SUBJECT: Insurance coverage for drugs used for non-FDA-approved purposes

COMMITTEE: Insurance — committee substitute recommended

VOTE: 6 ayes — Smithee, Eiland, G. Lewis, J. Moreno, Seaman, Thompson

0 nays

3 absent — Burnam, Olivo, Wise

WITNESSES: (*On original bill:*)
For — Jeff Kloster, Texas Association of Health Plans; David Nagler, Genentech, Inc.; Martin N. Raber, M.D., University of Texas M.D. Anderson Cancer Center

Against — Cynthia Leiferman, Advocacy, Inc.

BACKGROUND: Currently, Texas law does not require health-benefit plans that cover prescription drugs to pay for drugs when they are used for a purpose not approved by the U.S. Food and Drug Administration (FDA).

DIGEST: CSHB 2061 would require certain health-benefit plans, notably health maintenance organization (HMO) plans, that cover drugs to provide coverage for any drug prescribed for a covered serious illness if FDA had approved the drug for at least one indication and the drug had been recognized for the prescribed treatment by an authorized drug reference guide or by medical literature substantially accepted by other doctors. The affected health-benefit plans also would have to cover any medically necessary service used to administer the drug.

A health-benefit plan would not have to cover experimental drugs not approved by FDA, drugs that should not be used for the prescribed treatment according to FDA, or drugs used to treat any disease or condition not covered by the health-benefit plan.

A health-benefit plan could not deny drug coverage based on "medical necessity" except for reasons that were unrelated to the legal status of the drug use.

Health-benefit plans that would be covered by CSHB 2061 include plans offered by insurance companies, HMOs, group hospital benefit corporations, stipulated premium insurance companies, reciprocal exchanges, certified multiple-employer welfare arrangements, and certified nonprofit health corporations. CSHB 2061 would *not* apply to:

- health-benefit plans that offer coverage only for a specified disease or limited benefit, accidental death or dismemberment, lost wages, supplemental liability insurance, credit insurance, dental or vision care, hospital expenses, or indemnity for hospital confinement;
- small-employer health-benefit plans;
- Medicare supplemental policies;
- workers' compensation insurance coverage;
- medical payment insurance coverage issued as part of an automobile insurance policy; or
- a long-term care policy, including a nursing-home fixed indemnity policy, unless the commissioner of insurance determined that the policy was so comprehensive that it belonged within the scope of the bill.

CSHB 2061 would take effect September 1, 1999, and would apply only to a health-benefit plan delivered, issued for delivery, or renewed on or after January 1, 2000.

SUPPORTERS SAY:

CSHB 2061 would allow doctors in Texas to prescribe drugs for their patients when new uses for the drugs have been accepted by the medical community. Such prescriptions are called "off-label" use. Restrictive interpretations of FDA approval should not be used to deny insurance coverage for off-label drugs when formerly cutting-edge treatments have become commonplace.

Some doctors prescribe drugs for treatments other than their FDA-approved use because not all of the proven uses for a drug may have gone through the FDA approval process because of costs and delays. Medicine is progressing so quickly that FDA cannot keep up with the new uses being found for old drugs. For some drugs, drug companies pursue FDA approval only for the most common and profitable uses. It is unfair to deny insurance coverage for

people with rare diseases. For example, many adult drugs that can be used to treat children have not been approved by FDA for pediatric use because the ailment that the drug treats is more common in adults.

CSHB 2061 would not increase costs for health-benefit plans because it would apply only to plans that already cover prescription drugs. Drugs that FDA has not approved for all uses are not necessarily more or less expensive than other FDA-approved drugs.

CSHB 2061 would not authorize unsafe treatments. The bill would not require insurance coverage for drugs that FDA has not approved or drugs that FDA says should not be given for the prescribed use. CSHB 2061 would apply only to FDA-approved drugs accepted by the medical community for the prescribed use. The doctor prescribing the drug still would be liable if the drug was prescribed improperly.

OPPONENTS SAY:

CSHB 2061 could require insurance coverage for unsafe drugs. It would not require that a covered drug be approved by FDA for the prescribed use. While there would be an exception for drugs that the FDA has determined should not be used for the prescribed treatment, this is not the same as the FDA's approving the prescribed use.

Opinions often differ within the medical community about the off-label use of some drugs. If coverage were denied, it would be very hard for the insurer or the insured to prove that the medical community had accepted a certain use for a drug. Even reports in approved drug reference guides and peer-reviewed medical literature might generate conflicting opinions.

NOTES:

There are several major differences between the committee substitute and the original bill. The original would have required insurance coverage if the drug was FDA-approved, noted in approved drug reference guides, or substantially accepted in the medical literature. The substitute would require FDA approval for at least one use, and the prescribed use either would have to be found in approved drug reference guides or would have to be generally accepted in the medical literature.

The original bill would have required coverage “so long as” the drugs met the two requirements, whereas the substitute would require coverage “if” the drugs met the two requirements. The substitute also changed the lists of health-benefit plans that would be included and excluded from the bill’s scope.