BILL ANALYSIS

Senate Research Center
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H.B. 1033
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Engrossed

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 (HHSC) website.

H.B. 1033 will improve the statute created by H.B. 2536. The bill streamlines reporting by requiring manufacturers to disclose research and development 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.

H.B. 1033 will remove the requirement that the report include information regarding the Child Health Plan Program and the Medical Assistance Program. H.B. 1033 will also change the reporting date for pharmacy benefit managers and health plan issuers from February 1 of each year to March 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. The bill also changes the date by which the executive commissioner of HHSC must publish the report from May 1 to June 1 of each year.

H.B. 1033 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 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Rulemaking authority previously granted to the executive commissioner of the Health and Human Services Commission is rescinded in SECTION 3 of this bill.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 adding 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 the 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 REPORT AND INFORMATION. (a) Creates this subsection from existing text. Provides that 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. Requires a 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 prescription drug to which this subsection applies, to submit a report to the executive commissioner. Requires that the report 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.

Deletes existing text requiring that the report to include aggregate, company-level research and development costs for the most recent year for which final audit data is available, 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 the name of each of the manufacturer's prescription drugs that lost patent exclusivity in the United States in the previous three calendar years. Makes nonsubstantive and conforming changes.

(b) 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 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) Creates this subsection from existing text. Requires that the quality and types of information and data that a pharmaceutical drug manufacturer submits to DSHS under Subsections (a) and (b), rather than submits to the executive commissioner under 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 or 441.0053(a), 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. Makes nonsubstantive changes.

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, not to exceed $400.

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 that 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 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. Amends Sections 1369.502(a) and (c), Insurance Code, as follows:

(a) Requires each pharmacy benefit manager, not later than March 1, rather than February 1, of each year, to file a report with the commissioner of insurance (commissioner).

(c) Requires the commissioner. not later than June 1, rather than May 1, of each year, to publish the aggregated data from all reports for that year required by Section 1369.502 in an appropriate location on the Texas Department Insurer' (TDI)'s Internet website.

SECTION 7. Amends Sections 1369.503(a) and (c), Insurance Code, to make conforming changes.

SECTION 8. Amends Subchapter K, Chapter 1369, Insurance Code, by adding Section 1369.5035, as follows:

Sec. 1369.5035. CONTENT OF REPORTS. Requires that the reports required by Sections 1369.502 and 1369.503 (Health Benefit Plan Issuer Information) to include information relating to private health benefit plans that cover prescription drugs and are regulated by TDI. Prohibits the reports from including information relating to:

(1) the child health plan program under Chapter 62 (Child Health Plan for Certain Low-Income Children), Health and Safety Code, or the health benefits plan for children under Chapter 63 (Health Benefits Plan for Certain Children), Health and Safety Code; or

(2) the medical assistance program under Chapter 32 (Medical Assistance Program), Human Resources Code.

SECTION 9. (a) Makes application of Subchapter C, Chapter 441, Health and Safety Code, as added by this Act, prospective.

(b) Makes application of Section 1369.5035, Insurance Code, as added by this Act, prospective.

SECTION 10. Effective date: September 1, 2021.