## **BILL ANALYSIS**

Senate Research Center

H.B. 2571 By: Berlanga (Harris) Health & Human Services 5-16-97 Engrossed

## **DIGEST**

The Food and Drug Administration has identified approximately 25 narrow therapeutic index drugs (index drugs). Many of these drugs are used to treat critical medical conditions. These medications are associated with a high risk for toxic reactions and complex drug interactions. They require highly individualized doses and close supervision by the physician or health care provider to ensure safe use. Current medical practice makes if difficult to coordinate patient monitoring with product substitution because a patient can be switched from one formulation to another formulation at the pharmacy level without the knowledge of the physician and possibly without the knowledge of the patient. This bill will provide regulations regarding the substitution of certain drugs by a pharmacist.

#### **PURPOSE**

As proposed, H.B. 2571 provides regulations regarding the substitution of certain drugs by a pharmacist.

## **RULEMAKING AUTHORITY**

Rulemaking authority is granted to the State Board of Pharmacy in SECTION 1 (Section 40(m), Article 4542a-1, V.T.C.S.) of this bill.

# **SECTION BY SECTION ANALYSIS**

SECTION 1. Amends Section 40, Article 4542a-1, V.T.C.S., to provide that, except as provided by this subsection, drug product selection authorized in this section does not apply to the refill of a prescription for a narrow therapeutic index drug (index drug). Requires the State Board of Pharmacy (board), in consultation with the Texas State Board of Medical Examiners, to establish, by rule, a list of index drugs that are subject to this subsection. Authorizes a prescription for an index drug to be refilled only by using the same drug product by the same manufacturer that the pharmacist last dispensed under the prescription. Authorizes a pharmacist, if the pharmacist does not have the same drug product by the same manufacturer in stock to refill the prescription, to dispense a drug product that is generically equivalent if the pharmacist, before dispensing the generically equivalent drug product, notifies certain people of certain information.

SECTION 2. Effective date: September 1, 1997.

SECTION 3. Emergency clause.