HEALTH AND SAFETY CODE

TITLE 6. FOOD, DRUGS, ALCOHOL, AND HAZARDOUS SUBSTANCES

SUBTITLE A. FOOD AND DRUG HEALTH REGULATIONS

CHAPTER 441. DRUG COST TRANSPARENCY

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 441.0001. DEFINITIONS. In this chapter:

(1) "Animal health product" means a medical product approved and licensed for use in animal or veterinary medicine, including a pharmaceutical, a biologic, an insecticide, and a parasiticide.

(2) "Pharmaceutical drug manufacturer" means a person engaged in the business of producing, preparing, propagating, compounding, converting, processing, packaging, labeling, or distributing a drug. The term does not include a wholesale distributor or retailer of prescription drugs or a pharmacist licensed under Subtitle J, Title 3, Occupations Code.

(3) "Prescription drug" and "drug" have the meanings assigned by Section 551.003, Occupations Code, except that the term "prescription drug" does not include a device or an animal health product.

(4) "Wholesale acquisition cost" means, with respect to a drug, the pharmaceutical drug manufacturer's list price for the drug charged to wholesalers or direct purchasers in the United States, as reported in wholesale price guides or other publications of drug pricing data. The cost does not include any rebates, prompt pay or other discounts, or other reductions in price.

Added by Acts 2019, 86th Leg., R.S., Ch. 1291 (H.B. 2536), Sec. 1, eff. September 1, 2019.

Sec. 441.0003. RULES. The executive commissioner may adopt rules to implement this chapter.

Added by Acts 2021, 87th Leg., R.S., Ch. 50 (H.B. 1033), Sec. 1, eff. September 1, 2021.

SUBCHAPTER B. PRESCRIPTION DRUG PRICE DISCLOSURE

Sec. 441.0051. ANNUAL REPORT. Not later than the 15th day of each calendar year, a pharmaceutical drug manufacturer shall submit a report to the department stating the current wholesale acquisition cost information for the United States Food and Drug Administration-approved prescription drugs sold in or into this state by that manufacturer.

Added by Acts 2019, 86th Leg., R.S., Ch. 1291 (H.B. 2536), Sec. 1, eff. September 1, 2019.

Transferred, redesignated and amended from Health and Safety Code, Section 441.0002 by Acts 2021, 87th Leg., R.S., Ch. 50 (H.B. 1033), Sec. 3, eff. September 1, 2021.

Sec. 441.0052. PRESCRIPTION DRUG PRICE INFORMATION INTERNET WEBSITE. The department shall develop an Internet website to provide to the general public prescription drug price information submitted under Section 441.0051. The Internet website shall be made available on the department's Internet website with a dedicated link that is prominently displayed on the home page or by a separate easily identifiable Internet address.

Added by Acts 2019, 86th Leg., R.S., Ch. 1291 (H.B. 2536), Sec. 1, eff. September 1, 2019.

Transferred, redesignated and amended by Acts 2021, 87th Leg., R.S., Ch. 50 (H.B. 1033), Sec. 3, eff. September 1, 2021.

Sec. 441.0053. PRESCRIPTION DRUG COST INCREASE REPORT AND INFORMATION. (a) This subsection applies only to a prescription drug with a wholesale acquisition cost of at least $100 for a 30-day supply before the effective date of an increase described by this subsection. Not later than the 30th day after the effective date of an increase of 40 percent or more over the preceding three calendar years or 15 percent or more in the preceding calendar year in the wholesale acquisition cost of a prescription drug to which this subsection applies, a pharmaceutical drug manufacturer shall submit a report to the executive commissioner. The report must include the following information:

(1) the name of the prescription drug;

(2) whether the prescription drug is a brand name or generic;

(3) the effective date of the change in wholesale acquisition cost; and

(4) a statement regarding the factor or factors that caused the increase in the wholesale acquisition cost and an explanation of the role of each factor's impact on the cost.

(b) If during a calendar year a prescription drug with a wholesale acquisition cost of at least $100 for a 30-day supply increases in price by 40 percent or more over the preceding three calendar years or 15 percent or more in the preceding calendar year in the wholesale acquisition cost of the prescription drug, the pharmaceutical drug manufacturer must include in the annual report submitted under Section 441.0051 the following information:

(1) aggregate, company-level research and development costs for the most recent year for which final audit data is available;

(2) the name of each of the manufacturer's prescription drugs approved by the United States Food and Drug Administration in the previous three calendar years; and

(3) the name of each of the manufacturer's prescription drugs that lost patent exclusivity in the United States in the previous three calendar years.

(c) The quality and types of information and data that a pharmaceutical drug manufacturer submits to the department under Subsections (a) and (b) must be consistent with the quality and types of information and data that the manufacturer includes in the manufacturer's annual consolidated report on Securities and Exchange Commission Form 10-K or any other public disclosure.

Added by Acts 2019, 86th Leg., R.S., Ch. 1291 (H.B. 2536), Sec. 1, eff. September 1, 2019.

Transferred, redesignated and amended by Acts 2021, 87th Leg., R.S., Ch. 50 (H.B. 1033), Sec. 3, eff. September 1, 2021.

Sec. 441.0054. PUBLICATION OF COST INCREASE INFORMATION. Not later than the 60th day after receipt of the report submitted under Section 441.0051 or 441.0053(a), the department shall publish

the cost increase information required by Section 441.0053 on the department's prescription drug price information Internet website.
Added by Acts 2019, 86th Leg., R.S., Ch. 1291 (H.B. 2536), Sec. 1, eff. September 1, 2019.
Transferred, redesignated and amended by Acts 2021, 87th Leg., R.S., Ch. 50 (H.B. 1033), Sec. 3, eff. September 1, 2021.

Sec. 441.0055. FEE. (a) A pharmaceutical drug manufacturer shall submit a fee in the amount provided by department rule with each report submitted under this subchapter.

(b) The executive commissioner by rule shall set the fee in the amount necessary for the department to administer this chapter, not to exceed $400.
Added by Acts 2021, 87th Leg., R.S., Ch. 50 (H.B. 1033), Sec. 4, eff. September 1, 2021.

SUBCHAPTER C. ENFORCEMENT

Sec. 441.0101. RIGHT TO CORRECT. (a) If the department determines that a pharmaceutical drug manufacturer failed to submit a report or fee required under, or failed to submit the report or fee in the manner prescribed by, Subchapter B and the rules adopted under this chapter, the department shall provide written notice of the failure to the manufacturer.

(b) On receipt of notice described by Subsection (a), a pharmaceutical drug manufacturer shall submit, as applicable:

(1) a report that:

(A) complies with Subchapter B and rules adopted under this chapter; and

(B) addresses the issues raised in the notice; or

(2) the fee required by Section 441.0055.

(c) The department may not assess an administrative penalty under Section 441.0102 against a pharmaceutical drug manufacturer that submits to the department the required report or fee, as applicable, on or before the 45th day after the date the manufacturer receives notice under Subsection (a).
Added by Acts 2021, 87th Leg., R.S., Ch. 50 (H.B. 1033), Sec. 5,

eff. September 1, 2021.

Sec. 441.0102. ADMINISTRATIVE PENALTY. (a) The department may assess an administrative penalty against a person who violates this chapter or a rule adopted under this chapter.

(b) In determining the amount of the penalty, the department shall consider:

(1) the person's previous violations;

(2) the seriousness of the violation;

(3) the person's demonstrated good faith; and

(4) any other matters as justice may require.

(c) The penalty may not exceed $1,000 a day for each violation.

(d) Each day a violation continues may be considered a separate violation.

(e) The enforcement of the penalty may be stayed during the time the order is under judicial review if the person pays the penalty to the clerk of the court or files a supersedeas bond with the court in the amount of the penalty. A person who cannot afford to pay the penalty or file the bond may stay the enforcement by filing an affidavit in the manner required by the Texas Rules of Civil Procedure for a party who cannot afford to file security for costs, subject to the right of the board to contest the affidavit as provided by those rules.

(f) The attorney general may sue to collect the penalty. Money collected under this section shall be deposited in the state treasury and may be appropriated only to the department for the purposes of administrating this chapter.

Added by Acts 2021, 87th Leg., R.S., Ch. 50 (H.B. 1033), Sec. 5, eff. September 1, 2021.

Sec. 441.0103. ADMINISTRATIVE PROCEDURE. A proceeding to impose an administrative penalty under Section 441.0102 is considered to be a contested case under Chapter 2001, Government Code.

Added by Acts 2021, 87th Leg., R.S., Ch. 50 (H.B. 1033), Sec. 5, eff. September 1, 2021.