SUBJECT: Substitution of certain drugs by a pharmacist

COMMITTEE: Public Health — committee substitute recommended

VOTE: 7 ayes — Berlanga, Hirschi, Coleman, Davila, Glaze, Janek, Maxey

0 nays

1 absent — Delisi

WITNESSES: For — Juanita Gomez; Bruce Mayes, Sindi Rosales, Texas Epilepsy Association; James Todd, Health Alliance for NTI Patient Safety

Against — Lane Brunner, Timothy Sawyer, Barr Laboratories; Diane Ginsburg, Texas Society of Health-Systems Pharmacies; Kathleen Jaeger, National Pharmacy Alliance

On — Gay Dodson, Texas State Board of Pharmacy

BACKGROUND: Narrow therapeutic index (NTI) drugs are federal Food and Drug Administration (FDA)-identified drugs associated with a high risk for toxic reactions and complex drug interactions and include anticonvulsants, antiarrhythmics, and anticoagulants.

Pharmacists are authorized under the Texas Pharmacy Act to substitute drug products with pharmacy board and FDA-authorized generic bioequivalents when the prescribing physician notes on the prescription that substitutions may be made.

DIGEST: CSHB 2571 would amend the Texas Pharmacy Act to require NTI prescription refills only by using the same drug product by the same manufacturer that the pharmacist last dispensed.

If a pharmacist did not have the same drug product to refill the prescription, the pharmacist could dispense a drug that was the generic equivalent if the pharmacist notified the patient at the time the prescription was dispensed and the prescribing practitioner within 72 hours after dispensing the prescription.

The pharmacy board and the Board of Medical Examiners would have to establish a list of NTI drugs subject to this provision.

The bill would take effect September 1, 1997.

SUPPORTERS SAY:

CSHB 2571 would protect the public from adverse reactions caused by drug substitutions. A generic substitution for a name-brand drug may be produced by a variety of manufacturers. Due to FDA-allowable variances in the manufacture of generics, not all bioequivalent drugs are equally effective, and their effectiveness and any adverse side effects are related to the health condition of the patient. This bill would continue to allow pharmacists to substitute drugs as authorized, but would enact additional protections by requiring them to notify the patient and the patient's doctor of any variance in generic drug substitutions, so that both the patient and the doctor would have the opportunity to refuse such substitutions or be alerted to potentially adverse side effects.

For most drugs, substitution is hardly a problem. However, NTI drugs are specifically targeted by this bill because they are used to treat critical medical conditions such as epilepsy, depression and conditions arising from strokes, and variability in drugs could pose a threat to patients. This bill would not restrict the substitution of NTI drugs, only monitor it.

Pharmacy liability would not be increased, but reduced, as a result of the notification protections in this bill.

OPPONENTS SAY:

This bill is not necessary. There has been almost no public demand for this kind of protection, aside from concerns expressed by the drug company Dupont Merck, which wants to protect their drug Coumadin from substitution by a newly FDA-approved generic bioequivalent. This bill is anti-competitive in that it could restrict the use of substitutions for NTI drugs and erode consumer confidence in generics.

Also, pharmacy liability could be increased if a patient experienced an adverse impact resulting from a substitution and the physician claimed that the required pharmacist notification was never received.

NOTES: The original version of the bill would have required specific written physician authorization of NTI substitutions.