

By: Zaffirini

S.B. No. 674

A BILL TO BE ENTITLED

AN ACT

relating to health benefit plan coverage for routine patient care costs for enrollees participating in certain clinical trials.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subtitle E, Title 8, Insurance Code, is amended by adding Chapter 1379 to read 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. In this chapter:

(1) "Enrollee" means an individual entitled to coverage under a health benefit plan.

(2) "Life-threatening disease or condition" means a disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

(3) "Research institution" means the institution or other person or entity conducting a phase I, phase II, phase III, or phase IV clinical trial.

Sec. 1379.002. APPLICABILITY OF CHAPTER. (a) 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

1 of coverage or similar coverage document that is offered by:

2 (1) an insurance company;

3 (2) a group hospital service corporation operating  
4 under Chapter 842;

5 (3) a fraternal benefit society operating under  
6 Chapter 885;

7 (4) a stipulated premium company operating under  
8 Chapter 884;

9 (5) an exchange operating under Chapter 942;

10 (6) a health maintenance organization operating under  
11 Chapter 843;

12 (7) a multiple employer welfare arrangement that holds  
13 a certificate of authority under Chapter 846; or

14 (8) an approved nonprofit health corporation that  
15 holds a certificate of authority under Chapter 844.

16 (b) This chapter applies to group health coverage made  
17 available by a school district in accordance with Section 22.004,  
18 Education Code.

19 (c) Notwithstanding Section 172.014, Local Government Code,  
20 or any other law, this chapter applies to health and accident  
21 coverage provided by a risk pool created under Chapter 172, Local  
22 Government Code.

23 (d) Notwithstanding any provision in Chapter 1551, 1575,  
24 1579, or 1601 or any other law, this chapter applies to:

25 (1) a basic coverage plan under Chapter 1551;

26 (2) a basic plan under Chapter 1575;

27 (3) a primary care coverage plan under Chapter 1579;

1 and

2 (4) basic coverage under Chapter 1601.

3 (e) Notwithstanding any other law, a standard health  
4 benefit plan provided under Chapter 1507 must provide the coverage  
5 required by this chapter.

6 (f) Notwithstanding Section 1501.251 or any other law, this  
7 chapter applies to coverage under a small employer health benefit  
8 plan subject to Chapter 1501.

9 Sec. 1379.003. APPLICABILITY TO CERTAIN GOVERNMENT  
10 PROGRAMS. To the extent allowed by federal law, the state Medicaid  
11 program, and a managed care organization that contracts with the  
12 Health and Human Services Commission to provide health care  
13 services to Medicaid recipients through a managed care plan, shall  
14 provide the benefits required under this chapter to a Medicaid  
15 recipient.

16 Sec. 1379.004. EXCEPTION. This chapter does not apply to:

17 (1) a plan that provides coverage:

18 (A) for wages or payments in lieu of wages for a  
19 period during which an employee is absent from work because of  
20 sickness or injury;

21 (B) as a supplement to a liability insurance  
22 policy;

23 (C) for credit insurance;

24 (D) only for dental or vision care;

25 (E) only for hospital expenses; or

26 (F) only for indemnity for hospital confinement;

27 (2) a Medicare supplemental policy as defined by

1 Section 1882(g)(1), Social Security Act (42 U.S.C. Section 1395ss);

2 (3) a workers' compensation insurance policy;

3 (4) medical payment insurance coverage provided under  
4 a motor vehicle insurance policy; or

5 (5) a long-term care policy, including a nursing home  
6 fixed indemnity policy, unless the commissioner determines that the  
7 policy provides benefit coverage so comprehensive that the policy  
8 is a health benefit plan as described by Section 1379.002.

9 Sec. 1379.005. RULES. The commissioner, in accordance with  
10 Subchapter A, Chapter 36, may adopt rules to implement this  
11 chapter.

12 [Sections 1379.006-1379.050 reserved for expansion]

13 SUBCHAPTER B. COVERAGE FOR ROUTINE PATIENT CARE COSTS

14 Sec. 1379.051. ROUTINE PATIENT CARE COSTS. For purposes of  
15 this chapter, routine patient care costs means the costs of any  
16 medically necessary health care service for which benefits are  
17 provided under a health care plan, without regard to whether the  
18 enrollee is participating in a clinical trial. Routine patient  
19 care costs do not include:

20 (1) the cost of an investigational new drug or device  
21 that is not approved for any indication by the United States Food  
22 and Drug Administration, including a drug or device that is the  
23 subject of the clinical trial;

24 (2) the cost of a service that is not a health care  
25 service, regardless of whether the service is required in  
26 connection with participation in a clinical trial;

27 (3) the cost of a service that is clearly inconsistent

1 with widely accepted and established standards of care for a  
2 particular diagnosis; or

3 (4) a cost associated with managing a clinical trial.

4 Sec. 1379.052. COVERAGE REQUIRED. A health benefit plan  
5 issuer shall provide benefits for routine patient care costs to an  
6 enrollee in connection with a phase I, phase II, phase III, or phase  
7 IV clinical trial if the clinical trial is conducted in relation to  
8 the prevention, detection, or treatment of a life-threatening  
9 disease or condition and is approved by:

10 (1) the National Institutes of Health;

11 (2) the United States Food and Drug Administration;

12 (3) the United States Department of Defense;

13 (4) the United States Department of Veterans Affairs;

14 or

15 (5) another entity that supports research in clinical  
16 trials and that meets the grant standards of the National  
17 Institutes of Health.

18 Sec. 1379.053. RESEARCH INSTITUTION. (a) A health benefit  
19 plan issuer is not required to reimburse the research institution  
20 conducting the clinical trial for the cost of routine patient care  
21 provided through the research institution unless the research  
22 institution, and each health care professional providing routine  
23 patient care through the research institution, agrees to accept  
24 reimbursement under the health benefit plan, at the rates that are  
25 established under the plan, as payment in full for the routine  
26 patient care provided in connection with the clinical trial.

27 (b) A health benefit plan issuer is not required to provide

1 benefits under this section for services that are a part of the  
2 subject matter of the clinical trial and that are customarily paid  
3 for by the research institution conducting the clinical trial.

4 Sec. 1379.054. LIMITATIONS ON COVERAGE. (a)

5 Notwithstanding Section 1379.053, this chapter does not require a  
6 health benefit plan issuer to provide benefits for routine patient  
7 care services provided outside of the plan's health care provider  
8 network unless out-of-network benefits are otherwise provided  
9 under the plan.

10 (b) This chapter does not require a health benefit plan  
11 issuer to provide benefits for health care services provided  
12 outside this state unless the health benefit plan otherwise  
13 provides benefits for health care services provided outside this  
14 state.

15 Sec. 1379.055. DEDUCTIBLE, COINSURANCE, AND COPAYMENT  
16 REQUIREMENTS. The benefits required under this chapter may be made  
17 subject to a deductible, coinsurance, or copayment requirement  
18 comparable to other deductible, coinsurance, or copayment  
19 requirements applicable under the health benefit plan.

20 SECTION 2. Section 1506.151, Insurance Code, is amended by  
21 adding Subsection (d) to read as follows:

22 (d) Coverage provided by the pool is subject to Chapter  
23 1379.

24 SECTION 3. This Act applies only to a health benefit plan  
25 that is delivered, issued for delivery, or renewed on or after  
26 January 1, 2008. A health benefit plan that is delivered, issued  
27 for delivery, or renewed before January 1, 2008, is governed by the

1 law as it existed immediately before the effective date of this Act,  
2 and that law is continued in effect for that purpose.

3 SECTION 4. This Act takes effect September 1, 2007.