HOUSE RESEARCH ORGANIZATION bill analysis | 5/10/2003 | HB 3486 Delisi, et al. (CSHB 3486 by McReynolds)

SUBJECT: Returning unused prescription drugs in the Medicaid program

COMMITTEE: Public Health — committee substitute recommended

VOTE: 8 ayes — Capelo, Laubenberg, Truitt, Dawson, McReynolds, Naishtat, Taylor, Zedler

0 nays

1 absent — Coleman

WITNESSES: For — None

Against — None

On — Gay Dodson, Texas State Board of Pharmacy; David Gonzales, Texas Pharmacy Association

BACKGROUND: Health and Safety Code, ch. 431.021 prohibits reselling unused prescriptions drugs after they have been originally dispensed or sold, unless they are donated to a charitable medical clinic. Controlled substances cannot be donated.

Medicaid, the federal-state medical assistance program for the poor, elderly, and disabled, includes nursing home care and prescription drug benefits. The program is administered by the Health and Human Services Commission.

DIGEST: (*The author intends to offer a floor substitute, which is summarized in the Digest in lieu of CSHB 3486.*)

CSHB 3486, as substituted, would permit a pharmacist who practiced in a facility to return certain unused drugs to a pharmacy to be credited to the Medicaid program.

It would direct the Texas State Board of Pharmacy to adopt rules governing the return of unused drugs, except controlled substances that could not be returned. Unused drugs that could be returned would include Food and Drug

Administration (FDA)-approved drugs sealed in the original packaging that were not the subject of a recall. The drug would have to be returned before its expiration date or within the drug's recommended shelf life and inspected by a pharmacist. Pharmacies would be permitted to restock and redistribute drugs that met these criteria and would reimburse or credit the state Medicaid program for the returned drug. Only drugs that would generate a credit greater than the restocking fee would be eligible.

A pharmacy or manufacturer that returned or accepted unused drugs would not be held liable for harm caused by the acceptance, resale, or administration of the drug unless the harm was intentional or caused by negligence, conscious indifference, or noncompliance with the regulations concerning the return of drugs. It would not diminish the liability of a pharmacy or manufacturer under product liability laws and would not limit the liability of a pharmacy or manufacturer that did not comply with the required insurance provisions for charitable organizations under the Charitable Immunity and Liability Act.

The bill would direct the Health and Human Services Commission (HHSC) to adopt rules setting the amount of the credit for an unused drug and the restocking fee. It also would require a secure electronic system for the repayment of credits from pharmacies. The bill also would direct HHSC to establish a task force, including representatives of nursing facilities and long-term care facilities, to develop the commission's rules relating to the bill.

If an agency determined it needed a federal waiver or authorization, it could pursue one, and postpone implementation until one was obtained. Otherwise the Texas State Board of Pharmacy would be required to adopt the rules to implement this bill by December 1, 2003, and could not require a pharmacy to require acceptance of these drugs before January 1, 2004.

The bill would take immediate effect if finally passed by a two-thirds record vote of the membership of each house. Otherwise, it would take effect September 1, 2003.

SUPPORTERS SAY:

CSHB 3486 would prevent perfectly good drugs from being thrown away. Often a nursing home gets a prescription filled for a patient, but only a portion of the prescription is used. Under current law, the unused drugs must be

thrown away or donated, even if they are in their original packaging. Because the charitable donation program is not widely used, this results in millions of dollars of prescriptions being destroyed. Twenty-two other states have similar programs, some of which have been in place for years.

The bill would protect the health and pocketbooks of Texans. Only drugs in their original packaging could be returned and only those from a facility. An individual with leftover prescriptions could not bring them back. It would expose prescriptions to no greater risk of tampering.

The price of a returned drug would be credited to Medicaid, minus a small reclamation fee for the pharmacist. Expensive drugs would be worth it to return, and pharmacists would be willing to take the unused drugs because they would be compensated for their time. The Medicaid program would pay only for the drugs that were consumed, a possible savings of millions of dollars.

At a time when the state is faced with difficult fiscal decisions about whom it can serve with limited Medicaid funds, it should pursue any cost savings, but especially ones that recapture lost expenses. Texas cannot afford to keep throwing away drugs.

Nursing homes already pay to have drugs disposed of, so the reclamation fee for the pharmacist would not be an additional burden. Under current law, unused drugs must be destroyed in the presence of a pharmacist and disposed of by a licensed waste management company.

The bill is unlikely to have any impact on the charitable donation program. While that option has worked well in some areas, it is not widespread. Because the reclamation fee would make it prohibitively expensive to resell many drugs, facilities still could donate unused drugs. Also, the reason facilities participate in the donation program is because they want to donate, which this bill would not change.

Any concerns about the semantics of the program, such as tracking lot numbers or paperwork, would be addressed in the rule-making process. In addition, stakeholders would have input through the task force.

The bill would not expose pharmacists to any additional liability. It would protect pharmacists who complied with the law from liability for any unintentional harm. Patients would continue to be protected by product liability laws.

The federal guidelines are not requirements, as evidenced by the fact that other states have similar programs. The bill would authorize HHSC or the Texas State Board of Pharmacy to obtain any needed authorization or waiver to implement the program. This bill would not force agencies to write rules that broke federal law.

OPPONENTS SAY:

The FDA has informed Texas that the state cannot recycle drugs in this way based upon federal guidelines and supported by an Attorney General (AG) opinion, JC-0412 from September 2001. According to FDA guidelines, previously dispensed drugs may not be reused. Other states with programs like the one proposed put them in place without checking with the FDA. Texas has checked, has an AG opinion on the matter, and should not violate the federal guidelines.

The problem of unused drugs really is not as significant as it would seem. Hospitals and most large nursing homes have carts and automated dispensing machines that ensure only one day's dosages are dispensed, so none are left over. As the cost of automated dispensing machines continues to fall and the remaining homes purchase one, this issue will disappear altogether.

Pharmacists would be asked to shoulder an unacceptable level of risk of liability under this bill. Even though the bill contains some protection, and the author intends to offer an amendment to clarify that protection, pharmacists still would be in violation of federal guidelines, which would threaten their licenses. Also, pharmacists do not want to participate in a system that could harm patients, whether or not they could be sued. Because the recycling of drugs would make it impossible to track lot numbers or recalls, and would require the pharmacist to guess whether a drug had been tampered with at the nursing home, few pharmacists would be likely to participate.

If few pharmacists participated, the program could not generate savings. In Hawaii, a similar program failed under the weight of the Medicaid record-keeping requirements. Pharmacists would be unlikely to view the nominal

restocking fee as an incentive when they also would have to fill out Medicaid paperwork and return the profit they made on the original sale.

The changes to the bill from the committee substitute likely would cost the state. The fiscal note attached to the committee substitute estimated no savings to the state, though the Medicaid program would have been able to participate in the same way as in the floor substitute. In addition, the floor substitute would require HHSC to appoint a task force and create an electronic credit system. If the committee substitute did not project any saving to the state and the floor substitute would require HHSC to use resources implementing the program, the bill could end up as a cost to the state.

Texas should not encourage recycling of drugs. There would be no required disclosure to the recipient of the recycled drug. People who pay for a new drug expect it to be as the manufacturer sold it — not recycled. Also, there would be no way for the person taking the drug to know if it had been recycled once or six times, information that some people might find important.

OTHER OPPONENTS SAY:

The committee substitute was a better bill because it would have permitted all unused drugs to be returned — not just Medicaid drugs. Private insurance pays for nursing home care as well and should be encouraged to continue doing so by permitting those unused prescriptions to be returned. The majority of programs in other states permit the return of drugs without regard to the payor. These programs have a good track record and a similar program could work similarly well in Texas.

NOTES:

The floor substitute is identical to an amendment by Rep. Delisi to CSHB 2292 by Wohlgemuth, which passed the House on April 28. If enacted, CSHB 2292 would take precedence over any other conflicting legislation also enacted, regardless of the date of enactment.

The author also intends to offer an amendment to clarify the liability section to reflect the relationship between the facility and pharmacy.

Unlike the floor substitute, the committee substitute would authorize the return of unused drugs by facilities and credit the facility. It would not create the HHSC reimbursement setting, electronic payment system, and task force.

It also would not require review by a pharmacist when receiving the returned drug.

The fiscal note attached to the committee substitute estimated no fiscal implication to the state.