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An Act To Prevent Excessive Prices for Prescription Drugs

Received by the Secretary of the Senate on March 18, 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 President JACKSON of Aroostook.
Cosponsored by Speaker FECTEAU of Biddeford and
Senators: CLAXTON of Androscoggin, MAXMIN of Lincoln, RAFFERTY of York, SANBORN of Cumberland, Representatives: DOUDERA of Camden, TEPLER of Topsham, WHITE of Waterville.

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

PROHIBITION ON EXCESSIVE INCREASES IN GENERIC PRESCRIPTION DRUG PRICES

§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. Generic or off-patent prescription drug. "Generic or off-patent prescription drug" means any prescription drug for which any exclusive marketing rights granted under the Federal Food, Drug, and Cosmetic Act; the federal Public Health Service Act, Public Law 78-410, Section 351; and federal patent law have expired including any drug-device combination product for the delivery of a generic drug.

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

§2036. Excessive price increases for generic or off-patent prescription drugs prohibited

1. Excessive price increases prohibited. A prescription drug manufacturer may not impose an excessive price increase, whether directly or through a wholesale distributor, pharmacy or similar intermediary or intermediaries, on the sale of any generic or off-patent prescription drug sold, dispensed or delivered to any consumer in this State.

2. Determination of excessive price increases. A price increase of a generic or off-patent prescription drug is excessive for purposes of this section when:

A. The price increase, adjusted for inflation using the Consumer Price Index, exceeds:

(1) Fifteen percent of the wholesale acquisition cost of the immediately preceding calendar year; or

(2) Forty percent of the wholesale acquisition cost of 3 years prior to the current year; and

B. The price increase, adjusted for inflation using the Consumer Price Index, exceeds $30 for a 30-day supply of the generic or off-patent prescription drug or for a course of treatment of the generic or off-patent prescription drug that lasts less than 30 days.

3. Exception. It is not a violation of this section for a wholesale distributor or pharmacy to increase the price of a generic or off-patent prescription drug if the price increase is directly attributable to additional costs for the generic or off-patent prescription drug imposed on the wholesale distributor or pharmacy by the prescription drug manufacturer of the generic or off-patent prescription drug.

4. Registered agent. Any entity that sells, distributes, delivers or offers for sale any generic or off-patent prescription drug in this State is required to maintain a registered agent within the State.

5. Enforcement. The following provisions govern the enforcement of this section.

A. The administrator of benefits for state employees, or any entity of State Government that provides or purchases a prescription drug benefit, any entity under contract with State Government to provide prescription drug benefits or any other state agency shall notify a prescription drug manufacturer and the Attorney General of any price increase for a generic or off-patent prescription drug that is an excessive price increase in violation of this section.

B. Within 45 days of receipt of notice under paragraph A, the prescription drug manufacturer of the generic or off-patent prescription drug shall submit a statement to the Attorney General:

(1) Itemizing the components of the cost of producing the drug;

(2) Identifying the circumstances and timing of any increase in materials or manufacturing costs that caused any increase during the preceding year in the price of the drug; and

(3) Providing any other information that the prescription drug manufacturer believes to be pertinent to a determination of whether a violation of this chapter has occurred.

C. The Attorney General may require a prescription drug manufacturer and wholesale distributor to produce any records or documents that may be relevant to a determination of whether a violation of this section has occurred.

D. On petition of the Attorney General, a court may issue an order to:

(1) Compel the prescription drug manufacturer of the generic or off-patent prescription drug to:

(a) Provide a statement required under paragraph B; or

(b) Produce records or documents requested by the Attorney General under paragraph C that may be relevant to a determination of whether a violation of this section has occurred;

(2) Restrain or enjoin a violation of this section, including an order requiring that prices be restored to levels that comply with this section;

(3) Require the prescription drug manufacturer to provide an accounting to the Attorney General of all revenues generated in violation of this section;

(4) Restore to any consumer, including any 3rd-party payor, any money acquired as a result of an excessive price increase in violation of this section. With respect to this subparagraph, every individual transaction in violation of this section is determined to be a separate violation;

(5) Require that all revenues generated in violation of this section be remitted to the State to be used for efforts designed to reduce the cost to consumers of acquiring prescription drugs, if a prescription drug manufacturer is unable to determine the individual transactions necessary to provide the restitution described in subparagraph (4);

(6) Impose a civil penalty of up to $10,000 per day for each violation of this section; and

(7) Provide for any other appropriate relief, including attorney's fees and costs reasonably incurred by the Attorney General in bringing an action against a prescription drug manufacturer found in violation of this section.

§2037. Prohibition on withdrawal of generic or off-patent prescription drugs for sale

1. Withdrawal from sale prohibited. It is a violation of this chapter for any prescription drug manufacturer of a generic or off-patent prescription drug to withdraw that prescription drug from sale or distribution within this State, whether directly or through a wholesale distributor, for the purpose of avoiding the prohibition on excessive price increases set forth in section 2036.

2. Notice required. Any prescription drug manufacturer that intends to withdraw a generic or off-patent 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 the prohibition on excessive price increases set forth in section 2036, subsection 1.

3. Penalty. The Attorney General shall assess a penalty of $500,000 on any prescription drug manufacturer of a generic or off-patent prescription drug that the Attorney General determines has withdrawn that generic or off-patent prescription drug from sale or distribution in this State, whether directly or through a wholesale distributor, 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 excessive and unconscionable prices for prescription drugs, the enactment of this Act is necessary and the Legislature finds that:

1. Access to prescription drugs is necessary for consumers in this State to maintain or acquire good health;

2. Excessive and unconscionable prices negatively impact the ability of consumers in this State to obtain prescription drugs and excessive and unconscionable price increases thereby endanger the health and safety of consumers in this State to maintain or acquire good health;

3. Excessive and unconscionable prices for prescription drugs threaten the economic well-being of consumers in this State and endanger their ability to pay for other necessary and essential goods and services including housing, food and utilities;

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

5. Excessive and unconscionable prices for prescription drugs contribute significantly to rising state costs for health care provided and paid for through:

A. State-funded medical assistance programs for consumers in this State who are elderly, are living with disabilities or have low incomes; and

B. Health insurance programs for public employees, including employees of the State, municipalities, counties, school districts and institutions of higher education, and for 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.

SUMMARY

This bill prohibits excessive price increases for generic and off-patent prescription drugs sold in this State. The bill makes prescription drug manufacturers who violate the provisions subject to enforcement action by the Attorney General.