

## **BILL ANALYSIS**

C.S.H.B. 1443  
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Public Health  
Committee Report (Substituted)

### **BACKGROUND AND PURPOSE**

Several leading clinicians, including scholars at Texas Tech University, have completed studies on the dangers of substituting transplant medications – either brand to brand, brand to generic or generic to generic – without the permission of the transplant team or patient’s transplant surgeon because of the frail nature of the patient and the sensitivity of immune-compromised patients to small changes in drug strength and active or inactive ingredients.

The Texas Tech University study promotes the fact that pharmacists should notify the prescribing physician whenever a critical dose drug is dispensed differently and that “therapeutic substitution should not be made unless the prescribing physician has granted approval.” The National Kidney Foundation (NKF) produced a white paper on the subject-created consensus treatment guidelines calling for pharmacists to inform physicians any time switching has been recommended to take place from brand products to generic products. The American Heart Association echoed the same concerns in its support of the NKF guidelines.

Finally, the United Network on Organ Sharing, the largest Transplant organization in the United States, provides this advice for its membership:

- Generic products use the same active ingredient and have the same intended use as brand-name counterparts
- Generic drugs are not formulated in an identical manner to their brand name counterparts
- Generic products can have variations in the active ingredient that could affect absorption into the patient’s bloodstream, as well as different inactive ingredients (binders, fillers), that can cause differences in the patient’s response and side effects. (*United Network of Organ Sharing*)

Federal Medicaid law only allows brand-name products to be dispensed when a physician writes “brand name necessary” on the prescription; this legislation does not interfere in that process but goes further to put a duty on the pharmacist to contact a physician, most likely a member of the transplant team, to make sure that a generic product is what the physician intended to dispense. CSHB 1443 aims to protect the highly sensitive nature of transplant patients by requiring physician authorization to interchange transplant medications.

### **RULEMAKING AUTHORITY**

It is the committee's opinion that this bill does not expressly grant any additional rulemaking authority to a state officer, department, agency, or institution.

### **ANALYSIS**

CSHB 1443 amends the Occupations Code to provide that, notwithstanding Section 562.014. APPLICATION TO NARROW THERAPEUTIC INDEX DRUGS, a pharmacist may not interchange an immunosuppressant drug or formulation of an immunosuppressant drug, brand or generic, for the treatment of a patient following a transplant without prior notification of, and the signed informed consent of, such interchange from the prescribing physician. CSHB 1443 establishes the procedures for a pharmacist to document the notification of, and to secure the informed written consent of, a prescribing physician regarding the interchange of certain drugs. Such documented notification and consent shall be considered a statement that the prescription is

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“brand medically necessary” and shall be considered part of the prescription. The bill defines "immunosuppressant drug" and "interchange," and provides that if the prescription is for an “immunosuppressant drug” the pharmacist must comply with this bill.

#### **EFFECTIVE DATE**

Upon passage, or, if the Act does not receive the necessary vote, the Act takes effect September 1, 2007.

#### **COMPARISON OF ORIGINAL TO SUBSTITUTE**

CSHB 1443 provides that "a pharmacist may not interchange an immunosuppressant drug or formulation of an immunosuppressant drug, brand or generic, for the treatment of a patient following a transplant without prior notification of and the signed informed consent of such interchange from the prescribing physician" whereas the original provided that a "pharmacist may not dispense a drug for immunosuppressive therapy following transplant unless the drug is the specific formulation and manufactured by the specific manufacturer that is prescribed by the patient's physician," and authorizes a physician to substitute a generically equivalent drug product if the pharmacist "obtains a signed authorization" from the prescribing physician.

CSHB 1443 establishes the procedures for a pharmacist to document the notification of, and to secure the informed written consent of, a prescribing physician regarding the interchange of certain drugs. Such documented notification and consent shall be considered a statement that the prescription is “brand medically necessary” and shall be considered part of the prescription. It defines "immunosuppressant drug" and "interchange," and provides that if the prescription is for an “immunosuppressant drug” the pharmacist must comply with this bill.

The substitute changes the effective date from September 1, 2007 to upon passage, or September 1 2007.