

AMENDED IN ASSEMBLY MARCH 2, 1998

CALIFORNIA LEGISLATURE—1997–98 REGULAR SESSION

ASSEMBLY BILL

No. 1718

**Introduced by Assembly Members Richter, Baugh, and
Granlund**

January 29, 1998

An act to ~~amend Section 1370.4 of~~ *add Section 1370.5* to the Health and Safety Code, and to ~~amend Section 10145.3 of the Insurance Code,~~ *Code*, relating to health insurance.

LEGISLATIVE COUNSEL'S DIGEST

AB 1718, as amended, Richter. Health insurance.

Existing law requires every health care service plan ~~and disability insurer~~ to establish a reasonable external, independent review process to examine coverage decisions regarding experimental or investigational therapies for individual enrollees or insureds who have a terminal condition and meet certain specified criteria.

~~The bill would extend the independent review procedure to all enrollees and insureds regardless of whether the enrollee or insured has a terminal condition or the decision involves experimental or investigational therapies.~~

This bill would add similar provisions to require the Commissioner of Corporations to provide an external, independent review process to examine denials of coverage by health care service plans based on medical necessity, medical appropriateness, or whether the denied treatment is merited. The review process would be conducted by experts

selected by independent entities with which the commissioner is required to contract. The independent entities would be accredited by a private nonprofit accrediting organization with which the commissioner is required to contract by January 1, 2000. The independent review process would be required on and after July 1, 2000.

Since a violation of this provision by a health care service plan would be a crime, the bill would impose a state-mandated local program by expanding the scope of a 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.

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.—Section 1370.4 of the Health and Safety~~
- 2 *SECTION 1. Section 1370.5 is added to the Health and*
- 3 *Safety Code, to read:*
- 4 *1370.5. (a) The commissioner shall provide an*
- 5 *external, independent review process to examine denials*
- 6 *of coverage by plans based on medical necessity, medical*
- 7 *appropriateness, or whether the denied treatment is*
- 8 *merited. The enrollee seeking review shall meet all of the*
- 9 *following criteria:*
- 10 *(1) The enrollee shall have exhausted the internal plan*
- 11 *grievance process pursuant to Sections 1368, 1368.01,*
- 12 *1368.02, 1368.03, and 1368.04.*
- 13 *(2) Pay a one hundred dollar (\$100) application fee,*
- 14 *which is refundable if the enrollee prevails.*
- 15 *(3) The cost of the treatment denied is greater than*
- 16 *the cost of the external independent review.*
- 17 *(b) This section shall not apply to any Medi-Cal*
- 18 *beneficiary enrolled in a health care service plan under*
- 19 *the plan's contract with the Medi-Cal program or*
- 20 *Medicare beneficiaries.*



1 (c) The commissioner shall contract with one or more
2 impartial, independent entities that are accredited
3 pursuant to subdivision (d). The entity shall arrange for
4 review of the plan's coverage decision by selecting an
5 independent panel of at least three physicians or other
6 providers who are experts in the treatment of the
7 enrollee's medical condition and knowledgeable about
8 the recommended therapy. If the entity is an academic
9 medical center accredited in accordance with subdivision
10 (e), the independent panel may include experts affiliated
11 with or employed by the entity. A panel of two experts
12 may be arranged at the plan's request, provided the
13 enrollee consents in writing. The independent entity may
14 arrange for a panel of one expert only if the independent
15 entity certifies in writing that there is only one expert
16 qualified and able to review the recommended therapy.
17 Neither the plan nor the enrollee shall choose or control
18 the choice of the physician or other provider experts.

19 (1) Neither the expert, nor the independent entity,
20 nor any officer, director, or management employee of the
21 independent entity, shall have any material professional,
22 familial, or financial affiliation, as defined in paragraph
23 (2), with any of the following:

24 (A) The plan.

25 (B) Any officer, director, or management employee of
26 the plan.

27 (C) The physician, the physician's medical group, or
28 the independent practice association (IPA) proposing
29 the therapy.

30 (D) The institution at which the therapy would be
31 provided.

32 (E) The development or manufacture of the principal
33 drug, device, procedure, or other therapy proposed for
34 the enrollee whose treatment is under review.

35 (2) For purposes of this section, the following terms
36 shall have the following meanings:

37 (A) "Material familial affiliation" means any
38 relationship as a spouse, child, parent, sibling, spouse's
39 parent, or child's spouse.



1 (B) “Material financial affiliation” means any financial
2 interest of more than 5 percent of the total annual
3 revenue or the total annual income of an entity or
4 individual to which this subdivision applies. “Material
5 financial affiliation” shall not include payment by the
6 plan to the independent entity for the services required
7 by this section, nor shall “material financial affiliation”
8 include an expert’s participation as a contracting plan
9 provider where the expert is affiliated with an academic
10 medical center or a National Cancer Institute-designated
11 clinical cancer research center.

12 (C) “Material professional affiliation” means any
13 physician-patient relationship, any partnership or
14 employment relationship, a shareholder or similar
15 ownership interest in a professional corporation, or any
16 independent contractor arrangement that constitutes a
17 material financial affiliation with any expert or any officer
18 or director of the independent entity. The term “material
19 professional affiliation” shall not include affiliations
20 which are limited to staff privileges at a health facility.

21 (3) The plan shall provide to the independent entity
22 arranging for the panel of experts a copy of the following
23 documents within five business days of the plan’s receipt
24 of a request by an enrollee or an enrollee’s physician for
25 an external, independent review:

26 (A) The medical records relevant to the patient’s
27 condition for which the proposed therapy has been
28 recommended, provided the documents are within the
29 plan’s possession. Any medical records provided to the
30 plan after the initial documents are provided to the
31 independent entity shall be forwarded by the plan to the
32 independent entity within five business days. The
33 confidentiality of the medical records shall be maintained
34 pursuant to Section 56.10 of the Civil Code.

35 (B) A copy of any relevant documents used by the plan
36 in determining whether the proposed therapy should be
37 covered, and any statement by the plan explaining the
38 reasons for the plan’s decision not to provide coverage for
39 the proposed therapy. The plan shall provide, upon
40 request, a copy of the documents required by this



1 paragraph, except for the documents described in
2 subparagraphs (A) and (C), to the enrollee and the
3 enrollee's physician.

4 (C) Any information submitted by the enrollee or the
5 enrollee's physician to the plan in support of the
6 enrollee's request for coverage of the proposed drug,
7 device, procedure, or other therapy.

8 (4) The experts on the panel shall render their
9 analyses and recommendations within 30 days of the
10 receipt of a request for review. If the enrollee's physician
11 determines that the proposed therapy would be
12 significantly less effective if not promptly initiated, the
13 analyses and recommendations of the experts on the
14 panel shall be rendered within seven days of the request
15 for expedited review. At the request of the expert, the
16 deadline shall be extended by up to three days for a delay
17 in providing the documents required by paragraph (3) of
18 subdivision (c).

19 (5) Each expert's analysis and recommendation shall
20 be in written form and state the reasons the requested
21 therapy is or is not likely to be more beneficial for the
22 enrollee than any available standard therapy, and the
23 reasons that the expert recommends that the therapy
24 should or should not be provided by the plan, citing the
25 enrollee's specific medical condition, the relevant
26 documents provided pursuant to paragraph (3), and the
27 relevant medical and scientific evidence to support the
28 expert's recommendation.

29 (6) The independent entity shall provide the
30 commissioner, the plan, and the enrollee's physician with
31 the experts' analyses and recommendations, a description
32 of the qualifications of each expert, and any other
33 information that it chooses to provide to the
34 commissioner, the plan, and the enrollee's physician,
35 including, but not limited to, the names of the expert
36 reviewers. The independent entity shall not be required
37 to disclose the names of the expert reviewers to the plan
38 or the enrollee's physician, except pursuant to a properly
39 made request for discovery. If the independent entity
40 chooses to disclose the names of the experts on the panel



1 to the plan, the independent entity shall also disclose the
2 names of the experts to the enrollee's physician. The
3 enrollee's physician may provide these documents and
4 information to the enrollee.

5 (7) If the majority of experts on the panel recommend
6 providing the proposed therapy, pursuant to paragraph
7 (5), the recommendation shall be binding on the plan. If
8 the recommendations of the experts on the panel are
9 evenly divided as to whether the therapy should be
10 provided, then the panel's decision shall be deemed to be
11 in favor of coverage. If less than a majority of the experts
12 on the panel recommend providing the therapy, the plan
13 is not required to provide the therapy. Coverage for the
14 services required under this section shall be provided
15 subject to the terms and conditions generally applicable
16 to other benefits under the plan contract.

17 (8) The plan shall have written policies describing the
18 external, independent review process. The plan shall
19 disclose the availability of the external, independent
20 review process and how enrollees may access the review
21 process in the plan's evidence of coverage and disclosure
22 forms.

23 (d) The commissioner, in consultation with the
24 Insurance Commissioner, shall, by January 1, 2000,
25 contract with a private, nonprofit accrediting
26 organization to accredit the independent review entities
27 specified in subdivision (c). The accrediting organization
28 may grant and revoke accreditation, and shall develop,
29 apply, and enforce accreditation standards that ensure
30 the independence of the independent review entity, the
31 confidentiality of the medical records, and the
32 qualifications and independence of the health care
33 professionals providing the analyses and
34 recommendations requested of them. The accrediting
35 organization shall demonstrate the ability to objectively
36 evaluate the performance of independent entities and
37 shall demonstrate that it has no conflict of interest,
38 including any material professional, familial, or financial
39 affiliation, as defined in paragraph (2) of subdivision (c),
40 with any independent entity or plan, in accrediting



1 entities for the purpose of reviewing medical treatments,
2 treatment recommendations, and coverage decisions by
3 health care service plans.

4 (e) In order to receive accreditation for the purposes
5 of this section, an independent entity shall meet all of the
6 following requirements:

7 (1) The independent entity shall be an organization
8 that has as its primary function to provide expert reviews
9 and related services and receives a majority of its
10 revenues from these services, except that an academic
11 medical center may qualify as an independent entity for
12 purposes of this act without having as its primary function
13 providing expert reviews and related services and
14 without receiving a majority of its revenues from these
15 services. An independent entity may not be a subsidiary
16 of, nor in any way be owned or controlled by, a health
17 plan, a trade association of health plans, or a professional
18 association of health care providers.

19 (2) The independent entity shall submit to the
20 accrediting organization and to the department the
21 following information upon initial application for
22 accreditation and annually thereafter upon any change to
23 any of the following information:

24 (A) The names of all stockholders and owners of more
25 than 5 percent of any stock or options, if a publicly held
26 organization.

27 (B) The names of all holders of bonds or notes in excess
28 of one hundred thousand dollars (\$100,000), if any.

29 (C) The names of all corporations and organizations
30 that the independent entity controls or is affiliated with,
31 and the nature and extent of any ownership or control,
32 including the affiliated organization's type of business.

33 (D) The names and biographical sketches of all
34 directors, officers, and executives of the independent
35 entity, as well as a statement regarding any relationships
36 the directors, officers, and executives may have with any
37 health care service plan, disability insurer, managed care
38 organization, provider group, or board or committee.

39 (E) The percentage of revenue the independent
40 entity receives from expert reviews.



1 (F) A description of the review process, including, but
2 not limited to, the method of selecting expert reviewers
3 and matching the expert reviewers to specific cases.

4 (G) A description of the system the independent
5 entity uses to identify and recruit expert reviewers, the
6 number of expert reviewers credentialed, and the types
7 of cases the experts are credentialed to review.

8 (H) Documentation regarding the medical
9 institutions from which the independent entity has
10 selected the experts during the previous 12 months, and
11 the percentage of opinions obtained from each
12 institution.

13 (I) A description of the areas of expertise available
14 from expert reviewers retained by the independent
15 entity.

16 (J) A description of how the independent entity
17 ensures compliance with the conflict-of-interest
18 provisions of this section.

19 (3) The independent entity must demonstrate that it
20 has a quality assurance mechanism in place that does the
21 following:

22 (A) Ensures that the experts retained a appropriately
23 credentialed and privileged.

24 (B) Ensures that the reviews provided by the experts
25 are timely, clear, and credible, and that reviews are
26 monitored for quality on an ongoing basis.

27 (C) Ensures that the method of selecting expert
28 reviewers for individual cases achieves a fair and
29 impartial panel of experts who are qualified to render
30 recommendations regarding the clinical conditions and
31 therapies in question.

32 (D) Ensures the confidentiality of medical records
33 and the review materials, consistent with the
34 requirements of this section.

35 (E) Ensures the independence of the experts retained
36 to perform the reviews through conflict-of-interest
37 policies and prohibitions and adequate screening for
38 conflicts of interest, pursuant to paragraph (1) of
39 subdivision (c).



1 (f) The accrediting organization shall provide, upon
2 the request of any interested person, a copy of all
3 nonproprietary information filed with it by the
4 independent entity under paragraph (2) of subdivision
5 (e). The accrediting organization may charge a
6 reasonable fee to the interested person for photocopying
7 the requested information.

8 (g) The independent review process established by
9 this section shall be required on and after July 1, 2000.

10 Code is amended to read:

11 ~~1370.4. (a) Every health care service plan shall~~
12 ~~provide an external, independent review process to~~
13 ~~examine the plan's coverage decisions.~~

14 ~~(b) The plan's external, independent review shall~~
15 ~~meet the following criteria:~~

16 ~~(1) The plan shall offer all enrollees the opportunity to~~
17 ~~have the requested therapy reviewed under the external,~~
18 ~~independent review process. The plan shall notify~~
19 ~~enrollees in writing of the opportunity to request the~~
20 ~~external independent review within five business days of~~
21 ~~the decision to deny coverage.~~

22 ~~(2) The plan shall contract with one or more impartial,~~
23 ~~independent entities that are accredited pursuant to~~
24 ~~subdivision (c). The entity shall arrange for review of the~~
25 ~~coverage decision by selecting an independent panel of~~
26 ~~at least three physicians or other providers who are~~
27 ~~experts in the treatment of the enrollee's medical~~
28 ~~condition and knowledgeable about the recommended~~
29 ~~therapy. If the entity is an academic medical center~~
30 ~~accredited in accordance with subdivision (e), the~~
31 ~~independent panel may include experts affiliated with or~~
32 ~~employed by the entity. A panel of two experts may be~~
33 ~~arranged at the plan's request, provided the enrollee~~
34 ~~consents in writing. The independent entity may arrange~~
35 ~~for a panel of one expert only if the independent entity~~
36 ~~certifies in writing that there is only one expert qualified~~
37 ~~and able to review the recommended therapy. Neither~~
38 ~~the plan nor the enrollee shall choose or control the~~
39 ~~choice of the physician or other provider experts.~~



1 ~~(3) Neither the expert, nor the independent entity,~~
2 ~~nor any officer, director, or management employee of the~~
3 ~~independent entity shall have any material professional,~~
4 ~~familial, or financial affiliation, as defined in paragraph~~
5 ~~(4), with any of the following:~~

6 ~~(A) The plan.~~

7 ~~(B) Any officer, director, or management employee of~~
8 ~~the plan.~~

9 ~~(C) The physician, the physician's medical group, or~~
10 ~~the independent practice association (IPA) proposing~~
11 ~~the therapy.~~

12 ~~(D) The institution at which the therapy would be~~
13 ~~provided.~~

14 ~~(E) The development or manufacture of the principal~~
15 ~~drug, device, procedure, or other therapy proposed for~~
16 ~~the enrollee whose treatment is under review.~~

17 ~~(4) For purposes of this section, the following terms~~
18 ~~shall have the following meanings:~~

19 ~~(A) "Material familial affiliation" shall mean any~~
20 ~~relationship as a spouse, child, parent, sibling, spouse's~~
21 ~~parent, or child's spouse.~~

22 ~~(B) "Material professional affiliation" shall mean any~~
23 ~~physician-patient relationship, any partnership or~~
24 ~~employment relationship, a shareholder or similar~~
25 ~~ownership interest in a professional corporation, or any~~
26 ~~independent contractor arrangement that constitutes a~~
27 ~~material financial affiliation with any expert or any officer~~
28 ~~or director of the independent entity. The term "material~~
29 ~~professional affiliation" shall not include affiliations~~
30 ~~which are limited to staff privileges at a health facility.~~

31 ~~(C) "Material financial affiliation" shall mean any~~
32 ~~financial interest of more than 5 percent of total annual~~
33 ~~revenue or total annual income of an entity or individual~~
34 ~~to which this subdivision applies. "Material financial~~
35 ~~affiliation" shall not include payment by the plan to the~~
36 ~~independent entity for the services required by this~~
37 ~~section, nor shall "material financial affiliation" include~~
38 ~~an expert's participation as a contracting plan provider~~
39 ~~where the expert is affiliated with an academic medical~~



1 ~~center or a National Cancer Institute-designated clinical~~
2 ~~cancer research center.~~

3 ~~(5) The enrollee shall not be required to pay for the~~
4 ~~external, independent review. The costs of the review~~
5 ~~shall be borne by the plan.~~

6 ~~(6) The plan shall provide to the independent entity~~
7 ~~arranging for the panel of experts a copy of the following~~
8 ~~documents within five business days of the plan's receipt~~
9 ~~of a request by an enrollee or enrollee's physician for an~~
10 ~~external, independent review:~~

11 ~~(A) The medical records relevant to the patient's~~
12 ~~condition for which the proposed therapy has been~~
13 ~~recommended, provided the documents are within the~~
14 ~~plan's possession. Any medical records provided to the~~
15 ~~plan after the initial documents are provided to the~~
16 ~~independent entity shall be forwarded by the plan to the~~
17 ~~independent entity within five business days. The~~
18 ~~confidentiality of the medical records shall be maintained~~
19 ~~pursuant to Section 56.10 of the Civil Code.~~

20 ~~(B) A copy of any relevant documents used by the plan~~
21 ~~in determining whether the proposed therapy should be~~
22 ~~covered, and any statement by the plan explaining the~~
23 ~~reasons for the plan's decision not to provide coverage for~~
24 ~~the proposed therapy. The plan shall provide, upon~~
25 ~~request, a copy of the documents required by this~~
26 ~~paragraph, except for the documents described in~~
27 ~~subparagraphs (A) and (C), to the enrollee and the~~
28 ~~enrollee's physician.~~

29 ~~(C) Any information submitted by the enrollee or the~~
30 ~~enrollee's physician to the plan in support of the~~
31 ~~enrollee's request for coverage of the proposed drug,~~
32 ~~device, procedure, or other therapy.~~

33 ~~(7) The experts on the panel shall render their~~
34 ~~analyses and recommendations within 30 days of the~~
35 ~~receipt of the enrollee's request for review. If the~~
36 ~~enrollee's physician determines that the proposed~~
37 ~~therapy would be significantly less effective if not~~
38 ~~promptly initiated, the analyses and recommendations of~~
39 ~~the experts on the panel shall be rendered within seven~~
40 ~~days of the request for expedited review. At the request~~



1 of the expert, the deadline shall be extended by up to
2 three days for a delay in providing the documents
3 required by paragraph (6) of subdivision (b):

4 (8) Each expert's analysis and recommendation shall
5 be in written form and states the reasons the requested
6 therapy is or is not likely to be more beneficial for the
7 enrollee than any available standard therapy, and the
8 reasons that the expert recommends that the therapy
9 should or should not be provided by the plan, citing the
10 enrollee's specific medical condition, the relevant
11 documents provided pursuant to paragraph (6), and the
12 relevant medical and scientific evidence, including, but
13 not limited to, the medical and scientific evidence as
14 defined in subdivision (d), to support the expert's
15 recommendation.

16 (9) The independent entity shall provide the plan and
17 the enrollee's physician with the experts' analyses and
18 recommendations, a description of the qualifications of
19 each expert, and any other information that it chooses to
20 provide to the plan and the enrollee's physician,
21 including, but not limited to, the names of the expert
22 reviewers. The independent entity shall not be required
23 to disclose the names of the expert reviewers to the plan
24 or the enrollee's physician, except pursuant to a properly
25 made request for discovery. If the independent entity
26 chooses to disclose the names of the experts on the panel
27 to the plan, the independent entity must also disclose the
28 names of the experts to the enrollee's physician. The
29 enrollee's physician may provide these documents and
30 information to the enrollee.

31 (10) If the majority of experts on the panel
32 recommend providing the proposed therapy, pursuant to
33 paragraph (8), the recommendation shall be binding on
34 the plan. If the recommendations of the experts on the
35 panel are evenly divided as to whether the therapy
36 should be provided, then the panel's decision shall be
37 deemed to be in favor of coverage. If less than a majority
38 of the experts on the panel recommend providing the
39 therapy, the plan is not required to provide the therapy.



1 ~~(11) The plan shall have written policies describing~~
2 ~~the external, independent review process. The plan shall~~
3 ~~disclose the availability of the external, independent~~
4 ~~review process and how enrollees may access the review~~
5 ~~process in the plan's evidence of coverage and disclosure~~
6 ~~forms.~~

7 ~~(e) The Commissioner of Corporations, in~~
8 ~~consultation with the Insurance Commissioner, shall, by~~
9 ~~January 1, 1998, contract with a private, nonprofit~~
10 ~~accrediting organization to accredit the independent~~
11 ~~review entities specified in subdivision (b). The~~
12 ~~accrediting organization shall have the power to grant~~
13 ~~and revoke accreditation, and shall develop, apply, and~~
14 ~~enforce accreditation standards, including those required~~
15 ~~in subdivision (e), that ensure the independence of the~~
16 ~~independent review entity, the confidentiality of the~~
17 ~~medical records, and the qualifications and~~
18 ~~independence of the health care professionals providing~~
19 ~~the analyses and recommendations requested of them.~~
20 ~~The accrediting organization shall demonstrate the~~
21 ~~ability to objectively evaluate the performance of~~
22 ~~independent entities and shall demonstrate that it has no~~
23 ~~conflict of interest, including any material professional,~~
24 ~~familial, or financial affiliation as defined in paragraph (4)~~
25 ~~of subdivision (b) with any independent entity or plan,~~
26 ~~in accrediting entities for the purpose of reviewing~~
27 ~~medical treatments, treatment recommendations, and~~
28 ~~coverage decisions by health care service plans.~~

29 ~~(d) In order to receive accreditation for the purposes~~
30 ~~of this section, an independent entity shall meet all of the~~
31 ~~following requirements:~~

32 ~~(1) The independent entity must be an organization~~
33 ~~that has as its primary function to provide expert reviews~~
34 ~~and related services and receives a majority of its~~
35 ~~revenues from these services, except that an academic~~
36 ~~medical center may qualify as an independent entity for~~
37 ~~purposes of this act without having as its primary function~~
38 ~~providing expert reviews and related services and~~
39 ~~without receiving a majority of its revenues from these~~
40 ~~services. An independent entity may not be a subsidiary~~



1 of, nor in any way owned or controlled by, a health plan,
2 a trade association of health plans, or a professional
3 association of health care providers.

4 (2) The independent entity must submit to the
5 accrediting organization and to the Department of
6 Corporations the following information upon initial
7 application for accreditation and annually thereafter
8 upon any change to any of the following information:

9 (A) The names of all stockholders and owners of more
10 than 5 percent of any stock or options, if a publicly held
11 organization.

12 (B) The names of all holders of bonds or notes in excess
13 of one hundred thousand dollars (\$100,000), if any.

14 (C) The names of all corporations and organizations
15 that the independent entity controls or is affiliated with,
16 and the nature and extent of any ownership or control,
17 including the affiliated organization's type of business.

18 (D) The names and biographical sketches of all
19 directors, officers, and executives of the independent
20 entity, as well as a statement regarding any relationships
21 the directors, officers, and executives may have with any
22 health care service plan, disability insurer, managed care
23 organization, provider group or board or committee.

24 (E) The percentage of revenue the independent
25 entity receives from expert reviews.

26 (F) A description of the review process, including, but
27 limited not to, the method of selecting expert reviewers
28 and matching the expert reviewers to specific cases.

29 (G) A description of the system the independent
30 entity uses to identify and recruit expert reviewers, the
31 number of expert reviewers credentialed and the types
32 of cases the experts are credentialed to review.

33 (H) Documentation regarding the medical
34 institutions from which the independent entity has
35 selected the experts during the previous 12 months, and
36 the percentage of opinions obtained from each
37 institution.

38 (I) A description of the areas of expertise available
39 from expert reviewers retained by the independent
40 entity.



1 ~~(J) A description of how the independent entity~~
2 ~~ensures compliance with the conflict of interest~~
3 ~~provisions of this section.~~

4 ~~(3) The independent entity must demonstrate that it~~
5 ~~has a quality assurance mechanism in place that does the~~
6 ~~following:~~

7 ~~(A) Ensures that the experts retained are~~
8 ~~appropriately credentialed and privileged.~~

9 ~~(B) Ensures that the reviews provided by the experts~~
10 ~~are timely, clear and credible, and that reviews are~~
11 ~~monitored for quality on an ongoing basis.~~

12 ~~(C) Ensures that the method of selecting expert~~
13 ~~reviewers for individual cases achieves a fair and~~
14 ~~impartial panel of experts who are qualified to render~~
15 ~~recommendations regarding the clinical conditions and~~
16 ~~therapies in question.~~

17 ~~(D) Ensures the confidentiality of medical records~~
18 ~~and the review materials, consistent with the~~
19 ~~requirements of this section.~~

20 ~~(E) Ensures the independence of the experts retained~~
21 ~~to perform the reviews through conflict-of-interest~~
22 ~~policies and prohibitions and adequate screening for~~
23 ~~conflicts of interest, pursuant to paragraph (3) of~~
24 ~~subdivision (b).~~

25 ~~(e) (1) The Department of Corporations shall receive~~
26 ~~the information filed by independent entities pursuant to~~
27 ~~paragraph (2) of subdivision (d) for the purpose of~~
28 ~~creating a file of public records. The Department of~~
29 ~~Corporations shall not be responsible for accrediting~~
30 ~~independent entities.~~

31 ~~(2) The accrediting organization shall provide, upon~~
32 ~~the request of any interested person, a copy of all~~
33 ~~nonproprietary information filed with it by the~~
34 ~~independent entity under paragraph (2) of subdivision~~
35 ~~(d). The accrediting organization may charge a~~
36 ~~reasonable fee to the interested person for photocopying~~
37 ~~the requested information.~~

38 ~~SEC. 2. Section 10145.3 of the Insurance Code is~~
39 ~~amended to read:~~



1 ~~10145.3. (a) Every disability insurer that covers~~
2 ~~hospital, medical, or surgical benefits shall provide an~~
3 ~~external, independent review process to examine the~~
4 ~~insurer's coverage decisions.~~

5 ~~(b) The insurer's external, independent review shall~~
6 ~~meet the following criteria:~~

7 ~~(1) The insurer shall offer all insureds the opportunity~~
8 ~~to have the requested therapy reviewed under the~~
9 ~~external, independent review process. The insurer shall~~
10 ~~notify insureds in writing of the opportunity to request~~
11 ~~the external independent review within five business~~
12 ~~days of the decision to deny coverage.~~

13 ~~(2) The insurer shall contract with one or more~~
14 ~~impartial, independent entities that are accredited~~
15 ~~pursuant to subdivision (c). The entity shall arrange for~~
16 ~~review of the coverage decision by selecting an~~
17 ~~independent panel of at least three physicians or other~~
18 ~~providers who are experts in the treatment of the~~
19 ~~insured's medical condition and knowledgeable about~~
20 ~~the recommended therapy. If the entity is an academic~~
21 ~~medical center accredited in accordance with subdivision~~
22 ~~(c), the independent panel may include experts affiliated~~
23 ~~with or employed by the entity. A panel of two experts~~
24 ~~may be arranged at the insurer's request, provided the~~
25 ~~insured consents in writing. The independent entity may~~
26 ~~arrange for a panel of one expert only if the independent~~
27 ~~entity certifies in writing that there is only one expert~~
28 ~~qualified and able to review the recommended therapy.~~
29 ~~Neither the insurer nor the insured shall choose or control~~
30 ~~the choice of the physician or other provider experts.~~

31 ~~(3) Neither the expert, nor the independent entity,~~
32 ~~nor any officer, director, or management employee of the~~
33 ~~independent entity may have any material professional,~~
34 ~~familial, or financial affiliation, as defined in paragraph~~
35 ~~(4), with any of the following:~~

36 ~~(A) The insurer.~~

37 ~~(B) Any officer, director, or management employee of~~
38 ~~the insurer.~~



1 ~~(C) The physician, the physician’s medical group, or~~
2 ~~the independent practice association (IPA) proposing~~
3 ~~the therapy.~~

4 ~~(D) The institution at which the therapy would be~~
5 ~~provided.~~

6 ~~(E) The development or manufacture of the principal~~
7 ~~drug, device, procedure, or other therapy proposed for~~
8 ~~the insured whose treatment is under review.~~

9 ~~(4) For purposes of this section, the following terms~~
10 ~~have the following meanings:~~

11 ~~(A) “Material familial affiliation” means any~~
12 ~~relationship as a spouse, child, parent, sibling, spouse’s~~
13 ~~parent, or child’s spouse.~~

14 ~~(B) “Material professional affiliation” means any~~
15 ~~physician patient relationship, any partnership or~~
16 ~~employment relationship, a shareholder or similar~~
17 ~~ownership interest in a professional corporation, or any~~
18 ~~independent contractor arrangement that constitutes a~~
19 ~~material financial affiliation with any expert or any officer~~
20 ~~or director of the independent entity. The term “material~~
21 ~~professional affiliation” does not include affiliations that~~
22 ~~are limited to staff privileges at a health facility.~~

23 ~~(C) “Material financial affiliation” means any financial~~
24 ~~interest of more than 5 percent of total annual revenue~~
25 ~~or total annual income of an entity or individual to which~~
26 ~~this subdivision applies. “Material financial affiliation”~~
27 ~~does not include payment by the insurer to the~~
28 ~~independent entity for the services required by this~~
29 ~~section, nor does “material financial affiliation” include~~
30 ~~an expert’s participation as a contracting provider for the~~
31 ~~insurer where the expert is affiliated with an academic~~
32 ~~medical center or a National Cancer Institute-designated~~
33 ~~clinical cancer research center.~~

34 ~~(5) The insured shall not be required to pay for the~~
35 ~~external independent review. The costs of the review~~
36 ~~shall be borne by the insurer.~~

37 ~~(6) The insurer shall provide to the independent~~
38 ~~entity arranging for the panel of experts a copy of the~~
39 ~~following documents within five business days of the~~



1 insurer's receipt of a request by an insured or insured's
2 physician for an external independent review.

3 (A) The medical records relevant to the patient's
4 condition for which the proposed therapy has been
5 recommended, provided the documents are within the
6 insurer's possession. Any medical records provided to the
7 insurer after the initial documents are provided to the
8 independent entity shall be forwarded by the insurer to
9 the independent entity within five business days. The
10 confidentiality of the medical records shall be maintained
11 pursuant to Section 56.10 of the Civil Code.

12 (B) A copy of any relevant documents used by the
13 insurer in determining whether the proposed therapy
14 should be covered, and any statement by the insurer
15 explaining the reasons for the insurer's decision not to
16 provide coverage for the proposed therapy. The insurer
17 shall provide, upon request, a copy of the documents
18 required by this paragraph, except for the documents
19 described in paragraphs (A) and (C), to the insured and
20 the insured's physician.

21 (C) Any information submitted by the insured or the
22 insured's physician to the insurer in support of the
23 insured's request for coverage of the proposed drug,
24 device, procedure, or other therapy.

25 (7) The experts on the panel shall render their
26 analyses and recommendations within 30 days of the
27 receipt of the insured's request for review. If the insured's
28 physician determines that the proposed therapy would
29 be significantly less effective if not promptly initiated, the
30 analyses and recommendations of the experts on the
31 panel shall be rendered within seven days of the request
32 for expedited review. At the request of the expert, the
33 deadline shall be extended by up to three days for a delay
34 in providing the documents required by paragraph (6) of
35 subdivision (b).

36 (8) Each expert's analysis and recommendation shall
37 be in written form and state the reasons the requested
38 therapy is or is not likely to be more beneficial for the
39 insured than any available standard therapy, and the
40 reasons that the expert recommends that the therapy



1 should or should not be covered by the insurer, citing the
2 insured's specific medical condition, the relevant
3 documents provided pursuant to paragraph (6), and the
4 relevant medical and scientific evidence, including, but
5 not limited to, the medical and scientific evidence as
6 defined in subdivision (d), to support the expert's
7 recommendation.

8 (9) The independent entity shall provide the insurer
9 and the insured's physician with the expert's analyses and
10 recommendations, a description of the qualifications of
11 each expert, and any other information that it chooses to
12 provide to the insurer and the insured's physician,
13 including, but not limited to, the names of the expert
14 reviewers. The independent entity shall not be required
15 to disclose the names of the expert reviewers to the
16 insurer or to the insured's physician, except pursuant to
17 a properly made request for discovery. If the
18 independent entity chooses to disclose the names of the
19 experts on the panel to the insurer, the independent
20 entity must also disclose the names of the experts to the
21 insured's physician. The insured's physician may provide
22 these documents and information to the enrollee.

23 (10) If the majority of experts on the panel
24 recommend providing the proposed therapy, pursuant to
25 paragraph (8), the recommendation shall be binding on
26 the insurer. If the recommendations of the experts on the
27 panel are evenly divided as to whether the therapy
28 should be provided, then the panel's decision shall be
29 deemed to be in favor of coverage. If less than a majority
30 of the experts on the panel recommend providing the
31 therapy, the insurer is not required to provide the
32 therapy.

33 (11) The insurer shall have written policies describing
34 the external, independent review process. The insurer
35 shall disclose the availability of the external, independent
36 review process and how insureds may access the review
37 process in the insurer's evidence of coverage and
38 disclosure forms.

39 (c) The Commissioner of Corporations, in
40 consultation with the Insurance Commissioner, shall, by



1 ~~January 1, 1998, contract with a private, nonprofit~~
2 ~~accrediting organization to accredit the independent~~
3 ~~review entities specified in subdivision (b). The~~
4 ~~accrediting organization shall have the power to grant~~
5 ~~and revoke accreditation, and shall develop, apply, and~~
6 ~~enforce accreditation standards, including those required~~
7 ~~in subdivision (c), that ensure the independence of the~~
8 ~~independent review entity, the confidentiality of the~~
9 ~~medical records, and the qualifications and~~
10 ~~independence of the health care professionals providing~~
11 ~~the analyses and recommendations requested of them.~~
12 ~~The accrediting organization shall demonstrate the~~
13 ~~ability to objectively evaluate the performance of~~
14 ~~independent entities and shall demonstrate that it has no~~
15 ~~conflict of interest, including any material professional,~~
16 ~~familial, or financial affiliation as defined in paragraph (4)~~
17 ~~of subdivision (b) with any independent entity or~~
18 ~~disability insurer, in accrediting entities for the purpose~~
19 ~~of reviewing medical treatments, treatment~~
20 ~~recommendations, and coverage decisions by disability~~
21 ~~insurers.~~

22 (d) ~~In order to receive accreditation for the purposes~~
23 ~~of this section, an independent entity shall meet all of the~~
24 ~~following requirements:~~

25 (1) ~~The independent entity must be an organization~~
26 ~~that has as its primary function the provision of expert~~
27 ~~reviews and related services and receives a majority of its~~
28 ~~revenues from these services, except that an academic~~
29 ~~medical center may qualify as an independent entity for~~
30 ~~purposes of this act without meeting either of these~~
31 ~~criteria. An independent entity may not be a subsidiary~~
32 ~~of, nor in any way owned or controlled by, a health plan,~~
33 ~~a trade association of health plans, or a professional~~
34 ~~association of health care providers.~~

35 (2) ~~The independent entity must submit to the~~
36 ~~accrediting organization and to the Department of~~
37 ~~Corporations the following information upon initial~~
38 ~~application for accreditation and annually thereafter~~
39 ~~upon any change to any of the following information:~~



1 ~~(A) The names of all stockholders and owners of more~~
2 ~~than 5 percent of any stock or options, if a publicly held~~
3 ~~organization.~~

4 ~~(B) The names of all holders of bonds or notes in excess~~
5 ~~of one hundred thousand dollars (\$100,000), if any.~~

6 ~~(C) The names of all corporations and organizations~~
7 ~~that the independent entity controls or is affiliated with,~~
8 ~~and the nature and extent of any ownership or control,~~
9 ~~including the affiliated organization's type of business.~~

10 ~~(D) The names and biographical sketches of all~~
11 ~~directors, officers, and executives of the independent~~
12 ~~entity, as well as a statement regarding any relationships~~
13 ~~the directors, officers, and executives may have with any~~
14 ~~health care service plan, disability insurer, managed care~~
15 ~~organization, provider group or board or committee.~~

16 ~~(E) The percentage of revenue the independent~~
17 ~~entity receives from expert reviews.~~

18 ~~(F) A description of the review process, including, but~~
19 ~~limited not to, the method of selecting expert reviewers~~
20 ~~and matching the expert reviewers to specific cases.~~

21 ~~(G) A description of the system the independent~~
22 ~~entity uses to identify and recruit expert reviewers, the~~
23 ~~number of expert reviewers credentialed, and the types~~
24 ~~of cases the experts are credentialed to review.~~

25 ~~(H) Documentation regarding the medical~~
26 ~~institutions from which the independent entity has~~
27 ~~selected the experts during the previous 12 months, and~~
28 ~~the percentage of opinions obtained from each~~
29 ~~institution.~~

30 ~~(I) A description of the areas of expertise available~~
31 ~~from expert reviewers retained by the independent~~
32 ~~entity.~~

33 ~~(J) A description of how the independent entity~~
34 ~~ensures compliance with the conflict-of-interest~~
35 ~~provisions of this section.~~

36 ~~(3) The independent entity must demonstrate that it~~
37 ~~has a quality assurance mechanism in place that does the~~
38 ~~following:~~

39 ~~(A) Ensures that the experts retained are~~
40 ~~appropriately credentialed and privileged.~~



1 ~~(B) Ensures that the reviews provided by the experts~~
2 ~~are timely, clear and credible, and that reviews are~~
3 ~~monitored for quality on an ongoing basis.~~

4 ~~(C) Ensures that the method of selecting expert~~
5 ~~reviewers for individual cases achieves a fair and~~
6 ~~impartial panel of experts who are qualified to render~~
7 ~~recommendations regarding the clinical conditions and~~
8 ~~therapies in question.~~

9 ~~(D) Ensures the confidentiality of medical records~~
10 ~~and the review materials, consistent with the~~
11 ~~requirements of this section.~~

12 ~~(E) Ensures the independence of the experts retained~~
13 ~~to perform the reviews through conflict of interest~~
14 ~~policies and prohibitions and adequate screening for~~
15 ~~conflicts of interest, pursuant to paragraph (3) of~~
16 ~~subdivision (b).~~

17 ~~(e) (1) The Department of Corporations shall receive~~
18 ~~the information filed by independent entities pursuant to~~
19 ~~paragraph (2) of subdivision (d) for the purpose of~~
20 ~~creating a file of public records. The Department of~~
21 ~~Corporations shall not be responsible for accrediting~~
22 ~~independent entities.~~

23 ~~(2) The accrediting organization shall provide, upon~~
24 ~~the request of any interested person, a copy of all~~
25 ~~nonproprietary information filed with it by the~~
26 ~~independent entity under paragraph (2) of subdivision~~
27 ~~(d). The accrediting organization may charge a~~
28 ~~reasonable fee to the interested person for photocopying~~
29 ~~the requested information.~~

30 ~~SEC. 3.~~

31 ~~SEC. 2. No reimbursement is required by this act~~
32 ~~pursuant to Section 6 of Article XIII B of the California~~
33 ~~Constitution because the only costs that may be incurred~~
34 ~~by a local agency or school district will be incurred~~
35 ~~because this act creates a new crime or infraction,~~
36 ~~eliminates a crime or infraction, or changes the penalty~~
37 ~~for a crime or infraction, within the meaning of Section~~
38 ~~17556 of the Government Code, or changes the definition~~
39 ~~of a crime within the meaning of Section 6 of Article~~
40 ~~XIII B of the California Constitution.~~



1 Notwithstanding Section 17580 of the Government
2 Code, unless otherwise specified, the provisions of this act
3 shall become operative on the same date that the act
4 takes effect pursuant to the California Constitution.

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