BILL ANALYSIS

Senate Research Center

S.B. 241
By: Perry
Health & Human Services
5/31/2023
Enrolled

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Texas has a compelling interest in protecting the health of its residents. Nearly 3 million people in Texas have diabetes. The price of insulin has increased significantly over the last several decades and there is still no biosimilar or generic 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 in the market.

S.B. 241 requires insulin manufacturers whose drug appears on the Medicaid formulary, if a generic is not available, to fill out a document swearing to the state whether or not they are engaged in market manipulation through "Pay to Delay" schemes, "evergreening" or patent manipulation either first hand or facilitating another entity to commit these actions.

The committee substitute adds "or biosimilar" after each time generic is mentioned in the bill. Biosimilar is a better term than generic when discussing insulin.

S.B. 241 amends current law relating to written notification provided by drug manufacturers regarding the cause of generic or biosimilar insulin prescription drug unavailability.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 1 (Section 439.102, Health and Safety Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Chapter 439, Health and Safety Code, by adding Subchapter D, as follows:

SUBCHAPTER D. INSULIN

Sec. 439.101. DEFINITION. Defines "manufacturer."

Sec. 439.102. WRITTEN VERIFICATION REQUIRED FOR BRAND NAME INSULIN DRUG MANUFACTURER. (a) Requires the 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 to the Health and Human Services Commission (HHSC) a written verification stating whether or not the unavailability of the generic or biosimilar prescription drug is the result, wholly or partly, of:

(1) a scheme by the manufacturer to pay a generic or biosimilar prescription drug manufacturer to delay manufacturing or marketing the generic or biosimilar drug;

(2) a legal or business strategy to extend the life of a patent on the brand name prescription drug;

(3) the manufacturer directly manipulating a patent on the brand name prescription drug; or

(4) the manufacturer facilitating an action described by Subdivisions (1)-(3) on behalf of another entity.

(b) Requires the executive commissioner of HHSC to adopt rules prescribing the form and manner for submission of the written verification required under Subsection (a).

SECTION 2. Effective date: September 1, 2024.