HB3957

LRB10329676CPF56079b

103RD GENERAL ASSEMBLY

State of Illinois

2023 and 2024

HB3957

Introduced 2/17/2023, by Rep. Nabeela Syed

SYNOPSIS AS INTRODUCED:

New Act

Creates the Illinois Generic Drug Pricing Fairness Act. Provides that a manufacturer or wholesale drug distributor shall not engage in price gouging in the sale of an essential off-patent or generic drug. Provides that the Director of Healthcare and Family Services or Director of Central Management Services may notify the Attorney General of any increase in the price of any essential off-patent or generic drug under the Medical Assistance Program under the Illinois Public Aid Code or a State health plan, respectively, that amounts to price gouging. Provides that whenever the Attorney General has reason to believe that a manufacturer or wholesale drug distributor of an essential off-patent or generic drug has violated the Act, the Attorney General shall send a notice to the manufacturer or wholesale drug distributor requesting a specified statement. Provides that within 45 days after receipt of the request, the manufacturer or wholesale drug distributor shall submit the statement to the Attorney General. Provides that to accomplish the objectives and carry out the duties prescribed in the Act, the Attorney General may issue subpoenas or examine under oath any person to determine whether a manufacturer or wholesale drug distributor has violated the Act. Provides that upon petition of the Attorney General, a circuit court may issue specified orders against violations of the Act. Contains provisions concerning the disclosure of financial information provided by a manufacturer or wholesale drug distributor to the Attorney General. Effective January 1, 2024.

LRB103 29676 CPF 56079 b

A BILL FOR

AN ACT concerning regulation.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 1. Short title. This Act may be cited as the Pharmaceutical and Health Affordability: Restrictions on Manufacturers' Amoral Behavior through Reasonable Oversight Act.

Section 5. Definitions. As used in this Act:

"Essential off-patent or generic drug" means any prescription drug sold within the State:

(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 has been designated by the United States Secretary of Health and Human Services as 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 actively manufactured and marketed for

sale in the United States by 3 or fewer manufacturers.

"Essential off-patent or generic drug" includes any drug-device combination product used for the delivery of a drug 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.

"Manufacturer" has the meaning provided in Section 15 of the Wholesale Drug Distribution Licensing Act. Manufacturer" does not include an entity operating as a wholesale drug distributor as defined in Section 15 of the Wholesale Drug Distribution Licensing Act.

"Price gouging" means an unconscionable increase in a prescription drug's price that:

(1) would result in the wholesale acquisition cost of a 30-day supply of the essential off-patent or generic drug exceeding $20 and would result in an increase in the wholesale acquisition cost of the essential off-patent or generic drug of:

(A) 30% or more within the preceding year;

(B) 50% or more within the preceding 3 years; or

(C) 75% or more within the preceding 5 years;

(2) is otherwise excessive and unduly burdens consumers because of the importance of the essential off-patent or generic drug to their health and because of insufficient competition in the marketplace.

"Price gouging" does not include a price increase that can be reasonably justified by:

(1) an increase in the cost of producing the essential off-patent or generic drug; or

(2) the cost of appropriate expansion of access to the essential off-patent or generic drug to promote public health.

"State health plan" means the program of health benefits under the State Employees Group Insurance Act of 1971.

"Wholesale acquisition cost" has the meaning provided in 42 U.S.C. 1395w-3a.

"Wholesale drug distributor" has the meaning provided in Section 15 of the Wholesale Drug Distribution Licensing Act.

Section 10. Price gouging prohibited.

(a) A manufacturer or wholesale drug distributor shall not engage in price gouging in the sale of an essential off-patent or generic drug that is ultimately sold in Illinois.

It is not a violation of this Act for a wholesale distributor to increase the price of an essential off-patent or generic drug if the price increase is directly attributable to an increase in the wholesale acquisition cost for the essential off-patent or generic drug imposed on the wholesale drug distributor by the manufacturer of the drug or due to market forces in those cases where there are multiple competing generic drug products.

For the purpose of the enforcement of this Act:

(1) the Director of Healthcare and Family Services may notify the Attorney General of any increase in the price of any essential off-patent or generic drug under the Medical Assistance Program under Section V of the Illinois Public Aid Code that amounts to price gouging; and

(2) the Director of Central Management Services may notify the Attorney General of any increase in the price of any essential off-patent or generic drug under the State health plan that amounts to price gouging.

(b) If the Attorney General has reason to believe that a manufacturer or wholesale drug distributor of an essential off-patent or generic drug has violated this Act, then the Attorney General shall send a notice to the manufacturer or the wholesale drug distributor requesting a statement:

(1) itemizing the components of the cost of producing the essential off-patent or generic drug;

(2) identifying the circumstances and timing of an increase in materials or manufacturing costs that caused an increase in the wholesale acquisition cost of the essential off-patent or generic drug within the 5-year period preceding the date of the price increase;

(3) identifying the circumstances and timing of any expenditures made by the manufacturer to expand access to the essential off-patent or generic drug and explaining any improvement in public health associated with those

expenditures; and

(4) providing any other information that the manufacturer or wholesale drug distributor believes to be relevant to a determination of whether a violation of this Act has occurred.

Within 45 days after receipt of the request, the manufacturer or wholesale drug distributor shall submit the statement to the Attorney General.

To accomplish the objectives and carry out the duties prescribed in this Act, the Attorney General may issue subpoenas or examine under oath any person to determine whether a manufacturer or wholesale drug distributor has violated this Act.

(c) Upon petition of the Attorney General, a circuit court may issue an order:

(1) compelling a manufacturer or a wholesale drug distributor:

(A) to provide a statement required under subsection (b); or

(B) to produce specific records or other documents requested by the Attorney General that may be relevant to a determination of whether a violation of this Act has occurred;

(2) restraining or enjoining a violation of this Act;

(3) restoring to any consumer, including a third-party payor, any money acquired as a result of a price increase

that violates this Act;

(4) requiring a manufacturer or wholesale drug distributor that has engaged in price gouging in the sale of an essential off-patent or generic drug to make the drug available to participants in the State health plan or Medical Assistance Program under Section V of the Illinois Public Aid Code for a period of up to one year at the price at which the drug was made available to participants in Illinois immediately before the violation of this Act;

(5) imposing a civil penalty of up to $10,000 for each violation of this Act; or

(6) granting any other relief.

In response to any petition brought by the Attorney General under this Section, a manufacturer or wholesale drug distributor who is alleged to have violated this Act may not assert as a defense that the manufacturer or wholesale drug distributor did not directly sell a product to a consumer residing in Illinois.

(d) Any financial information provided by a manufacturer or a wholesale drug distributor to the Attorney General in accordance with this Section may not be disclosed to the public by the Attorney General. The financial information, while in the possession of the Attorney General, shall be exempt from disclosure by the Attorney General under the Freedom of Information Act. Notwithstanding the other provisions of this subsection, if it appears to the Attorney

General that a manufacturer or wholesale drug distributor has engaged in or is engaging in any practice declared to be in violation of this Act and that legal proceedings would be in the public interest, then the Attorney General may disclose any financial information provided in accordance with this Section in support of the filing of an action in the circuit court.

Section 99. Effective date. This Act takes effect January 1, 2024.