SUBJECT: Labeling requirements for prescription drugs dispensed by pharmacists

COMMITTEE: Public Health — committee substitute recommended

VOTE: 9 ayes — Kolkhorst, Naishtat, J. Davis, Gonzales, Hopson, S. King, McReynolds, Truitt, Zerwas

0 nays

2 absent — Coleman, Laubenberg

WITNESSES: For — Richard Beck, Texas Pharmacy Business Council; (*Registered, but did not testify*: Carlos Higgins, Texas Silver-Haired Legislature)

Against — None

On — Kathy Barber, Texas Federation of Drug Stores; Gay Dodson, Texas State Board of Pharmacy

BACKGROUND: Occupations Code, sec. 562.006(a) establishes labeling requirements for drugs dispensed by pharmacies and charges the Texas State Board of Pharmacy (TSBP) with enforcing them. Under current law, the label on a drug dispensing container must indicate in plain language and in an easily readable font size:

- the brand name of the drug;
- the generic name, if there is not a brand name;
- the strength of the drug;
- if the drug selected by the pharmacist is different than the one prescribed, the words "Substituted for brand prescribed"; and
- the name of the drug's manufacturer or distributor.

Current law does not require the display of a "use-by date."

A "pharmacy" means a facility at which a prescription drug or medication order is received, processed, or dispensed under the Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970. TSBP classifies pharmacies by license as Class A, Class B, Class C, Class D, or Class E.

A Class A license is a community pharmacy license that authorizes a pharmacy to dispense a drug or medical device to the public under a prescription drug order. A Class E license is a nonresident pharmacy license that authorizes out-of-state pharmacies to deliver drugs or devices by mail to Texas residents.

DIGEST:

CSHB 19 would require the label on a drug dispensing container dispensed by a Class A or Class E pharmacy to indicate, in addition to the information required by Occupation Code, sec. 562.006(a):

- the name, address, and telephone number of the pharmacy;
- the date the prescription drug was dispensed;
- the name of the prescribing practitioner;
- the patient's name, or if prescribed for an animal, the animal's species and name of the owner;
- instructions for using the drug;
- the quantity dispensed;
- the date after which the prescription should not be used ("use-by date") if the drug was dispensed in a container other than the manufacturer's original container; and
- any other information required by TSBP rule.

The bill would allow the use-by date to be recorded on any label affixed to the dispensing container. The criteria for determining the use-by date would be established by TSBP rule based on standards in the United States Pharmacopeia-National Formulary.

The new labeling requirements would not apply to a prescription drug dispensed to a person at the time of release from prison or jail if the prescription did not contain more than a 10-day supply of medication.

The bill would require TSBP to adopt rules implementing the new labeling requirements by January 1, 2010. The new requirements would apply only to a drug dispensed on or after June 1, 2010.

CSHB 19 would take effect September 1, 2009.

SUPPORTERS SAY:

CSHB 19 would give prescription drug users more information about a prescription drug's use-by date, dosage level, and instructions for use. The use-by date in particular would address a common situation where people

unknowingly take leftover prescription medications that have lost their effectiveness. Although some pharmacies include a use-by date on their labels, others do not. CSHB 19 would help alleviate the issue by requiring a container, other than a manufacturer's original container, dispensed by Class A and Class E pharmacies to clearly display the use-by date on the label, thus enabling prescription drug users to easily determine if their leftover medications are still effective.

CSHB 19 especially would assist senior citizens and other medically vulnerable groups who depend upon prescription drugs to maintain their health. These groups are inadequately served by the current labeling standards, which do not require the display of a drug's use-by date. CSHB 19 would help ensure that these groups have the necessary information to take their medications in a safe, effective way.

The bill also would allow flexibility in addressing future labeling issues by requiring labels to display any other information that may be required by TSBP rule at a later date. For example, new technology has enabled some drug manufacturers and pharmacies to display a colored image of an individual capsule or tablet on a container label for identification purposes. If needed, TSBP could enact new rules that would take advantage of technological advances to provide more and better information on container labels.

CSHB 19 would give pharmacies and other businesses adequate time to adjust to the new labeling requirements by delaying its implementation until June 1, 2010. Even if TSBP did not issue new rules until the last allowable date of January 1, 2010, affected businesses still would have five months to adjust their labeling practices.

OPPONENTS SAY:

No apparent opposition.

NOTES:

The committee substitute differs from the bill as filed by adding the specification that the new label requirements apply to Class A and E pharmacies. The committee substitute also added a provision that would allow the use-by date information to be recorded on any label affixed to a dispensing container. It further added an exemption for prescriptions dispensed to a person at the time of release from prison or jail if the prescription contained not more than a 10-day supply of medication. The substitute changed the date by which TSBP would have to adopt rules

implementing the new labeling requirements from not later than December 1, 2009, to not later than January 1, 2010. Finally, the committee substitute changed the date on which the label requirements would apply from on or after January 1, 2010, to on or after June 1, 2010.