By: Blanco H.B. No. 697

A BILL TO BE ENTITLED

AN ACT

relating to required prescription drug cost and rebate reporting; authorizing a civil penalty.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Section 430.001, Health and Safety Code, is amended by amending Subdivision (1) and adding Subdivision (1-a) to read as follows:

(1) "Commission" means the Health and Human Services Commission.

(1-a) "Commissioner" means the commissioner of state health services.

SECTION 2. Subchapter E, Chapter 431, Health and Safety Code, is amended by adding Sections 431.1165 and 431.1166 to read as follows:

Sec. 431.1165. PRESCRIPTION DRUG MANUFACTURER COST REPORTING; CIVIL PENALTY. (a) In this section:

(1) "Manufacturer" means a person licensed or approved by the United States Food and Drug Administration to engage in the manufacture of drugs or devices, consistent with the federal agency's definition of "manufacturer" under the agency's regulations and guidances implementing the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100-293). The term does not include a pharmacist engaged in compounding that is within the practice of pharmacy and is in accordance with a prescription drug

order or initiative from a practitioner for a patient or prepackaging that complies with Section 562.154, Occupations Code.

(2) "Prescription drug" has the meaning assigned by 21 C.F.R. Section 203.3.

(b) Not later than February 1 of each year, the commission shall:

(1) identify the prescription drugs and the wholesale price for each drug the commission determines is essential to treating diabetes in this state, including insulin and biguanides;

(2) identify the prescription drugs described by Subdivision (1) for which the wholesale price has increased in an amount equal to or greater than:

(A) the percentage of price increase in the medical care component of the consumer price index as published by the Bureau of Labor Statistics of the United States Department of Labor during the preceding calendar year; or

(B) two times the percentage of price increase in the medical care component of the consumer price index as published by the Bureau of Labor Statistics of the United States Department of Labor during the preceding two calendar years; and

(3) post the information compiled under Subdivisions (1) and (2) on the commission's Internet website.

(c) Not later than August 1 of each year, a manufacturer shall submit to the commission, in the manner and form prescribed by the executive commissioner, a report for each prescription drug identified under Subsection (b) that is manufactured by the manufacturer and available for sale in this state.

(d) For each prescription drug identified under Subsection (b)(1) and included in the report under Subsection (c), the manufacturer, for the preceding calendar year, shall provide:

(1) the cost incurred by the manufacturer in producing the drug;

(2) the wholesale price of the drug;

(3) a history of any increases in the wholesale price of the drug for the preceding five years, including the amount of each increase expressed as a percentage of the total wholesale price of the drug, the month and year the price increase took effect, and any explanation for the price increase;

(4) the profit derived from the sale of the drug, expressed as an amount and as a percentage of the manufacturer's total profit from all prescription drugs sold by the manufacturer;

(5) the administrative, marketing, and advertising costs of promoting the drug;

(6) the cost to the manufacturer of coupons provided directly to consumers to assist consumers in paying copayments and the value of the coupons redeemed;

(7) the cost to the manufacturer of programs designed to assist consumers in paying copayments for the drug;

(8) the amount of financial assistance provided for the drug by the manufacturer through patient prescription assistance programs; and

(9) the aggregate amount of rebates paid to pharmacy benefit managers, as defined by Section 4151.151, Insurance Code, for sales of the drug in this state.

(e) For each prescription drug identified under Subsection (b)(2) and included in the report under Subsection (c), the manufacturer, for the preceding calendar year, shall provide information that justifies the increase in the wholesale price, including:

(1) the factors contributing to the wholesale price increase;

(2) the percentage of the total wholesale price increase attributable to each factor; and

(3) an explanation of the role of each factor in contributing to the wholesale price increase.

(f) Not later than December 1 of each year, the commission shall prepare and post on the commission's Internet website a report outlining the information provided by a manufacturer under this section. The report may not include information likely to compromise the financial, competitive, or proprietary nature of the information.

(g) Information provided by a manufacturer to the commission under this section is confidential and is not subject to disclosure under Chapter 552, Government Code.

(h) A manufacturer that does not submit the report required by Subsection (c) is liable to the state for a civil penalty of not more than $5,000 for each violation. The commission may waive the civil penalty if a manufacturer provides good cause for the manufacturer's failure to submit the report. Each failure to provide information to the commission is a separate violation and each day of continuing violation constitutes a separate violation.

The attorney general at the request of the commission may bring suit to provide for injunctive relief or to recover a civil penalty, or both. The attorney general may recover court costs and reasonable attorney's fees.

Sec. 431.1166. PHARMACY BENEFIT MANAGER PRESCRIPTION DRUG REBATE REPORTING. (a) In this section:

(1) "Manufacturer" means a person licensed or approved by the United States Food and Drug Administration to engage in the manufacture of drugs or devices, consistent with the federal agency's definition of "manufacturer" under the agency's regulations and guidances implementing the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100-293). The term does not include a pharmacist engaged in compounding that is within the practice of pharmacy and is in accordance with a prescription drug order or initiative from a practitioner for a patient or prepackaging that complies with Section 562.154, Occupations Code.

(2) "Pharmacy benefit manager" has the meaning assigned by Section 4151.151, Insurance Code.

(3) "Prescription drug" has the meaning assigned by 21 C.F.R. Section 203.3.

(b) Not later than August 1 of each year, a pharmacy benefit manager shall submit a report to the commission, in the manner and form prescribed by the executive commissioner, regarding rebates for each prescription drug identified under Section 431.1165(b)(1) that is available for sale in this state. The report must include:

(1) the total amount of rebates the pharmacy benefit manager negotiated with all manufacturers during the preceding

calendar year;

(2) the amount of the rebates described in Subdivision (1) that were retained by the pharmacy benefit manager; and

(3) the amount of any rebates described in Subdivision (1) that were negotiated for use by persons who receive prescription drug benefits or assistance under Medicare or a state, local, or federal public program.

(c) This section does not apply to prescription drug benefits provided under a health care benefit plan established under the Employee Retirement Income Security Act of 1974 (29 U.S.C. Section 1001 et seq.).

(d) Not later than December 1 of each year, the commission shall prepare and post on the commission's Internet website a report outlining the information provided by a pharmacy benefit manager under this section. The report may not include information that is likely to compromise the financial, competitive, or proprietary nature of the information.

(e) Information provided by a pharmacy benefit manager to the commission under this section is confidential and is not subject to disclosure under Chapter 552, Government Code.

SECTION 3. As soon as practicable after the effective date of this Act, the executive commissioner of the Health and Human Services Commission shall adopt rules necessary to implement Sections 431.1165 and 431.1166, Health and Safety Code, as added by this Act.

SECTION 4. This Act takes effect September 1, 2019.