

1999 DRAFTING REQUEST

Assembly Amendment (AA-ASA1-AB133)

Received: **06/25/99**

Received By: **kahlepj**

Wanted: **Soon**

Identical to LRB:

For: **Assembly Democratic Caucus**

By/Representing: **Wittwer**

This file may be shown to any legislator: **NO**

Drafter: **kahlepj**

May Contact:

Alt. Drafters:

Subject: **Insurance - health**

Extra Copies:

Pre Topic:

No specific pre topic given

Topic:

Require coverage of FDA-approved clinical trials for treatment of cancer in children

Instructions:

See Attached

Drafting History:

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Typed</u>	<u>Proofed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Required</u>
/?	kahlepj 06/26/99	jgeller 06/27/99		_____			
/1			kfollet 06/27/99	_____	gretskl 06/27/99	lrb_docadmin 06/28/99	

FE Sent For:

<END>

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1/?	kahlepj	h 6/27 jlg	KJF 6/27	KJF/f 6/27			

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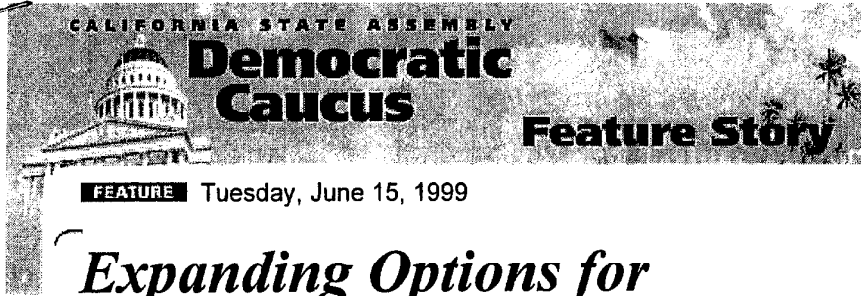
ADC

Budget Amendment Drafting Instructions

Author: Rep. Kreuser

Intent: Require HMO's to cover the costs associated with FDA-approved clinical trials for the treatment of cancer in children (please see attached copy of bill passed by the California Assembly).

Staff Contact: Jake Wittwer, ADC 7-5266
294-9452 (home)
225-5008 (cell)



Expanding Options for Kids with Cancer

Don't despair. Jackson bill cuts HMO red tape for kids with cancer.



Children stricken with cancer and their families face numerous hardships in pursuit of a cure. HMO red tape shouldn't be among them.

Jackson bill makes more treatments available

Recognizing the value of clinical trial therapy in the fight against cancer, the Assembly has approved a proposal to make those treatment options more widely available to cash-strapped families.



Assemblymember
Hannah-Beth
Jackson

Assembly Bill 610 by Assemblymember Hannah-Beth Jackson (D-Santa Barbara) would require health insurers to cover patient care costs in connection with FDA-approved clinical trials for the treatment of children's cancer.

"This measure will guarantee that appropriate care will be made available to children stricken with cancer," said Jackson. "The tremendous medical advances we've seen have given new hope to children and families who face this tragedy, and we must take every step to assure that no child is denied the best possible treatment. Cost control is not an issue when you're talking about a child's life."

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- NEWS SUMMARY
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- RESOURCES

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Bill would exempt hazard pay, provide

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1 in every 330 children will contract cancer

Jackson cited figures showing that one of every 330 children will suffer some form of cancer by the age of 18, but that more than 70 percent of those are able to have their cancer cured.

According to the National Childhood Cancer Foundation, the remarkable increase in life expectancy of children with cancer over the last 30 years is directly attributable to the advances made and the knowledge gained through clinical trial therapy.

Clinical trials evaluate new drugs and new medical procedures. Generally, clinical trials cover costs for experimental treatments, but, because the programs are considered experimental, many health plans do not cover related care.

As a result, fewer families are able to take advantage of these potentially life-saving options. Furthermore, fewer clinical trial participants means fewer opportunities to discover new cures.

"These procedures represent not only the best chance for full recovery, but they also provide the means for new breakthroughs in treatment to be achieved," said Jackson.

AB 610 passed the Assembly by a vote of 61-10 and now moves to the State Senate.

AMENDED IN ASSEMBLY APRIL 27, 1999

AMENDED IN ASSEMBLY APRIL 15, 1999

CALIFORNIA LEGISLATURE—1999-2000 REGULAR SESSION

ASSEMBLY BILL

No. 610

Introduced by Assembly Member Jackson
(Coauthors: Assembly Members Aroner, Honda, Knox,
Kuehl, Leach, Romero, Washington, and Wildman)
(Coauthor: Senator Baca)

February 19, 1999

An act to add Section 1370.5 to the Health and Safety Code, and to add Sections 10145.4 and 11074 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 610, as amended, Jackson. Health care coverage: children's cancer.

Existing law provides for the licensure and regulation of health care service plans by the Commissioner of Corporations. A violation of these provisions is subject to criminal sanction. Existing law also provides for the regulation of policies of disability insurance by the Insurance Commissioner.

Existing law requires every health care service plan, and every disability insurer that covers hospital, medical, or surgical benefits, to provide an external independent review process to examine the plan's coverage decisions regarding experimental or investigational therapies for individual

enrollees or insureds who, among other things, have a terminal condition that has a probability of causing death within 2 years according to the enrollee's or insured's physician and the physician certifies certain shortcomings exist with regard to standard therapies.

This bill would require every health care service plan *contract* and with certain exceptions a policy of disability insurance that covers hospital, medical, or surgical benefits that is issued, amended, delivered, or renewed on or after July 1, 2000, and that provides medical coverage for dependent children, to provide coverage for the routine patient care costs incurred in connection with the provision of goods, services, and benefits to dependent children in connection with approved clinical trial programs for the treatment of children's cancer with respect to dependent children who meet certain criteria.

The bill would also require that any provisions of a health care service plan contract and of certain policies of disability insurance that provide ~~major~~ medical coverage for dependent children in connection with generally recognized therapies or regimens for the treatment of children's cancer, and any provisions that provide exclusions, reductions, or limitations for purposes of providing this coverage shall apply to the benefits, payments, or reimbursement for any dependent child who is enrolled in an approved clinical trial program for the treatment of children's cancer when certain conditions are met.

Existing law regulates fraternal benefit societies. Under existing law, fraternal benefit societies are authorized to make provision for the payment of benefits on behalf of members of the society and their beneficiaries.

This bill would set forth provisions applicable to the benefit certificates, or similar contracts specifying the amount of benefits provided to a member of a fraternal benefit society, comparable to the provisions proposed by the bill with regard to health care service plans and certain disability insurers.

By changing the definition of a crime applicable to health care service plans, this bill would impose a state-mandated local program.

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.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

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

1 SECTION 1. This act shall be known as "The
2 Childhood Cancer Clinical Trials Act of 1999."

3 SEC. 2. Section 1370.5 is added to the Health and
4 Safety Code, to read:

5 1370.5. (a) Every health care service plan *contract*
6 that is issued, amended, delivered, or renewed on or after
7 July 1, 2000, that provides ~~major~~ medical coverage for
8 dependent children shall provide coverage for the
9 routine patient care costs incurred in connection with
10 providing goods, services, and benefits to dependent
11 children in connection with approved clinical trial
12 programs for the treatment of children's cancer with
13 respect to dependent children that meet all of the
14 following criteria:

15 (1) Are covered dependents under a health care
16 service plan.

17 (2) Have been diagnosed with a childhood cancer
18 prior to their 19th birthday or are older than 19 years of
19 age and have been diagnosed with a childhood cancer.

20 (3) Are enrolled in an approved clinical trial program
21 for treatment of children's cancer.

22 (4) Are not otherwise eligible for benefits, payments,
23 or reimbursements from any other third-party payers or
24 other similar sources.

25 (b) (1) For purposes of this section, "patient care
26 costs" mean the costs of a medically necessary health care
27 service that ~~is~~ *are* incurred as a result of the treatment
28 being provided to the member or dependent child for

1 purposes of the clinical trial program for treatment of
2 children's cancer.

3 (2) "Patient care costs" do not include the following:

4 (A) The cost of any investigational drug or device.

5 (B) The cost of nonhealth care services that a patient
6 may be required to receive as a result of the treatment
7 being provided for purposes of the clinical trial.

8 (C) The cost associated with managing the research
9 associated with the clinical trial.

10 (D) The cost that would be covered under the
11 patient's plan for noninvestigational treatments.

12 (c) Nothing in this section shall be construed as
13 follows:

14 (1) To prohibit a health care service plan from issuing
15 or continuing a contract that has benefits that are greater
16 than the minimum benefit required by this section or
17 from issuing or continuing to issue any contract that
18 provides benefits that are generally more favorable to the
19 enrollee or subscriber than those in this section.

20 (2) To change the contractual relations between any
21 health care service plan and its enrollees or subscribers or
22 covered dependents.

23 (d) A health care service plan shall provide notice to
24 the parents or guardians of children eligible for
25 participation in clinical trials covered under this section
26 when those clinical trials are sponsored by the National
27 Cancer Institute, the Pediatric Oncology Group, the
28 Children's Cancer Group, or any successor group thereto.

29 (e) Any provisions of a health care service plan
30 contract that provide ~~major~~ medical coverage for
31 dependent children in connection with generally
32 recognized therapies or regimens for the treatment of
33 children's cancer, and any provisions that provide
34 exclusions, reductions, or limitations for purposes of
35 providing this coverage, shall apply to the benefits,
36 payments, or reimbursement for any dependent child
37 who is enrolled in an approved clinical trial program for
38 the treatment of children's cancer when the following
39 conditions are met:

1 (1) Treatment is being provided pursuant to a Pilot
2 Study, Phase I, Phase II, Phase III, or Phase IV clinical trial
3 that has been reviewed for safety, scientific adequacy,
4 and for potential efficacy by the National Institutes of
5 Health (NIH) in cooperation with the National Cancer
6 Institute, by community clinical oncology programs, by
7 the Food and Drug Administration in the form of an
8 investigational new drug (IND) exemption, by the
9 United States Department of Veterans Affairs, or by a
10 qualified nongovernmental research entity as identified
11 in the guidelines for National Cancer Institute cancer
12 center support grants.

13 (2) The proposed protocol is scientifically adequate
14 and has been reviewed and approved by a qualified
15 institutional review board (IRB).

16 (3) The facility and personnel providing the
17 treatment are capable of doing so by virtue of their
18 experience and training and the volume of patients they
19 have treated to maintain expertise.

20 (4) The patients receiving the investigational
21 treatment meet all protocol requirements.

22 (5) There is no clearly superior, noninvestigational
23 alternative to the protocol treatment.

24 (6) The available clinical or preclinical data provides
25 a reasonable expectation that the protocol treatment will
26 be at least as efficacious as the noninvestigational
27 alternative.

28 (f) This section shall not apply to specialized health
29 care service—plans plan contracts, contracts that only
30 provide coverage for specified diseases other than
31 cancer, or Medicare supplement contracts.

32 SEC. 3. Section 10145.4 is added to the Insurance
33 Code, to read:

34 10145.4. (a) Every policy of disability insurance that
35 covers hospital, medical, or surgical benefits, or similar
36 policy of insurance regulated by the commissioner, that
37 is issued, amended, delivered, or renewed on or after July
38 1, 2000, that provides ~~major~~ medical coverage for
39 dependent children shall provide coverage for the
40 routine patient care costs incurred in connection with

← *Policy
or included*

⊗

└

1 providing goods, services, and benefits to dependent
2 children in connection with approved clinical trial
3 programs for the treatment of children's cancer with
4 respect to dependent children that meet all of the
5 following criteria:

6 (1) Are covered dependents under a policy of
7 disability insurance.

8 (2) Have been diagnosed with a childhood cancer
9 prior to their 19th birthday or are older than 19 years of
10 age and have been diagnosed with a childhood cancer.

11 (3) Are enrolled in an approved clinical trial program
12 for treatment of children's cancer.

13 (4) Are not otherwise eligible for benefits, payments,
14 or reimbursements from any other third-party payers or
15 other similar sources.

16 (b) (1) For purposes of this section, "patient care
17 costs" mean the costs of a medically necessary health care
18 service that ~~is~~ are incurred as a result of the treatment
19 being provided to the member or dependent child for
20 purposes of the clinical trial program for treatment of
21 children's cancer.

22 (2) "Patient care costs" do not include the following:

23 (A) The cost of any investigational drug or device.

24 (B) The cost of nonhealth care services that a patient
25 may be required to receive as a result of the treatment
26 being provided for purposes of the clinical trial.

27 (C) The cost associated with managing the research
28 associated with the clinical trial.

29 (D) The cost that would be covered under the
30 patient's policy of disability insurance for
31 noninvestigational treatments.

32 (c) Nothing in this section shall be construed as
33 follows:

34 (1) To prohibit a disability insurer from issuing or
35 continuing a contract that has benefits that are greater
36 than the minimum benefit required by this section or
37 from issuing or continuing to issue any contract that
38 provides benefits that are generally more favorable to the
39 insured than those in this section.

Handwritten annotations: a bracket on the right side of the text from line 6 to 31, and a signature or initials next to line 24.



1 (2) To change the contractual relations between any
2 disability insurer and its insured or covered dependents.

3 (d) A disability insurer shall provide notice to the
4 parents or guardians of children eligible for participation
5 in clinical trials covered under this section when those
6 clinical trials are sponsored by the National Cancer
7 Institute, the Pediatric Oncology Group, the Children's
8 Cancer Group, or any successor group thereto.

9 (e) Any provisions of a policy of disability insurance
10 that provide ~~major~~ medical coverage for dependent
11 children in connection with generally recognized
12 therapies or regimens for the treatment of children's
13 cancer, and any provisions that provide exclusions,
14 reductions, or limitations for purposes of providing this
15 coverage, shall apply to the benefits, payments, or
16 reimbursement for any dependent child who is enrolled
17 in an approved clinical trial program for the treatment of
18 children's cancer when the following conditions are met:

*other provisions
may apply*

19 (1) Treatment is being provided pursuant to a Pilot
20 Study, Phase I, Phase II, Phase III, or Phase IV clinical trial
21 that has been reviewed for safety, scientific adequacy,
22 and for potential efficacy by the National Institutes of
23 Health (NIH) in cooperation with the National Cancer
24 Institute, by community clinical oncology programs, by
25 the Food and Drug Administration in the form of an
26 investigational new drug (IND) exemption, by the
27 United States Department of Veterans Affairs, or by a
28 qualified nongovernmental research entity as identified
29 in the guidelines for National Cancer Institute cancer
30 center support grants.

31 (2) The proposed protocol is scientifically adequate
32 and has been reviewed and approved by a qualified
33 institutional review board (IRB).

34 (3) The facility and personnel providing the
35 treatment are capable of doing so by virtue of their
36 experience and training and the volume of patients they
37 have treated to maintain expertise.

38 (4) The patients receiving the investigational
39 treatment meet all protocol requirements.



1 (5) There is no clearly superior, noninvestigational
2 alternative to the protocol treatment.

3 (6) The available clinical or preclinical data provides
4 a reasonable expectation that the protocol treatment will
5 be at least as efficacious as the noninvestigational
6 alternative.

7 (f) This section shall not apply to accident-only,
8 specified disease hospital indemnity, Medicare
9 supplement, or long-term care health insurance policies.

10 SEC. 4. Section 11074 is added to the Insurance Code,
11 to read:

12 11074. (a) Every benefit certificate, or similar
13 contract specifying the amount of benefits provided to a
14 member of a fraternal benefit society, that is issued,
15 amended, delivered, or renewed on or after July 1, 2000,
16 that provides major medical coverage for dependent
17 children shall provide coverage for the routine patient
18 care costs incurred in connection with providing goods,
19 services, and benefits to dependent children in
20 connection with approved clinical trial programs for the
21 treatment of children's cancer with respect to dependent
22 children that meet all of the following criteria:

23 (1) Are covered dependents under a benefit
24 certificate, or similar contract specifying the amount of
25 benefits provided to a member of a fraternal benefit
26 society.

27 (2) Have been diagnosed with a childhood cancer
28 prior to their 19th birthday or are older than 19 years of
29 age and have been diagnosed with a childhood cancer.

30 (3) Are enrolled in an approved clinical trial program
31 for treatment of children's cancer.

32 (4) Are not otherwise eligible for benefits, payments,
33 or reimbursements from any other third-party payers or
34 other similar sources.

35 (b) (1) For purposes of this section, "patient care
36 costs" mean the costs of a medically necessary health care
37 service that ~~is~~ are incurred as a result of the treatment
38 being provided to the member or dependent child for
39 purposes of the clinical trial program for treatment of
40 children's cancer.

1 (2) "Patient care costs" do not include the following:

2 (A) The cost of any investigational drug or device.

3 (B) The cost of nonhealth care services that a patient
4 may be required to receive as a result of the treatment
5 being provided for purposes of the clinical trial.

6 (C) The cost associated with managing the research
7 associated with the clinical trial.

8 (D) The cost that would be covered under the
9 patient's benefit certificate, or a similar contract
10 specifying the amount of benefits provided to a member
11 of a fraternal benefit society, for noninvestigational
12 treatments.

13 (c) Nothing in this section shall be construed as
14 follows:

15 (1) To prohibit a fraternal benefit society from issuing
16 or continuing a contract that has benefits that are greater
17 than the minimum benefit required by this section or
18 from issuing or continuing to issue any contract that
19 provides benefits that are generally more favorable to a
20 member than those in this section.

21 (2) To change the contractual relations between any
22 fraternal benefit society and a member of the society or
23 covered dependents.

24 (d) A fraternal benefit society shall provide notice to
25 the parents or guardians of children eligible for
26 participation in clinical trials covered under this section
27 when those clinical trials are sponsored by the National
28 Cancer Institute, the Pediatric Oncology Group, the
29 Children's Cancer Group, or any successor group thereto.

30 (e) Any provisions of a benefit certificate, or a similar
31 contract specifying the amount of benefits provided to a
32 member of a fraternal benefit society, that provide ~~major~~
33 medical coverage for dependent children in connection
34 with generally recognized therapies or regimens for the
35 treatment of children's cancer, and any provisions that
36 provide exclusions, reductions, or limitations for purposes
37 of providing this coverage shall apply to the benefits,
38 payments, or reimbursement for any dependent child
39 who is enrolled in an approved clinical trial program for



1 the treatment of children's cancer when the following
2 conditions are met:

3 (1) Treatment is being provided pursuant to a Pilot
4 Study, Phase I, Phase II, Phase III, or Phase IV clinical trial
5 that has been reviewed for safety, scientific adequacy,
6 and for potential efficacy by the National Institutes of
7 Health (NIH) in cooperation with the National Cancer
8 Institute, by community clinical oncology programs, by
9 the Food and Drug Administration in the form of an
10 investigational new drug (IND) exemption, by the
11 United States Department of Veterans Affairs, or by a
12 qualified nongovernmental research entity as identified
13 in the guidelines for National Cancer Institute cancer
14 center support grants.

15 (2) The proposed protocol is scientifically adequate
16 and has been reviewed and approved by a qualified
17 institutional review board (IRB).

18 (3) The facility and personnel providing the
19 treatment are capable of doing so by virtue of their
20 experience and training and the volume of patients they
21 have treated to maintain expertise.

22 (4) The patients receiving the investigational
23 treatment meet all protocol requirements.

24 (5) There is no clearly superior, noninvestigational
25 alternative to the protocol treatment.

26 (6) The available clinical or preclinical data provides
27 a reasonable expectation that the protocol treatment will
28 be at least as efficacious as the noninvestigational
29 alternative.

30 (f) This section shall not apply to benefit certificates,
31 or similar contracts that specify the amount of benefits
32 provided to a member of a fraternal benefit society, that
33 only provide coverage for specified diseases other than
34 cancer or to Medicare supplement contracts.

35 SEC. 5. No reimbursement is required by this act
36 pursuant to Section 6 of Article XIII B of the California
37 Constitution because the only costs that may be incurred
38 by a local agency or school district will be incurred
39 because this act creates a new crime or infraction,
40 eliminates a crime or infraction, or changes the penalty

1 for a crime or infraction, within the meaning of Section
2 17556 of the Government Code, or changes the definition
3 of a crime within the meaning of Section 6 of Article
4 XIII B of the California Constitution.

O





State of Wisconsin
1999 - 2000 LEGISLATURE

LRBb1291/1
PJK.....

JLg

ADC

~~PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION~~

ASSEMBLY AMENDMENT,

TO ASSEMBLY SUBSTITUTE AMENDMENT 1,

TO 1999 ASSEMBLY BILL 133

soon
(11-25)
J-note

(B) ↓
children's cancer

1 At the locations indicated, amend the substitute amendment as follows:

2 1. Page 1404, line 15: after that line insert:

3 "SECTION 3037r. 609.86 of the statutes is created to read:

4 **609.86 Coverage of clinical trials.** (1) A managed care plan shall provide

5 coverage for health care costs, including the cost of drugs, incurred in connection

6 with a clinical trial program for the treatment of children's cancer if all of the

7 following apply:

8 (a) The clinical trial program is approved by the federal food and drug
9 administration.

10 (b) The person enrolled in the clinical trial program:

11 1. Has coverage under the plan.

D-note

P This coverage requirement applies only
to managed care plans ~~that are HMO's~~
because the ~~instructions~~ instructions were
limited to "HMO's". ✓

PJK

**DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU**

LRBb1291/1dn
PJK:jlq:kjf

June 27, 1999

This coverage requirement applies only to managed care plans because the instructions were limited to "HMO's".

Pamela J. Kahler
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E-mail: Pam.Kahler@legis.state.wi.us