

BILL ANALYSIS

Senate Research Center
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S.B. 39
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AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Currently, many patients with life-threatening illnesses who choose to participate in clinical trials receive no remuneration for the same routine medical care that would be covered by their insurance companies were they not trial participants.

Persons with life-threatening illnesses in Texas must often 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. The goal of a clinical trial is to find better ways to treat diseases. However, fewer than three percent of potentially eligible oncology patients enroll in trials, in part due to the practice of many insurance companies of denying medical coverage for these persons.

In Texas, there is no regulation requiring insurance companies to cover routine medical care for persons who choose to participate in clinical trials. Between 1995 and 2006 however, 23 states passed legislation or entered into agreements requiring health plans to pay these costs for trial participants: Arizona, California, Connecticut, Delaware, Georgia, Illinois, Louisiana, Maine, Maryland, Massachusetts, Michigan, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, Ohio, Rhode Island, Tennessee, Vermont, Virginia, and West Virginia. In 2000, Medicare also began covering beneficiaries' routine care costs for persons who choose to participate in clinical trials.

As proposed, S.B. 39 sets forth provisions for coverage for routine medical care for persons with life-threatening illnesses who have elected to participate in certain clinical trials.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the commissioner of insurance in SECTION 1 (Section 1379.005, Insurance Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Subtitle E, Title 8, Insurance Code, by adding Chapter 1379, as follows:

CHAPTER 1379. COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR ENROLLEES PARTICIPATING IN CERTAIN CLINICAL TRIALS

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 1379.001. DEFINITIONS. Defines "enrollee," "life-threatening disease or condition," and "research institution."

Sec. 1379.002. APPLICABILITY OF CHAPTER. (a) Provides that this chapter 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 an individual, group, blanket, or franchise insurance policy or insurance agreement, a group hospital service contract, or an individual or group evidence of coverage or similar coverage document that is offered by certain entities.

(b) Provides that this chapter applies to group health coverage made available by a school district in accordance with Section 22.004 (Group Health Benefits for School), Education Code.

(c) Provides that, notwithstanding Section 172.014 (Application for Certain Laws), Local Government Code, or any other law, this chapter applies to health and accident coverage provided by a risk pool created under Chapter 172 (Texas Political Subdivisions Uniform Group Benefits Program), Government Code.

(d) Provides that, notwithstanding any provision in Chapter 1551, 1575, 1579, or 1601, or any other law, this chapter applies to a basic coverage plan under Chapter 1551 (Texas Employees Group Benefits Act), Insurance Code; a basic plan under Chapter 1575 (Texas Public School Employees Group Benefits Program), Insurance Code; a primary care coverage plan under Chapter 1579 (Texas School Employees Uniform Group Health Coverage), Insurance Code; and basic coverage under Chapter 1601 (Uniform Insurance Benefits Act For Employees of the University of Texas System and the Texas A&M University System), Insurance Code.

(e) Provides that, notwithstanding Section 1501.251 (Exception From Certain Mandated Benefit Requirements) or any other law, this chapter applies to coverage under a small employer health benefit plan subject to Chapter 1501 (Health Insurance Portability and Availability Act), Insurance Code.

Sec. 1379.003. **APPLICABILITY TO CERTAIN GOVERNMENT PROGRAMS.** Requires the state Medicaid program to the extent allowed by federal law, and a managed care organization that contracts with the Health and Human Services Commission (HHSC) to provide health care services to Medicaid recipients through a managed care plan, to provide benefits required under this chapter to a Medicaid recipient.

Sec. 1379.004. **EXCEPTION.** Provides that this chapter does not apply to certain plans, policies, and coverages.

Sec. 1379.005. **RULES.** Authorizes the commissioner of insurance (commissioner) in accordance with Subchapter A (Rules), Chapter 36 (Department Rules and Procedures), Insurance Code, to adopt rules to implement this chapter.

[Reserves Sections 1379.006-1379.050 for expansion.]

SUBCHAPTER B. COVERAGE FOR ROUTINE PATIENT CARE COSTS

Sec. 1379.051. **ROUTINE PATIENT CARE COSTS.** Defines "routine patient care costs" for the purposes of this chapter. Sets forth certain costs that are not included as routine patient care costs.

Sec. 1379.052. **COVERAGE REQUIRED.** Requires a health benefit plan issuer 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 clinical trial is conducted in relation to the prevention, detection, or treatment of a life-threatening disease or condition and is approved by certain federal entities or an institutional services.

Sec. 1379.053. **RESEARCH INSTITUTION.** (a) 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 research institution unless the research institution, and each health care professional providing patient care through the research 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.

(b) Provides that a health benefit plan issuer is not required to provide benefits under this section for services that are a part of the subject matter of a clinical trial customarily paid for by the research institution conducting the trial.

Sec. 1379.054. **LIMITATIONS ON COVERAGE.** (a) Provides that notwithstanding Section 1379.053, a health benefit plan issuer is not required under this chapter to provide benefits 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.

(b) Provides that a health benefit plan issuer is not required under this chapter to provide benefits for health care services provided outside of this state unless the plan otherwise provides benefits for health care services provided outside of this state.

Sec. 1379.055. **DEDUCTIBLE, COINSURANCE, AND COPAYMENT REQUIREMENTS.** Authorizes the benefits required under this chapter to be made subject to certain deductible, copayment, and coinsurance requirements comparable to other deductible, copayment, and coinsurance requirements applicable under the health benefit plan.

Sec. 1379.056. **CANCELLATION OR NONRENEWAL PROHIBITED.** Prohibits the issuer of a health benefit plan from canceling or refusing to renew coverage under a plan solely because an enrollee participates in a clinical trial described by Section 1379.052.

SECTION 2. Amends Section 1506.151, Insurance Code, by adding Subsection (d) to provide that coverage provided by the Texas Health Insurance Risk Pool is subject to Chapter 1379.

SECTION 3. Makes application of this Act prospective to January 1, 2010.

SECTION 4. Effective date: September 1, 2009.