BILL ANALYSIS

S.B. 241
By: Perry
Public Health
Committee Report (Unamended)

BACKGROUND AND PURPOSE

Texas has a compelling interest in protecting the health of its residents. According to the American Diabetes Association, nearly three million Texans have diabetes. The price of insulin has increased over the last several decades and there is still no generic or biosimilar version. Despite the decades that insulin has been on the market, there are still only three manufacturers of insulin. There are concerns that there may be other factors involved in the lack of generics or biosimilars in the market. S.B. 241 requires insulin manufacturers whose drug appears on the Medicaid formulary, if a generic or biosimilar is not available, to submit a written verification to the Health and Human Services Commission stating whether or not the unavailability of a generic or biosimilar insulin on the market is due to the manufacturer being engaged in market manipulation through "pay to delay" schemes, "evergreening," or patent manipulation either first hand or facilitating another entity to commit these actions.

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 SECTION 1 of this bill.

ANALYSIS

S.B. 241 amends the Health and Safety Code to require the manufacturer, including a subsidiary or an affiliate of a manufacturer, of a brand name insulin prescription drug for which a generic or biosimilar prescription drug is not available and that is included in the Medicaid vendor drug program formulary to submit a written verification to the Health and Human Services Commission (HHSC) stating whether or not the unavailability of the generic or biosimilar prescription drug is the result, wholly or partly, of the following:

- a scheme by the manufacturer to pay a generic or biosimilar prescription drug manufacturer to delay manufacturing or marketing the generic or biosimilar drug;
- a legal or business strategy to extend the life of a patent on the brand name prescription drug;
- the manufacturer directly manipulating a patent on the brand name prescription drug; or
- the manufacturer facilitating such actions on behalf of another entity.

The bill requires the executive commissioner of HHSC to adopt rules prescribing the form and manner for the submission of the required verification.

EFFECTIVE DATE

September 1, 2024.