A BILL FOR AN ACT

RELATING TO PRESCRIPTION DRUGS.

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

SECTION 1. The legislature finds that access to prescription drugs is necessary for people to maintain or acquire good health. The legislature recognizes that increases in many prices charged by manufacturers of high-cost and high-volume prescription drugs are not supported by adequate evidence of improved clinical benefit or by significant increases in costs incurred by the manufacturers related to producing or selling the drugs. These unsupported price increases for prescription drugs negatively impact the ability of residents to obtain those drugs, and contribute significantly to a dramatic and unsustainable rise in health care costs and health insurance, and ultimately endanger and threaten the health, safety, and well-being of residents and their ability to maintain or acquire good health.

The legislature also finds that unsupported price increases for prescription drugs contribute significantly to rising state costs for health care provided and paid for through state-funded
medical assistance programs for older residents, residents with disabilities, and residents with low incomes. These price increases also affect the costs of health insurance programs for public employees and retirees whose health care costs are funded by public programs, thereby threatening the ability of the State to fund those programs adequately, and further threatening the ability of the State to fund other programs necessary for the public good and safety, such as public education and public safety.

The legislature further finds that unsupported price increases also threaten the economic well-being of residents and endanger their ability to pay for other necessary and essential goods and services, including housing, food, and utilities.

The purpose of this Act is to protect the safety, health, and economic well-being of the people of this State from the negative and harmful impact of unsupported price increases for prescription drugs.

SECTION 2. The Hawaii Revised Statutes is amended by adding a new chapter to title 24 to be appropriately designated and to read as follows:
"CHAPTER

UNSUPPORTED PRICE INCREASES ON PRESCRIPTION DRUGS

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

"Commissioner" means the insurance commissioner.

"Consumer price index" means the consumer price index for all urban consumers published by the United States Department of Labor, as of the close of the twelve-month period ending on December 31 of each calendar year.

"Identified drug" means any prescription drug for which the increase in price was, at any time, determined by the commissioner to be an unsupported price increase.

"Manufacturer" shall have the same meaning as in section 328-112.

"Prescription drug" shall have the same meaning as in section 328-1.

"Unsupported price increase" means an increase in price for a prescription drug for which the increase in price is not adequately supported by new clinical evidence.

"Wholesale acquisition cost" shall have the same meaning as in title 42 United States Code section 1395w-3a.
§ 2 Penalty. (a) A manufacturer with no less than $250,000 of sales of prescription drugs in the State in a calendar year shall be assessed a penalty on the sales in the State for each identified drug pursuant to subsection (c).

(b) A prescription drug shall not be deemed by the commissioner to be an identified drug if the increase in price for the prescription drug is supported by new clinical evidence. In determining whether the price increase for the prescription drug is supported by new clinical evidence, the commissioner shall use and rely upon the analyses of prescription drugs prepared annually by the Institute for Clinical and Economic Review and published in its annual Unsupported Price Increase Report.

(c) The penalty in any calendar year shall equal eighty per cent of the difference between the revenue generated by sales in the State of the identified drug and the revenue that would have been generated if the manufacturer had maintained the wholesale acquisition cost from the previous calendar year, adjusted for inflation utilizing the consumer price index.

(d) Within sixty days of the annual publication of Institute for Clinical and Economic Review's Unsupported Price
Increase Report, the commissioner shall identify the manufacturers of identified drugs. The commissioner shall notify each manufacturer that sales in the State of identified drugs shall be subject to the penalty assessed in this section for a period of two calendar years following the identified drug's appearance in the Unsupported Price Increase Report.

(e) The penalty assessed by this section shall be collected annually. Any manufacturer in receipt of the notification issued pursuant to subsection (d) shall submit to the commission a completed form prescribed and furnished by the commission and pay the penalty by of the following calendar year.

(f) The form completed pursuant to subsection (e) shall include, at a minimum:

(1) The total amount of sales of the identified drug in the State;

(2) The total number of units sold of the identified drug in the State;

(3) The wholesale acquisition cost of the identified drug during the tax period and any changes in the wholesale acquisition cost during the calendar year;
(4) The wholesale acquisition cost during the previous calendar year;
(5) A calculation of the penalty owed; and
(6) Any other information that the commissioner determines is necessary to calculate the correct amount of the penalty owed.

(g) Any manufacturer that fails to file the form required by subsection (e) shall pay an additional penalty of ten percent of the penalty imposed by subsection (c), or $50,000, whichever is greater.

§ -3 Withdrawal of prescription drugs for sale; prohibited. (a) A manufacturer of an identified drug shall not withdraw that drug from sale or distribution in this State for the purpose of avoiding the penalty set forth in section -2.
(b) Any manufacturer that intends to withdraw an identified drug from sale or distribution in the State shall provide a notice of withdrawal in writing to the commissioner no less than one hundred eighty days before the withdrawal.
(c) The commissioner shall assess a penalty of $500,000 on any manufacturer that the commissioner determines has withdrawn
an identified drug from distribution or sale in the State in violation of this section.

§ -4 Appeals and judicial review. (a) Any manufacturer aggrieved by a decision of the commissioner may request an appeal of the decision within thirty days after the decision.

(b) The commissioner 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 manufacturer aggrieved by a final decision of the commissioner may petition for judicial review by the circuit court of the first circuit. The review shall be as provided by chapter 91.

§ -5 Identified drug offset special fund; established; legislative reports. (a) There is established within the state treasury the identified drug offset special fund. The commissioner shall deposit the penalties collected pursuant to this chapter into the special fund.

(b) Moneys in the special fund:

(1) Shall be used to offset the out-of-pocket cost to consumers for identified drugs; provided that the
commissioner shall work in cooperation with other state agencies to determine the most effective method of offsetting this cost; and

(2) May be used to pay administrative costs necessary to:

(A) Assess and collect the penalties imposed by this chapter;

(B) Audit manufacturers that are required to submit forms pursuant to section -2(e); and

(C) Defend appeals from manufacturers;

provided there is no significant negative impact on the availability of funds for consumer costs offsets pursuant to paragraph (1).

(c) No later than twenty days prior to the convening of each regular session, the commissioner shall provide to the legislature a report that shall include, at a minimum:

(1) The amount of moneys that have been deposited into the identified drug offset special fund in the most recent fiscal year as a result of the penalties imposed by this chapter, segregated by manufacturer and product;

(2) The amount of moneys remaining in the special fund at the end of the most recent fiscal year;
(3) A description of how moneys from the special fund have been used to benefit consumers pursuant to subsection (b)(1) during the most recent fiscal year; and

(4) A breakdown of funds used for administrative costs during the most recent fiscal year.

§ 6 Rules. The commissioner shall adopt rules in accordance with chapter 91 that are necessary for the purposes of this section."

SECTION 3. This Act does not affect rights and duties that matured, penalties that were incurred, and proceedings that were begun before its effective date.

SECTION 4. This Act shall take effect upon its approval.

INTRODUCED BY: 

JAN 20 2021
Report Title:
Prescription Drugs; Unsupported Price Increases; Insurance; Insurance Commissioner

Description:
Requires certain drug manufacturers to pay monetary penalties to the insurance commissioner for unsupported price increases on prescription drugs sold in the State. Provides for appeals and judicial review. Establishes the identified drug offset special fund. Requires annual reports to the legislature.

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