SUBJECT: Regulating manufacturers' compliance with drug price disclosures

COMMITTEE: Insurance — committee substitute recommended

VOTE: 8 ayes — Oliverson, González, Hull, Israel, Middleton, Paul, Romero, Sanford

0 nays

1 absent — Vo

WITNESSES: For — Blake Hutson, AARP Texas; Jamie Dudensing, Texas Association of Health Plans; (*Registered, but did not testify*: David Reynolds, American College of Physicians - Texas Chapter; Jamaal Smith, City of Houston, Office of the Mayor; Stacey Pogue, Every Texan; Mindy Ellmer, Pharmaceutical Care Management Association.; Neal T Buddy Jones, Pharmaceutical Researchers and Manufacturers Association; Charles Miller, Texas 2036; Megan Herring, Texas Association of Business; Bill Hammond, Texas Employers for Insurance Reform; Clayton Stewart, Texas Medical Association; Thomas Parkinson)

Against — None

On — Stephen Pahl, Department of State Health Services; (*Registered, but did not testify*: Luke Bellsnyder, Texas Department of Insurance)

BACKGROUND: Health and Safety Code ch. 441 outlines certain drug cost transparency requirements. Sec. 441.0002 requires a pharmaceutical drug manufacturer to submit an annual report to the executive commissioner of the Health and Human Services Commission (HHSC). The report is due within 15 days of the start of each calendar year and must contain current wholesale acquisition cost information for approved drugs sold in or into Texas by the manufacturer. Information submitted in these annual reports is posted on the commission's website.

Drug manufacturers also must submit reports to the HHSC executive

commissioner when they increase prices on certain drugs by more than 40 percent over the previous three years or by 15 percent or more in the previous year. This provision only applies to drugs that cost more than $100 for a 30-day-supply before the effective date of a reported increase. These reports must be submitted within 30 days after the effective date of a price increase and must contain certain information specified in statute.

Insurance Code sec. 1369.502 and sec. 1369.503 require each pharmacy benefit manger and health benefit plan issuer to file a report with the commissioner of the Texas Department of Insurance (TDI) by February 1 of each year. These reports must include information on payments collected from drug manufacturers and passed to health benefit plan issuers or enrollees or retained as revenue. The commissioner of insurance must publish the report on the TDI website by May 1 of each year.

DIGEST:

CSHB 1033 would alter when pharmaceutical drug manufacturers would be required to report certain information after prescription drug price increases, establish fees for manufacturers who submitted reports, and authorize certain administrative penalties. The bill also would change reporting requirements for pharmacy benefit managers (PBMs) and health benefit plan issuers.

Manufacturer reports. CSHB 1033 would specify that the requirements of Health and Safety Code ch. 441 applied only to prescription drugs and would make changes to the reporting requirements for drug manufacturers who increased the price of certain drugs. Certain information no longer would have to be reported by manufacturers within 30 days of a price increase but instead included as part of the annual report required under ch. 441. The affected information would include:

- aggregate, company-level research and development costs for the most recent year for which final audit data was available;
- the name of each of the manufacturer's prescription drugs approved by the U.S. Food and Drug Administration in the previous three years; and
- the name of each of the manufacturer's prescription drugs that lost

patent exclusivity in the U.S. in the previous three years.

The bill also would change the agency to which a drug manufacturer had to submit reports from the executive commissioner of the Health and Human Services Commission (HHSC) to the Department of State Health Services (DSHS). Applicable website duties also would be transferred from HHSC to DSHS.

Pharmacy benefit manager and health plan reports. CSHB 1033 would require reports submitted by PBMs and health plan issuers under Insurance Code sec. 1369.502 and 1369.503 to include information related to private health benefit plans that covered prescription drugs and that were regulated by the Texas Department of Insurance (TDI). The reports could not include information relating to the child health plan program (CHIP), the health benefits plan for certain other children, or Medicaid.

The bill also would change the reporting deadline for PBMs and health plan issuers from February 1 to March 1. The date by which TDI would have to publish aggregated data would be changed from May 1 to June 1.

Fees. Under the bill, a pharmaceutical drug manufacturer would have to pay a fee specified by DSHS rule with each submitted report. The executive commissioner of HHSC would have to set the fee, which could not exceed $400.

If DSHS determined that a drug manufacturer had failed to submit a report or fee in the prescribed manner, the department would have to provide written notice of the failure to the manufacturer. Upon receipt of notice, the manufacturer would be required to comply with the bill's reporting and fee requirements and address any issues raised in the notice.

Administrative penalty. Under CSHB 1033, DSHS could assess an administrative penalty against a person who violated Health and Safety Code ch. 441 or applicable adopted rules. The penalty could not exceed $1,000 per day for each violation. DSHS could not assess an administrative penalty against a drug manufacturer that submitted a

required report or fee on or before the 45th day after the manufacturer received notice under the bill.

The attorney general could sue to collect the penalty. Money collected would be deposited in the state treasury and could only be appropriated to DSHS to administer ch. 441.

A proceeding to impose an administrative penalty would be considered a contested case under the Administrative Procedure Act.

Other provisions. The executive commissioner of HHSC could adopt rules to implement Health and Safety Code ch. 441.

The bill would take effect September 1, 2021, and would apply only to a violation occurring and reports submitted on or after that date.

SUPPORTERS SAY:

CSHB 1033 would strengthen the enforcement of certain drug cost transparency and reporting requirements and would ensure timely compliance with these requirements. In 2019 the 86th Legislature enacted HB 2536, which required drug manufacturers to disclose price increases and explanations for those increases. However, concerns have been raised that some manufacturers are not submitting the required reports or are not specifying their reasons for price increases. Allowing the Department of State Health Services to issue administrative penalties for those who failed to submit reports in prescribed manners would incentivize non-compliant manufacturers to meet existing requirements.

The bill also would provide flexibility to drug manufacturers by changing how they were required to report research and development costs. Requiring manufacturers to submit this data once a year rather than multiple times a year also could help decrease the cost of storing related data.

CRITICS SAY:

CSHB 1033 could increase regulatory compliance costs by establishing a reporting fee for drug manufacturers and allowing DSHS to issue certain administrative penalties.