By: Reynolds H.B. No. 1794

A BILL TO BE ENTITLED

AN ACT

relating to price transparency for certain prescription drugs; authorizing civil penalties.

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

SECTION 1. Subtitle A, Title 6, Health and Safety Code, is amended by adding Chapter 441 to read as follows:

CHAPTER 441. PRESCRIPTION DRUG PRICE TRANSPARENCY

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 441.0001. DEFINITIONS. In this chapter:

(1) "Advisory committee" means the drug price transparency advisory committee established under Subchapter D.

(2) "Average wholesale price" means the average wholesale cost of an expensive drug that is based on the Medi-Span price references for the drug's 11-digit national drug code as submitted and used by the dispensing pharmacy to fill the prescription for the drug.

(3) "Expensive drug" means a prescription drug made available by a manufacturer in this state that has a wholesale acquisition cost of $2,500 or more per year or through the course of a patient's treatment.

(4) "Manufacturer" means a person who:

(A) is authorized by the United States Food and Drug Administration to market and sell an expensive drug in the United States as an originator or license holder; or

(B) directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with a person described by Paragraph (A).

(5) "Purchaser" means a person who purchases a prescription drug under a health benefit plan, including:

(A) this state or an administrator of a health benefit plan sponsored by this state, including:

(i) the state Medicaid program operated under Chapter 32, Human Resources Code;

(ii) a basic coverage plan under Chapter 1551, Insurance Code; and

(iii) the child health plan program under Chapter 62;

(B) a political subdivision of this state;

(C) a health benefit plan issuer subject to regulation by this state; and

(D) a pharmacy benefit manager as defined by Section 4151.151, Insurance Code.

(6) "Therapeutic class" means a therapeutic category or class of prescription drugs established by the United States Pharmacopeia that reflects therapeutic uses of drugs based on the International Classification of Diseases diagnostic codes.

(7) "Wholesale acquisition cost" has the meaning assigned by 42 U.S.C. Section 1395w-3a.

SUBCHAPTER B. MANUFACTURER REPORTING

Sec. 441.0051. ANNUAL REPORT REQUIRED. Not later than March 31 of each year, a manufacturer of an expensive drug sold or

offered for sale in this state shall submit a report to the department in the form and manner prescribed by department rule and in accordance with this subchapter.

Sec. 441.0052. REPORT CONTENTS. A manufacturer shall include in the report described by Section 441.0051 for each expensive drug:

(1) the total research and development costs for the drug, including the costs:

(A) incurred by the manufacturer;

(B) incurred by any predecessor to the manufacturer;

(C) incurred by any other person; and

(D) paid by or through governmental sources or grants;

(2) the intellectual property rights, approvals, and associated regulatory costs for the drug, including:

(A) a list of all product and process patents and all data market and exclusivity awarded by the United States Patent and Trademark Office for the drug;

(B) all reverse payment settlements involving the drug; and

(C) all regulatory costs paid by the manufacturer or its predecessors in obtaining the rights and approvals, including the United States Food and Drug Administration user and filing fees and patent filing fees;

(3) the manufacturing, production, marketing, and advertising costs, including:

(A) the total annual and cumulative itemized costs to produce the drug from the time the manufacturer began producing the drug;

(B) the manufacturer's total direct costs for materials, manufacturing, and administration attributable to the drug; and

(C) all marketing and advertising costs to promote the drug directly to consumers, including:

(i) costs associated with consumer copay coupons;

(ii) amounts redeemed with consumer copay coupons; and

(iii) marketing and advertising costs for promotion of the drug directly or indirectly to individuals who are prescribed the drug;

(4) the prices of the drug and revenue from the drug's sales, including:

(A) the total revenues from sales in this state and in the United States, listed separately, for each of the preceding five calendar years; and

(B) a cumulative monthly history of increases in the average wholesale price or wholesale acquisition cost for the drug in the preceding five calendar years, including each month in which an increase took effect;

(5) the manufacturer's federal, state, and local income tax rates, governmental benefits, and credits, including:

(A) the federal income tax rate paid by the

manufacturer;

(B) the total amount paid by any person other than the manufacturer for materials, manufacturing, marketing, advertising, administration, and other costs associated with the drug, including any federal, state, or local tax credits or subsidies, tax deductions, grants, or other support received or deferred; and

(C) income from any source for any of the following activities occurring in a foreign country by or on behalf of the manufacturer:

(i) the research, development, manufacture, or production of the drug;

(ii) the sale, exchange, or disposition of the drug; or

(iii) the lease, rental, or licensing of the drug;

(6) the manufacturer's financial assistance to patients, including:

(A) the total amount of financial assistance to patients the manufacturer has provided for the drug during the preceding five calendar years, including:

(i) discounts;

(ii) rebates and patient prescription assistance programs;

(iii) copay assistance costs; and

(iv) total donations to patient assistance nonprofits and the related tax deductions; and

(B) the number of patients who have benefited from the manufacturer's financial assistance for each of the preceding five calendar years;

(7) the comparative effectiveness of the drug, including:

(A) the therapeutic class of the drug;

(B) the names of any other brand or generic drug approved by the United States Food and Drug Administration in the same therapeutic class; and

(C) any clinical or pharmacoeconomic evidence indicating the drug's improved efficacy compared to all other brand or generic drugs described by Paragraph (B); and

(8) any other information required to be included under rules adopted under this chapter.

Sec. 441.0053. MANUFACTURER DUTIES. A manufacturer required to submit a report under Section 441.0051 shall:

(1) separately identify by page number and line the information included in the report to the maximum extent possible to promote public transparency and understanding of the information;

(2) provide documentation for the information included in the report;

(3) have the information in the annual report audited by an independent third-party auditor before the report is filed with the department; and

(4) include information for the preceding calendar year unless otherwise required under this subchapter or a rule

adopted under this chapter.

Sec. 441.0054. PUBLIC INFORMATION. (a) A report described by Section 441.0051 is public information under Chapter 552, Government Code.

(b) The department shall post each report described by Section 441.0051 on the department's Internet website.

Sec. 441.0055. ENFORCEMENT. (a) If a manufacturer violates this subchapter or a rule adopted under this subchapter:

(1) the manufacturer is liable for a civil penalty not to exceed $10,000 for each day the violation continues; and

(2) the attorney general may bring a writ of mandamus against the manufacturer to compel compliance with this subchapter.

(b) If the attorney general brings a writ of mandamus under Subsection (a):

(1) the attorney general shall provide written notice to the manufacturer not later than the seventh day before the date the attorney general brings the writ; and

(2) the attorney general may recover attorney's fees and costs if the attorney general prevails.

(c) The attorney general may sue to collect a civil penalty imposed under this section and may recover attorney's fees and costs if the attorney general prevails.

SUBCHAPTER C. DISCLOSURE OF PRICE INCREASES

Sec. 441.0101. NOTICE REQUIRED. (a) Not later than the 60th day before the date a price increase takes effect, a manufacturer shall submit written notice to the department before the manufacturer increases the average wholesale price or wholesale

acquisition cost of an expensive drug by more than:

(1) the lesser of 10 percent or $2,500 during a 12-month period; or

(2) 15 percent cumulatively during any 24-month period.

(b) The notice described by Subsection (a) must state:

(1) the justification for the price increase;

(2) the marketing budget for the drug in the preceding calendar year;

(3) if the drug was not developed by the manufacturer, the date the drug was acquired by the manufacturer and the price of the acquisition; and

(4) the history of all price increases for the drug that took effect during the preceding five calendar years.

Sec. 441.0102. DEPARTMENT DUTIES; RULES. (a) Not later than 15 days after the date a manufacturer submits a notice under Section 441.0101, the department shall:

(1) post the notice on the department's Internet website; and

(2) send electronic notice of the submission to:

(A) purchasers that have requested to receive notification; and

(B) the Texas State Board of Pharmacy.

(b) The executive commissioner by rule shall establish a process through which a purchaser may request to receive notice of a submission under this subchapter.

Sec. 441.0103. PUBLIC INFORMATION. A notice described by

Section 441.0101 is public information under Chapter 552, Government Code.

Sec. 441.0104. CIVIL PENALTY. (a) If a manufacturer violates this subchapter or a rule adopted under this subchapter the manufacturer is liable for a civil penalty in an amount not to exceed $10,000 for each day the violation continues.

(b) The attorney general may sue to collect a civil penalty imposed under this section and may recover attorney's fees and costs if the attorney general prevails.

SUBCHAPTER D. DRUG PRICE TRANSPARENCY ADVISORY COMMITTEE

Sec. 441.0151. ESTABLISHMENT. The department shall establish the drug price transparency advisory committee.

Sec. 441.0152. COMPOSITION. (a) The advisory committee consists of nine members appointed by the commissioner as follows:

(1) the commissioner or the commissioner's designee;

(2) two academic public health researchers;

(3) one economist;

(4) one certified public accountant;

(5) one licensed physician who practices in this state;

(6) one licensed pharmacist who practices in this state; and

(7) two consumer representatives.

(b) An advisory committee member may not be affiliated with a manufacturer or have any other conflict of interest regarding advisory committee duties.

(c) The commissioner or the commissioner's designee serves

as the presiding officer of the advisory committee.

Sec. 441.0153. DUTIES. The advisory committee shall advise the department or executive commissioner, as applicable, regarding:

(1) the development of rules adopted under this chapter;

(2) the review of annual reports required under Section 441.0051; and

(3) the preparation of a report the department is required to publish under Section 441.0202.

Sec. 441.0154. ADVISORY COMMITTEE RULES. The executive commissioner shall adopt rules necessary to implement this subchapter, including rules on:

(1) the number of times the advisory committee is required to meet each year;

(2) the compensation for and reimbursement for expenses incurred by advisory committee members; and

(3) the terms of advisory committee members.

SUBCHAPTER E. RULES AND DEPARTMENT REPORT

Sec. 441.0201. RULES. The executive commissioner, in consultation with the advisory committee, shall adopt rules necessary to implement this chapter. The rules must:

(1) facilitate public transparency regarding:

(A) the pricing of expensive drugs;

(B) the revenue realized by the manufacturers from the sale of expensive drugs; and

(C) the return on public investment in the

development of expensive drugs made through federal, state, or local grants or other governmental financial assistance;

(2) identify any additional specific information within each of the categories listed in Section 441.0052 that a manufacturer must include in the report; and

(3) include a uniform reporting form that a manufacturer must use to facilitate the disclosure of information required to be reported under this chapter and the department's preparation of the report required under Section 441.0202.

Sec. 441.0202. DEPARTMENT REPORT. (a) Not later than September 30 of each year, the department shall prepare and publish on the department's Internet website a report that summarizes the reports filed by manufacturers under Subchapter B during the preceding calendar year.

(b) The department shall provide a copy of the report described by Subsection (a) to the governor, lieutenant governor, speaker of the house of representatives, and each member of the legislature.

SECTION 2. (a) A manufacturer is not required to submit an annual report under Section 441.0051, Health and Safety Code, as added by this Act, before March 31, 2021.

(b) The Department of State Health Services is not required to publish a report under Section 441.0202, Health and Safety Code, as added by this Act, before September 30, 2021.

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

Chapter 441, Health and Safety Code, as added by this Act.

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