As Introduced

135th General Assembly
Regular Session **H. B. No. 588**
2023-2024

Representatives Holmes, John

A BILL

To enact section 4729.521 of the Revised Code to prohibit drug manufacturers and wholesalers from taking certain actions regarding reimbursements made to 340B covered entities.

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

Section 1. That section 4729.521 of the Revised Code be enacted to read as follows:

Sec. 4729.521. (A) As used in this section:

(1) "340B covered entity" has the same meaning as in section 5167.01 of the Revised Code.

(2) "340B drug" means a drug that meets all of the following criteria:

(a) The drug is a covered outpatient drug under the 340B drug pricing program.

(b) The drug is subject to any offer for reduced prices by a manufacturer pursuant to the 340B drug pricing program.

(c) The drug is purchased by a 340B covered entity or would have been purchased by a covered entity if not for an

action prohibited under division (B) of this section.

(3) "340B drug pricing program" means the program authorized by section 340B of the "Public Health Service Act," 42 U.S.C. 256b.

(4) "Package" has the same meaning as in 21 U.S.C. 360eee.

(B) No manufacturer of dangerous drugs, repackager of dangerous drugs, third-party logistics provider, or wholesale distributor of dangerous drugs, or an agent or affiliate of any of those entities, shall do either of the following:

(1) Deny, prohibit, restrict, discriminate against, or otherwise limit the acquisition of a 340B drug by or delivery of a 340B drug to a 340B covered entity, unless the purchase or delivery is prohibited by the United States department of health and human services;

(2) Require a 340B covered entity to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug by or delivery of a 340B drug to a covered entity, unless the claims or utilization data sharing is required by the United States department of health and human services.

(C) The commission of any act prohibited by division (B) of this section is an unlawful practice under section 1345.02 of the Revised Code. The attorney general may enforce compliance with this section and take the actions permitted under section 1345.02 of the Revised Code, except that the attorney general may assess a civil penalty of $50,000 for each violation. Each package of 340B drugs determined by the attorney general to be subject to a prohibited act under division (B) of this section constitutes a separate violation. In addition to the civil penalty, the attorney general may refer any complaint of a

violation of division (B) of this section to the state board of pharmacy for the board to consider one or more of the sanctions set forth in division (A)(1) of section 4729.56 of the Revised Code.

(D) The attorney general may adopt rules, or may delegate authority to the board of pharmacy to adopt rules, pursuant to Chapter 119. of the Revised Code, to implement the provisions of this section.

(E) Nothing in this section shall be construed to conflict with or be less restrictive than applicable federal law or regulations, including 21 U.S.C. 355-1, or applicable laws or regulations of this state.