SUBJECT: Requiring pharmacists to inform patients before substituting a generic drug

COMMITTEE: Public Health — committee substitute recommended

VOTE: 8 ayes — Delisi, Laubenberg, Truitt, Coleman, Dawson, Jackson, McReynolds, Solis

0 nays

1 absent — Zedler

WITNESSES: For — None

Against — None

On — Richard Beck, American Pharmacies, Inc.; Gay Dodson, Texas State Board of Pharmacy; Mick McMahan, McMahan Pharmacy Services, Inc.; AJ Patel, Texas Federation of Drug Stores; Kristie Zamrazil, Texas Pharmacy Association; (*Registered, but did not testify:* Cristen Wohlgemuth, Texas Pharmacy Association)

BACKGROUND: Pharmacists, under Occupations Code, ch. 562, may substitute a generic drug for a brand-name drug unless the health provider has marked that the specific prescribed brand is medically necessary. To alert patients to the potential substitution, the pharmacist or an employee of the pharmacist must inform the patient of the substitution and, either orally or via a sign posted in the pharmacy, notify him or her of the right to decline the substitution. By Texas State Board of Pharmacy rule, the pharmacist also must mark the bottle or package with a sticker indicating that the brand drug was substituted by a generic.

A brand-name drug is a pharmaceutical product that is marketed under an exclusive patent, whereas a generic drug has the same active ingredients as the brand but may be marketed only after the patent on the brand-name drug has expired.

DIGEST: CSHB 836 would require a pharmacist or a pharmacist's employee to inform a patient that a generic drug was available for substitution and would repeal the option of informing the patient via a sign in the

pharmacy. The bill also would require a pharmacist to disclose to a patient if the cost of a drug were lower than the co-payment required by the patient's insurance and offer the option of paying the lower price.

The bill would take effect September 1, 2005.

SUPPORTERS SAY:

HB 836 is about consumer choice — permitting consumers to choose to substitute before the pharmacist fills the prescription, rather than refusing after the substitution has taken place. The consumer often does not realize that a generic drug has been substituted for a brand name until arriving home with the unwanted generic prescription. Under current law, the consumer can refuse the substitution, but then must wait for the pharmacist to change the prescription. This bill would put the consumer's choice at the front end of the process.

In addition, this bill would ensure that consumers knew they had a choice about whether or not to accept a generic drug substitution. Under current law, a pharmacist can satisfy the consumer notification requirements simply by posting a sign in the pharmacy. This does not go far enough to inform consumers about their right to choose brand-name drugs.

Pharmacists should be required to disclose the price difference between a drug and the patient's copayment so that consumers can make informed purchases.

OPPONENTS SAY:

Requiring consent for every substitution would harm efficient customer service. The bill would prohibit the pharmacist from filling the generic substitute before speaking with either the patient or the doctor's office. Instead of allowing pharmacists to fill prescriptions ahead of time, it would require the patient to give consent at the pharmacy and wait for the prescription to be filled. Alternately, the bill would require the pharmacist to call the doctor's office to confirm that every prescription that did not specify "brand-only" could be substituted. Either way, the requirement would add time and hassle for most consumers.

The bill would burden doctor offices. Physicians know to indicate on the prescription if a brand-name drug is required, and the absence of such an indication means that a substitution is permitted. This bill, nevertheless, would make the pharmacist confirm that the absence of a statement meant that a substitution could occur, requiring the doctor's office to communicate the same information twice.

Consumers already are aware that generic substitution can occur based on the sign posted in the pharmacy and are alerted when it has occurred by a sticker on the packaging. Also, current law requires that the original instructions for a prescription be followed through the life of the prescription, so refills should be governed in the same way.

Remedies exist for deviations and mistakes that may occur. The Texas State Board of Pharmacy can receive complaints and take corrective action against a pharmacist who inappropriately substitutes drugs. Instead of changing the law, individual cases of mistakes should be handled by the existing regulatory system.

The requirement for pharmacists to disclose the price difference between the usual and customary price and the patient's co-payment is not needed due to federal law. The federal Health Insurance Portability and Accountability Act (HIPAA) requires that pharmacies report their usual and customary price to health plans, which then default to the lower of the two prices. The only time a patient would be charged anything but the lower amount would be if the health plan required an enrollment fee that was charged to the patient.

NOTES:

The substitute deleted a provision from the original version that would have required pharmacists to inform patients of the price difference between the brand name and generic versions of a drug. The substitute also would not allow a pharmacist to post a sign explaining that a generic drug substitution might occur.