective
- 6                    therapeutic alternatives;
- 7           (5) The relative clinical merits of the prescription drug
- 8                    under review compared to effective therapeutic
- 9                    alternatives;
- 10          (6) The cost to payors based upon patient access;
- 11          (7) The impact on patient access resulting from the cost
- 12                    of the prescription drug relative to insurance
- 13                    benefits;
- 14          (8) The current or expected value of manufacturer-
- 15                    supported, drug-specific, patient access programs;
- 16          (9) The relative financial impacts to health, medical, and
- 17                    other social services costs; provided that those costs
- 18                    can be quantified and compared to the baseline effects
- 19                    of existing effective therapeutic alternatives; and
- 20          (10) Other factors as may be specified by rule by the
- 21                    commission.



1 (c) If, after considering the factors in subsection (b),  
2 the commission is unable to determine whether a prescription  
3 drug will produce or has produced excess costs, the commission  
4 may consider the following:

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

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

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

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

20 **§ -9 Rate setting.** (a) If the commission finds that  
21 the spending on the prescription drug under review creates



1 excess costs for payors and consumers, the commission shall  
2 establish the level of reimbursement that shall be billed and  
3 paid among payors and providers in a deductible period.

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

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

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

14 **§ -10 Appeals and judicial review.** (a) Any person  
15 aggrieved by a decision of the commission may request an appeal  
16 of the decision within thirty days after the decision of the  
17 commission.

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



1 (c) Any person aggrieved by a final decision of the  
2 commission may petition for judicial review by the circuit court  
3 of the first circuit. The review shall be as provided by  
4 chapter 91.

5 **§ -11 Annual reports.** (a) The commission shall report  
6 annually to the legislature and the governor on general  
7 prescription drug price trends, the number of companies required  
8 to report because of prescription drug pricing decisions, and  
9 the number of prescription drugs that were subject to commission  
10 review and analysis, including the results of the analysis, as  
11 well as the number and disposition of appeals and judicial  
12 reviews.

13 **§ -12 Scope of law and relation with other laws; ERISA**  
14 **plans and medicare drug plans.** (a) This chapter shall require  
15 state-sponsored and state-regulated health plans and health  
16 programs to limit drug reimbursements and drug payments to no  
17 more than the commission-established upper payment limit.

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

20 (c) Providers who dispense and administer drugs in the  
21 State to individuals in the State shall bill all payors at no



1 more than the upper payment limit to the patient without regard  
2 to whether or not an ERISA plan or medicare part D plan chooses  
3 to reimburse the provider above the upper payment limit."

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

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

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

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



1 SECTION 6. This Act shall take effect on July 1, 2020.

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INTRODUCED BY:

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JAN 23 2020



# H.B. NO. 2561

**Report Title:**

Prescription Drugs; Rate Reviews; Rate Setting; Appropriation

**Description:**

Establishes a prescription affordability commission within the Department of Commerce and Consumer Affairs to review prescription drug costs and establish levels of reimbursement. Appropriates moneys.

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