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An Act To Increase Consumer Prescription Drug Protections

Submitted by the Department of the Attorney General pursuant to Joint Rule 204.
Reference to the Committee on Health and Human Services suggested and ordered printed.

HEATHER J.R. PRIEST
Secretary of the Senate

Presented by Senator VITELLI of Sagadahoc.
Cosponsored by Representatives: GATTINE of Westbrook, HERBIG of Belfast.

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

Sec. 1. 5 MRSA §200-K is enacted to read:

§200-K. Consumer protections; prescription drugs

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Brand-name drug" means a prescription drug approved under 21 United States Code, Section 355(b), 42 United States Code, Section 262(a) or 42 United States Code, Section 262(k).

B. "Essential off-patent or generic drug" means a prescription drug or drug-device combination product used for the delivery of a drug:

(1) For which all exclusive marketing rights, if any, granted under the Federal Food, Drug, and Cosmetic Act, Section 351 of the federal Public Health Service Act and federal patent law have expired;

(2) That appears on the model list of essential medicines most recently adopted by the World Health Organization or that is otherwise an essential medicine due to its efficacy in treating a life-threatening health condition or a chronic health condition that substantially impairs an individual's ability to engage in activities of daily living; and

(3) That is made available for sale in the State.

C. "Generic drug" means a prescription drug approved under 21 United States Code, Section 355(j).

D. "Manufacturer" means an entity that is engaged in producing, preparing, propagating, compounding, processing, packaging, repackaging or labeling a brand-name drug or a generic drug but does not include an entity that is engaged in the preparation and dispensing of a brand-name or generic drug pursuant to a prescription.

E. "Manufacturer-sponsored assistance program" means a program offered by a manufacturer or a manufacturer-supported intermediary through which a brand-name drug or a generic drug is offered to a patient at no charge or at a discounted cost.

F. "Net price" means the price after all discounts and rebates have been applied.

G. "Pharmacy benefits manager" means an entity that directly or indirectly manages prescription drug coverage provided by a 3rd-party payor, including, but not limited to, processing and payment of claims for prescription drugs, performance of drug utilization reviews, processing of prior authorization requests for prescription drugs, adjudication of appeals or grievances related to prescription drug coverage, contracting with network pharmacies and controlling the cost of covered prescription drugs.

H. "Price gouging" means an increase in the price of a prescription drug that:

(1) Is excessive and not justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug to promote public health; and

(2) Results in consumers for whom the drug has been prescribed having no meaningful choice about whether to purchase the drug at an excessive price because of:

(a) The importance of the drug to their health; and

(b) Insufficient competition in the market for the drug.

I. "Wholesale acquisition cost" means the manufacturer's list price for a brand-name drug or a generic drug per person per year or course of treatment to wholesalers or direct purchasers in the United States, not including discounts or rebates, for the most recent month for which information is available.

J. "Wholesale distributor" means a person engaged in the distribution of an essential off-patent or generic drug to persons other than consumers or patients.

2. Price gouging in essential off-patent or generic drugs; prohibition. A manufacturer or wholesale distributor may not engage in price gouging in the sale of an essential off-patent or generic drug.

A. The Attorney General may obtain data from the Maine Health Data Organization as established in Title 22, section 8703 concerning any increase in the price of an essential off-patent or generic drug when:

(1) Three or fewer manufacturers are actively manufacturing and marketing the drug for sale in the United States;

(2) The price increase, by itself or in combination with other price increases:

(a) Would result in an increase of 50% or more in the wholesale acquisition cost of the drug within the preceding 3-year period; or

(b) Would result in an increase of 50% or more in the price paid for the drug within the preceding 3-year period; and

(3) One of the following applies:

(a) A 30-day supply of the maximum recommended dosage of the drug for any indication, according to the label for the drug approved under the Federal Food, Drug, and Cosmetic Act, would cost more than $80 at the drug's wholesale acquisition cost;

(b) A full course of treatment with the drug, according to the label for the drug approved under the Federal Food, Drug, and Cosmetic Act, would cost more than $80 at the drug's wholesale acquisition cost; or

(c) If the drug is made available to consumers only in quantities that do not correspond to a 30-day supply or a full course of treatment or in a single dose, it would cost more than $80 at the drug's wholesale acquisition cost to obtain a 30-day supply or a full course of treatment.

B. On request of the Attorney General, the manufacturer of an essential off-patent or generic drug identified under paragraph A shall submit a statement to the Attorney General within 20 days after the request:

(1) Itemizing the components of the cost of producing the drug and identifying the circumstances and timing of any increase in materials or manufacturing costs that caused the increase in the price of the drug within the 3-year period preceding the date of the price increase;

(2) Identifying the circumstances and timing of any expenditures made by the manufacturer to expand access to the drug and explaining any improvement in public health associated with those expenditures; and

(3) Providing any other information that the manufacturer believes to be relevant to a determination of whether a violation of this section has occurred.

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

3. Pharmaceutical cost transparency. Upon the request of the Attorney General, the Maine Health Data Organization as established in Title 22, section 8703 shall identify annually up to 15 prescription drugs on which the State spends significant amounts of money and for which the wholesale acquisition cost has increased by 50% or more over the past 5 years or by 15% or more over the past 12 months.

A. The Maine Health Data Organization shall provide to the Attorney General a list of prescription drugs identified pursuant to this subsection and the percentage of the wholesale acquisition cost increase for each drug.

B. For each prescription drug identified on the list provided to the Attorney General pursuant to paragraph A, the Attorney General shall require the drug's manufacturer to provide a justification for the increase in the wholesale acquisition cost of the drug in a format that the Attorney General determines to be understandable and appropriate. The manufacturer shall submit to the Attorney General all relevant information and supporting documentation necessary to justify the manufacturer's wholesale acquisition cost increase, which may include:

(1) All factors that have contributed to the wholesale acquisition cost increase;

(2) The percentage of the total wholesale acquisition cost increase attributable to each factor; and

(3) An explanation of the role of each factor in contributing to the wholesale acquisition cost increase.

C. Nothing in this section may be construed to restrict the legal ability of a prescription drug manufacturer to change prices to the extent permitted under federal law.

D. The Attorney General shall provide a report to the joint standing committee of the Legislature having jurisdiction over health and human services matters on or before December 1st of each year based on the information received from manufacturers

pursuant to paragraph B. The Attorney General shall also post the report on the Office of the Attorney General's publicly accessible website.

E. Information provided to the Office of the Attorney General pursuant to this subsection is exempt from public inspection and copying under the Freedom of Access Act and may not be released in a manner that allows for the identification of an individual drug or manufacturer or that is likely to compromise the financial, competitive or proprietary nature of the information.

4. Net prices paid by pharmacy benefits managers. By March 1st of each year, a manufacturer of brand-name drugs or generic drugs sold in the State shall furnish the Attorney General with the net prices of the brand-name drugs and generic drugs paid for by pharmacy benefits managers.

5. Manufacturer-sponsored assistance programs. By March 1st of each year, a manufacturer of a brand-name drug or a generic drug sold in the State shall provide the Attorney General with a description of all manufacturer-sponsored assistance programs for that drug in the previous year, including the terms of the programs, the total amount of financial assistance provided to residents of the State and the average amount of assistance per resident of the State for whom assistance was provided.

6. Certification; penalties for noncompliance. A manufacturer of a brand-name drug or a generic drug shall certify as accurate reports required under this section. The Attorney General may bring an action in Superior Court for injunctive relief, costs and attorney's fees and to impose a civil penalty on a manufacturer of a brand-named drug or a generic drug that fails to provide the information required by this section. Failure to report required information may result in a civil penalty of up to $10,000 each day after the reporting deadline.

A violation of this section is a violation of the Maine Unfair Trade Practices Act. In any action brought pursuant to this section, the Attorney General has the same authority to investigate and to obtain remedies as if the action were brought under the Maine Unfair Trade Practices Act.

SUMMARY

This bill requires the Maine Health Data Organization to annually identify, upon the request of the Attorney General, prescription drugs on which the State spends significant amounts of money and for which the manufacturer's list price for the drug has increased by 50% or more over the past 5 years or 15% or more over the past 12 months. The Maine Health Data Organization is required to provide the list to the Attorney General, who must require the manufacturer of the drugs to provide a justification for the increase.

The bill also prohibits manufacturers and wholesale distributors from price gouging in the sale of essential off-patent or generic drugs. It authorizes the Attorney General to obtain data from the Maine Health Data Organization concerning increases in prices of essential off-patent or generic drugs and requires manufacturers of essential off-patent or generic drugs to submit information to the Attorney General upon request of the Attorney General.