

SUBJECT: Covering routine patient care for persons participating in clinical trials

COMMITTEE: Insurance — favorable, without amendment

VOTE: 7 ayes — Smithee, Martinez Fischer, Eiland, Hancock, Hunter, Isett,
Taylor

0 nays

2 absent — Deshotel, Thompson

SENATE VOTE: On final passage, March 23 — 31-0

WITNESSES: (*On House companion bill, HB 390:*)

For — Kristen Doyle, The Leukemia and Lymphoma Society; Beth Emery; Marsha Fountain, American Cancer Society; Marjorie Gallece, Breast Cancer Resource Centers of Austin; Betty Razvillas, Oncology Nursing Society; Michael Shearn, Genzyme; Stanley Wang, Texas Medical Association; Jerry Worden, Alamo Breast Cancer Foundation; (*Registered, but did not testify:* Kathy Adjemian; Joseph Annis; Tony Aventa; Miryam Bujanda, Methodist Healthcare Ministries; Bruna Callegari-Puente; Graciela Cigarroa; Dale Eastman; Pamela Hall; John Hawkins, Texas Hospital Association; Jerry Hunsaker; Keely Hunsaker; Lauren Hutton, Lance Armstrong Foundation; Patricia Kistner, Alamo Breast Cancer Foundation; Carrie Kroll, Texas Pediatric Society; Suzanne Loonam; David Marwitz, Texas Dermatology Society; Kelly Montiville; Amber Pearce, Texas Healthcare and Bioscience Institute; Jack Pierce; Doris Robitaille; Jaime Ronderos, Pinnacle Partners in Medicine; Stephanie Roth, Texas Medical Association; Mustasim Rumi; Morgan Sanders, March of Dimes; Paulette Shaw, Nueces County Medical Society; Jane Stafford; Wesley Stafford; Deborah Vollmer Dahlke, Texas Life Science Foundation; Kakhi Wakefield, Greentech, Inc.; Kelly Worden)

Against — Jay Thompson, Texas Association of Life and Health Insurers

On — Gabriel Hortobagyi, University of Texas MD Anderson Cancer Center; Dianne Longley, Texas Department of Insurance; Jared Wolfe, Texas Association of Health Plans

BACKGROUND: Insurance Code, Title 8, subtitle E provides provisions for benefits payable under health coverage.

DIGEST: SB 39 would amend Title 8, subtitle E of the Insurance Code, adding ch. 1379, requiring coverage for routine patient care costs for health plan enrollees participating in clinical trials.

Required coverage. A health benefits plan issuer would have to provide benefits for routine patient care costs to an enrollee in connection with a phase I, phase II, phase III, or phase IV clinical trial if the trial was conducted in relation to the prevention, detection, or treatment of a life-threatening disease or condition and was approved by:

- the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services (HHS);
- the National Institutes of Health;
- the U.S. Food and Drug Administration (FDA);
- the U.S. Department of Defense;
- the U.S. Department of Veterans Affairs; or
- an institutional review board of an institute within Texas that has an agreement with the Office for Human Research Protections of HHS.

Routine patient care costs. Routine patient care costs would be costs of any medically necessary health care service for which benefits were provided under a health benefit plan, regardless of whether the person entitled to coverage under a health benefit plan was participating in a clinical trial. Routine patient care costs would not include:

- the cost of an investigational new drug or device not approved by the FDA, including a drug or device that was the subject of the clinical trial;
- the cost of a service that was not a health care service, regardless of whether the service was required in connection with clinical trial participation;

- the cost of a service that was 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 specifically was excluded from coverage under a health benefit plan.

A health benefit plan issuer could not cancel or refuse to renew coverage solely because an enrollee in the health plan participated in a clinical trial.

A health benefit plan issuer would not be required to reimburse the research institution conducting the clinical trial for the cost of routine patient care provided through the research institution unless the institution and health care professional providing routine patient care through the institution agreed to accept reimbursement under the health plan, at established rates, as payment for the routine patient care provided in connection with the clinical trial.

The bill would not require a health benefit plan issuer to provide routine patient care services provided outside the plan's health care provider network unless out-of-network benefits were otherwise provided by the plan.

Applicability of coverage. The bill would apply only to a health benefit plan that provided benefits for medical or surgical expenses incurred because of a health condition, accident, or sickness, including an individual, group, blanket, or franchise insurance policy or insurance agreement, a group hospital service contract, or group evidence of coverage or similar coverage document offered by:

- an insurance company;
- a group hospital service corporation;
- a fraternal benefit society;
- a stipulated premium company;
- a reciprocal or inter-insurance exchange;
- a health maintenance organization;
- a multiple employer welfare arrangement; or
- an approved nonprofit health corporation.

The coverage requirement also would apply to group health coverage through a school district and to health and accident coverage provided by a risk pool, notwithstanding existing provisions of the law.

Additionally, the bill would apply to the following health plans:

- a basic coverage plan;
- a basic plan;
- a primary care coverage plan;
- basic coverage; and
- a small employer health benefit plan.

The state Medicaid program and a managed care organization contract with the Texas Health and Human Services Commission to provide health care services to Medicaid recipients would have to provide coverage for routine patient care costs for health plan enrollees participating in clinical trials, to the extent allowed by federal law.

Exceptions to coverage. The bill would not apply to a plan that provided coverage:

- for wages or payments in lieu of wages from when an employee was absent from work due to injury or sickness;
- as a supplement to a liability insurance policy;
- for credit insurance; or
- only for dental or vision care, hospital expenses, or indemnity for hospital confinement.

Additionally, the bill would not apply to:

- a Medicare supplemental policy;
- a workers' compensation insurance policy;
- medical payment insurance coverage provided under a motor vehicle insurance policy; or
- a long-term care policy.

Other provisions. The Texas Department of Insurance (TDI) would adopt rules to implement the bill's provisions.

Benefits required under the bill could be made subject to a deductible, coinsurance, or copayment requirement comparable to other applicable requirements under the health plan.

The bill would take effect September 1, 2009, and would apply only to a health benefit plan that was delivered, issued for delivery, or renewed on or after January 1, 2010.

**SUPPORTERS
SAY:**

SB 39 would require health benefit plans to cover the routine costs of care for a patient enrolled in a clinical trial. Routine costs would include any medically necessary health care service, including doctor visits, hospital stays, tests, and x-rays, for which benefits would be provided to a patient even if the patient were not enrolled in a clinical trial.

The success of clinical trials is crucial to the introduction of new and life-saving therapies for patients facing serious and life-threatening illnesses. Unfortunately, lack of insurance coverage for routine care costs often can be a significant financial barrier to many patients who might otherwise enroll in a trial as patients must bear these routine costs on their own. This is a crucial issue, as the success of trials depends on adequate patient enrollment. Currently, people with life-threatening illnesses in Texas often must make the difficult choice between enrolling in a clinical trial that offers the hope of a life-saving treatment and having health insurance that will reimburse routine care costs. SB 39 would remove this barrier and provide an important tool to ensure that seriously ill patients had access to clinical trials by placing restrictive conditions on what a health plan would have to pay for in the context of a clinical trial.

This is not a new concept. The bill would allow Texas to join the roughly 24 other states that have either enacted legislation or have instituted special agreements requiring health plans to pay such costs. In 2000, Medicare also began covering beneficiaries' routine care costs for persons who choose to participate in clinical trials. Additionally, the American Association of Health Insurance Plans has adopted the position that insurers should cover routine medical costs associated with clinical trials.

In its interim report to the 81st Legislature, the Senate State Affairs Committee concluded that it should be the public policy of Texas to require this coverage for patients in medical trials. The committee also found that, while there are concerns that such a requirement could serve as a subsidy for drug companies, these concerns are mitigated by the fact that

coverage of only routine costs would be required. The trial sponsor would continue to be responsible for the costs of any pre-trial testing, experimental drug or therapy, and all administrative costs associated with the trial.

**OPPONENTS
SAY:**

SB 39 would impose yet another mandate on health benefit plans, further increasing health costs to individuals and small businesses. Even if the mandate cost consumers and employers a small amount, these amounts could become a burden when combined with the costs of the many other health insurance mandates.

In tight economic times, many employers already must decide how to cut overhead in order to stay in business. Higher health care costs due to mandated coverage increases the burden on small employers, who may be forced to lay off employees or cease or decrease existing health coverage. In the aggregate, these legislative mandates contribute significantly to the cost of health coverage. It would be better that health costs stay low even if it means a narrow group of individuals did not receive coverage.

Instead of the required coverage as proposed by SB 39, the Texas Department of Insurance should conduct a study examining the utilization of this provision and its impact on health plans. This would be a more prudent step in light of the bill's fiscal note of more than \$600,000 in general revenue funds alone.

NOTES:

According to the Legislative Budget Board, the bill's requirement for health care coverage of routine patient care in clinical trials as it applied to state employees would cost the state just over \$600,000 in general revenue in fiscal 2010-11 and over \$2.7 million over the next five years. Additionally, over the next five years, the bill would cost over \$112,000 in general revenue-dedicated funds and over \$628,000 in state highway funds.

The House companion bill, HB 390 by Zerwas, was considered by the House Insurance Committee in a public hearing on March 3 and left pending.