130th MAINE LEGISLATURE

FIRST REGULAR SESSION-2021

Legislative Document **No. 675**

S.P. 262 In Senate, March 4, 2021

An Act To Protect Maine Consumers from Unsupported Price Increases on Prescription Medicines by Creating an Independent Review Process

Received by the Secretary of the Senate on March 2, 2021. Referred to the Committee on Health Coverage, Insurance and Financial Services pursuant to Joint Rule 308.2 and ordered printed.

DAREK M. GRANT
Secretary of the Senate

Presented by Senator CLAXTON of Androscoggin.
Cosponsored by Senators: BRENNER of Cumberland, CURRY of Waldo, President JACKSON of Aroostook, LUCHINI of Hancock, MAXMIN of Lincoln, RAFFERTY of York, VITELLI of Sagadahoc.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 5 MRSA c. 166 is enacted to read:

CHAPTER 166

PROTECTION OF CONSUMERS FROM UNSUPPORTED PRESCRIPTION DRUG PRICE INCREASES

§2035. Definitions

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

1. Consumer Price Index. "Consumer Price Index" means the Consumer Price Index, Annual Average, for All Urban Consumers, CPI-U: U.S. City Average, All items, reported by the United States Department of Labor, Bureau of Labor Statistics, or its successor or, if the index is discontinued, an equivalent index reported by a federal authority or, if no such index is reported, "Consumer Price Index" means a comparable index chosen by the Bureau of Labor Statistics.

2. Identified prescription drug. "Identified prescription drug" means a prescription drug that has at any time been identified as having an unsupported price increase.

3. Prescription drug. "Prescription drug" has the same meaning as in Title 32, section 13702-A, subsection 30.

4. Prescription drug manufacturer. "Prescription drug manufacturer" means a business operating in this State that manufactures prescription drugs for sale to another person or business in this State.

5. Superintendent. "Superintendent" means the Superintendent of Insurance within the Department of Professional and Financial Regulation.

6. Unsupported price increase. "Unsupported price increase" means an increase in price for a prescription drug for which there was no, or inadequate, new clinical evidence to support the price increase, as demonstrated by the analyses of prescription drugs prepared annually by the Institute for Clinical and Economic Review, or successor organization, and published in the institute's annual report on unsupported price increases.

7. Wholesale acquisition cost. "Wholesale acquisition cost" has the meaning stated in 42 United States Code, Section 1395w-3a.

§2036. Sales of identified prescription drugs prohibited

1. Sales of identified prescription drugs prohibited; penalty. A prescription drug manufacturer responsible for the sale of any identified prescription drug in this State commits a civil violation for which a fine must be adjudged as provided in this section.

A. The fine is assessed on the sales within the State of identified prescription drugs.

B. The fine in any calendar year is equal to 80% of the difference between the revenue generated by sales within the State of the identified prescription drugs and the revenue that would have been generated if the prescription drug manufacturer had maintained

the wholesale acquisition cost from the previous calendar year, adjusted for inflation using the Consumer Price Index.

C. In order for the fine to be assessed, a prescription drug manufacturer must have at least $250,000 in total annual sales within the State in the calendar year for which the fine is assessed.

D. Within 60 days of the publication of the annual report on unsupported price increases by the Institute for Clinical and Economic Review, or successor organization, the State Tax Assessor shall identify the prescription drug manufacturers of identified prescription drugs. The State Tax Assessor shall notify each prescription drug manufacturer that sales within the State of identified prescription drugs are subject to the fine described in this section for a period of 2 calendar years following the identified prescription drug's appearance in the annual report on unsupported price increases by the Institute for Clinical and Economic Review, or successor organization.

E. A prescription drug manufacturer shall pay any fine adjudged under this section annually. Any manufacturer notified by the State Tax Assessor pursuant to paragraph D shall submit the information required by paragraph F on a form prescribed and furnished by the State Tax Assessor and pay the penalty by April 15th for the previous calendar year.

F. A prescription drug manufacturer notified by the State Tax Assessor pursuant to paragraph D shall provide, at a minimum, the following information to the State Tax Assessor:

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

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

(3) The wholesale acquisition cost of the identified prescription drug during the tax period and any changes in the wholesale acquisition cost during the calendar year;

(4) The wholesale acquisition cost of the identified prescription drug during the previous calendar year;

(5) A calculation of the fine owed; and

(6) Any other information that the State Tax Assessor determines is necessary to calculate the correct amount of the fine owed.

G. The failure by any prescription drug manufacturer to file the form required by paragraph E results in an additional fine of 10% of the fine calculated pursuant to paragraph B or $50,000, whichever is greater.

2. Fund established. The Unsupported Prescription Drug Price Increases Fund, referred to in this section as "the fund," is established as a nonlapsing fund in the Department of Professional and Financial Regulation, Bureau of Insurance for the purposes specified in this subsection. The State Controller shall credit to the fund any fines assessed for violations of this chapter payable pursuant to this section. The fund must be used by the superintendent to offset costs to consumers. The superintendent may work in cooperation with other state agencies to determine the most effective method of optimizing the consumer benefit.

3. Administrative costs. Upon request from the State Tax Assessor, the superintendent may transfer money available in the fund to the State Tax Assessor for the administrative costs of performing the duty required by subsection 1, paragraph D. The superintendent may grant a request only upon finding that there will be no significant negative impact on the availability of funds to meet the requirements of subsection 2.

4. Annual report. Beginning June 1, 2023 and annually thereafter, the superintendent shall submit a report to the joint standing committee of the Legislature having jurisdiction over prescription drug matters that describes the amount of revenue from fines paid in accordance with subsection 1, segregated by manufacturer and identified prescription drug; the current amount available to the superintendent for the purposes described in subsection 2; how the fine revenue has been used to benefit consumers pursuant to subsection 2; and any funds made available to the State Tax Assessor for administrative costs pursuant to subsection 3.

§2037. Prohibition on withdrawal of identified prescription drugs for sale

1. Withdrawal from sale prohibited. It is a violation of this chapter for any prescription drug manufacturer or distributor of an identified prescription drug to withdraw that prescription drug from sale or distribution within this State for the purpose of avoiding the fine set forth in section 2036.

2. Notice required. A prescription drug manufacturer who intends to withdraw an identified prescription drug from sale or distribution within the State must provide 180 days' prior notice to the Attorney General of the withdrawal in order to avoid violation of section 2036, subsection 1.

3. Penalty. The Attorney General shall assess a penalty of $500,000 on any entity, including any manufacturer or distributor of an identified prescription drug, that it determines has withdrawn an identified prescription drug from sale or distribution in this State in violation of this section.

Sec. 2. Legislative findings; impact of price increases for prescription drugs. In order to protect the safety, health and economic well-being of the residents of this State by guarding them from the negative and harmful impact of unsupported price increases for prescription drugs, the enactment of this Act is necessary and the Legislature finds that:

1. Access to prescription drugs is necessary for the residents of this State to maintain or acquire good health;

2. Unsupported price increases negatively impact the ability of residents of this State to obtain prescription drugs and thereby endanger the health and safety of residents of this State to maintain or acquire good health;

3. Unsupported price increases for prescription drugs threaten the economic well-being of residents of this State and endanger their ability to pay for other necessary and essential goods and services including housing, food and utilities;

4. Unsupported price increases for prescription drugs contribute significantly to a dramatic and unsustainable rise in health care costs and health insurance that threatens the overall ability of residents of this State to obtain health coverage and maintain or acquire good health;

5. 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 residents of this State who are older, living with disabilities or have low incomes and health insurance programs for public employees, including employees of the State, municipalities and counties, school districts and institutions of higher education, 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; and

6. Analysis of the increase in prices charged by manufacturers of prescription drugs demonstrates that many price increases for high-cost and high-volume prescription drugs are not supported by adequate evidence of improved clinical benefit or by significant increase in costs to the manufacturer related to the production or sale of the product.

SUMMARY

This bill makes prescription drug manufacturers subject to fines for the sale of prescription drugs in this State identified as having an unsupported price increase. The determination of what constitutes an unsupported price increase for a prescription drug is based on whether there was no, or inadequate, new clinical evidence to support the price increase, as demonstrated by the analyses of prescription drugs prepared annually by the Institute for Clinical and Economic Review, or successor organization.