BILL ANALYSIS

C.S.H.B. 1033
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Insurance
Committee Report (Substituted)

BACKGROUND AND PURPOSE

In 2019, the Texas Legislature passed legislation regarding drug cost transparency that requires pharmaceutical drug manufacturers to disclose certain drug price increases, along with the reasons for those increases. These disclosures were meant to serve as a powerful tool in preventing certain price increases for lifesaving drugs. However, there have been suggestions for improvements to that disclosure process that would help improve efficiency, streamline information gathering, and increase compliance with the disclosure requirements. C.S.H.B. 1033 seeks to address this issue by, among other things, moving the regulation of pharmaceutical drug price disclosures into the purview of the Department of State Health Services, authorizing the executive commissioner of the Health and Human Services Commission to adopt rules to implement provisions relating to drug price transparency, and establishing an administrative penalty for a manufacturer's failure to comply with those provisions.

CRIMINAL JUSTICE IMPACT

It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change the eligibility of a person for community supervision, parole, or mandatory supervision.

RULEMAKING AUTHORITY

It is the committee's opinion that rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTIONS 1 and 4 of this bill.

ANALYSIS

C.S.H.B. 1033 amends the Health and Safety Code to revise requirements for pharmaceutical drug manufacturers to report annually drug wholesale acquisition cost information and to report, within a certain period, certain drug cost increase information. The bill authorizes the executive commissioner of the Health and Human Services Commission (HHSC) to adopt rules to implement provisions regarding drug cost transparency.

C.S.H.B. 1033 revises the respective reporting requirements as follows:

- by clarifying that those requirements apply only to prescription drugs;
- by changing the entity to which a manufacturer must annually report the wholesale acquisition cost information from the executive commissioner of HHSC to the Department of State Health Services (DSHS);
- by transferring the applicable website development duties from the executive commissioner of HHSC to DSHS; and
- by requiring the following information to be included in the annual report on wholesale acquisition cost information if the applicable increase in the cost occurs during a calendar year, instead of in the prescription drug cost increase report:

- 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 FDA 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.

C.S.H.B. 1033 requires a pharmaceutical drug manufacturer to submit a fee, capped at $400, with each submitted report and requires the executive commissioner by rule to set the fee in the amount necessary for DSHS to administer provisions relating to drug cost transparency.

C.S.H.B. 1033 establishes, as follows, certain enforcement provisions regarding a manufacturer's failure to submit a required report or fee or a failure to submit a required report or fee in the prescribed manner:

- DSHS, on determining such a failure, must provide written notice of such a failure to the manufacturer;
- on receipt of the notice, the manufacturer is required to submit, as applicable, the fee or a report that complies with the applicable provisions and the adopted rules and that addresses the issues raised in the notice;
- DSHS may assess an administrative penalty against a person who violates the applicable provisions or an adopted rule; and
- DSHS may not assess an administrative penalty against a manufacturer that submits the report or fee, as applicable, on or before the 45th day after the date the manufacturer receives the notice.

The bill provides the following with respect to the administrative penalty:

- the penalty is capped at $1,000 a day for each violation;
- each day a violation continues may be considered a separate violation;
- enforcement of the penalty may be stayed, as specified by the bill, during the time the order is under judicial review;
- the attorney general may sue to collect the penalty;
- money collected from the penalty must be deposited in the state treasury; and
- money collected from the penalty may be appropriated only to DSHS for the purposes of administrating drug cost transparency provisions.

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

C.S.H.B. 1033 amends the Insurance Code to change from February 1 of each year to March 1 of each year the date by which each pharmacy benefit manager or each health benefit plan issuer, as applicable, must file a prescription drug cost report with the commissioner of insurance. The bill changes from May 1 of each year to June 1 of each year the date by which the commissioner must publish aggregated data from such reports on the Texas Department of Insurance (TDI) website. The bill requires those reports to include information relating to private health benefit plans that cover prescription drugs and are regulated by TDI and sets out the information that may not be included in the reports.

EFFECTIVE DATE

September 1, 2021.

COMPARISON OF ORIGINAL AND SUBSTITUTE

While C.S.H.B. 1033 may differ from the original in minor or nonsubstantive ways, the following summarizes the substantial differences between the introduced and committee substitute versions of the bill.

The substitute does not include the following provisions:

- the provision that removes the specification that the wholesale acquisition cost of the applicable prescription drug, for purposes of reporting an increase in the cost, is the cost before the effective date of an increase; and
- the provision that removes the deadline for submitting a report that is based on the effective date of an increase.

The substitute does not include the provision requiring all information included in the prescription drug cost increase report to also be included in the annual report regarding wholesale acquisition cost. Instead, the substitute requires the inclusion of only certain information regarding the manufacturer's recent research and development costs, the name of the manufacturer's prescription drugs recently approved by the FDA, and the name of manufacturer's prescription drugs that recently lost patent exclusivity in the United States.

The substitute includes a provision capping at $400 the fee a manufacturer must submit with each wholesale acquisition cost report and a prescription drug cost increase report.

The substitute includes a provision requiring DSHS, on determining that a manufacturer failed to submit a required fee or report in the prescribed manner, to provide written notice of the failure to the manufacturer.

The substitute includes Insurance Code provisions that, as follows:

- change the date by which each pharmacy benefit manager or each health benefit plan issuer must file a prescription drug cost report with the commissioner of insurance;
- change the date by which the commissioner must publish aggregated data from such reports on the TDI website;
- require such reports to include information relating to private health benefit plans that cover prescription drugs and are regulated by TDI; and
- set out the information that may not be included in such reports.