SPONSOR: Rep. Bennett & Rep. Michael Smith & Sen. Paradee
Reps. Baumbach, Bentz, Brady, Dorsey Walker, Heffernan, K. Johnson, Kowalko, Lambert, Longhurst, Lynn, Minor-Brown, Mitchell, Osienski, D. Short, K. Williams; Sens. Ennis, Sokola

HOUSE OF REPRESENTATIVES
151st GENERAL ASSEMBLY

HOUSE BILL NO. 62

AN ACT TO AMEND TITLE 6 OF THE DELAWARE CODE RELATING TO THE PROHIBITION OF EXCESSIVE AND UNCONSCIONABLE PRICES FOR PRESCRIPTION DRUGS.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. The General Assembly finds and declares all of the following:

(1) Access to prescription drugs is necessary for Delawareans to maintain or acquire good health.

(2) Excessive and unconscionable prices for prescription drugs negatively impact the ability of Delawareans to obtain such drugs and accordingly endanger their health and safety.

(3) Excessive and unconscionable prices for prescription drugs threaten Delawareans' economic well-being by adversely affecting 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 costs and the cost of health care insurance which threaten the overall ability of Delawareans to obtain health care coverage and maintain or acquire good health.

(5) Excessive and unconscionable prices for prescription drugs contribute significantly to rising State costs for health care provided by and paid for through: a) state funded medical assistance programs for Delawareans who are older, living with disabilities or have low incomes, and b) health insurance programs for public employees, including state, municipal, county, school district, and institutions of higher education employees, as well as retirees whose health care costs are paid for by public funds. Rising State costs for health care threatens the ability of the State to fund the programs that provide health care for its employees and retirees as well as to fund other programs necessary for the public good and safety such as public education and public safety.

(6) It is in the public interest to provide the protections contained in this Act to shield Delawareans from the threat imposed on their safety and well-being from excessive and unconscionable prices for prescription drugs.

Section 2. Amend Chapter 25, Title 6 of the Delaware Code by adding a new Subchapter XI by making deletions as shown by strike through and insertions as shown by underline as follows:

Subchapter XI. ~~Cumulative Remedies and Enhanced Penalties~~ Prevention of Excessive and Unconscionable Prices for Prescription Drugs

§ 2598 ~~Violation of order or injunction; penalty.~~ Purpose.

It is the purpose of this subchapter to protect the safety, health and economic well-being of Delawareans by shielding them from the negative and harmful impact of excessive and unconscionable prices for prescription drugs.

(1) Definitions.

a. "Prescription Drug" means a drug required by federal or state law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients, subject to § 503(b) of the Federal Food, Drug and Cosmetic Act (21 U.S.C.§ 353(b)).

b. "Wholesale Acquisition Cost" means an estimate of the manufacturer's list price for a drug to wholesalers or other direct purchasers, not including discounts or rebates and is defined in 42 U.S.C. § 1395w-3a.

c. "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.

d. "Generic or Off-Patent Drug" means any Prescription Drug as to which any exclusive marketing rights granted under a) the federal Food, Drug, and Cosmetic Act, b) §351 of the federal Public Health Service Act, and c) federal patent law have expired and includes any drug-device combination product for the delivery of a generic drug.

(2) Excessive Price Increases Prohibited.

a. It is a violation of this subchapter for a manufacturer to impose an excessive price increase, whether directly through a wholesale distributor, pharmacy or similar intermediary or intermediaries, on the sale of any Generic or Off-Patent Drug sold, dispensed or delivered in this State to any consumer in this State.

b. A price increase is excessive for purposes of this subchapter when the following occurs:

1. The price increase, adjusted for inflation utilizing the Consumer Price Index, exceeds: a) 15 % of the Wholesale Acquisition Cost during the immediately preceding calendar year, or b) 40 % of the Wholesale Acquisition Cost during the immediately preceding 3 calendar years.

2. The price increase, adjusted for inflation using the Consumer Price Index, exceeds $30 for: a) a 30-day supply of the Generic or Off-Patent Drug, or b) a course of treatment using the Generic or Off-Patent Drug lasting less than 30 days.

c. It is not a violation of this subchapter for a wholesale distributor or pharmacy to increase the price of a Generic or Off-Patent Drug if the price increase is directly attributable to additional costs for the drug imposed on the wholesale distributor or pharmacy by the manufacturer of the drug.

(3) Registered agent.

a. Any entity that sells, distributes, delivers or offers for sale any Prescription Drug in this State is required to maintain a registered agent and office within this State.

§2599 Enforcement.

(1) The Pharmacy Benefits Manager as defined by §3302A, Title 18 of the Delaware Code, or any State agency that provides or purchases a pharmacy benefit, or any entity under contract with the State to provide pharmacy benefits, or any other State agency, shall notify the manufacturer of a Generic or Off-Patent Drug and the Attorney General of any price increase in violation of §2598(2) of this subchapter.

(2) Within 45 days of receipt of the notice required by §2599(1) of this subchapter, the manufacturer of the Generic or Off-Patent Drug shall submit a statement to the Attorney General which does all of the following:

a. Itemizes the components of the cost of producing the drug.

b. Identifies the circumstances and timing of any increase in materials or manufacturing costs that caused any increase in the price of the drug during the preceding calendar year.

c. Provides any other information that the manufacturer believes to be pertinent to a determination of whether a violation of this subchapter has occurred.

(3) The Attorney General may require a manufacturer and distributor to produce any records or documents that may be relevant to a determination of whether a violation of this subchapter has occurred.

(4) Upon a petition by the Attorney General, a court of competent jurisdiction may issue an order for any of the following:

a. Compelling the manufacturer of the Generic or Off-Patent Drug to: a) provide the statement required under §2599(2) of this subchapter, or b) produce records or documents requested by the Attorney General under §2599(3) of this subchapter that may be relevant to a determination of whether a violation of this Subchapter has occurred.

b. Restraining or enjoining a violation of this subchapter, including an order requiring prices be restored to levels that do not exceed the limits established by §2598(2)b 1 and 2 of this subchapter.

c. Requiring the manufacturer to provide an accounting to the Attorney General of all revenues generated by prescription drug prices charged in excess of the limits established by §2598(2)b 1 and 2 of this subchapter.

d. Restoring to any consumer, including any third-party payor, any money acquired as a result of a price increase that violates this subchapter.

e. Requiring that all revenues generated in violation of §2598(2) of this subchapter be remitted to this State to be used for efforts designed to reduce the cost to Delaware consumers of acquiring Prescription Drugs, if a manufacturer is unable to determine the individual transactions necessary to provide the restitution described in §2599(4)d of this subchapter.

f. Imposing a civil penalty of up to $10,000 per day for each violation of this subchapter.

g. Providing any other appropriate relief, including attorney's fees and costs reasonably incurred by the Attorney General in bringing an action against a manufacturer for violation of this subchapter.

(5) In calculating the amount of the civil penalty authorized by §2599(4)d 6 of this subchapter, every individual transaction in which a price is charged in excess of the limits set forth in §2598(2)b 1 and 2 of this subchapter constitutes a separate violation.

(6) A manufacturer or distributor of a Generic or Off-Patent Drug shall not withdraw a drug from sale or distribution within this State for the purpose of avoiding the prohibitions against excessive or unconscionable price increases contained in this subchapter.

(7) Any manufacturer who intends to withdraw a Generic or Off-Patent Drug from sale or distribution from within this State to avoid violating this subchapter shall provide written notice of its intent to withdraw to the Board of Pharmacy established under Chapter 25, Title 24 of the Delaware Code and to the Attorney General at least 180 days prior to withdrawal of the Generic or Off-Patent Drug from sale or distribution in this State.

(8) The Attorney General shall assess a penalty of $500,000 on any entity, including any manufacturer or distributor of a Generic or Off-Patent Drug, that is determined to have withdrawn a Generic or Off-Patent Drug from distribution or sale in this State in violation of §2599(6) or (7) of this subchapter.

Section 3. This Act shall become effective on January 1, 2022.

SYNOPSIS

This Act is based on a Model Act to Prevent Excessive and Unconscionable Prices for Prescription Drugs developed by the National Academy for State Health Policy. It prohibits manufacturers from raising the price of prescription drugs outside of certain market conditions that might justify a price hike. It is specifically limited to the prices charged to consumers in the State of Delaware for generic and off-patent drugs.

It authorizes the Attorney General to investigate price increases identified by State agencies above a certain threshold. Manufacturers or distributors may be fined up to $10,000 per day for sales which violate the Act. Each sale of a drug excessively and unconscionably priced constitutes a separate violation. A manufacturer or distributor is prohibited from withdrawing a generic or off-patent drug for sale in this State to avoid application of the Act.