SB3727

LRB10337700RTM67827b

103RD GENERAL ASSEMBLY

State of Illinois

2023 and 2024

SB3727

Introduced 2/9/2024, by Sen. Ann Gillespie

SYNOPSIS AS INTRODUCED:

New Act

Creates the Patient Access to Pharmacy Protection Act. Defines terms. Provides that no person, including a pharmaceutical manufacturer, may deny, restrict, prohibit, condition, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B covered entity or a 340B contract pharmacy authorized to receive 340B drugs on behalf of the 340B covered entity unless such receipt is prohibited by federal law. Provides that no person, including a pharmaceutical manufacturer, may impose any restriction on the ability of a 340B covered entity to contract with or designate a 340B contract pharmacy including restrictions relating to the number, location, ownership, or type of 340B contract pharmacy. Provides that no person, including a pharmaceutical manufacturer, may require or compel a 340B covered entity or 340B contract pharmacy to submit or otherwise provide ingredient cost or pricing data pertinent to 340B drugs; institute requirements in any way relating to how a 340B covered entity manages its inventory of 340B drugs that are not required by a State or federal agency, including requirements relating to the frequency or scope of audits of inventory management systems of a 340B covered entity or a 340B contract pharmacy; or require a 340B covered entity or its 340B contract pharmacy to submit or otherwise provide data or information that is not required by State or federal law. Sets forth provisions concerning enforcement of this Act; preemption of this Act; and severability of this Act. Effective immediately.

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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 Patient Access to Pharmacy Protection Act.

Section 5. Findings. The General Assembly finds that:

(a) It is within the traditional authority of the State to regulate the acquisition and delivery of drugs to pharmacies and providers.

(b) Drug manufacturers are impeding access to lifesaving drugs to Illinois residents, especially those in rural and medically underserved communities, by limiting or placing conditions on acquisition and delivery of drugs purchased through the federal 340B drug discount program by 340B covered entities that utilize contract pharmacies to distribute 340B drugs.

(c) The federal 340B statute is silent on distribution of 340B-acquired drugs to 340B covered entities and their contract pharmacy partners.

(d) The State's compelling interest in preserving and improving access to health care services for the People of the State of Illinois requires it to ensure that 340B covered entities continue to be allowed to contract with one or more

pharmacies to receive 340B drugs and dispense them to the patients of 340B covered entities.

(e) That addressing accessibility of these life-saving medications is a matter of health, safety, and welfare for the people of the State of Illinois.

Section 10. Definitions. As used in this Act:

"340B drug discount program" means the program established under Section 340B of the federal Public Health Service Act, 42 U.S.C. 256b.

"340B contract pharmacy" means any pharmacy that is under contract with a 340B covered entity to dispense 340B drugs on behalf of the 340B covered entity and is either (i) located in Illinois and qualifies as a pharmacy under Section 3 of the Pharmacy Practice Act; or (ii) is located in a state, commonwealth, or territory of the United States, other than Illinois, and dispenses 340B drugs on behalf of the 340B covered entity.

"340B covered entity" means an entity in Illinois that qualifies as a covered entity under Section 340B of the federal Public Health Service Act, 42 U.S.C. 256b(a)(4).

"340B drug" means a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. 256b and is purchased by a 340B covered entity.

"Department" means the Department of Financial and Professional Regulation.

"Manufacturer" has the meaning given to that term in the Wholesale Drug Distribution Licensing Act.

"Person" means and includes a natural person, partnership, association, corporation, or any other legal business entity, but does not include any federal or state government entity or body.

"Secretary" means the Secretary of Financial and Professional Regulation.

Section 15. Protection of patient access to pharmacy.

(a) No person, including a pharmaceutical manufacturer, may deny, restrict, prohibit, condition, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B covered entity or a 340B contract pharmacy authorized to receive 340B drugs on behalf of the 340B covered entity unless such receipt is prohibited by federal law.

(b) No person, including a pharmaceutical manufacturer, may impose any restriction on the ability of a 340B covered entity to contract with or designate a 340B contract pharmacy including restrictions relating to the number, location, ownership, or type of 340B contract pharmacy.

(c) No person, including a pharmaceutical manufacturer, may require or compel a 340B covered entity or 340B contract pharmacy to:

(1) submit or otherwise provide ingredient cost or

pricing data pertinent to 340B drugs;

(2) institute requirements in any way relating to how a 340B covered entity manages its inventory of 340B drugs that are not required by a state or federal agency, including requirements relating to the frequency or scope of audits of inventory management systems of a 340B covered entity or a 340B contract pharmacy; or

(3) require a 340B covered entity or its 340B contract pharmacy to submit or otherwise provide data or information that is not required by State or federal law.

(d) Each individual saleable unit, as such term is defined in 21 U.S.C. 360eee-11, of 340B drugs that is subject to a prohibited act in subsections (a) and (b) shall constitute a separate violation of this Act. Each communication received by a 340B covered entity or 340B contract pharmacy in violation of subsection (c) shall constitute a separate violation of this Act.

Section 20. Enforcement.

(a) The Department is authorized to enforce this Act and investigate possible violations of this Act by any person, including a pharmaceutical manufacturer, including, but not limited to, the issuance of subpoenas to:

(1) require the person, including a pharmaceutical manufacturer, to file a statement or report or answer interrogatories in writing as to all information relevant

to the alleged violations;

(2) examine under oath any person, including a pharmaceutical manufacturer, who possesses knowledge or information directly related to the alleged violations; or

(3) examine any record, book, document, account, or paper necessary to investigate the alleged violation.

(b) If the Department determines that there is a reason to believe that any person, including a pharmaceutical manufacturer, has violated this Act, the Secretary may, in the name of the People of the State of Illinois, through the Attorney General of the State of Illinois or the State's Attorney of a county in which the action is brought, bring an action to obtain, and a court may order:

(1) temporary, preliminary, or permanent injunctive relief for any act, policy, or practice that violates this Act;

(2) money damages to be paid to the 340B covered entity as a result of the violation of this Section;

(3) the assessment of a civil penalty of up to $10,000 for each violation of Section 15; or

(4) any other relief.

(c) Whenever a 340B covered entity or 340B contract pharmacy has reason to believe that any person, including a pharmaceutical manufacturer, has violated Section 15, a 340B covered entity or 340B contract pharmacy may bring a civil

action to obtain, and a court may order:

(1) temporary, preliminary, or permanent injunctive relief for any act, policy, or practice that violates this Act;

(2) money damages to be paid to the 340B covered entity as a result of the violation of this Section;

(3) the assessment of a civil penalty of up to $10,000 for each violation of Section 15;

(4) reimbursement for the costs and reasonable attorney's fees incurred in bringing the action; or

(5) any other relief.

(d) The actions described in subsections (b) and (c) may be consolidated or combined if a court believes that an action in such form is in the best interests of judicial economy. If an action brought under subsection (b) involves the same or similar allegations as an action brought under subsection (c), then the actions may be combined.

Section 25. Preemption.

(a) Nothing in this Act shall be construed or applied to be less restrictive than federal law for a person regulated by this Act.

(b) Nothing in this Act shall be construed or applied in a manner that would conflict with:

(1) applicable federal law; or

(2) other laws of this State if the State law is

compatible with applicable federal law.

(c) Limited distribution of a drug required under 21 U.S.C. 355-1 may not to be construed as a violation of this Act.

Section 90. Severability. If any provision of this Act or its application to any person or circumstance is held invalid, the invalidity of that provision or application does not affect other provisions or applications of this Act that can be given effect without the invalid provision or application. Each paragraph defining "340B contract pharmacy" in Section 10 is severable.

Section 99. Effective date. This Act takes effect upon becoming law.