BILL ANALYSIS

S.B. 39
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Insurance
Committee Report (Unamended)

BACKGROUND AND PURPOSE

There is currently no statutory requirement for Texas insurers to cover routine patient care costs for individuals who elect to participate in clinical trials. The Texas Medical Association reports that lack of health insurance coverage for routine medical costs could be a significant barrier to patients who might otherwise enroll in a beneficial clinical trial, noting that less than three percent of potentially eligible cancer patients were enrolled in clinical trials as of May 2008. This is due in part to many insurers denying medical coverage for clinical trial participants. Since 1995, nearly half of all states have passed legislation or entered into agreements requiring health plans to cover routine patient care costs for trial participants and, in 2000, Medicare beneficiaries who chose to participate in clinical trials were eligible for routine patient care cost coverage.

S.B. 39 sets forth health benefit plan coverage requirements for routine patient care costs for persons with life-threatening illnesses who have elected to participate in certain clinical trials.

RULEMAKING AUTHORITY

It is the committee's opinion that rulemaking authority is expressly granted to the commissioner of insurance in SECTION 1 of this bill.

ANALYSIS

S.B. 39 amends the Insurance Code to require a health benefit plan issuer to provide benefits for routine patient care costs to an enrollee in connection with a phase I, II, III, or IV clinical trial, if the trial is conducted in relation to the prevention, detection, or treatment of a life-threatening disease or condition, and is approved by certain federal health, defense, or veterans affairs agencies or certain state institutional review boards. The bill applies the requirement only to certain health benefit plans, coverages, and risk pools. The bill requires the state Medicaid program and a managed care organization that contracts with the Health and Human Services Commission to provide, to the extent allowable by federal law, benefits under these provisions to a Medicaid recipient. The bill specifies the types of plans excluded from these provisions. The bill excludes from routine patient care costs the cost of any investigational new drug or device that is not approved for any indication by the United States Food and Drug Administration, the cost of a service that is not a health care service, the cost of a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis, a cost associated with managing a clinical trial, or the cost of a health care service that is specifically excluded from coverage under a health benefit plan. The bill defines "enrollee," "life-threatening disease or condition," and "research institution."

S.B. 39 provides that a health benefit plan issuer is not required to reimburse the research institution conducting the clinical trial for the cost of routine patient care provided through the institution unless the institution and each health care professional providing routine patient care through the institution agrees to accept reimbursement under the health benefit plan at the rates established under the plan as payment in full for the routine patient care provided in connection

with the clinical trial. The bill provides that a plan issuer is not required to provide benefits for services that are a part of the subject matter of the clinical trial and that are customarily paid by the research institution conducting the trial, for routine patient care services provided outside of the plan's health care provider network, unless out-of-network benefits are otherwise provided under the plan, or for health care services provided outside Texas unless the health benefit plan otherwise provides such benefits. The bill establishes that the benefits required under these provisions may be subject to a deductible, coinsurance, or copayment requirement comparable to other such requirements applicable under the health benefit plan. The bill prohibits the plan issuer from canceling or refusing to renew coverage under a plan solely because an enrollee in the plan participates in an approved clinical trial.

S.B. 39 authorizes the commissioner of insurance to adopt rules to implement these provisions. The bill makes its provisions applicable to a health benefit plan that is delivered, issued for delivery, or renewed on or after January 1, 2010.

EFFECTIVE DATE

September 1, 2009.