BILL ANALYSIS

Senate Research Center

C.S.H.B. 2061
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Economic Development
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Committee Report (Substituted)

DIGEST

Currently, Texas does not require health plans to cover "off-label" uses of certain drugs. An "off-label" use involves using a federal Food and Drug Administration (FDA) approved drug that is already deemed safe and effective for one medical condition to treat another medical condition. Twenty-six other states have enacted legislation to cover at least some medically accepted off-label uses of FDA approved drugs. This bill would allow certain prescription drugs to be available for health benefit plan enrollees that suffer certain illnesses, as long as the drug has been approved by the FDA, and is supported by clinical research that appears in peer-reviewed literature for the medical condition, or is supported or accepted in one of the standard reference compendia.

PURPOSE

As proposed, C.S.H.B. 2061 establishes coverage requirements for certain prescription drugs by a health benefit plan, if the health plan provides prescription benefits.

RULEMAKING AUTHORITY

Rulemaking authority is granted to the commissioner of insurance in SECTION 1 (Section 4, Article 21.53M, Insurance Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Chapter 21E, Insurance Code, by adding Article 21.53M, as follows:

Art. 21.53M. COVERAGE FOR OFF-LABEL DRUG USE

Sec. 1. DEFINITIONS. Defines "contraindication," "drug," "health benefit plan," "indication," and "peer-reviewed medical literature."

Sec. 2. SCOPE OF ARTICLE. Provides that this article applies only to a health benefit plan that provides benefits for medical or surgical expenses incurred as a result of a health condition, accident, or sickness, including insurance policies or agreements, hospital contracts, or coverage documents offered by certain entities. Provides that this article does not apply to: certain plans that provide limited coverage; a small employer health benefit plan written under Chapter 26 of this code; a Medicare supplemental policy; workers' compensation insurance coverage; medical payment insurance coverage issued as part of a motor vehicle insurance policy; or a long-term care policy, unless the commissioner of insurance (commissioner) determines that the policy is a health benefit plan.

Sec. 3. MINIMUM STANDARDS OF COVERAGE. Requires a health benefit plan that provides coverage for drugs to provide coverage for any drug prescribed to treat an enrollee for a covered illness if the drug has been approved by the Food and Drug Administration (FDA) and is recognized for treatment of the indication for which the drug is prescribed in a prescription drug reference compendium approved by the commissioner or substantially accepted peer-reviewed medical literature. Requires coverage of a drug required by this section to include coverage of medically necessary services associated with the administration of the drug. Prohibits a drug use that is covered under this section from being denied based on a "medical necessity" requirement except for reasons that are unrelated to the legality of its use. Provides that this section does not require coverage for experimental drugs or any disease or condition that is excluded from coverage under the plan. Provides that a health benefit plan is not required to cover a drug FDA has

determined to be contraindicated for treatment of the current indication.

Sec. 4. RULES. Authorizes the commissioner to adopt rules to implement this article.

SECTION 2. Effective date: September 1, 1999.
Makes application of this Act prospective to January 1, 2000.

SECTION 3. Emergency clause.

SUMMARY OF COMMITTEE CHANGES

SECTION 1.

Adds Section 4, Article 21.53M, Insurance Code, to authorize the commissioner to adopt rules to implement this article.