

AMENDED IN SENATE MARCH 13, 2001

**SENATE BILL**

**No. 37**

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**Introduced by Senator Speier**

(Principal coauthors: Assembly Members Jackson and Wayne)

December 4, 2000

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An act to add Section 1370.6 to the Health and Safety Code, and to add Section 10145.4 to the Insurance Code, relating to health insurance, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

SB 37, as amended, Speier. Health insurance: coverage for clinical trials.

Existing law provides for the regulation and licensing of health care service plans by the Director of the Department of Managed Health Care and for the regulation of disability insurers by the Insurance Commissioner. Existing law provides that a willful violation of provisions governing health care service plans is a crime.

Existing law requires health care service plans and certain disability insurers to provide an external review process to examine coverage decisions regarding experimental or investigational therapies under certain conditions.

This bill would require health care service plans and certain disability insurers to provide coverage for all health care services related to the treatment of an enrollee or insured *diagnosed with cancer and accepted* in a clinical trial meeting specified requirements.

Because a willful violation of the bill's requirements with respect to health care service plans would be a crime, this bill would impose a state-mandated local program by creating a new crime.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

This bill would declare that ~~its provisions would become effective~~ *it is to take effect* immediately as an urgency statute.

Vote: <sup>2</sup>/<sub>3</sub>. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1 ~~SECTION 1.—It is the intent of the Legislature in enacting this~~  
 2 ~~act to require health care service plans and disability insurers to~~  
 3 ~~cover the costs of health care services that the patient would~~  
 4 ~~normally receive had the patient not enrolled in a clinical trial to~~  
 5 ~~treat cancer. It is not the intent of the Legislature to require health~~  
 6 ~~care service plans and disability insurers to cover costs that are~~  
 7 ~~above and beyond what would be customary had the patient not~~  
 8 ~~enrolled in a clinical trial to treat cancer.~~

9 ~~SEC. 2.~~

10 *SECTION 1.* Section 1370.6 is added to the Health and Safety  
 11 Code, to read:

12 1370.6. (a) For the purposes of this section, “clinical or  
 13 principal investigator” means the person managing the clinical  
 14 trial.

15 (b) (1) For an enrollee *diagnosed with cancer and* accepted  
 16 into a Phase I, Phase II, Phase III, or Phase IV clinical trial for  
 17 cancer, every health care service plan contract, except a ~~specified~~  
 18 *specialized* health care service *plan* contract, that is issued,  
 19 amended, delivered, or renewed in this state, shall provide  
 20 coverage for all health care services related to the clinical trial if  
 21 the enrollee’s physician, who is either under contract with or  
 22 employed by the plan, recommends participation in the clinical  
 23 trial.

24 (2) Nothing in this subdivision shall be construed to require a  
 25 health care service plan to provide coverage for any of the  
 26 following:



1 (A) The cost of a drug or device that has not been approved by  
2 the federal Food and Drug Administration and that is associated  
3 with the clinical trial.

4 (B) The cost related to managing the research associated with  
5 the clinical trial.

6 (C) The cost of travel and other nonclinical expenses.

7 (D) *Items and services provided free of charge by the research*  
8 *sponsors to an enrollee in the clinical trial.*

9 (c) The treatment shall be provided in a clinical trial that either  
10 involves a drug that is exempt ~~from the requirement~~ under federal  
11 regulations ~~of~~ from a new drug application or that is approved by  
12 one of the following:

13 (1) One of the National Institutes of Health.

14 (2) The federal Food and Drug Administration, in the form of  
15 an investigational new drug application.

16 (3) The *United States* Department of Defense.

17 (4) The *United States* Veterans' Administration.

18 (d) In the case of health care services provided by a  
19 participating provider, the payment rate shall be at the  
20 agreed-upon rate. In the case of a nonparticipating provider, the  
21 payment rate shall be at the rate the plan would pay to a  
22 participating provider for ~~comparable~~ *the same* services. Nothing  
23 in this section shall be construed to prohibit a health care service  
24 plan from restricting coverage for clinical trials to participating  
25 hospitals and physicians in California unless the protocol for the  
26 clinical trial is not provided for at a California hospital or by a  
27 California physician.

28 (e) (1) The clinical or principal investigator ~~seeking~~ *providing*  
29 coverage on behalf of an enrollee for treatment in a clinical trial  
30 approved pursuant to subdivision (c) shall post electronically on  
31 the National Cancer Institute's national physician data query data  
32 base a current list of the clinical trials for which he or she is ~~seeking~~  
33 *providing* coverage and that meets the requirements of *paragraph*  
34 *(1)* of subdivision (b). This information shall also be provided to  
35 the enrollee's health care service plan.

36 (2) The list shall include, for each clinical trial, all of the  
37 following:

38 (A) The name of the trial.

39 (B) The phase of the trial.

40 (C) The condition being treated by the trial.



1 (D) The method by which further information about the trial  
2 may be obtained.

3 (f) The provision of services when required by this section shall  
4 not, in itself, give rise to liability on the part of the health care  
5 service plan.

6 (g) Nothing in this section shall be construed to limit, prohibit,  
7 or modify an enrollee's rights to the independent review process  
8 available under Section 1370.4 or to the Independent Medical  
9 Review System available under Article 5.55 (commencing with  
10 Section 1374.30).

11 (h) Nothing in this section shall be construed to otherwise limit  
12 or modify any existing requirements under the provisions of this  
13 chapter *or to prevent application of copayment or deductible*  
14 *provisions in a plan.*

15 ~~(i) On or before April 1 of each year, each health care service  
16 plan shall submit a report to the director in a form required by the  
17 director that summarizes each of the clinical trials in which an  
18 enrollee has participated, that states the number of enrollees who  
19 have enrolled in a clinical trial, and that indicates whether the  
20 National Institutes of Health, the federal Food and Drug  
21 Administration, the Department of Defense, or the Veterans'  
22 Administration approved the clinical trial that the plan covered.  
23 The director shall compile an annual summary report in  
24 cooperation with the Insurance Commissioner pursuant to  
25 subdivision (j) of Section 10145.4 of the Insurance Code. A copy  
26 of the joint annual summary report shall be provided to the  
27 Governor and to appropriate committees of the Legislature. The  
28 director shall also post a copy of the report on the department's web  
29 site.~~

30 ~~SEC. 3.~~

31 *SEC. 2.* Section 10145.4 is added to the Insurance Code, to  
32 read:

33 10145.4. (a) For purposes of this section, "clinical or  
34 principal investigator" means the person managing the clinical  
35 trial.

36 (b) (1) For an insured *diagnosed with cancer and* accepted into  
37 a Phase I, Phase II, Phase III, or Phase IV clinical trial for cancer,  
38 every policy of disability insurance that provides hospital,  
39 medical, or surgical coverage in this state shall provide coverage



1 for all health care services related to the clinical trial if the  
2 insured’s physician recommends participation in the clinical trial.

3 (2) Nothing in this subdivision shall be construed to require a  
4 disability insurer to provide coverage for any of the following:

5 (A) The cost of a drug or device that has not been approved by  
6 the federal Food and Drug Administration and that is associated  
7 with the clinical trial.

8 (B) The cost related to managing the research associated with  
9 the clinical trial.

10 (C) The cost of travel and other nonclinical expenses.

11 (D) *Items and services provided free of charge by the research*  
12 *sponsors to an insured in the clinical trial.*

13 (c) The treatment shall be provided in a clinical trial that either  
14 involves a drug that is exempt ~~from the requirement~~ under federal  
15 regulations ~~of~~ *from* a new drug application or that is approved by  
16 one of the following:

17 (1) One of the National Institutes of Health.

18 (2) The federal Food and Drug Administration, in the form of  
19 an investigational new drug application.

20 (3) The *United States* Department of Defense.

21 (4) The *United States* Veterans’ Administration.

22 (d) In the case of health care services provided by a contracting  
23 provider, the payment rate shall be at the agreed-upon rate. In the  
24 case of a noncontracting provider, the payment rate shall be at the  
25 rate the insurer would pay to a contracting provider for ~~comparable~~  
26 *the same* services. Nothing in this section shall be construed to  
27 prohibit a disability insurer from restricting coverage for clinical  
28 trials to hospitals and physicians in California unless the protocol  
29 for the clinical trial is not provided for at a California hospital or  
30 by a California physician.

31 (e) (1) The clinical or principal investigator ~~seeking~~ *providing*  
32 coverage on behalf of an insured for treatment in a clinical trial  
33 approved pursuant to subdivision (c) shall post electronically on  
34 the National Cancer Institute’s national physician data query data  
35 base a current list of the clinical trials for which he or she is ~~seeking~~  
36 *providing* coverage and that meets the requirements of *paragraph*  
37 *(1)* of subdivision (b). This information shall also be provided to  
38 the insured’s disability insurer.

39 (2) The list shall include, for each clinical trial, all of the  
40 following:



1 (A) The name of the trial.

2 (B) The phase of the trial.

3 (C) The condition being treated by the trial.

4 (D) The method by which further information about the trial  
5 may be obtained.

6 (f) The provision of services when required by this section shall  
7 not, in itself, give rise to liability on the part of the insurer.

8 (g) This section shall not apply to vision-only, dental-only,  
9 accident-only, specified disease, hospital indemnity, Medicare  
10 supplement, *CHAMPUS supplement*, long-term care, or disability  
11 income insurance, except that for specified disease and hospital  
12 indemnity insurance, coverage for benefits under this section shall  
13 apply, but only to the extent that the benefits are covered under the  
14 general terms and conditions that apply to all other benefits under  
15 the policy. Nothing in this section shall be construed as imposing  
16 a new benefit mandate on specified disease or hospital indemnity  
17 insurance.

18 (h) Nothing in this section shall be construed to prohibit, limit,  
19 or modify an insured's rights to the independent review process  
20 available under Section 10145.3 or to the Independent Medical  
21 Review System available under Article 3.5 (commencing with  
22 Section 10169).

23 (i) Nothing in this section shall be construed to otherwise limit  
24 or modify any existing requirements under the provisions of this  
25 chapter *or to prevent application of deductible or copayment*  
26 *provisions contained in the policy.*

27 ~~(j) On or before April 1 of each year, every disability insurer  
28 shall submit a report to the commissioner in a form required by the  
29 commissioner that summarizes each of the clinical trials in which  
30 an insured has participated, that states the number of insureds who  
31 have enrolled in a clinical trial, and that indicates whether the  
32 National Institutes of Health, the federal Food and Drug  
33 Administration, the Department of Defense, or the Veterans'  
34 Administration approved the clinical trial that the insurer covered.  
35 The commissioner shall compile an annual summary report in  
36 cooperation with the Director of the Department of Managed  
37 Health Care pursuant to subdivision (i) of Section 1370.6 of the  
38 Health and Safety Code. A copy of the joint annual summary  
39 report shall be provided to the Governor and to appropriate~~



1 ~~committees of the Legislature. The commissioner shall also post~~  
2 ~~a copy of the report on the department's web site.~~

3 ~~SEC. 4.~~

4 *SEC. 3.* No reimbursement is required by this act pursuant to  
5 Section 6 of Article XIII B of the California Constitution because  
6 the only costs that may be incurred by a local agency or school  
7 district will be incurred because this act creates a new crime or  
8 infraction, eliminates a crime or infraction, or changes the penalty  
9 for a crime or infraction, within the meaning of Section 17556 of  
10 the Government Code, or changes the definition of a crime within  
11 the meaning of Section 6 of Article XIII B of the California  
12 Constitution.

13 ~~This~~

14 *SEC. 4.* *This* act is an urgency statute necessary for the  
15 immediate preservation of the public peace, health, or safety  
16 within the meaning of Article IV of the Constitution and shall go  
17 into immediate effect. The facts constituting the necessity are:

18 There is abundant evidence that health care service plans and  
19 disability insurers are not providing access to and coverage for  
20 medically necessary health care services related to clinical trials  
21 for cancer patients who may die without this treatment. Given the  
22 urgent circumstances for these individuals to receive this vital  
23 treatment on a timely basis, it is necessary ~~hat~~ *that* this act take  
24 effect immediately.

