BILL ANALYSIS

Senate Research Center
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S.B. 875
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AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

In 2019, H.B. 2536 was enacted. The bill requires drug manufacturers to report the wholesale acquisition cost (WAC) of all United States Food and Drug Administration-approved drugs sold in or into Texas. Manufacturers are also required to report on price increases exceeding a certain threshold compared to prices at certain time frames, and manufacturers are required to provide reasons for the price increase on the Health and Human Services Commission website.

C.S.S.B. 875 will improve the statute created by H.B. 2536. The bill streamlines reporting by requiring manufacturers to disclose research and development (R&D) costs annually, limits the scope of the word drug to pharmaceutical drugs, and allows the Department of State Health Services to administer a fee for implementation and fines for failures to disclose price increases.

The committee substitute will remove the requirement that the report include information regarding the Child Health Plan Program and the Medical Assistance Program. The committee substitute will also change the reporting date for pharmacy benefit managers and health plan issuers from March 1 of each year to May 1 of each year. This change is necessary because the data that the pharmacy benefit managers and health plan issuers are required to include in the report is not available at the earlier date.

As proposed, S.B. 875 amends current law relating to prescription drug price disclosure; authorizes a fee; and provides an administrative penalty.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission (executive commissioner) in SECTION 1 (Section 441.0003, Health and Safety Code) and SECTION 4 (Section 441.0055, Health and Safety Code) of this bill.

Rulemaking authority previously granted to the executive commissioner is rescinded in SECTION 3 (Section 441.0054, Health and Safety Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Subchapter A, Chapter 441, Health and Safety Code, by adding Section 441.0003, as follows:

> Sec. 441.0003. RULES. Authorizes the executive commissioner of the Health and Human Services Commission (executive commissioner; HHSC) to adopt rules to implement Chapter 441 (Drug Cost Transparency).

SECTION 2. Amends Chapter 441, Health and Safety Code, by adding Subchapter B, and adds a heading to that subchapter, to read as follows:

SUBCHAPTER B. PRESCRIPTION DRUG PRICE DISCLOSURE

SECTION 3. Transfers Section 441.0002, Health and Safety Code, to Subchapter B, Chapter 441, Health and Safety Code, as added by this Act, redesignates it as Sections 441.0051, 441.0052, 441.0053, and 441.0054, Health and Safety Code, and amends it, as follows:

Sec. 441.0051. New heading: ANNUAL REPORT. Requires a pharmaceutical drug manufacturer, not later than the 15th day of each calendar year, to submit a report to the Department of State Health Services (DSHS), rather than to the executive commissioner, stating the current wholesale acquisition cost information for the United States Food and Drug Administration-approved prescription drugs, rather than United States Food and Drug Administration-approved drugs, sold in or into this state by that manufacturer. Makes a nonsubstantive change.

Sec. 441.0052. PRESCRIPTION DRUG PRICE INFORMATION INTERNET WEBSITE. Requires DSHS, rather than the executive commissioner, to develop an Internet website to provide to the general public prescription drug price information submitted under Section 441.0051, rather than under Subsection (a). Requires that the Internet website be made available on DSHS's Internet website, rather than HHSC's Internet website, with a dedicated link that is prominently displayed on the home page or by a separate easily identifiable Internet address. Makes a conforming and a nonsubstantive change.

Sec. 441.0053. PRESCRIPTION DRUG COST INCREASE INFORMATION. (a) Creates this subsection from existing text. Requires the pharmaceutical drug manufacturer, 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, to include in the annual report submitted under Section 441.0051 certain information. Deletes existing text providing that this subsection applies only to a 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. Deletes existing text requiring the pharmaceutical drug manufacturer, 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 drug to which this subsection applies, to submit a report to the executive commissioner.

(b) Redesignates existing Subsection (a) as Subsection (b). Requires that the quality and types of information and data that a pharmaceutical drug manufacturer submits to DSHS, rather than submits to the executive commissioner, under Subsection (a), rather than Subsection (c), 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.

Sec. 441.0054. PUBLICATION OF COST INCREASE INFORMATION. Requires DSHS, not later than the 60th day after receipt of the report submitted under Section 441.0051, to publish the cost increase information required by Section 441.0053 on DSHS's prescription drug price information Internet website. Deletes existing text requiring the executive commissioner, not later than the 60th day after receipt of the report submitted under Subsection (c), to publish the report on HHSC's Internet website described by Subsection (b) and authorizing the executive commissioner to adopt rules to implement this section.

SECTION 4. Amends Subchapter B, Chapter 441, Health and Safety Code, as added by this Act, by adding Section 441.0055, as follows:

Sec. 441.0055. FEE. (a) Requires a pharmaceutical drug manufacturer to submit a fee in the amount provided by DSHS rule with each report submitted under Subchapter B.

(b) Requires the executive commissioner by rule to set the fee in the amount necessary for DSHS to administer Chapter 441.

SECTION 5. Amends Chapter 441, Health and Safety Code, by adding Subchapter C, as follows:

SUBCHAPTER C. ENFORCEMENT

Sec. 441.0101. RIGHT TO CORRECT. (a) Requires DSHS, if DSHS determines that a pharmaceutical drug manufacturer failed to submit a report or fee required under Subchapter B and the rules adopted under Chapter 441, to provide written notice of the failure to the manufacturer.

(b) Requires a pharmaceutical drug manufacturer, on receipt of notice described by Subsection (a), to submit, as applicable:

(1) a report that complies with Subchapter B and rules adopted under Chapter 441, and addresses the issues raised in the notice; or

(2) the fee required by Section 441.0055.

(c) Prohibits DSHS from assessing an administrative penalty under Section 441.0102 against a pharmaceutical drug manufacturer that submits to DSHS the required report or fee, as applicable, on or before the 45th day after the date the manufacturer receives notice under Subsection (a).

Sec. 441.0102. ADMINISTRATIVE PENALTY. (a) Authorizes DSHS to assess an administrative penalty against a person who violates Chapter 441 or a rule adopted under Chapter 441.

(b) Requires DSHS, in determining the amount of the penalty, to consider the person's previous violations, the seriousness of the violation, the person's demonstrated good faith, and any other matters as justice may require.

(c) Prohibits the penalty from exceeding $1,000 a day for each violation.

(d) Authorizes each day a violation continues to be considered a separate violation.

(e) Authorizes the enforcement of the penalty to 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 as bond with the court in the amount of the penalty. Authorizes a person who cannot afford to pay the penalty or file the bond to 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 State Board of Insurance to contest the affidavit as provided by those rules.

(f) Authorizes the attorney general to sue to collect the penalty. Requires that money collected under this section be deposited in the state treasury and authorizes it to be appropriated only to DSHS for the purposes of administrating Chapter 441.

Sec. 441.0103. ADMINISTRATIVE PROCEDURE. Provides that a proceeding to impose an administrative penalty under Section 441.0102 is considered to be a contested case under Chapter 2001 (Administrative Procedure), Government Code.

SECTION 6. Makes application of Subchapter C, Chapter 441, Health and Safety Code, as added by this Act, prospective.

SECTION 7. Effective date: September 1, 2021.